

Stroke Rehabilitation

APPENDICES

Clinical guideline 162

Appendices

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Final

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Appendices

Appendix A: Scope

FINAL

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Stroke rehabilitation: the rehabilitation and support of stroke patients

1.1 *Short title*

Stroke rehabilitation

2 The remit

The Department of Health has asked NICE 'to produce a joint clinical and social care guideline on the long-term rehabilitation and support of stroke patients'.

3 Clinical need for the guideline

3.1 *Epidemiology*

- a) Stroke is a major healthcare problem in the UK. It can have a devastating and lasting impact on the lives of people and their carers. Approximately 110,000 people in England have a first or recurrent stroke each year, and 25% of strokes occur in people younger than 65 years. The risk of recurrent stroke within 5 years of a first stroke is between 30 and 40%.
- b) Most people survive a first stroke, often with significant morbidity. There are more than 900,000 people living in England who have had a stroke. It is the single largest cause of complex impairment, activity limitation and participation restriction in England and approximately 300,000 people are living with moderate to severe impairment, activity limitation and participation restriction as a result.

- c) **Mood disturbance such as anxiety and depression is common in people after stroke. It is often related to the severity of both cognitive and motor impairments and the severity of activity of limitation. Mood disturbance in people after stroke may exacerbate their other impairments and limit functional recovery, and may have a significant impact on family and carers.**
- d) **Stroke is the third largest cause of death in England and accounts for 11% of all deaths in England and Wales.**

3.2 Current practice

a) Many people have a high burden of impairment, activity limitation and participation restriction after stroke, and much of post-stroke care relies on rehabilitation interventions.

b) A rehabilitation service comprises an appropriately skilled multidisciplinary team of people who work together towards common goals for each person with stroke, involve and educate the person, family and carers, and can resolve most of the common problems faced by people with stroke. The World Health Organisation International Classification Function (ICF) provides a conceptual framework for rehabilitation, defining impairments of body structure and function, activities and participation roles. Stroke rehabilitation is a reiterative, active, educational, problem solving process focused on the individuals needs with the following components: assessment, goal setting, intervention, and evaluation. The rehabilitation process aims to maximise the participation of the person in his or her social setting; and to minimise the pain and distress experienced by the individual and their family and carers.

c) There are a wide range of interventions which aim to improve outcomes for people with stroke. Much of the evidence supporting stroke rehabilitation has been based on evaluating the multidisciplinary approach, or on the effect of a particular discipline. There is a need to examine the clinical and cost effectiveness of individual components of treatment in stroke rehabilitation.

d) Consideration will be given to health care interventions that may be delivered within a social care setting or where provision would normally be made by social services in order to ensure that recommendations made will dovetail with social care provision.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

- a) Adults and young people 16 years and older who have had a stroke with continuing impairment, activity limitation or participation restriction.

4.1.2 Groups that will not be covered

- a) Infants and children under 16 years.
- b) People who have had a transient ischaemic attack.

4.2 Healthcare setting

Primary, secondary, tertiary and community care setting

4.2.1 Key clinical issues that will be covered

- a) Interventions used within the primary, secondary, tertiary and community care setting, including:

- Exercise therapies to develop efficient movement, motor learning, gait and balance, upper limb function and hand dexterity, for example strength training, and aerobic fitness training.
 - Repetitive task training for limb function and movement
 - Orthoses for upper and lower limbs
 - FES (functional electrical stimulation) for upper limbs.
 - Other therapies to improve physical function, for example, treadmill training, body-weight-supported treadmill training, constraint-induced movement therapy, and gait trainers for lower limbs.
 - Cognitive function interventions, for example interventions to improve memory, attention, orientation, spatial awareness and/or neglect.
 - Speech and language therapies including treatments focussing on the underlying level of linguistic impairment
 - Eye movement therapy.
 - Treatment of dysphagia.
- b) Rehabilitation of daily activities, for example washing and dressing.
- c) Rehabilitation of participation roles, for example leisure and return to work.
- d) Support for people after stroke and their carers for example, systemic family therapy and group education support.
- e) Provision of information for people after stroke and their carers, including provision of information for people after stroke with aphasia.
- f) Intensity of rehabilitation.

g) Early supported discharge.

4.2.2 Clinical issues that will not be covered

- a) Primary prevention of stroke.
- b) Secondary prevention of stroke.
- c) Assessment for rehabilitation
- d) Assessment and management of acute stroke.

4.3 *Main outcomes*

- a) Physical function, communication and activities of daily living outcomes appropriate to each intervention, including assessment using:
 - Barthel Index
 - Nottingham Extended Activities of Daily Living (EADL) scale
 - 10-metre timed walk, 6-minute walk and the timed 'up and go' test
 - General Health Questionnaire (GHQ)
 - Hospital Anxiety and Depression Scale (HADS)
 - SF-36
 - EuroQol.

4.4 *Economic aspects*

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually only be from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.5 Status

4.5.1 Scope

This is the final scope.

4.5.2 Timing

The development of the guideline recommendations will begin in April 2010.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be incorporated

This guideline will incorporate the following NICE guidance.

- Depression in adults (update). NICE clinical guideline 90 (2009). Available from www.nice.org.uk/guidance/CG90
- Depression in adults with a chronic physical health problem. NICE clinical guideline 91 (2009). Available from www.nice.org.uk/guidance/CG91
- Functional electrical stimulation for drop foot of central neurological origin. NICE interventional procedure guidance 278 (2009). Available from www.nice.org.uk/guidance/IPG278
- Faecal incontinence. NICE clinical guideline 49 (2007). Available from www.nice.org.uk/guidance/CG49
- Nutrition support in adults. NICE clinical guideline 32 (2006). Available from www.nice.org.uk/guidance/CG32

5.1.2 Other related NICE guidance

- Managing long-term sickness and incapacity for work. NICE public health guidance 19 (2009). Available from www.nice.org.uk/guidance/PH19
- Stroke NICE clinical guideline 68 (2008). Available from www.nice.org.uk/guidance/CG68
- Neuropathic pain – pharmacological management. NICE clinical guideline. Publication March 2010. www.nice.org.uk/guidance/CG96
-

5.2 *Guidance under development*

NICE is currently developing the following related guidance (details available from the NICE website).

- Anxiety (partial update). NICE clinical guideline. Publication expected January 2011.

6 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders' the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website

(www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).

Appendix B: Process Protocol

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Stroke rehabilitation

Process and protocol framework for post consultation GDG consensus meeting

B.1 Background

The draft version of the full guideline was made public for stakeholder consultation from the 30th August 2011 to 25th October 2011. During consultation, substantial stakeholder comments were received which raised a number of significant issues in relation to the guideline scope and recommendations developed in the guideline.

The issues raised by stakeholders are broadly summarised as the following key themes (see also appendix II):

- Inconsistency between the remit and the guideline scope
- Lack of stroke rehabilitation patient care pathway
- Lack of recommendations on service delivery, roles and responsibility of the multidisciplinary team/stroke rehab services
- Lack of recommendations on holistic assessment, care planning, goal setting, ongoing review and monitoring
- Lack of recommendations on transfer of care/discharge planning and interface with social care, including care/nursing home
- Lack of recommendations on long-term health and social support for people after stroke
- Lack of recommendations on patient information needs
- Other areas commented as important that need to be included:
 - o those covered by the scope: mood disorders (depression and anxiety), physical fitness and exercise, other speech and language therapies, diplopia.
 - o Those not covered by the scope: nutrition and diet, spasticity, pain, incontinence, fatigue.

Stakeholders had concerns that because the guideline did not present a complete stroke rehabilitation patient pathway this may lead to services being reduced or even withdrawn. Stakeholders also noted the agreed approach to rehabilitation was a holistic one that reflected individual patient need provided by a multidisciplinary team but this was not considered by the guideline which had focused only on the delivery of interventions.

From scoping of the guideline it was apparent to the developers that it would not be possible to cover all aspects of what is a complex area, and that the evidence base was also weak for many of these areas. The approach taken was to concentrate on rehabilitation for which there was some evidence, and to focus on questions which would have the greatest impact on improving patient outcomes. The starting point of the guideline as stated in the introduction, is that all people should receive a package of rehabilitation, but there is variation in practice, both in the amount and content. The focus of the outcomes for the interventions included in the guideline has been on function and mobility as these were considered by the GDG to have the biggest impact on patients' lives. However many stakeholders considered that the patient experience and holistic approaches to care had been neglected and represented a major gap in the guidance.

In light of the comments received from stakeholders, the GDG agreed that additional work could be carried out for some of these areas or reference made to other NICE guidance, in order to produce a more complete piece of guidance that would be useful to health professionals delivering rehabilitation to a stroke population. The current guidance has followed standard NICE methodology and the GDG were in agreement that for those areas where either weak or no evidence was available a robust process needed to be followed that would be defensible.

In agreement with NICE and the members of the Guideline Development Group (GDG) the NCGC technical team will conduct additional work following an agreed process as detailed in this protocol.

B.2 Process and methodology

Overview

Additional work will be conducted to address the structure and process of stroke rehabilitation such as, multi-disciplinary team working, assessment and ongoing review and care planning, and delivery in different settings which was not included in the original scope. These and the areas highlighted by stakeholders as outlined in appendix II will be considered.

Additional searches and reviews of the clinical and economic literature will be undertaken following the usual NICE process and presented to the GDG who will use this evidence as a basis for further recommendations to be made. Where there are recommendations in other NICE guidance that are relevant to the stroke population and address comments highlighted by stakeholders, cross reference will be made to these rather than undertaking further original work.

In conjunction with the NICE editor a stroke rehabilitation pathway will be developed to provide a framework for the recommendations and signpost to other NICE guidance.

The current layout and order of the guideline will be reviewed and an additional section incorporated covering the prerequisites for rehabilitation including: assessment for rehabilitation, goal setting, and information and communication.

Where there is a lack of published evidence the NCGC technical team will identify and invite relevant health professionals from both health and social care sectors, to participate in the development of consensus statements based on the literature available or their expert opinion using a modified Delphi formal consensus technique. The resulting statements will form the basis for the GDG to consider and utilise to develop further recommendations,

No new economic modelling is currently planned due to the limited scope of this additional work and the likelihood that clinical evidence will be limited.

B.3 Stage 1

Mapping of patient care pathway:

In partnership with the NICE editor and GDG input an algorithm will be developed outlining the structure, process and outcomes of the framework for stroke rehabilitation and the current recommendations will be incorporated.

The additional areas identified to be included will be mapped to the NICE pathway, and any new recommendations made following the additional work carried out will be added.

Signposts will be made to other relevant NICE guidance for those areas outside of the scope or that provide additional sources of information for those areas covered by the scope. Where other relevant NICE guidance is available no additional original work will be conducted.

Expected outputs from Stage One:

Sign posts to NICE guidance will be made and relevant recommendations cross referred to in the following:

- Patient Experience in adult NHS services (CG138): to address patient information needs, care planning and continuity of care. .
- Depression: the treatment and management of depression in adults (CG 90), Depression in adults with a chronic physical health problem (CG 91) and Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults (CG113): to address mood disorders
- Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition (CG32) and Stroke: diagnosis and initial management of acute stroke and transient ischaemic attack (CG 68): to address nutrition and dietary support.
- Neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings (CG 96): to address some aspects of pain.
- Urinary incontinence in neurological disease: management of lower urinary tract dysfunction in neurological disease (publication august 2012) and faecal incontinence: the management of faecal incontinence in adults (CG 49): to address incontinence.
- Spasticity in children and young people with non progressive brain disorders: management of spasticity and co-existing motor disorders and their early musculoskeletal complications (publication June 2012): to address spasticity within a sub population.

B.4 Stage 2

Systematic reviews: develop review questions, PICO(s) and review protocol(s)

Evidence for the following areas will be sought as described below:

- Service delivery, multidisciplinary team working
- Assessment for rehabilitation, care planning, goal setting, and ongoing review of patients.
- Transfer of care, discharge planning and interface between health and social care
- Long term health and social support for people after stroke.
- Visual impairment including Diplopia
- Speech and language therapies
- Shoulder pain

The patient experience guideline will be cross referred to for the above areas where adequately covered and in agreement with the GDG. For areas not covered by the Patient Experience guideline, literature searches will be undertaken to identify relevant evidence. As noted by the GDG there may be a large literature base for many of these topics much of which will be of limited value in terms of enabling further recommendations to be made, therefore the following strategy will be used.

Firstly, a search will be undertaken to identify the areas where useful evidence exists to guide drafting of formal review questions. The search will be a comprehensive literature search of databases with terms designed to identify evidence related to the topics outlined above. It will be conducted following the NICE process but filters will be applied to restrict the retrieval to other guidelines and systematic reviews only.

In addition a similar scoping search will be done for economic evidence relating to the same areas. The search strategy will be the same as that used to identify clinical evidence except that it will not be limited to systematic reviews or guidelines and will have instead a search filter to capture only economic evaluations (NCGC recommended economics filter). A first sift will be undertaken to identify potentially relevant economic papers related to the topics listed above.

Where recent systematic reviews are found these will be used as the basis for drafting formal review questions and protocols in collaboration with the GDG and signed off by the group (see appendix III). Full searches will then be undertaken for these review questions. Inclusion will be restricted to the review and any new studies that update the reviews. Systematic reviews will be assessed using the usual NICE quality check list and will be reviewed following NICE methods. Economic evidence will also be sought using the same search strategy and an economic filter. Economic analyses based on studies included in the clinical review will be critically appraised using standard NICE methods. This evidence will be presented to the GDG for their consideration and recommendations will be drafted following usual NICE process. From the scoping search conducted, systematic reviews have been identified for the following areas:

- Physical fitness/exercise.
- Goal setting
- speech and language therapies
- Service delivery – stroke units

Relevant guidelines that are identified from the scoping search will be quality assessed using the AGREE II tool checklist. Those of sufficient quality will be reviewed for recommendations relating to the topics outlined at the start of this section. The evidence base for these recommendations will be checked to ensure that no areas with a significant evidence base have been missed by the approach taken above.

The guideline recommendations will be used as the starting point for consensus work (see Stage 3 below). Once consensus work is completed the economic scoping sift results will be rechecked to see if there are any economic analyses relating to areas where recommendations will be made. Due to the nature of the process set out above it is possible that economic analyses may be identified where clinical evidence has not been formally reviewed. This may make interpretation of the economic studies difficult. We will make a judgement at the time in discussion with the GDG about whether it is useful to include such economic studies.

Patient information needs

As agreed with the GDG relevant recommendations from the patient experience guideline will be incorporated where appropriate. In addition, consensus statements will be developed as part of the modified Delphi survey that will enable the GDG to provide specific information for the stroke population.

B.5 Stage 3

Develop draft consensus statements:

Once the areas for which there is little or no evidence have been established, a combination of the GDG with identified health care professionals, supported by the NCGC technical team will form the targeted consensus group of approximately 150 people. The modified Delphi approach will provide a strong primary research output from the expert group for the GDG to interpret and distil into

consensus based recommendations. Relevant health care professionals will be identified through nominations made by the GDG, the RCP Intercollegiate Stroke Working Party and NICE colleagues. The group will reflect the health professional community who deliver care to patients after stroke, and as a minimum will represent those professions delivering care for the topics included in the survey. Both the Chair of the GDG and the RCP Intercollegiate Stroke Working Party will review the list of nominees to ensure that relevant experts have been identified and are representative of the stroke rehabilitation professional constituency. Invited Delphi consensus participants will comply with NICE methods and will have no other input into the subsequent development of the guideline.

The technical team will distill key aspects of the national guidelines identified by the search and appraised using the AGREE II tool to map the areas for which there is no evidence or limited evidence. This document will provide the basis for statements that will feature in Round 1 of the modified Delphi Survey.

This pre-survey development phase will be managed by the NCGC technical team in collaboration with two external independent consultant experts who will be co-opted onto the guideline to support this important additional work. The consultant experts' role will be to provide guidance to the technical team in the formulation and validation of consensus statements at each round of the survey. They will not be participants in the survey or have any other involvement in further development of the guideline. The survey questionnaire will be sent to all members of the consensus group utilising Survey Monkey software. Responses will remain anonymous to an external audience, but individual participants will carry a unique code that enables the technical team to feedback original responses alongside group responses in the latter sequential rounds. It is anticipated that the whole process will be conducted electronically, with a 4-6 week cycle time between rounds. This will allow for the questionnaire invitation to be sent, two reminders and for the analysis to be conducted prior to the next sequential round.

The NCGC technical team has the expertise to analyse the survey results and it is expected that a further two to three rounds of questionnaires will be necessary to produce the robust consensus output for GDG consideration.

Once the modified Delphi Survey is completed, a report of the analysis and final results will be circulated to all consensus group participants for their information. A GDG meeting will be convened where the results will be presented by the NCGC technical team and discussed by the GDG. This process will be similar to consideration of evidence reviews with final recommendations formulated that will populate discrete areas of the stroke rehabilitation pathway. The whole process will be written up and will feature as part of the methods section, and captured in the Link of evidence to recommendations (LETR) sections of the guidance to illustrate the rationale used to form recommendations.

Modified Delphi Technique

The Delphi technique has been used successfully for generating, analysing and synthesising expert view, and moving this through iteration to reach a consensus position. The technique uses sequential questionnaires to solicit individual responses, with the potential threat of peer pressure removed^a. This is an important consideration and is a key strength of the technique.

Strauss and Ziegler's^b (1975) seminal work on the technique highlights the features of the technique:

^a Goodman C (1986) A Delphi Survey of clinical nursing research priorities within a regional health authority. Unpublished MSc Thesis University of London

^b Strauss H and Ziegler H (1975) The Delphi Technique and its uses in social sciences research. *Journal of Creative Behaviour* 9 (4) 253-259

- Enables the effective use of a panel of experts
- Data is generated through sequential questioning
- Highlights consensus and divergent opinion
- Anonymity is guaranteed
- Iterative in style, it facilitates controlled feedback
- Results are summarised from previous rounds and then communicated to participants
- It handles judgemental data effectively

The modification to the technique largely focuses on the preparation of a Round 1 questionnaire. Typically experts may be asked to highlight the top five priorities in any given area. We believe that this should be replaced and informed by the synthesis of national guidelines identified from the search published and quality assured by the AGREE II instrument. The technical team will work to develop initial statements validated by the co-opted and independent (from the GDG and Intercollegiate Group) consultant experts in forming the Round 1 questionnaire. Sequential rounds will then move the whole group of participants to a consensus position. It is anticipated that we will need to conduct 3 iterations (sequential rounds) via Survey Monkey conducted fairly rapidly to ensure we maintain high return from the invited group of participants. As with any research methodology, it has potential limitations, particularly around accountability for expressed views due to anonymity. In considering the application of this technique to stroke rehabilitation, we do not think this is a risk at all, given the interest generated in the area and the desire by the specialists' professional groupings to get this guidance right.

The consensus group participants will rate each round of statements using a four point Likert scale. Results will be summarised from previous rounds and communicated to participants through Survey Monkey. The second and third rounds of surveys will invite participants to re-rate the statements until consensus is reached. The threshold of 70% will be used as a measure of consensus agreement for each statement and these statements will not be included in subsequent rounds.

Quantitative data results will be analysed using relevant statistical tests (eg. paired T test). Qualitative data will be through conventional themed analysis. The process will be written up as a discrete section in the full guideline, and targeted for peer review publication.

As reported by Sleep et al (1995)^c, the technique offers a significant tool for prioritising issues, offering a cost effectiveness solution in determining consensus which can inform policy. This seems to be the ideal technique that is fit for this purpose with Sim and Wright (2000)^d agreeing that the technique is ideal for collecting structured quantitative data. This with regard to the current challenges with stroke rehabilitation seems ideal.

B.6 Stage 4

GDG meetings

An agenda and relevant paperwork will be circulated to GDG members prior to the meeting. The areas to be covered, the methods that will be employed on the day, the attendees and their role within the meeting and the outputs of the meeting will have been agreed and circulated beforehand and will act as the terms of reference. Dr Diane Playford will be the Chair of this and any other GDG meetings held. Only the areas listed on the agenda will be discussed.

^c Sleep J, Bullock I and Grayson K (1995) Establishing priorities for research in education within one college of nursing and midwifery. *Nurse Education Today* 15 439-445

^d Sim J and Wright C (2000) *Research in Healthcare: Concepts, Design and Methods*. Stanley Thomas Publishing: Cheltenham.

The consensus statements emerging from the iterative modified Delphi technique will be presented to the GDG and will form the basis of discussion. The GDG will formulate recommendations based on the consensus statements. The original modified Delphi survey participants will not attend any GDG meetings and will not play any part in the decision making, formulation of new recommendations or in the editing/changing of recommendations made previously.

Outputs

Minutes for all additional GDG meetings held will be circulated and NICE minutes made available via the NICE website. The process and methodology used for all additional work conducted will be recorded in the methods section of the guideline. The additional questions reviewed and evidence presented will be incorporated into the relevant chapter of the guideline and resulting discussion and rationale behind recommendations made will be entered into the 'recommendations and link to evidence' section of the chapter. For those topic areas where recommendations are made resulting from formal consensus methods, an additional section will be added to the link of evidence to recommendations (LETR) section and a synopsis of the process, discussion and decision making will be made explicit.

All additional work conducted and recommendations made will be subject to a second consultation where stakeholders will be invited to comment on the changes made following usual NICE process.

B.7 Process Protocol Appendix I

Summary of key themes on issues raised by stakeholders

1. Inconsistency between the remit and the guideline scope
 - a. There are significant comments from stakeholders that the elements of 'social care', 'long-term' and 'support' in the remit were not currently covered by the guideline scope and guideline recommendations.

2. Lack of stroke rehabilitation patient care pathway
 - a. There are stakeholders that commented the guideline recommendations are narrowly focused on a range of very specific interventions, without any context.
 - b. There are stakeholders that commented there is a lack of clarity on stages of rehabilitation in terms of patients pathways and timescales, include care pathway from hospital to community based rehabilitation

3. Lack of recommendations on service delivery, roles and responsibility of the multidisciplinary team/stroke rehab services
 - a. There are stakeholders that commented there is a lack of recommendations for the following:
 - Composition of MDT/Stroke rehab services
 - Roles and responsibility of MDT/stroke rehab services at different stages of patient care pathway
 - Coordination of patient care plan by MDT/stroke rehab services at different stages patient care pathway

4. Lack of recommendations on holistic assessment, care planning, goal setting, ongoing review and monitoring
 - a. There are stakeholders that commented there is a lack of recommendations for the following:
 - Assessment and care planning based on individual needs
 - Goal setting at different stages of patient pathways
 - Patient performance review and ongoing monitoring

5. Lack of recommendations on transfer of care/discharge planning and interface with social care, including care/nursing home
 - a. There are stakeholders that commented there is a lack of recommendations on transfer of care/discharge planning for the following:
 - between hospital and primary/community care
 - between health and social care, including transitional process for admitting/returning to care/nursing home
 - role of MDT on coordinating the discharge planning/transfer of care

6. Lack of recommendations on long-term health and social support for people after stroke
 - a. There are stakeholders that commented there is a lack of recommendations on the following:

- Self-care/self management on patient activities of daily living/extended activities of daily living (i.e. "Life after stroke")
 - Employment
 - Driving
 - Housing/finance
 - Leisure/social participation
 - Relationships/family life
 - Carer support
7. Lack of recommendations on patient information needs for example
- a. There are stakeholders that commented there is a lack of recommendations on patient information needs on the following areas:
- Standard of information provision
 - Specific information on dietary needs
 - Specific information on Early supported discharge
 - Specific information on transition between health and social care
 - Review of information needs throughout the different stages of patient care pathway (not just at the start and on completion)
 - The emphasis on the positive effect of information provision on mood and well being
8. Other topics commented as important that need to be included in the guideline
- a. There are stakeholders that commented the following topics need to be included in the guideline:
- i. Topics covered by the scope:
 - Mood disorders (depression and anxiety)
 - Physical fitness/exercise
 - Other speech and language therapies
 - Diplopia
 - ii. Topics not covered by the scope
 - Nutrition and diet
 - Spasticity
 - Pain including shoulder pain
 - Incontinence

B.8 Process Protocol Appendix II – Areas to address

Areas to address	Evidence
service delivery multidisciplinary teams stroke units	consensus systematic review identified
assessment for rehab care plans goal setting ongoing monitoring	consensus consensus systematic review identified consensus
discharge planning/transfer of care interface with social care	consensus consensus
long term health and social support	consensus
visual impairment (diplopia)	consensus
physical fitness	systematic review identified
speech and language therapies aphasia apraxia dysarthria	systematic review identified consensus consensus
shoulder pain	consensus
patient information	cross refer to NICE guidance consensus

B.9 Process protocol Appendix III - Review protocols

Review Protocol stroke rehab – fitness training	
Component	Description GDG – post consultation (exercise training to increase fitness after stroke)
Review question	In people after stroke does cardiorespiratory or resistance training improve outcome (fitness, function, quality of life, mood and reduce disability)?
Population	Adults and young people 16 or older who have had a stroke
Intervention	Any cardiorespiratory or resistance fitness training such as: Aquatic physical exercise Cycle, rowing or treadmill ergometry Weight bearing resistance training Dynamic and isokinetic muscle strength training
Comparison	Usual care (other physiotherapy)
Outcomes	Mortality rate, dependence / or level of disability, physical fitness, mobility, physical function, quality of life and mood (indices and scales may include: blood pressure, body mass, maximal oxygen uptake (peak VO ₂ (ml/kg/min)), endurance, Barthel, Rivermead mobility index, SF-36, EuroQuol, HADS, Becks, Geriatric depression scale, Epidemiologic studies for depression scale (CES-D))
Exclusion	In the resistance group outcomes will be dropped that had already been reported in the completed guideline review on strength training (see chapter 9 of the Stroke rehab guideline)
Search strategy	Cochrane search strategy
Search terms	Cochrane search terms
The review strategy	Only studies restricted to stroke patients to be included Post stroke but irrespective of the time since onset of stroke No minimum time of follow-up Outcome assessments at the end of intervention or at the end of follow-up period

Review Protocol stroke rehab – stroke rehabilitation units	
Component	Description GDG – post consultation organisation of rehabilitation stroke care
Review question	In people after stroke does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?
Population	Adults and young people 16 or older who have had a stroke
Intervention	Organised stroke units such as: Stroke ward (including a multidisciplinary team in a discrete area caring exclusively for stroke patients). Subdivided into: Rehabilitation stroke units (accepting patients after acute management) Comprehensive (combined acute as well as rehabilitation) Mixed rehabilitation (a multidisciplinary team including specialist nursing staff providing rehabilitation service)
Comparison	General medical ward: care in an acute medical or neurology ward without routine multidisciplinary input.
Outcomes	Primary outcomes: Death, dependency and requirement for institutional care at the end of scheduled follow up of the original trial. Dependency is defined as a requirement for physical attention such as assistance for transfers, mobility, dressing, feeding or toileting. This would be equivalent to a modified Rankin score of 0 to 2, a Barthel Index of more than 18 out of 20 or an Activity Index (AI) of more than 83. Requirement for long-term institutional care is taken to mean care in a residential home, nursing home, or hospital at the end of scheduled follow up. Quality of life Patient and carer satisfaction Duration of stay in hospital or institution or both.
Exclusion	Studies not focusing solely on patients with stroke.
Search strategy	systematic reviews Search for randomised control trials which have been published since the search of the Cochrane review search cut-off date (April 2006)
Search terms	Cochrane search terms
The review strategy	Only studies restricted to stroke patients to be included Post stroke but irrespective of the time since onset of stroke No minimum time of follow-up Mortality by length of follow-up Type of organised stroke unit (comprehensive / rehabilitation)

Review Protocol stroke rehab	
Component	Description GDG – post consultation (goal setting)
Review question	Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity ?
Population	Adults and young people 16 or older who have had a stroke
Intervention	Any patient goal setting approach
Comparison	Alternative rehabilitation goal setting approaches
Outcomes	Psychological measures and health related quality of life physical function ADL These may include: Barthel, Nottingham extended activities of daily living, FIM, rating scales, survey data (quantitative), themes identified by qualitative studies
Exclusion	Studies with mixed neurological populations where the proportion of patients with stroke is < 50%
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL, Psychinfo, Sports Discuss Guidelines systematic reviews (if new search is conducted it should include observational and qualitative studies)
Search terms	If systematic reviews are identified search strategies could be checked and used by the IS for an update or new search
The review strategy	Post stroke but irrespective of the time since onset of stroke No minimum time of follow-up No minimum participant numbers

Review Protocol stroke rehab – aphasia	
Component	Description GDG – post consultation aphasia after stroke
Review question	In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language / communication abilities and / or psychological wellbeing?
Population	Adults and young people 16 or older who have had a stroke
Intervention	Speech and language therapy: Any form of targeted practice tasks or methodologies with the aim of improving language or communication abilities
Comparison	No speech and language therapy. Placebo (social support and stimulation)
Outcomes	Functional communication which mean the ability to communicate in ‘real world settings’ (defined as language or communicational skills sufficient to permit the transmission of a message via spoken, spoken, written or non-verbal modalities, or a combination of these channels). Measures include Formal measures of receptive language skills (language understanding) Formal measures of expressive language skills (language production) Overall level of severity of aphasia as measured by specialist test batteries (may include Western Aphasia Battery or Porch Index of Communicative Abilities) Psychological or social wellbeing including depression, anxiety and distress Patient satisfaction / carer and family views Compliance / drop-out
Exclusion	Studies not focusing solely on patients with stroke.
Search strategy	systematic reviews Search for randomised control trials which have been published since the search of the Cochrane review search cut-off date (April 2009)
Search terms	Cochrane search terms
The review strategy	Only studies restricted to stroke patients to be included Post stroke but irrespective of the time since onset of stroke No minimum time of follow-up Type of control (SLT vs. no SLT and in a second analysis SLT vs. Social support and stimulation)

B.10 Process Protocol Appendix IV - Consensus protocols

consensus protocols - stroke rehab	
Component	Description GDG – post consultation organisation of rehabilitation stroke care
Population	Adults and young people 16 or older who have had a stroke
Review question	What should be the constituency of a multidisciplinary rehabilitation team and how should the team work together to ensure the best outcomes for people who have had a stroke?
Intervention	the constituency of a multidisciplinary rehabilitation team Working practices, such as communication and co-ordination of services (team and family meetings, co-ordination of care between rehab specialties and other agencies)
Outcomes	Patient and carer satisfaction optimised strategies to minimise impairment and maximise activity/participation
Review question	In planning rehabilitation for a person after stroke what assessments and monitoring should be undertaken to optimise the best outcomes?
intervention	assessment care plans monitoring
outcomes	Patient and carer satisfaction optimised strategies to minimise impairment and maximise activity/participation
review question	What planning and support should be undertaken by the multidisciplinary rehabilitation team before a person who had a stroke is discharged from hospital or transfers to another team/setting to ensure a successful transition of care?
intervention	discharge planning, emotional/educational support and co-ordination and resources of other services/agencies
outcomes	Patient and carer satisfaction successful discharge quality of life optimised strategies to minimise impairment and maximise activity/participation
review question	What ongoing health and social support does the person after stroke and their carer(s) require to maximise social participation and long term recovery?
intervention	continued monitoring and re-access into rehab long term support/care at home social participation activities carer/family support & education

outcomes	Patient and carer satisfaction quality of life optimised strategies to minimise impairment and maximise activity/participation
Review question	How should people with shoulder pain after stroke be managed to reduce pain?
intervention	assessment pain management FES physical therapies
outcomes	mobility & function pain
review question	What interventions improve communication in people with apraxia or dysarthria after a stroke?
intervention	assessment speech and language therapies communication aids
outcomes	quality of life communication skills social participation
review question	How should people with visual impairments including diplopia be best managed after a stroke?
intervention	screening & assessment information on compensatory strategies
outcomes	quality of life Activities of daily living social participation

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C.1 Introduction

All members of the GDG and all members of the NCGC staff were required to make formal declarations of interest at the outset of each meeting, and these were updated at every subsequent meeting throughout the development process. No interests were declared that required actions.

C.2 GDG members

C.2.1 Ali: Khalid

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.2 Bird: Martin

GDG meeting	Date	Declaration of Interest
GDG Application		Work with the Stroke Association and other groups to improve the quality of rehabilitation but hold no formal appointments elsewhere.
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	With effect from 17 th May, 2011 I will be a permanent employee of the Stroke Association in the role of Head of Stroke training.
GDG Meeting 10	22/06/2011	Since 17 th May 2011 I have been employed as Head of Stroke Training with the Stroke Association.
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.3 Cant: Robin

GDG meeting	Date	Declaration of Interest
GDG Application		Lay member for the Stroke Research Network Rehabilitation CSG.
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.4 Chambers: Sandra

GDG meeting	Date	Declaration of Interest
GDG Application		<u>Personal non-pecuniary interest</u> : Executive Committee Member in ACPIN, Association of Chartered Physiotherapists in Neurology, a clinical special interest group of the Chartered Society of Physiotherapy.
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.5 Clark: Louise

GDG meeting	Date	Declaration of Interest
GDG Application		None.
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.6 Drummond: Avril

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	Resigned from Guideline Development Group
GDG Meeting 15	05/03/2013	N/A

C.2.7 Forster: Anne

GDG meeting	Date	Declaration of Interest
GDG Application		<p><u>Non-personal pecuniary interest:</u> I and my research team have received funding from the Stroke Association. Over the years this has included funding for two bursaries, a Senior Fellowship and a number of project grants. Currently funding is provided for a Junior Fellowship and contribution to an on-going community based randomised trial, both of which were awarded in open competition.</p> <p>I and colleagues in the Unit have also undertaken a number of presentations on behalf of their community services.</p> <p>I am clinical Lead for the Yorkshire Stroke Research network which involves oversight of the implementation of some industry studies but I have no direct relationship with these commercial bodies.</p> <p>All current grants are listed below. Our Unit has also undertaken commissioned work for the Commission for Rural Communities (2008) but have had no subsequent involvement with that body.</p> <p>Formerly an Editor in the Cochrane Stroke Review Group</p> <p><u>Personal non-pecuniary interest:</u> Undertook a number of trials and authored a number of papers relevant to stroke rehabilitation including an over view for the British Medical Journal 2007;334 (7584): 86-90.</p> <p>I and my research team have undertaken a number Cochrane reviews which will relate to topics under review within this guideline.</p>
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	<p><u>Personal non-pecuniary interest</u> Co-author of relevant paper (Psychological therapies evidence review). Instigating author and author of Cochrane Review on Information provision Research interest in information provision.</p>
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes. Resignation submitted in March 2013.

C.2.8 Head: Kathryn

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.9 Holmes: Pamela

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	Resigned from Guideline Development Group
GDG Meeting 9	11/05/2011	N/A
GDG Meeting 10	22/06/2011	N/A
GDG Meeting 11	29/05/2012	Re-joined GDG. No new declaration of interest
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.10 Hunter: Helen

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.11 Khan-Bourne : Najma

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.12 Mac Dermott: Keith

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.13 O'Connor: Rory

GDG meeting	Date	Declaration of Interest
GDG Application		<u>Personal non-pecuniary interest:</u> NHR funded i4i Project II-FS-0908-10045 Gait retraining in the community through use of an instrumented walking aid (IWA) running from 01/04/2009 to 31/03/2010.
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.14 Playford: Diane

GDG meeting	Date	Declaration of Interest
GDG Application		<p><u>Non-personal pecuniary interest:</u> Trustee for Speakability – charity campaigning and working to provide support for aphasic patients.</p> <p>Trustee for Brain and Spine foundation, charity providing information for people with neurological conditions, also education research and campaigning.</p> <p>Trustee for Institute of Social Psychiatry – provides small research funding in field of social psychiatry.</p> <p><u>Personal non-pecuniary interest:</u> Chair of Vocational Rehabilitation special interest group of the BSRM. Executive committee member of the BSRM.</p>
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No Change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.2.15 Thelwell: Sue

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	No change
GDG Meeting 1	27/04/2010	No change
GDG Meeting 2	07/07/2010	No change
GDG Meeting 3	01/09/2010	No change
GDG Meeting 4	13/10/2010	No change
GDG Meeting 5	24/11/2010	No change
GDG Meeting 6	12/01/2011	No change
GDG Meeting 7	23/02/2011	No change
GDG Meeting 8	30/03/2011	No change
GDG Meeting 9	11/05/2011	No change
GDG Meeting 10	22/06/2011	No change
GDG Meeting 11	29/05/2012	No change
GDG Meeting 12	22/06/2012	No change
GDG Meeting 13	23/11/2012	No change
GDG Meeting 14	08/11/2012	No change
GDG Meeting 15	05/03/2013	No changes

C.3 Cooptee Members

C.3.1 Parnaby: Julia Co-optee

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	N/A
GDG Meeting 1	27/04/2010	N/A
GDG Meeting 2	07/07/2010	N/A
GDG Meeting 3	01/09/2010	N/A
GDG Meeting 4	13/10/2010	N/A
GDG Meeting 5	24/11/2010	N/A
GDG Meeting 6	12/01/2011	N/A
GDG Meeting 7	23/02/2011	N/A
GDG Meeting 8	30/03/2011	N/A
GDG Meeting 9	11/05/2011	Attended GDG meeting No change
GDG Meeting 10	22/06/2011	N/A
GDG Meeting 11	29/05/2012	N/A
GDG Meeting 12	22/06/2012	N/A
GDG Meeting 13	23/11/2012	N/A
GDG Meeting 14	08/11/2012	N/A
GDG Meeting 15	05/03/2013	No changes

C.3.2 Pound: Carole Co-optee

GDG meeting	Date	Declaration of Interest
GDG Application		<u>Personal pecuniary interest:</u> Occasional paid consultancy/training work through advocacy agency (Connect the communication disability network) and University Departments. No current research grants. Scholarship bursary from Brunel University.
GDG Induction	28/04/2010	N/A
GDG Meeting 1	27/04/2010	N/A
GDG Meeting 2	07/07/2010	N/A
GDG Meeting 3	01/09/2010	N/A
GDG Meeting 4	13/10/2010	attended GDG meeting Personal pecuniary interest: Occasional consultancy with Connect and NHS Stroke Services.
GDG Meeting 5	24/11/2010	N/A
GDG Meeting 6	12/01/2011	N/A
GDG Meeting 7	23/02/2011	N/A
GDG Meeting 8	30/03/2011	N/A
GDG Meeting 9	11/05/2011	N/A
GDG Meeting 10	22/06/2011	N/A
GDG Meeting 11	29/05/2012	N/A
GDG Meeting 12	22/06/2012	N/A
GDG Meeting 13	23/11/2012	N/A
GDG Meeting 14	08/11/2012	N/A
GDG Meeting 15	05/03/2013	No changes

C.3.3 Rowe: Fiona co-optee N/A – Cooptee

GDG meeting	Date	Declaration of Interest
GDG Application		<p><u>Non-personal pecuniary interest:</u> Grant funding: Warrington and Halton Hospitals NHS Foundation Trust. 2010 Determination of true visual field impairment in unreliable visual field results.</p> <p>Warrington and Halton Hospitals NHS Foundation Trust. 2010 Effectiveness of visual rehabilitation for stroke survivors with homonymous hemianopia. To cover salary of a part-time research assistant to undertake exploratory work on the effectiveness of prism therapy.</p> <p>University of Liverpool School of Health Sciences Pump Priming Fund. 2007 Impact of visual impairment on functional performance in stroke patients.</p> <p>Will be seeking further funding to explore efficacy of treatment options for visual impairment following stroke through grant applications to charitable organisations and the NIHR.</p> <p>Equipment Loan: Haag Streit International. Research loan of Octopus 900 perimeter for investigation of visual field loss. 2008 to present.</p> <p>personal-pecuniary</p> <p>Travel expenses; Haag Streit International has paid my travel expenses for attendance at one conference in 2008 and another in 2009.</p> <p><u>Personal non-pecuniary interest:</u> Research lead for the British and Irish Orthoptic Society. Orthoptic representative on the UK Stroke Forum steering committee.</p>
GDG Induction	28/04/2010	N/A
GDG Meeting 1	27/04/2010	N/A
GDG Meeting 2	07/07/2010	N/A
GDG Meeting 3	01/09/2010	N/A
GDG Meeting 4	13/10/2010	N/A
GDG Meeting 5	24/11/2010	N/A
GDG Meeting 6	12/01/2011	N/A
GDG Meeting 7	23/02/2011	<p><u>Attended GDG meeting</u></p> <p><u>Non-personal pecuniary interest:</u> Small grant awarded from Warrington and Halton Hospitals NHS Foundation Trust to cover salary of a part-time research assistant to undertake exploratory work on the effectiveness of prism therapy for stroke patients with homonymous hemianopia.</p> <p>VISION trial funded by the Stroke Association. This trial is a 3-arm trial comparing prism therapy and hand-held visual search training versus information only (control – standard care).</p> <p><u>Personal non-pecuniary interest:</u> Will be seeking further funding to explore efficacy of treatment options for visual impairment following stroke through grant applications to charitable organisations and the NIHR.</p> <p>Involved in author group for Cochrane systematic review of therapy interventions for homonymous hemianopia.</p>
GDG Meeting 8	30/03/2011	Attended GDG meeting No change
GDG Meeting 9	11/05/2011	N/A
GDG Meeting 10	22/06/2011	N/A
GDG Meeting 11	29/05/2012	N/A
GDG Meeting 12	22/06/2012	N/A
GDG Meeting 13	23/11/2012	N/A
GDG Meeting 14	08/11/2012	N/A
GDG Meeting 15	05/03/2013	No changes

C.3.4 White: Ronald Barney Co-optee

GDG meeting	Date	Declaration of Interest
GDG Application		None
GDG Induction	28/04/2010	N/A
GDG Meeting 1	27/04/2010	N/A
GDG Meeting 2	07/07/2010	N/A
GDG Meeting 3	01/09/2010	N/A
GDG Meeting 4	13/10/2010	N/A
GDG Meeting 5	24/11/2010	N/A
GDG Meeting 6	12/01/2011	N/A
GDG Meeting 7	23/02/2011	attended GDG meeting No change
GDG Meeting 8	30/03/2011	N/A
GDG Meeting 9	11/05/2011	N/A
GDG Meeting 10	22/06/2011	N/A
GDG Meeting 11	29/05/2012	N/A
GDG Meeting 12	22/06/2012	N/A
GDG Meeting 13	23/11/2012	N/A
GDG Meeting 14	08/11/2012	N/A
GDG Meeting 15	05/03/2013	No changes

C.4 Delphi Survey External Team

C.4.1 Davie: Charles

Delphi Survey	April to July, 2012	Declaration of Interest
		None.

C.4.2 Skrypak: Mirek

Delphi Survey	April to July, 2012	Declaration of Interest
		<p><u>Non Personal Pecuniary Interest</u></p> <p>Member of London Stroke Clinical Advisory Group</p> <p>Chair of NCL Cardiovascular and Stroke Network Life after Stroke Group</p> <p>Panel member for CLAHRC (Collaboration for Leadership in Applied Health Research and Care) and NHS Stroke Improvement Programme modified Delphi consensus activity, which aims to provide guidelines on how to implement effective community stroke services for stroke survivors following acute care in hospital.</p> <p>Presented as a guest speaker at a joint funded project by the EU and the Polish Ministry of Health and Education about Occupational Therapy. Received hospitality and accommodation and flights to and from Poland.</p> <p>Currently undertaking a pilot study for my dissertation at Brunel University, which is approved and registered with NHS ethics and Research and Development at NOCLOR. The study is titled 'The effects of self-modelled action observation on upper limb motor rehabilitation of patients with stroke'.</p> <p>Co-applicant for an NIHR SDO funded bid focused on Enhanced ESD for Stroke. Proposal submitted to NIHR.</p> <p>Published NHS Evidence QIPP case study titled 'Management of patients with stroke: REDS' showing cost savings service has made which I manage.</p> <p>Featured in Mind the Gap publication focusing on implementation of NICE QS 7 in regards to 45 minute daily therapy</p> <p>HSJ article published focused on adequate commissioning, resourcing and operational management of an ESD team.</p>

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Search strategies used for the Stroke Rehabilitation guideline were run in accordance with the NICE Guidelines Manual 2009: http://www.nice.org.uk/media/5F2/44/The_guidelines_manual_2009_-_All_chapters.pdf

All searches were run up to 05/10/12. Any studies added to the databases after this date were not included unless specifically stated in the text.

D.1 Clinical Searches

Searches for **clinical reviews** were run in Medline (OVID), Embase (OVID), the Cochrane Library (Wiley) and Cinahl (EBSCO). In addition to the databases outlined above, some searches (A.3.1, A.3.9 and A.3.10) were run in PsychINFO (OVID). Typically, searches were constructed in the following way:

- A PICO format was used for intervention searches. **Population** (P) terms were combined with **Intervention** (I) and sometimes **Comparison** (C) terms (as indicated in the tables under each individual question in Section A.3). An intervention can be a drug, a procedure or a diagnostic test. **Outcomes** (O) are rarely used in search strategies for interventions. Study type filters were used where appropriate (see A.1).

D.2 Economic searches

Searches for economic reviews were run in Medline (Ovid), Embase (Ovid), the NHS Economic Evaluations Database (NHS EED), and the Health Technology Assessment (HTA) database (see A.1.4). NHS EED and HTA were searched via the Centre for Reviews and Dissemination (CRD) interface. Post consultation searches the Health Economic Evaluations Database (HEED) was also search which was unavailable at the time of the initial searches. For Medline and Embase an economic filter was applied to the standard population. All other searches were conducted using only population terms.

D.3 Study design search terms

D.3.1 Systematic review (SR) search terms

Medline search terms

1.	"review"/ or review.pt. or review.ti.
2.	(systematic or evidence* or methodol* or quantitativ* or analys* or assessment*).ti,sh,ab.
3.	1 and 2
4.	meta-analysis.pt.
5.	Meta-Analysis/
6.	exp Meta-Analysis as Topic/
7.	(meta-analy* or metanaly* or metaanaly* or meta analy*).mp.
8.	((systematic* or evidence* or methodol* or quantitativ*) adj5 (review* or survey* or overview*)).ti,ab,sh.
9.	((pool* or combined or combining) adj (data or trials or studies or results)).ti,ab.
10.	or/3-9

Embase search terms

1.	"review"/ or review.pt. or review.ti.
----	---------------------------------------

2.	(systematic or evidence* or methodol* or quantitativ* or analys* or assessment*).ti,sh,ab.
3.	1 and 2
4.	Meta-Analysis/
5.	"Systematic review"/
6.	(meta-analy* or metanaly* or metaanaly* or meta analy*).mp.
7.	((systematic* or evidence* or methodol* or quantitativ*) adj5 (review* or survey* or overview*)).ti,ab,sh.
8.	((pool* or combined or combining) adj (data or trials or studies or results)).ti,ab.
9.	or/3-8

PsychINFO search terms

1.	"Review" / or review.pt. or review.ti.
2.	(systematic or evidence* or methodol* or quantitativ*).ti,ab.
3.	1 and 2
4.	Meta-Analysis/
5.	meta-analy* or metanaly* or metaanaly* or meta analy*).ti,ab.
6.	((systematic* or evidence* or methodol* or quantitativ*) adj3 (review* or overview*)).ti,ab.
7.	((pool* or combined or combining) adj2 (data or trials or studies or results)).ti,ab.
8.	(systematic* or meta*).pt. or (literature review or meta analysis or systematic review).md.
9.	or/3-8

D.3.2 Randomised controlled studies (RCTs) search terms

Medline search terms

1.	randomized controlled trial.pt.
2.	controlled clinical trial.pt.
3.	randomi#ed.ab.
4.	placebo.ab.
5.	clinical trials as topic.sh.
6.	randomly.ab.
7.	trial.ti.
8.	or/1-7

Embase search terms`

1.	random*.ti,ab.
2.	factorial*.ti,ab.
3.	(crossover* or cross over* or cross-over*).ti,ab.
4.	((doubl* or singl*) adj blind*).ti,ab.
5.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
6.	Crossover procedure/
7.	Double blind procedure/
8.	Single blind procedure/
9.	Randomized controlled trial/
10.	or/1-9

PsychINFO search terms

1.	exp Clinical Trial/
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2.	randomi*.ti,ab.
3.	((clinical* or control*) adj3 trial*).ti,ab.
4.	((singl* or doubl* or trebl* or tripl*) adj5 (blind* or mask*)).ti,ab.
5.	Placebos/ or placebo*.ti,ab.
6.	(volunteer* or "control group" or controls).ti,ab.
7.	((crossover or cross-over or cross over) adj2 (design* or stud* or procedure* or trial*)).ti,ab.
8.	or/1-7

D.3.3 Observational studies search terms

Medline search terms

1.	Epidemiologic studies/
2.	exp Case control studies/
3.	exp Cohort studies/
4.	case control.tw.
5.	(cohort adj (study or studies)).tw.
6.	cohort analy*.tw.
7.	(follow up adj (study or studies)).tw.
8.	(observational adj (study or studies)).tw.
9.	longitudinal.tw.
10.	retrospective.tw.
11.	prospective.tw.
12.	or/1-11

Embase search terms

1.	Clinical study/
2.	Case control study/
3.	Family study/
4.	Longitudinal study/
5.	Retrospective study/
6.	Prospective study/
7.	Randomized controlled trials/
8.	6 not 7
9.	Cohort analysis/
10.	(cohort adj (study or studies)).mp.
11.	(case control adj (study or studies)).tw.
12.	(follow up adj (study or studies)).tw.
13.	(observational adj (study or studies)).tw.
14.	(epidemiologic* adj (study or studies)).tw.
15.	or/1-5,8-14

D.3.4 Health economic search terms

Medline search terms

1.	exp "Costs and cost analysis"/
2.	Economics/

3.	(economic* or pharmacoeconomic*).ti,ab.
4.	(cost or costs or costed or costly or costing* or price or prices or pricing).ti.
5.	(expenditure or budget*).ti,ab.
6.	cost-effective*.ti,ab.
7.	(cost adj2 (effectiv* or reduc* or saving*)).ti,ab.
8.	(value adj2 money).ti,ab.
9.	Quality-adjusted life years/
10.	QALY*.ti,ab.
11.	or/1-10
12.	((metabolic or energy or oxygen) adj2 (expenditure or cost*)).ti,ab.
13.	11 not 12

Embase search terms

1.	exp Economic aspect/
2.	(economic* or pharmacoeconomic*).ti,ab.
3.	(cost or costs or costed or costly or costing* or price or prices or pricing).ti.
4.	(expenditure or budget*).ti,ab.
5.	cost-effective*.ti,ab.
6.	(cost adj2 (effectiv* or reduc* or saving*)).ti,ab.
7.	(value adj2 money).ti,ab.
8.	Quality-adjusted life years/
9.	QALY*.ti,ab.
10.	or/1-9
11.	((metabolic or energy or oxygen) adj2 (expenditure or cost*)).ti,ab.
12.	10 not 11

D.4 Standard population search strategy

Medline search terms

1.	exp Stroke/
2.	exp Cerebral Hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5.	"brain attack*".ti,ab.
6.	or/1-5
7.	Letter/
8.	editorial.pt.
9.	historical article.pt.
10.	Case report/
11.	exp Animal/ not Human/
12.	Animals, Laboratory/
13.	exp Animal experiment/
14.	exp Animal model/
15.	exp Rodentia/
16.	or/7-15

17.	6 not 16
18.	limit 17 to english language

Embase search terms

1.	exp Stroke/
2.	exp Cerebrovascular accident/
3.	exp Brain infarction/
4.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
6.	"brain attack*".ti,ab.
7.	exp Intracerebral hemorrhage/
8.	or/1-7
9.	letter.pt.
10.	Letter/
11.	editorial.pt.
12.	note.pt.
13.	Case report/
14.	Case study/
15.	exp Animal/ not Human/
16.	Nonhuman/
17.	exp Animal Studies/
18.	Animals, Laboratory/
19.	exp Experimental animal/
20.	exp Animal experiment/
21.	exp Animal model/
22.	exp Rodentia/
23.	conference abstract.pt.
24.	or/9-23
25.	8 not 24
26.	limit 25 to english language

Cinahl search terms

S1	MW Stroke or MH Cerebral Hemorrhage
S2	stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident"
S3	(cerebro* OR brain OR brainstem OR cerebral*) AND (infarct* OR accident*)
S4	"brain attack*"
S5	S1 or S2 or S3 or S4

Cochrane search terms

#1	MeSH descriptor Stroke explode all trees
#2	MeSH descriptor Cerebral Hemorrhage explode all trees
#3	(stroke or strokes or cva or poststroke* or apoplexy):ti,ab
#4	((cerebro* or brain or brainstem or cerebral*) next (infarct* or accident*)):ti,ab
#5	"brain attack*":ti,ab
#6	#1 OR #2 OR #3 OR #4 OR #5

PsychINFO search terms

1.	exp Stroke/
2.	exp Cerebral hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5.	"brain attack*".ti,ab.
6.	Cerebrovascular accidents/
7.	exp Brain damage/
8.	(brain adj2 injur*).ti.
9.	or/1-8
10.	Letter/
11.	Case report/
12.	exp Rodents/
13.	or/10-12
14.	9 not 13

D.5 Searches by specific questions

D.5.1 Cognitive functions

Searches for the following three questions were run as one search:

- Q. In people after stroke what is the clinical and cost-effectiveness of memory strategies versus usual care to improve memory?**
- Q. In people after stroke what is the clinical and cost-effectiveness of sustained attention training versus usual care to improve attention?**
- Q. In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and/or visual neglect?**

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Memory strategies OR Attention training OR Cognitive rehabilitation		RCTs and Systematic Reviews [Medline, Embase and PsychINFO only]	All years to 05/10/12

Medline search terms

1.	exp Perceptual disorders/
2.	Perception/ or Visual perception/ or exp Space perception/
3.	Extinction, Psychological/
4.	Attention/
5.	Cognition/
6.	Cognition disorders/ or Auditory perceptual disorders/
7.	exp Memory/
8.	exp Memory Disorders/
9.	(hemi-neglect or hemineglect).ti,ab.
10.	((unilateral or spatial or visual or visuo-spatial) adj2 neglect).ti,ab.

11.	((perceptual or visuo-spatial or visuo-perceptual or attentional) adj3 (disorders* or deficit* or impairment* or abilit*)).ti,ab.
12.	(inattention or hemi-attention or extinction).ti,ab.
13.	exp Hemianopsia/
14.	(hemianopia or hemianopsia).ti,ab.
15.	(orientate or orientation).ti,ab.
16.	or/1-15
17.	Rehabilitation/
18.	Therapeutics/ or Therapy, Computer-assisted/
19.	exp Cerebrovascular disorders/rh
20.	(training or re-training or retraining or therap* or rehab* or treatment* or therap*).ti,ab.
21.	Neuropsychological tests/
22.	or/17-21
23.	16 and 22
24.	Cognitive therapy/
25.	neurorehab*.ti,ab.
26.	((neuro* or cognitive or memory) adj2 (retrain* or rehab*)).ti,ab.
27.	Reminder systems/
28.	((perceptual or visuo-spatial or visuo-perceptual or attention or cognitive or cognition or scanning) adj3 (training or re-training or retraining or rehabilitation or intervention or therapy)).ti,ab.
29.	((meta-cognitive or metacognitive or cognitive) adj2 strateg*).ti,ab.
30.	or/23-29

Embase search terms

1.	exp Perception disorder/
2.	Perception/
3.	Depth perception/
4.	Visual deprivation/
5.	exp Attention/
6.	Reinforcement/
7.	Cognition/
8.	Cognitive defect/
9.	Perception deafness/
10.	exp Memory/
11.	exp Memory Disorder/
12.	(hemi-neglect or hemineglect).ti,ab.
13.	((unilateral or spatial or visual or visuo-spatial) adj2 neglect).ti,ab.
14.	((perceptual or visuo-spatial or visuo-perceptual or attentional) adj3 (disorders* or deficit* or impairment* or abilit*)).ti,ab.
15.	(inattention or hemi-attention or extinction).ti,ab.
16.	hemianopia/
17.	(hemianopia or hemianopsia).ti,ab.
18.	(orientate or orientation).ti,ab.
19.	or/1-18
20.	Rehabilitation/

21.	Therapy/
22.	Computer assisted therapy/
23.	exp Cerebrovascular disease/rh [Rehabilitation]
24.	(training or re-training or retraining or therap* or rehab* or treatment* or therap*).ti,ab.
25.	Neuropsychological test/
26.	or/20-25
27.	19 and 26
28.	Cognitive therapy/
29.	Cognitive rehabilitation/
30.	neurorehab*.ti,ab.
31.	((neuro* or cognitive or memory) adj2 (retrain* or rehab*)).ti,ab.
32.	Reminder system/
33.	((perceptual or visuo-spatial or visuo-perceptual or attention or cognitive or cognition or scanning) adj3 (training or re-training or retraining or rehabilitation or intervention or therapy)).ti,ab.
34.	((meta-cognitive or metacognitive or cognitive) adj2 strateg*).ti,ab.
35.	or/27-34

Cinahl search terms

S1	Perceptual disorders/
S2	Visual perception/ or Perception/
S3	Cognition/ or Cognition disorders/
S4	Auditory perceptual disorders/
S5	Spatial perception/
S6	Memory/ OR Memory disorders/
S7	hemi-neglect OR hemineglect
S8	(unilateral OR spatial OR visual OR visuo-spatial) AND neglect
S9	(perceptual OR visuo-spatial OR visuo-perceptual OR attentional) NEAR (disorders* OR deficit* OR impairment* OR abilit*)
S10	inattention OR hemi-attention OR extinction
S11	hemianopia OR hemianopsia
S12	orientate OR orientation
S13	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12
S14	exp Rehabilitation/
S15	Therapeutics/
S16	exp Therapy, Computer assisted/
S17	training OR re-training OR retraining OR therap* OR rehab* OR treatment* OR therap*
S18	Neuropsychological tests/
S19	S14 OR S15 OR S16 OR S17 OR S18
S20	S13 AND S19
S21	Cognitive therapy/ OR "Cognitive Therapy (IOWA NIC) (NON-CINAHL)"/
S22	neurorehab*
S23	neuro* OR cognitive OR memory) NEAR (retrain* OR rehab*)
S24	Reminder systems/
S25	(perceptual OR visuo-spatial OR visuo-perceptual OR attention OR cognitive OR cognition OR scanning) NEAR (training OR re-training OR retraining OR rehabilitation OR intervention OR

	therapy)
S26	(meta-cognitive OR metacognitive OR cognitive) NEAR strateg*
S27	S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26

Cochrane search terms

#1	MeSH descriptor Perceptual Disorders explode all trees
#2	MeSH descriptor Perception, this term only
#3	MeSH descriptor Visual Perception, this term only
#4	MeSH descriptor Space Perception explode all trees
#5	MeSH descriptor Extinction, Psychological, this term only
#6	MeSH descriptor Attention, this term only
#7	MeSH descriptor Cognition, this term only
#8	MeSH descriptor Cognition disorders, this term only
#9	MeSH descriptor Auditory Perceptual Disorders, this term only
#10	MeSH descriptor Memory explode all trees
#11	MeSH descriptor Memory Disorders explode all trees
#12	(hemi-neglect or hemineglect):ti,ab
#13	((unilateral or spatial or visual or visuo-spatial) next neglect):ti,ab
#14	((perceptual or visuo-spatial or visuo-perceptual or attentional) next (disorders* or deficit* or impairment* or abilit*)):ti,ab
#15	(inattention or hemi-attention or extinction):ti,ab
#16	MeSH descriptor Hemianopsia explode all trees
#17	(hemianopia or hemianopsia):ti,ab
#18	(orientate or orientation):ti,ab
#19	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18
#20	MeSH descriptor Rehabilitation, this term only
#21	MeSH descriptor Therapeutics, this term only
#22	MeSH descriptor Therapy, Computer-Assisted, this term only
#23	(training or re-training or retraining or therap* or rehab* or treatment* or therap*):ti,ab
#24	MeSH descriptor Neuropsychological Tests, this term only
#25	#20 OR #21 OR #22 OR #23 OR #24
#26	#19 AND #25
#27	MeSH descriptor Cognitive Therapy, this term only
#28	neurorehab*:ti,ab
#29	((neuro* or cognitive or memory) NEXT (retrain* or rehab*)):ti,ab
#30	MeSH descriptor Reminder Systems, this term only
#31	((perceptual or visuo-spatial or visuo-perceptual or attention or cognitive or cognition or scanning) NEXT (training or re-training or retraining or rehabilitation or intervention or therapy)):ti,ab
#32	((meta-cognitive or metacognitive or cognitive) NEXT strateg*):ti,ab
#33	#26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32

PsychINFO search terms

1.	Perception/ or Visual perception/ or exp Space perception/
2.	exp Attention/
3.	Cognition/

4.	exp Memory/
5.	exp Memory disorders/
6.	hemi-neglect or hemineglect).ti,ab.
7.	((unilateral or spatial or visual or visuo-spatial) adj2 neglect).ti,ab.
8.	((perceptual or visuo-spatial or visuo-perceptual or attentional) adj3 (disorders* or deficit* or impairment* or abilit*)).ti,ab.
9.	(inattention or hemi-attention or extinction).ti,ab.
10.	exp Hemianopsia/
11.	(hemianopia or hemianopsia).ti,ab.
12.	(orientate or orientation).ti,ab.
13.	Hemianopia/
14.	exp Perception/
15.	Perceptual disturbances/
16.	perception/ or auditory perception/ or perceptual distortion/ or perceptual localization/ or perceptual orientation/ or spatial perception/ or visual perception/
17.	Sensory neglect/
18.	Memory/ or memory disorders/
19.	Hemianopia/
20.	Cognitive impairment/
21.	or/1-20
22.	Rehabilitation/
23.	(training or re-training or retraining or therap* or rehab* or treatment* or therap*).ti,ab.
24.	Neuropsychological rehabilitation/
25.	neurorehab*.ti,ab.
26.	or/22-25
27.	21 and 26
28.	Cognitive therapy/
29.	neurorehab*.ti,ab.
30.	((neuro* or cognitive or memory) adj2 (retrain* or rehab*)).ti,ab.
31.	((perceptual or visuo-spatial or visuo-perceptual or attention or cognitive or cognition or scanning) adj3 (training or re-training or retraining or rehabilitation or intervention or therapy)).ti,ab.
32.	((meta-cognitive or metacognitive or cognitive) adj2 strateg*).ti,ab.
33.	exp Cognitive behavior therapy/
34.	Cognitive techniques/
35.	(behavior therapy or cognitive behavioral therapy or cognitive restructuring or cognitive techniques or cognitive therapy).sh,id.
36.	cbt.ti,ab.
37.	((cognit* or behavio#r* or metacognit*) adj3 (analy* or interven* or modif* or program* or psychoanaly* or psychotherap* or restructur* or retrain* or technique* or therap* or train* or treat*)).ti,ab.
38.	(behav* and cognit* and (analy* or interven* or modif* or program* or psychoanaly* or psychotherap* or restructur* or retrain* or technique* or therap* or train* or treat*)).ti,ab.
39.	(rational emotive behavior therapy or self instructional training).sh,id. or (self management.sh. and (cognit* or behavio#r* or metacognit*)).ti,ab,id.)
40.	((selfinstruct* or self* instruct* or selfmanag* or self manag* or selfattribut* or self attribut* or (self* adj2 (instruct* or manag* or attribution*))) and (cognit* or behavio#r* or

	metacognit*) or ((rational* adj3 emotiv*) or ret*0 or rebt*0)).ti,ab.
41.	or/27-40

D.5.2 Sensory functions: visual field

Q. In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Eye movement therapy		RCTs and Systematic Reviews [Medline and Embase only]	All years to 05/10/12

Medline search terms

1.	(scotom* or nystag* or strabism*).ti,ab.
2.	exp Dyslexia, Acquired/
3.	(dyslex* or alexi*).ti,ab.
4.	exp Eye movements/
5.	exp Eye movement measurements/
6.	saccad*.ti,ab.
7.	(visual adj2 (field or acuity)).ti,ab.
8.	exp Visual perception/ph, pp [Physiology, Physiopathology]
9.	exp Photic stimulation/mt [Methods]
10.	exp Vision tests/
11.	((ocul* or vis*) adj5 (rehab* or therap* or train* or search* or scan* or screen*)).ti,ab.
12.	or/1-11

Embase search terms

1.	(scotom* or nystag* or strabis*).ti,ab.
2.	exp Alexia/
3.	(dyslex* or alexi*).ti,ab.
4.	exp Eye movement disorder/
5.	exp Visual field/
6.	exp Visual field defect/
7.	(visual adj2 (field or acuity)).ti,ab.
8.	exp Saccadic eye movement/
9.	saccad*.ti,ab.
10.	exp Vision test/
11.	exp Photostimulation/
12.	((ocul* or vis*) adj5 (rehab* or therap* or train* or search* or scan* or screen*)).ti,ab.
13.	or/1-12

Cinahl search terms

S1	(hemianop* or scotom* or nystag* or strabis*)
S2	(dyslex* or alexi*)
S3	saccad*

S4	("visual field*" or "visual acuity")
S5	((("eye movement*") or ("eye movement*" n3 therap*))
S6	perimet*
S7	(ocul* and (rehab* or therap* or train* or search* or scan* or screen*))
S8	(visual* and (rehab* or therap* or train* or search* or scan* or screen*))
S9	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8

Cochrane search terms

#1	(hemianop* or scotom* or nystag* or strab*):ti,ab
#2	MeSH descriptor Dyslexia, Acquired explode all trees
#3	(dyslex* or alexi*):ti,ab
#4	MeSH descriptor Eye Movements explode tree 2
#5	MeSH descriptor Eye Movement Measurements explode all trees
#6	(visual NEAR/2 (field or acuity)):ti,ab
#7	saccad*:ti,ab
#8	MeSH descriptor Vision Tests explode all trees
#9	MeSH descriptor Photoc Stimulation, this term only
#10	MeSH descriptor Visual Perception explode all trees
#11	((ocul* or vis*) NEAR/5 (rehab* or therap* or train* or search* or scan* or screen*))
#12	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8OR #9 OR #11 OR #11

D.5.3 Digestive system functions

Q. In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions/usual care to improve swallowing (dysphagia)?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Dysphagia therapies		RCTs, Systematic Reviews and observational studies [Medline and Embase only]	All years to 05/10/12

Medline search terms

1.	Deglutition/
2.	exp Deglutition disorders/
3.	exp Gagging/
4.	Pneumonia, Aspiration/
5.	Respiratory aspiration/
6.	Pharyngeal diseases/
7.	(dysphagi* or odynophagi* or achalasi*).ti,ab.
8.	(swallow* or deglutiti* or oropharyn*).ti,ab.
9.	(masticat* or chew* or (food and bolus)).ti,ab.
10.	(aspiration adj4 (silent or penetration or pneumonia or videofluoroscop*)).ti,ab.
11.	(FEESST or VFSS or Mendelsohn* or supraglottic).ti,ab.
12.	or/1-11

Embase search terms

1.	Swallowing/
2.	exp Dysphagia/
3.	Esophagus achalasia/
4.	Oropharynx/
5.	Pharynx disease/
6.	Aspiration pneumonia/
7.	exp Respiratory tract aspiration procedure/
8.	(dysphagi* or odynophagi* or achalasi*).ti,ab.
9.	(swallow* or deglutiti* or oropharynx*).ti,ab.
10.	(masticat* or chew* or gagging or (food and bolus)).ti,ab.
11.	(aspiration adj4 (silent or penetrative or pneumonia or videofluoroscop*)).ti,ab.
12.	(FEESST or VFSS or Mendelsohn* or supraglottic*).ti,ab.
13.	or/1-12

Cinahl search terms

S1	(MH "Deglutition")
S2	(MH "Deglutition Disorders")
S3	(MH "Gagging")
S4	(MH "Pneumonia, Aspiration")
S5	(MH "Pharyngeal Diseases+")
S6	(dysphagi* or odynophagi* or achalasi*)
S7	(swallow* or deglutiti* or oropharynx*)
S8	(aspiration and (silent or penetration or pneumonia or videofluoroscop*))
S9	(FEESST or VFSS or Mendelsohn* or supraglottic)
S10	food and bolus
S11	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10

Cochrane search terms

#1	MeSH descriptor Deglutition, this term only
#2	MeSH descriptor Deglutition Disorders explode all trees
#3	MeSH descriptor Gagging explode all trees
#4	MeSH descriptor Pneumonia, Aspiration, this term only
#5	MeSH descriptor Respiratory Aspiration, this term only
#6	MeSH descriptor Pharyngeal Diseases, this term only
#7	(deglutit* or swallow*):ti,ab
#8	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7

D.5.4 Communication

Searches for the following two questions were run as one search:

- Q. What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?**
- Q. In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?**

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
	Aphasia or speech disorder/therapy*		RCTs and Systematic Reviews [Medline and Embase only]	All years to 05/10/12

*Search did not employ standard population search strategy outlined in Section C.2. Only intervention terms included.

Medline search terms

1.	exp Aphasia/
2.	Language disorder/ or Anomia/
3.	(aphasia* or dysphasi* or anomia or anomic).ti,ab.
4.	((language or lingusitic) adj5 (disorder* or impair* or problem* or dysfunction)).ti,ab.
5.	or/1-4
6.	Language therapy/ or Speech therapy/
7.	Speech-language pathology/
8.	((speech or language or aphasia or dysphagia or phonolog*) adj5 (therp* or train* or rehabilitat* or treat* or remediat* or pathol*)).ti,ab.
9.	remedial therap*.ti,ab.
10.	(conversat* or volunteer* or partner* or layperson* or laypeople or support* or computer* or word* or software or voice).ti,ab.
11.	or/6-10
12.	5 and 11
13.	exp Aphasia/rh, th or Language disorders/rh, th or Anomia/rh, th
14.	12 or 13
15.	Letter/
16.	Editorial/
17.	exp Historical article/
18.	Anecdotes as Topic/
19.	Comment/
20.	Case report/
21.	Animal/ not (Animal/ and Human/)
22.	Animals, Laboratory/
23.	exp Animal experiment/
24.	exp Animal model/
25.	exp Rodentia/
26.	or/15-25
27.	14 not 26
28.	limit 27 to english language

Embase search terms

1.	exp Aphasia/
2.	Language disorder/ or Anomia/
3.	(aphasia* or dysphasi* or anomia or anomic).ti,ab.
4.	((language or lingusitic) adj5 (disorder* or impair* or problem* or dysfunction)).ti,ab.
5.	or/1-4
6.	Language therapy/ or Speech therapy/

7.	Speech-language pathology/
8.	((speech or language or aphasia or dysphagia or phonolog*) adj5 (therp* or train* or rehabilitat* or treat* or remediat* or pathol*)).ti,ab.
9.	remedial therap*.ti,ab.
10.	(conversat* or volunteer* or partner* or layperson* or laypeople or support* or computer* or word* or software or voice).ti,ab.
11.	or/6-10
12.	5 and 11
13.	exp Aphasia/rh, th or Language disorders/rh, th or Anomia/rh, th
14.	12 or 13
15.	limit 14 to english language
16.	letter.pt.
17.	Letter/
18.	editorial.pt.
19.	note.pt.
20.	Case report/
21.	Case study/
22.	Animal/ not (Animal/ and Human/)
23.	Nonhuman/
24.	exp Animal studies/
25.	Animals, Laboratory/
26.	exp Experimental animal/
27.	exp Animal experiment/
28.	exp Animal model/
29.	exp Rodent/
30.	or/16-29
31.	15 not 30

Cinahl search terms

S1	MH Aphasia or MH Aphasia, Broca or MH Aphasia, Wernick or aphasi* or dysphasi* or anomia or anomic or ((language or linguistic) and (disorder* or impair* or problem* or dysfunction))
S2	MH Speech Therapy or MH Rehabilitation, Speech and Language or MH Language Therapy or MH Alternative and Augmentative Communication or ((speech or language or aphasia or dysphasia) and (therap* or train* or rehabilitat* or treat* or pathol*))
S3	conversat* or volunteer* or partner* or layperson* or laypeople or support* or computer or word or software or voice
S4	S2 or S3
S5	S1 and S4

Cochrane search terms

#1	MeSH descriptor Aphasia explode all trees
#2	MeSH descriptor Language Disorders explode all trees
#3	MeSH descriptor Anomia explode all trees
#4	#1 OR #2 OR #3
#5	MeSH descriptor Language Therapy explode all trees
#6	MeSH descriptor Speech Therapy explode all trees
#7	MeSH descriptor Speech-Language Pathology explode all trees

#8	conversat* or volunteer* or partner* or layperson* or laypeople or support* or computer* or word* or software or voice:ti,ab,kw
#9	#5 OR #6 OR #7 OR #8
#10	#4 AND #9
#11	(child*):ti
#12	#10 NOT #11

An additional search was run on the website of the journal **Aphasiology**:

<http://www.tandf.co.uk/journals/titles/02687038.asp>

11	aphasia and stroke
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D.5.5 Mobility

Searches for the following six questions were run as one search:

- Q. In people after stroke what is the clinical and cost effectiveness of repetitive task training versus usual care on improving function and reducing disability?**
- Q. In people after stroke what is the clinical and cost effectiveness of all treadmill versus usual care on improving walking?**
- Q. In people after stroke who can walk, what is the clinical and cost effectiveness of treadmill plus body support versus treadmill only on improving walking?**
- Q. In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?**
- Q. In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?**
- Q. In people after stroke what is the clinical and cost effectiveness of constraint induced therapy versus usual care on improving function and reducing disability?**

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Repetitive task training OR Treadmill training OR Strength training OR Gait training OR Constraint therapy OR Electrical stimulation		RCTs and Systematic Reviews [Medline and Embase only]	All years to 05/10/12

Medline search terms

1.	(mobili\$ adj2 aid\$).ti,ab.
2.	((constraint-induced or constraint induced) adj movement therap\$).ti,ab.
3.	((gait or balance or equilibrium) adj1 (retrain\$ or re-train\$)).ti,ab.
4.	exp *gait disorders, neurologic/rh or *motor skills disorders/rh or postural balance/rh
5.	electric stimulation therapy/
6.	(electric\$ stimulation or electrotherapy\$).ti,ab.
7.	exercise movement techniques/ or walking/
8.	(treadmill or tread mill).ti,ab.
9.	(electromechanic\$ adj2 device\$).ti,ab.
10.	((force adj (platform\$ or plate\$)) or force-plate\$ or force-platform\$).ti,ab.
11.	early ambulation/
12.	((early or accelerat\$) adj1 (mobili\$ or ambluat\$)).ti,ab.

13.	((motor or movement\$ or task\$ or skill\$ or performance) adj5 (repetit\$ or repeat\$ or train\$ or re?train\$ or learn\$ or re?learn\$ or practic\$ or practis\$ or rehears\$ or rehers\$)).ti,ab.
14.	((motor or movement\$ or task\$ or skill\$ or performance) adj5 (schedule\$ or intervention or therap\$ or program\$ or regim\$ or protocol\$)).ti,ab.
15.	(functional adj5 (task\$ or movement)).ti,ab.
16.	transcranial magnetic stimulation/
17.	((magnetic stimulation\$ adj1 transcranial) or rtms or tms).ti,ab.
18.	(strength adj2 train*).ti,ab.
19.	or/1-18

Embase search terms

1.	(mobili\$ adj2 aid\$).ti,ab.
2.	((constraint-induced or constraint induced) adj movement therap\$).ti,ab.
3.	((gait or balance or equilibrium) adj1 (retrain\$ or re-train\$)).ti,ab.
4.	exp *gait disorders, neurologic/rh or *motor skills disorders/rh or postural balance/rh
5.	electric stimulation therapy/
6.	(electric\$ stimulation or electrotherapy\$).ti,ab.
7.	exercise movement techniques/ or walking/
8.	(treadmill or tread mill).ti,ab.
9.	(electromechanic\$ adj2 device\$).ti,ab.
10.	((force adj (platform\$ or plate\$)) or force-plate\$ or force-platform\$).ti,ab.
11.	early ambulation/
12.	((early or accelerat\$) adj1 (mobili\$ or ambluat\$)).ti,ab.
13.	((motor or movement\$ or task\$ or skill\$ or performance) adj5 (repetit\$ or repeat\$ or train\$ or re?train\$ or learn\$ or re?learn\$ or practic\$ or practis\$ or rehears\$ or rehers\$)).ti,ab.
14.	((motor or movement\$ or task\$ or skill\$ or performance) adj5 (schedule\$ or intervention or therap\$ or program\$ or regim\$ or protocol\$)).ti,ab.
15.	(functional adj5 (task\$ or movement)).ti,ab.
16.	transcranial magnetic stimulation/
17.	((magnetic stimulation\$ adj1 transcranial) or rtms or tms).ti,ab.
18.	(strength adj2 train*).ti,ab.
19.	or/1-18

Cinahl search terms

S1	strength and train*
S2	(magnetic stimulation* and transcranial) or (rtms or tms)
S3	functional and (task* or movement)
S4	(motor or movement* or task* or skill* or performance) and (Schedule* or intervention or therap* or program* or regim* or protocol*)
S5	(motor or movement* or task* or skill* or performance) and (repetit* or repeat* or train* or re?train* or learn* or re?learn* or practic* or practis* or rehears* or rehers*)
S6	(early or accelerat*) and (mobili* or ambluat*)
S7	MH early ambulation
S8	(force and (platform* or plate*)) or (force-plate* or force-platform*)
S9	electromechanic* and device*
S10	treadmill* or tread mill
S11	(electric* and stimulation and therapy) or electrotherapy*
S12	(neurologic and rehabilitat*) or ("motor skills disorders" and rehabilitat*) or ("motor postural balance" and rehabilitat*)
S13	MJ gait disorders
S14	mobili* and aid*
S15	(gait or balance or equilibrium) and (retrain* or re-train*)
S16	(constraint-induced or constraint induced) and movement therap*
S17	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16

Cochrane search terms

#1	MeSH descriptor Gait Disorders, Neurologic, this term only
#2	MeSH descriptor Motor Skills Disorders, this term only
#3	MeSH descriptor Postural Balance explode all trees
#4	MeSH descriptor Electric Stimulation Therapy explode all trees
#5	MeSH descriptor Early Ambulation explode all trees
#6	MeSH descriptor Transcranial Magnetic Stimulation explode all trees
#7	(motor or movement* or task* or skill* or performance) near (repetit* or repeat* or train* or re*train or learn* or re*learn* or practic* or practis* or rehears* or rehers*):ti,ab,kw
#8	(functional near (task* or movement)):ti,ab,kw or (magnetic stimulation* near transcranial):ti,ab,kw or (rtms or tms):au
#9	(constraint-induced or constraint induced near movement therap*):ti,ab,kw
#10	gait near train*:ti,ab,kw
#11	treadmill*:ti,ab,kw
#12	strength near train*:ti,ab,kw
#13	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12

D.5.6 Mobility: Functional Electrical Stimulation

Q. In people after stroke what is the clinical and cost-effectiveness of Functional Electrical Stimulation for hand function versus usual care?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Stroke	Upper Limb	Functional electrical Stimulation	SRs RCTs and observational studies (Medline and Embase only)	All years to 05/10/12

Medline search terms

1.	(upper adj2 (limb\$ or extremity\$)).ti,ab.
2.	(shoulder\$ or hand\$ or wrist\$ or arm\$).ti,ab.
3.	(reach\$ adj2 grasp\$).ti,ab.
4.	Or/1-3
5.	Electric Stimulation Therapy/
6.	Electric Stimulation/
7.	Transcutaneous Electric Nerve Stimulation/
8.	Transcranial Magnetic Stimulation/
9.	((function\$ or neuromuscul\$ or peripheral\$ or transcutan\$ or electric\$) adj4 stimulat\$).ti,ab.
10.	electrotherapy.ti,ab.
12.	(FES or TENS or NMES or FNS).ti,ab.
13.	Robotic\$.ti,ab.
14.	Or/5-13
15.	4 and 14

Embase search terms

1.	(upper adj2 (limb\$ or extremity\$)).ti,ab.
2.	(shoulder\$ or hand\$ or wrist\$ or arm\$).ti,ab.

3.	(reach\$ adj2 grasp\$).ti,ab.
4.	Or/1-3
5.	Electric Stimulation Therapy/
6.	Electric Stimulation/
7.	Transcutaneous Electric Nerve Stimulation/
8.	Transcranial Magnetic Stimulation/
9.	((function\$ or neuromuscul\$ or peripheral\$ or transcutan\$ or electric\$) adj4 stimulat\$).ti,ab.
10.	electrotherapy.ti,ab.
12.	(FES or TENS or NMES or FNS).ti,ab.
13.	Robotic\$.ti,ab.
14.	Or/5-13
15.	4 and 14

Cinahl search terms

S1	(upper and (limb* or extremi*) or shoulder* or hand* or wrist* or arm* or (reach* and grasp*)
S2	MH Electric Stimulation Therapy or MH Electric Stimulation or MW Transcutaneous Electric Nerve Stimulation or MH Transcranial Magnetic Stimulation
S3	FES or TENS or NMES or FNS
S4	S2 or S3
S5	S1 and S4

Cochrane search terms

#1	upper near limb* or extremi*:ti,ab
#2	shoulder* or hand* or wrist* or arm*: ti,ab
#3	reach* and grasp: ti,ab
#4	#1 or #2 or #3
#5	(MeSH descriptor Electric Stimulation Therapy, this term only)
#6	MeSH descriptor Electric Stimulation, this term only
#7	MeSH descriptor Transcutaneous Electric Nerve Stimulation, this term only
#8	((function* or neuromuscul* or peripheral* or transcutan* or electric*) near/3 stimulat*)
#9	#5 or #6 or #7 or #8
#10	#4 and #9

D.5.7 Mobility: Orthoses

Searches for the following two questions were run as one search:

- Q. In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of upper limb versus usual care?**
- Q. In people after stroke what if the clinical and cost-effectiveness of ankle-foot orthoses of all types to improve walking function versus usual care?**

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke *	Orthoses (upper OR lower limb)		RCTs and Systematic Reviews [Medline	All years to 05/10/12

Population	Intervention	Comparison	Study filter used and Embase only]	Date parameters
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*Population differs from standard population search strategy outlined in Section A.2, with additional terms included for hemiplegia and hemipareses. As a consequence both population and intervention terms have been included below for each database.

Medline search terms

1.	exp Stroke/
2.	exp Cerebral hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5.	"brain attack*".ti,ab.
6.	exp Hemiplegia/
7.	(hemiplegi* or hemipare*).ti,ab.
8.	or/1-7
9.	Letter/
10.	editorial.pt.
11.	historical article.pt.
12.	Case report/
13.	exp Animal/ not Human/
14.	Animals, Laboratory/
15.	exp Animal experiment/
16.	exp Animal model/
17.	exp Rodentia/
18.	or/9-17
19.	8 not 18
20.	limit 19 to english language
21.	exp Orthopedic fixation devices/
22.	exp Orthotic devices/
23.	(orthos#s or orthoti* or splint* or AFO or DAFO or brace*).ti,ab.
24.	exp Biomechanics/
25.	or/21-24
26.	20 and 25

Embase search terms

1.	exp Stroke/
2.	exp Cerebrovascular accident/
3.	exp Brain infarction/
4.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
6.	"brain attack*".ti,ab.
7.	exp Intracerebral hemorrhage/
8.	exp Hemiplegia/
9.	exp Hemiparesis/
10.	(hemiplegi* or hemipare*).ti,ab.
11.	or/1-10

12.	letter.pt.
13.	Letter/
14.	editorial.pt.
15.	note.pt.
16.	Case report/
17.	Case study/
18.	exp Animal/ not Human/
19.	Nonhuman/
20.	exp Animal studies/
21.	Animals, Laboratory/
22.	exp Experimental animal/
23.	exp Animal experiment/
24.	exp Animal model/
25.	exp Rodentia/
26.	conference abstract.pt.
27.	or/12-26
28.	11 not 27
29.	limit 28 to english language
30.	exp Orthosis/
31.	exp Foot orthosis/
32.	exp Orthotics/
33.	exp Orthopedic equipment/
34.	exp Biomechanics/
35.	(orthos#s or orthoti* or splint* or AFO or DAFO or brace*).ti,ab.
36.	or/30-35
37.	29 and 36

Cinahl search terms

S1	MW Stroke or MH Cerebral Hemorrhage
S2	stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident"
S3	(cerebro* OR brain OR brainstem OR cerebral*) AND (infarct* OR accident*)
S4	"brain attack*"
S5	(MH "Hemiplegia")
S6	hemiplegi* or hemipare*
S7	S1 OR S2 OR S3 OR S4 OR S5 OR S6
S8	(MH "Orthopedic Fixation Devices+")
S9	(MH "Orthoses+")
S10	(orthosis or orthoses or orthoti* or splint* or AFO or DAFO or brace*)
S11	S8 OR S9 OR S10
S12	S7 and S11

Cochrane search terms

#1	MeSH descriptor Stroke explode all trees
#2	MeSH descriptor Cerebral Hemorrhage explode all trees
#3	(stroke or strokes or cva or poststroke* or apoplexy):ti,ab
#4	((cerebro* or brain or brainstem or cerebral*) NEXT (infarct* or accident*)):ti,ab

#5	"brain attack*":ti,ab
#6	MeSH descriptor Hemiplegia explode all trees
#7	(hemiplegi* or hemipare*):ti,ab
#8	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
#9	MeSH descriptor Orthopedic Fixation Devices explode all trees
#10	MeSH descriptor Orthotic Devices explode all trees
#11	(orthos?s or orthoti* or splint* or AFO or DAFO or brace*):ti,ab
#12	#9 OR #10 OR #11
#13	#8 AND #12

D.5.8 Domestic life

Q. In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing/others) versus usual care?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Intensive therapy for daily activities		RCTs and Systematic Reviews [Medline, and Embase only]	All years to 05/10/12

Medline search terms

1.	Occupational therapy/
2.	occupational therapy.ti,ab.
3.	1 or 2
4.	((personal or day or daily) adj3 activit*).ti,ab.
5.	(bath* or dress* or groom* or eat* or wash* or toilet*).ti,ab.
6.	*Self Care/
7.	exp "Activities of Daily Living"/
8.	or/4-7
9.	3 and 8

Embase search terms

1.	Occupational therapy/
2.	occupational therapy.ti,ab.
3.	1 or 2
4.	((personal or day or daily) adj3 activit*).ti,ab.
5.	(bath* or dress* or groom* or eat* or wash* or toilet*).ti,ab.
6.	*Self Care/
7.	exp "Activities of Daily Living"/
8.	or/4-7
9.	3 and 8

Cinahl search terms

S1	MW Occupational Therapy or Occupational Therapy or ((personal or day or daily) AND activit*) or ((bath* or dress* or groom* or eat* or wash* or toilet*)) or "Activities of Daily Living"+
----	--

Cochrane search terms

#1	MeSH descriptor Occupational Therapy explode all trees
#2	(occupational therapy):ti,ab,kw
#3	#1 OR #2
#4	(personal or day or daily) near activit*:ti,ab,kw or (bath* or dress* or groom* or eat* or wash* or toilet*):ti,ab,kw
#5	MeSH descriptor Self Care, this term only
#6	MeSH descriptor Activities of Daily Living explode all trees
#7	(#4 OR #5 OR #6) AND #3

D.5.9 Employment

Q. In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke or brain injury*	Return to work (support of)			All years to 05/10/12

*Population differs from standard population search strategy outlined in Section A.2, with additional terms included for brain injury. As a consequence both population and intervention terms have been included below for each database.

Medline search terms

1.	exp Stroke/
2.	exp Cerebral hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5.	"brain attack*".ti,ab.
6.	Brain Injuries/
7.	(brain adj2 injur*).ti,ab.
8.	or/1-7
9.	Letter/
10.	editorial.pt.
11.	historical article.pt.
12.	Case report/
13.	exp Animal/ not Human/
14.	Animals, Laboratory/
15.	exp Animal experiment/
16.	exp Animal model/
17.	exp Rodentia/
18.	or/9-17
19.	8 not 18
20.	limit 19 to english language
21.	exp Rehabilitation, Vocational/
22.	Employment, supported/ or Unemployment/ or Employment/
23.	(occupation* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.

24.	(employ* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
25.	(vocation* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
26.	(job* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
27.	(work* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
28.	((sheltered or permitted or voluntary) adj2 work).ti,ab.
29.	or/21-28
30.	20 and 29

Embase search terms

1.	exp Stroke/
2.	exp Cerebrovascular accident/
3.	exp Brain infarction/
4.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
6.	"brain attack".ti,ab.
7.	exp Intracerebral hemorrhage/
8.	or/1-7
9.	letter.pt.
10.	Letter/
11.	editorial.pt.
12.	note.pt.
13.	case report/
14.	Case study/
15.	exp Animal/ not Human/
16.	Nonhuman/
17.	exp Animal studies/
18.	Animals, Laboratory/
19.	exp Experimental animal/
20.	exp Animal experiment/
21.	exp Animal model/
22.	exp Rodentia/
23.	conference abstract.pt.
24.	or/9-23
25.	8 not 24
26.	limit 25 to english language
27.	exp Rehabilitation, Vocational/
28.	exp Employment/ or Unemployment/
29.	(occupation* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
30.	(employ* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
31.	(vocation* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
32.	(job* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
33.	(work* adj2 (return* or retrain* or support* or rehabilitat*)).ti,ab.
34.	((sheltered or permitted or voluntary) adj2 work).ti,ab.
35.	or/27-34
36.	26 and 35

Cinahl search terms

S1	MW Stroke or MH Cerebral Hemorrhage
S2	stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident"
S3	(cerebro* OR brain OR brainstem OR cerebral*) AND (infarct* OR accident*)
S4	"brain attack*"
S5	brain AND injury
S6	MH Brain Injuries
S7	S1 or S2 or S3 or S4 or S5 or S6
S8	MH Rehabilitation, Vocational or MH Employment or MH Unemployment
S9	occupation* and (return* or retrain* or support* or rehabilitat*)
S10	employ* and (return* or retrain* or support* or rehabilitat*)
S11	vocation* and (return* or retrain* or support* or rehabilitat*)
S12	job* and (return* or retrain* or support* or rehabilitat*)
S13	work* and (return* or retrain* or support* or rehabilitat*)
S14	(sheltered or permitted or voluntary) and work
S15	S8 or S9 or S10 or S11 or S12 or S13 or S14
S16	S7 and S15

Cochrane search terms

#1	MeSH descriptor Stroke explode all trees
#2	MeSH descriptor Cerebral Hemorrhage explode all trees
#3	(stroke or strokes or cva or poststroke* or apoplexy):ti,ab
#4	((cerebro* or brain or brainstem or cerebral*) next (infarct* or accident*)):ti,ab
#5	brain attack* or brain near injur*:ti,ab
#6	MeSH descriptor Brain Injuries explode all trees
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	MeSH descriptor Rehabilitation, Vocational explode all trees
#9	MeSH descriptor Employment, Supported explode all trees
#10	MeSH descriptor Unemployment explode all trees
#11	MeSH descriptor Employment, this term only
#12	occupation* near (return* or retrain* or support* or rehabilitat*):ti,ab
#13	employ* near (return* or retrain* or support* or rehabilitat*):ti,ab
#14	vocation* near (return* or retrain* or support* or rehabilitat*):ti,ab
#15	job* near (return* or retrain* or support* or rehabilitat*):ti,ab
#16	work* near (return* or retrain* or support* or rehabilitat*):ti,ab
#17	(sheltered or permitted or voluntary) near work:ti,ab
#18	#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17
#19	#7 AND #18

D.5.10 Patient information

Q. What is the effectiveness of supported versus unsupported information provision on mood and depression in people with stroke?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke*	Patient information		RCTs and	All years to

Population	Intervention	Comparison	Study filter used	Date parameters
			Systematic Reviews [Medline, Embase and PsychINFO only]	05/10/12

*Population for Medline and Embase differs from standard population search outlined in Section A.2, with with a more focussed strategy employed. As a consequence both population and intervention terms have been included in this section.

Medline search terms

1.	exp *Stroke/ or exp Stroke/rh
2.	exp *Cerebral hemorrhage/
3.	(stroke or strokes or brain attack* or cva or poststroke* or apoplexy or "cerebrovascular accident").ti.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti.
5.	((stroke or strokes) adj10 (aphasi* or hemipar* or hemiplegi* or dysphasi* or hemianopi* or rehab*)).ti,ab.
6.	or/1-5
7.	Letter/
8.	editorial.pt.
9.	historical article.pt.
10.	Case report/
11.	exp Animal/ not Human/
12.	Animals, Laboratory/
13.	exp Animal experiment/
14.	exp Animal model/
15.	exp Rodentia/
16.	or/7-15
17.	6 not 16
18.	limit 17 to english language
19.	Patient education as Topic/
20.	Patient education handout/
21.	exp Consumer health information/
22.	Access to information/
23.	exp Information centers/
24.	exp Communications media/
25.	exp Computer communication networks/ or Internet/
26.	Health Knowledge, Attitudes, Practice/
27.	Knowledge/
28.	Library services/
29.	Information services/
30.	Search engine/
31.	Computer-assisted instruction/
32.	*Learning/
33.	Social support/ or *Counseling/ or exp Patient participation/
34.	*Communication/

35.	Communication barriers/ or Information dissemination/ or Information seeking behavior/ or Persuasive communication/
36.	Answering services/ or Health communication/ or Hotlines/ or Information literacy/
37.	or/19-36
38.	18 and 37
39.	(doctor patient communic* or patient doctor communic* or nurse patient communic* or patient nurse communic* or professional patient communic* or patient professional communic*).ti,ab.
40.	((client* or patient or inpatient or carer* or care?giver* or consumer*) adj1 (helpline* or advice line* or newsletter* or knowledge or inform* or educ* or advoc* or literature or infopack* or knowledge or leaflet* or booklet* or handout* or decision aid* or pamphlet* or training or factsheet* or counsel* or internet or website*).ti,ab.
41.	(stroke adj2 (information or education*) adj2 (intervention* or program* or resource* or material* or pack* or leaflet* or need* or requirement* or support* or accessible or pathway*).ti,ab.
42.	("information for patients" or patient participat* or community voices or peer support or patient story or patient stories or "access to information").ti,ab.
43.	((active or individuali* or passive or aphasia or interactive or prescription*) adj2 (information* or education* or learn*).ti,ab.
44.	(online adj2 (forum* or communit*).ti,ab.
45.	(strokeline or talkstroke or social networking or facebook or twitter or messageboard*).ti,ab.
46.	(stroke adj2 (helpline* or advice line* or website*).ti,ab.
47.	(workshop* or groupwork or seminar* or "discussion group*").ti,ab.
48.	or/39-47
49.	18 and 48
50.	38 or 49

Embase search terms

1.	exp *Stroke/ or exp Stroke/rh or *Stroke patient/
2.	exp *Cerebrovascular accident/ or exp Cerebrovascular accident/rh
3.	exp *Brain infarction/
4.	(stroke or strokes or "brain attack*" or cva or poststroke* or apoplexy or "cerebrovascular accident").ti.
5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*).ti.
6.	((stroke or stroke*) adj10 (aphasi* or hemipar* or hemiplegi* or dysphasi* or hemianopi* or rehab*).ti,ab.
7.	exp *Intracerebral hemorrhage/
8.	or/1-7
9.	letter.pt.
10.	Letter/
11.	editorial.pt.
12.	note.pt.
13.	Case report/
14.	Case study/
15.	exp Animal/ not Human/
16.	Nonhuman/
17.	exp Animal studies/
18.	Animals, Laboratory/

19.	exp Experimental animal/
20.	exp Animal experiment/
21.	exp Animal model/
22.	exp Rodentia/
23.	conference abstract.pt.
24.	or/9-23
25.	8 not 24
26.	limit 25 to english language
27.	(doctor patient communic* or patient doctor communic* or nurse patient communic* or patient nurse communic* or professional patient communic* or patient professional communic*).ti,ab.
28.	((client* or patient or inpatient or carer* or care?giver* or consumer*) adj1 (helpline* or advice line* or newsletter* or knowledge or inform* or educ* or advoc* or literature or infopack* or knowledge or leaflet* or booklet* or handout* or decision aid* or pamphlet* or training or factsheet* or counsel* or internet or website*)).ti,ab.
29.	(stroke adj2 (information or education*) adj2 (intervention* or program* or resource* or material* or pack* or leaflet* or need* or requirement* or support* or accessible or pathway*)).ti,ab.
30.	("information for patients" or patient participat* or community voices or peer support or patient story or patient stories or "access to information").ti,ab.
31.	((active or individual* or passive or aphasia or interactive or prescription*) adj2 (information* or education* or learn*)).ti,ab.
32.	(online adj1 (forum* or communit*)).ti,ab.
33.	(strokeline or talkstroke or social networking or facebook or twitter or messageboard*).ti,ab.
34.	(stroke adj2 (helpline* or advice line* or website*)).ti,ab.
35.	(workshop* or groupwork or seminar* or "discussion group*").ti,ab.
36.	or/27-35
37.	exp *Patient information/
38.	exp *Patient advocacy/
39.	exp *Patient education/
40.	exp *Patient counseling/
41.	exp *Consumer health information/
42.	exp *Patient participation/
43.	exp *Social support/
44.	exp *Access to information/
45.	*Information center/ or *Information Dissemination/
46.	*Interpersonal communication/ or *Communication skill/ or *Persuasive communication/
47.	exp *Internet/
48.	*Search engine/
49.	exp *Information service/
50.	exp *Teaching/
51.	exp *Learning/
52.	*Mass medium/
53.	*Mass communication/ or *E-mail/ or *Fax/ or *Mobile phone/ or *Postal mail/ or exp *Telecommunication/ or *Telephone/ or *Television/ or *Videoconferencing/ or *Wireless communication/
54.	exp *Publication/

55.	or/37-54
56.	26 and (36 or 55)

Cinahl search terms

S1	MW Stroke or MH Cerebral hemorrhage
S2	stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident"
S3	(cerebro* OR brain OR brainstem OR cerebral*) AND (infarct* OR accident*)
S4	"brain attack*"
S5	S1 or S2 or S3 or S4
S6	(MH "Patient Education")
S7	(MH "Consumer Health Information")
S8	(MH "Access to Information+")
S9	(MH "Libraries+") OR (MH "Information Centers") OR (MH "Information Services") OR (MH "Library Services") OR (MH "Telephone Information Services")
S10	(MH "Information Needs") OR (MH "Information Literacy") OR (MH "Information Resources+")
S11	(MH "Information Seeking Behavior") OR (MH "Communication Barriers") OR (MM "Communication")
S12	(MH "Communications Media") OR (MH "Mail+") OR (MH "Telecommunications+")
S13	(MH "Computer Assisted Instruction") OR (MH "Electronic Data Interchange+") OR (MH "Computer Communication Networks+")
S14	(MM "Knowledge") OR (MH "Health Knowledge")
S15	(MM "Learning") OR (MH "Support, Psychosocial+") OR (MM "Counseling") OR (MH "Peer Counseling") OR (MH "Consumer Participation")
S16	S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15
S17	S5 and S16
S18	(patient N2 information) or (patient N2 education) or (patient N2 knowledge) or (patient N2 website*) or (patient N2 advocac*) or (patient N2 leaflet*) or (patient N2 factsheet*) or (patient N2 helpline*) or (patient N2 counsel*) or (carer* N2 information) or (carer* N2 education) or (caregiver* N2 information) or (caregiver* N2 education*) or (carer* N2 training) or (caregiver* N2 training)
S19	("stroke information" or "stroke education") and (intervention* or program* or resource* or material* or leaflet * or need* or requirement* or support* or pathway*)
S20	"patient participation" or "accessible information" or "community voic*" or "peer support" or "patient story" or "patient stories" or "access to information"
S21	(active N2 learn*) or (individuali* N2 learn*) or (passive N2 learn*) or (aphasia N2 information) or (interactive N2 learn*) or (interactive N2 education) or (individuali* N2 education*) or (individuali* N2 information) or (interactive N2 information)
S22	"online forum*" or "online communit*" or "information prescription*" or strokeline or talkstroke or "social networking" or messageboard* or twitter or facebook or workshop* or "discussion group*" or groupwork or seminar*
S23	stroke and (helpline* or "advice line*" or website*)
S24	S18 or S19 or S20 or S21 or S22 or S23
S25	S5 and S24
S26	S17 or S25
S27	Limit 26 to: English Language; Exclude MEDLINE records; Clinical Queries: Review or Therapy - High Sensitivity; Human; Age Groups: All Adult

Cochrane search terms

#1	MeSH descriptor Stroke explode all trees
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#2	MeSH descriptor Cerebral Hemorrhage explode all trees
#3	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident"):ti
#4	brain attack*:ti,ab
#5	((cerebro* or brain or brainstem or cerebral) NEXT (infarct* or accident*)):ti
#6	((stroke or strokes) NEAR (aphasi or hemipar* or hemiplegi* or dysphasi* or hemianopi* or rehab*)):ti,ab
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	MeSH descriptor Patient Education as Topic explode all trees
#9	MeSH descriptor Consumer Health Information explode all trees
#10	MeSH descriptor Access to Information, this term only
#11	MeSH descriptor Information Centers, this term only
#12	MeSH descriptor Communications Media explode all trees
#13	MeSH descriptor Computer Communication Networks explode all trees
#14	MeSH descriptor Health Knowledge, Attitudes, Practice explode all trees
#15	MeSH descriptor Knowledge, this term only
#16	MeSH descriptor Library Services, this term only
#17	MeSH descriptor Information Services, this term only
#18	MeSH descriptor Search Engine, this term only
#19	MeSH descriptor Computer-Assisted Instruction, this term only
#20	MeSH descriptor Learning, this term only
#21	MeSH descriptor Social Support, this term only
#22	MeSH descriptor Counseling, this term only
#23	MeSH descriptor Patient Participation, this term only
#24	MeSH descriptor Communication, this term only
#25	MeSH descriptor Communication Barriers, this term only
#26	MeSH descriptor Information Dissemination, this term only
#27	MeSH descriptor Information Seeking Behavior, this term only
#28	MeSH descriptor Persuasive Communication, this term only
#29	MeSH descriptor Answering Services, this term only
#30	MeSH descriptor Hotlines, this term only
#31	#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30
#32	#7 AND #31
#33	(strokeline or talkstroke or "social networking" or facebook or twitter or messageboard*):ti,ab
#34	stroke NEXT (helpline* or "advice line*" or website*):ti,ab
#35	online NEXT (forum* or communit*):ti,ab
#36	((active or individuali* or passive or aphasia or interactive or prescription) NEAR (information or education or learning)):ti,ab
#37	("information for patients" or "patient participat*" or "community voic*" or "peer support" or "patient story" or "patient stories" or "access to information" or workshop* or groupwork or seminar* or "discussion group" or "discussion groups"):ti,ab
#38	((client* or patient* or carer* or caregiver* or consumer*) NEXT (helpline* or information or education or advocacy)):ti,ab
#39	((education* or information) NEXT (provision or intervention* or program* or resource* or material* or support or need* or prescription* or pathway*)):ti,ab
#40	((client* or patient or carer* or caregiver* or consumer*) NEXT (leaflet* or pamphlet* or

	training or counsel* or website*)):ti,ab
#41	#33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40
#42	#7 AND #41
#43	#32 OR #42

PsychINFO search terms

1	exp Stroke/
2	exp Cerebral Hemorrhage/
3	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5	"brain attack*".ti,ab.
6	Cerebrovascular accidents/
7	or/1-6
8	Letter/
9	Letter*/
10	Case report/
11	exp Rodents/
12	or/8-11
13	7 not 12
14	exp Client education/ or Health knowledge/ or Health literacy/ or Client participation/
15	Information seeking/ or Computer searching/ or Information/ or Information literacy/ or Information services/
16	Audiovisual communications media/
17	exp Communications media/
18	Learning/
19	Computer assisted instruction/
20	Internet/
21	exp Social networks/
22	exp Social support/
23	Counseling/ or Peer counseling/
24	exp Hot line services/
25	exp Information dissemination/
26	Persuasive communication/
27	exp Interpersonal communication/ or Group discussion/ or Communication barriers/
28	exp Educational programs/
29	or/14-28
30	13 and 29
31	(doctor patient communic* or patient doctor communic* or nurse patient communic* or patient nurse communic* or professional patient communic* or patient professional communic*).ti,ab.
32	((client* or patient or inpatient or carer* or care?giver* or consumer*) adj2 (helpline* or advice line* or newsletter* or knowledge or inform* or educ* or advoc* or literature or infopack* or knowledge or leaflet* or booklet* or handout* or decision aid* or pamphlet* or training or factsheet* or counsel* or internet or website*)).ti,ab.
33	(stroke adj2 (information or education*) adj2 (intervention* or program* or resource* or material* or pack* or leaflet* or need* or requirement* or support* or accessible or pathway*)).ti,ab.

34	("information for patients" or patient participat* or community voices or peer support or patient story or patient stories or "access to information").ti,ab.
35.	((active or individuali* or passive or aphasia or interactive or prescription*) adj2 (information* or education* or learn*)).ti,ab.
36.	(online adj2 (forum* or communit*)).ti,ab.
37.	(strokeline or talkstroke or social networking or facebook or twitter or messageboard*).ti,ab.
38.	(stroke adj2 (helpline* or advice line* or website*)).ti,ab.
39.	(workshop* or groupwork or seminar* or "discussion group*").ti,ab.
40.	or/31-39
41.	13 and 40
42.	30 or 41

D.5.11 Psychological therapy

Q. In people after stroke what is the clinical and cost effectiveness of psychological interventions provided to the family (including the patient)?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke*	Psychological interventions		RCTs and Systematic Reviews [Medline, Embase and PsychINFO only]	All years to 05/10/12

*Population differs from standard population search strategy outlined in Section A.2, with additional terms included for brain injury. As a consequence both population and intervention terms have been included below for each database.

Medline search terms

1.	exp Stroke/
2.	exp Cerebral hemorrhage/
3.	(stroke or strokes or "brain attack*" or cva or poststroke* or apoplexy or "cerebrovascular accident").ti.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti.
5.	((stroke or strokes or poststroke*) adj3 (patient* or rehab* or survivor* or carer* or family or families or caregiver*)).ti,ab.
6.	exp Brain injuries/
7.	(brain adj2 injur*).ti.
8.	or/1-7
9.	Letter/
10.	editorial.pt.
11.	historical article.pt.
12.	Case report/
13.	exp Animal/ not Human/
14.	Animals, Laboratory/
15.	exp Animal experiment/
16.	exp Animal model/
17.	exp Rodentia/

18.	or/9-17
19.	8 not 18
20.	limit 19 to english language
21.	Psychotherapy/ or Psychotherapy, brief/ or Psychotherapy, multiple/ or Cognitive therapy/ or Socioenvironmental therapy/ or exp Milieu therapy/ or exp Psychotherapy, group/
22.	exp Counseling/
23.	Psychoanalysis/ or Psychoanalytic therapy/
24.	*Spouses/px [Psychology]
25.	*Caregivers/px [Psychology]
26.	(CBT or psychotherap* or counsel* or psychoeducation* or psycho-education*).ti,ab.
27.	(cognitive adj2 behavio?r* adj2 therap*).ti,ab.
28.	(psycholog* adj2 treatment*).ti,ab.
29.	(support adj2 program*).ti,ab.
30.	talking therap*.ti,ab.
31.	((psycholog* or psychosocial or family or families or family-based or family-centered or carer* or caregiver* or relationship or couple*) adj3 (intervention* or support or therapy or therapies)).ti,ab.
32.	or/21-31
33.	20 and 32
34.	(infant or paediatric or pediatric or neonat*).ti.
35.	"cognitive rehab*".ti.
36.	34 or 35
37.	33 not 36

Embase search terms

1.	exp *Stroke/ or *stroke patient/
2.	exp *Cerebrovascular accident/
3.	exp *Brain infarction/
4.	(stroke or strokes or cva or brain attack* or poststroke* or apoplexy or "cerebrovascular accident").ti.
5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti.
6.	((stroke or strokes or poststroke*) adj3 (patient* or rehab* or survivor* or carer* or caregiver* or care-giver* or family or families)).ti,ab.
7.	exp *Intracerebral hemorrhage/
8.	exp *Brain injury/
9.	(brain adj2 injur*).ti.
10.	or/1-9
11.	conference abstract.pt.
12.	letter.pt.
13.	Letter/
14.	editorial.pt.
15.	note.pt.
16.	Case report/
17.	Case study/
18.	exp Animal/ not Human/
19.	Nonhuman/

20.	exp Animal studies/
21.	Animals, Laboratory/
22.	exp Experimental animal/
23.	exp Animal experiment/
24.	exp Animal model/
25.	exp Rodentia/
26.	or/11-25
27.	10 not 26
28.	limit 27 to english language
29.	exp *Counseling/
30.	*Psychoanalysis/ or *Psychoanalytic therapy/
31.	(CBT or psychotherap* or counsel* or psychoeducation* or psycho-education*).ti,ab.
32.	(cognitive adj2 behavio?r* adj2 therap*).ti,ab.
33.	(psycholog* adj2 treatment*).ti,ab.
34.	(support adj2 program*).ti,ab.
35.	talking therap*.ti,ab.
36.	((psycholog* or psychosocial* or family or families or family-based or family-centered or carer* or caregiver* or relationship or couple*) adj3 (intervention* or support or therapy or therapies)).ti,ab.
37.	Marital therapy/
38.	*Psychotherapy/
39.	*Cognitive therapy/ or *Milieu therapy/
40.	*Group therapy/
41.	Family therapy/
42.	*Sociotherapy/ or *Psychosocial care/
43.	or/29-42
44.	28 and 43
45.	(paediatric or pediatric or infant* or neonat*).ti.
46.	cognitive rehab*.ti.
47.	45 or 46
48.	44 not 47

Cinahl search terms

S1	Stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident"
S2	(cerebro* OR brain OR brainstem OR cerebral*) AND (infarct* OR accident*)
S3	"brain attack*"
S4	(MH "Stroke Patients") OR (MH "Stroke") OR (MH "Cerebral Hemorrhage")
S5	(MH "Brain Injuries+") or brain N2 injur*
S6	S1 or S2 or S3 or S4 or S5
S7	(MH "Psychotherapy, Brief") OR (MM "Psychotherapy, Group+") OR (MH "Socioenvironmental Therapy") OR (MH "Psychotherapy") OR (MH "Cognitive Therapy")
S8	(MH "Counseling+")
S9	(MH "Psychoanalysis")
S10	cbt or psychotherap* or counsel* or psychoeducation* or psycho-education*
S11	cognitive N2 behavio?r N2 therap*
S12	psycholog* N2 treatment* or support N2 program* or talking N2 therap*

S13	(psycholog* N2 intervention* or psycholog* N2 support or psycholog* N2 therap* or famil* N3 intervention* or famil* N3 support or famil* N3 therap*) or (carer* N2 support or carer* N2 intervention* or carer* N2 therap*) or (caregiver* N2 support or caregiver N2 intervention* or caregiver* N2 therap*)
S14	couple* N2 therap* or couple* N2 intervention or couple* N2 support or relationship N2 support or relationship N2 therap* or relationship N2 intervention*
S15	S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14
S16	S6 and S15
S17	Limit S16 to: English Language; Exclude MEDLINE records; Clinical Queries: Therapy or Review - High Sensitivity; Human; Age Groups: All Adult

Cochrane search terms

#1	MeSH descriptor Stroke explode all trees
#2	MeSH descriptor Cerebral Hemorrhage explode all trees
#3	(stroke or strokes or cva or poststroke* or "brain attack*" or apoplexy):ti
#4	((cerebro* or brain or brainstem or cerebral*) next (infarct* or accident*)):ti
#5	((stroke or strokes or poststroke*) NEAR (patient* or rehab* or survivor* or carer* or family or families or care-giver* or caregiver*)):ti,ab
#6	#1 OR #2 OR #3 OR #4 OR #5
#7	MeSH descriptor Brain Injuries explode all trees
#8	(brain NEXT injur*):ti
#9	#6 OR #7 OR #8
#10	MeSH descriptor Psychotherapy, this term only
#11	MeSH descriptor Counseling explode all trees
#12	MeSH descriptor Psychoanalysis, this term only
#13	MeSH descriptor Caregivers, this term only with qualifier: PX
#14	MeSH descriptor Spouses, this term only with qualifier: PX
#15	(CBT or psychotherap* or counsel* or psychoeducation* or psycho-education* or "talking therap*"):ti,ab
#16	((cognitive NEXT behavio?r) NEXT therap*):ti,ab
#17	(psycholog* NEXT treatment*):ti,ab
#18	(support NEXT program*):ti,ab
#19	((psycholog* or psychosocial* or family or families or family-centred or family-centered or couple* or relationship or carer* or caregiver* or care-giver*) NEAR (intervention* or support or therapy or therapies)):ti,ab
#20	MeSH descriptor Cognitive Therapy, this term only
#21	MeSH descriptor Socioenvironmental Therapy, this term only
#22	MeSH descriptor Milieu Therapy explode all trees
#23	MeSH descriptor Psychotherapy, Group explode all trees
#24	MeSH descriptor Psychoanalytic Therapy, this term only
#25	MeSH descriptor Psychotherapy, Brief, this term only
#26	MeSH descriptor Psychotherapy, Multiple, this term only
#27	#10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26
#28	#9 AND #27
#29	(cognitive NEXT rehab*):ti
#30	#28 NOT #29

#31	(neonat* or paediatric or pediatric or infant*):ti
#32	#30 NOT #31

PsychINFO search terms

1	exp Stroke/
2	exp Cerebral hemorrhage/
3	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5	"brain attack*".ti,ab.
6	Cerebrovascular accidents/
7	exp Brain damage/
8	(brain adj2 injur*).ti.
9	or/1-8
10	Letter/
11	letter*/
12	Case report/
13	exp Rodents/
14	or/10-13
15	9 not 14
16	psychotherapy/ or brief psychotherapy/ or client centered therapy/ or exp cognitive behavior therapy/ or exp group psychotherapy/ or individual psychotherapy/ or relationship therapy/ or supportive psychotherapy/ or cognitive therapy/ or couples therapy/
17	exp Counseling/ or exp Psychotherapeutic counseling/ or Psychosocial rehabilitation/ or Psychosocial readjustment/ or Rehabilitation counseling/
18	Psychoanalysis/ or Psychoanalytic therapy/
19	(CBT or psychotherap* or counsel* or psychoeducation* or psycho-education*).ti,ab.
20	(cognitive adj2 behavior?r* adj2 therap*).ti,ab.
21	(psycholog* adj2 treatment*).ti,ab.
22	(support adj2 program*).ti,ab.
23	talking therap*.ti,ab.
24	((psycholog* or psychosocial or family or families or family-based or family-centered or carer* or caregiver* or relationship or couple*) adj3 (intervention* or support or therapy or therapies)).ti,ab.
25	or/16-24
26	15 and 25
27	cognitive rehab*.ti.
28	(neonat* or paediatric or pediatric or infant*).ti.
29	27 or 28
30	26 not 29

D.5.12 Supported discharge

Q. In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Supported discharge		RCTs and	All years to

Population	Intervention	Comparison	Study filter used	Date parameters
			Systematic Reviews [Medline and Embase only]	05/10/12

Medline search terms

1.	*Home care services/
2.	*Home nursing/
3.	*Patient discharge/
4.	*Length of stay/
5.	((early or earlier or earliest or hospital or patient* or support*) adj4 discharg*).ti,ab.
6.	((hospital or home) adj3 (care or nurs*)).ti,ab.
7.	(subacute adj2 rehabilit*).ti,ab.
8.	or/1-7

Embase search terms

1.	*Home care services/
2.	*Home nursing/
3.	*Patient discharge/
4.	*Length of stay/
5.	((early or earlier or earliest or hospital or patient* or support*) adj3 discharg*).ti,ab.
6.	((hospital or home) adj2 (care or nurs*)).ti,ab.
7.	(subacute adj2 rehabilit*).ti,ab.
8.	or/1-7

Cinahl search terms

S1	MH home care services or MH home nursing or MH patient discharge or MH Length of Stay
S2	(early or earlier or earliest or hospital or patient* or support*) and discharg*
S3	(hospital or home) and (care or nurs*)
S4	subacute and rehabilit*
S5	S1 or S2 or S3 or S4

Cochrane search terms

#1	MeSH descriptor Home Care Services, this term only
#2	MeSH descriptor Home Nursing, this term only
#3	MeSH descriptor Patient Discharge, this term only
#4	MeSH descriptor Length of Stay, this term only
#5	#1 OR #2 OR #3 OR #4

D.5.13 Intensive rehabilitation

Q. In people after stroke what is the clinical and cost- effectiveness of intensive rehabilitation versus standard rehabilitation?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke*	Intensive rehabilitation		RCTs and Systematic Reviews [Medline	All years to 05/10/12

Population	Intervention	Comparison	Study filter used and Embase only]	Date parameters
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*Population differs from standard population search strategy outlined in Section A.2, with additional terms included for brain injury. As a consequence both population and intervention terms have been included below for each database.

Medline search terms

1.	exp Stroke/
2.	exp Cerebral hemorrhage/
3.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.
4.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
5.	"brain attack*".ti,ab.
6.	Brain injuries/
7.	(brain adj2 injur*).ti,ab.
8.	or/1-7
9.	Letter/
10.	editorial.pt.
11.	historical article.pt.
12.	Case report/
13.	exp Animal/ not Human/
14.	Animals, Laboratory/
15.	exp Animal experiment/
16.	exp Animal model/
17.	exp Rodentia/
18.	or/9-17
19.	8 not 18
20.	limit 19 to english language
21.	((intensive* or intensity or dose*) adj3 (exercise* or physical* activ* or physical training or formal training or aerobic*)).ti,ab.
22.	(duration adj3 (exercise* or physical* activ* or physical training or formal training or aerobic*)).ti,ab.
23.	((high* frequency or low* frequency) adj2 (exercise* or training or program* or activit* or regime*)).ti,ab.
24.	((high* intensi* or low* intensi*) adj2 (exercise* or training or program* or activit* or regime*)).ti,ab.
25.	((day* or time or timing or dose* or hour*) adj2 (training or program* or activit* or regime*)).ti,ab.
26.	((day* or time or timing or dose* or hour* or month* or year*) adj2 rehabilit*).ti,ab.
27.	((intensi* or frequen* or duration or therap*) adj3 rehabilit*).ti,ab.
28.	or/21-27
29.	20 and 28

Embase search terms

1.	Exp Stroke/
2.	exp Cerebrovascular accident/
3.	exp Brain infarction/
4.	(stroke or strokes or cva or poststroke* or apoplexy or "cerebrovascular accident").ti,ab.

5.	((cerebro* or brain or brainstem or cerebral*) adj3 (infarct* or accident*)).ti,ab.
6.	"brain attack*".ti,ab.
7.	exp Intracerebral hemorrhage/
8.	exp Brain injury/
9.	(brain adj2 injur*).ti,ab.
10.	or/1-9
11.	conference abstract.pt.
12.	letter.pt.
13.	Letter/
14.	editorial.pt.
15.	note.pt.
16.	Case report/
17.	Case study/
18.	exp Animal/ not Human/
19.	Nonhuman/
20.	exp Animal studies/
21.	Animals, Laboratory/
22.	exp Experimental animal/
23.	exp Animal experiment/
24.	exp Animal model/
25.	exp Rodentia/
26.	or/11-25
27.	10 not 26
28.	limit 27 to english language
29.	((intensive* or intensity or dose*) adj3 (exercise* or physical* activ* or physical training or formal training or aerobic*)).ti,ab.
30.	(duration adj3 (exercise* or physical* activ* or physical training or formal training or aerobic*)).ti,ab.
31.	((high* frequency or low* frequency) adj2 (exercise* or training or program* or activit* or regime*)).ti,ab.
32.	((high* intensi* or low* intensi*) adj2 (exercise* or training or program* or activit* or regime*)).ti,ab.
33.	((day* or time or timing or dose* or hour*) adj2 (training or program* or activit* or regime*)).ti,ab.
34.	((day* or time or timing or dose* or hour* or month* or year*) adj2 rehabilit*).ti,ab.
35.	((intensi* or frequen* or duration or therap*) adj3 rehabilit*).ti,ab.
36.	or/29-35
37.	28 and 36

Cinahl search terms

S1	MW Stroke or MH Cerebral Hemorrhage
S2	stroke* or cva or poststroke* or apoplexy or "cerebrovascular accident"
S3	(cerebro* OR brain OR brainstem OR cerebral*) AND (infarct* OR accident*)
S4	"brain attack*"
S5	brain AND injury
S6	MH Brain Injuries

S7	S1 or S2 or S3 or S4 or S5 or S6
S8	day* or timing or time* or dose* or hour* or month* or years* or intensi* or frequen* or duration or therap*
S9	rehabilit*
S10	S8 and S9
S11	S7 and S10
S12	Limit S11 to: English Language; Exclude MEDLINE records; Human; Age Groups: All Adult

Cochrane search terms

#1	MeSH descriptor Stroke explode all trees
#2	MeSH descriptor Cerebral Hemorrhage explode all trees
#3	(stroke or strokes or cva or poststroke* or apoplexy):ti,ab
#4	((cerebro* or brain or brainstem or cerebral*) next (infarct* or accident*)):ti,ab
#5	brain attack* or brain near injur*:ti,ab
#6	MeSH descriptor Brain Injuries explode all trees
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	(day* or time* or timing or dose* or hour* or month* or year*) AND rehabilit*:ti,ab
#9	(intensi* or frequen* or duration or therap*) AND rehabilit*:ti,ab
#10	#8 OR #9
#11	#7 AND #10

D.5.14 Post consultation searches

Fitness and rehabilitation

Q. In people after stroke does cardiorespiratory or resistance training improve outcome (fitness, function, quality of life, mood and reduce disability)?

Update of: Physical fitness training for stroke patient. Brazzelli, M. Saunders, DH. Grieg, CA. Mead, *Cochrane Database Syst Rev* 2001. Issue 11 CD003316

Q. In people after stroke does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?

Search results from A.3.5 Mobility and additional search below

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Stroke (including brain injury)			SRs, Guidelines (Medline only)	All years to 05/10/12

Medline search terms

1.	exp rehabilitation/ or exp rehabilitation centers/ or exp rehabilitation nursing/
2.	exp physical medicine/ or exp physical therapy modalities/
3.	exp exercise therapy/
4.	exp occupational therapy/
5.	exp social work/
6.	rh.fs.
7.	rehab\$.ti,ab.
8.	(physiotherap\$ or (physi\$ adj therap\$) or (occupational adj therap\$) or ((speech or language)

	adj3 therap\$) or (social adj2 (work\$ or service\$)))ti,ab.
9.	exp "Delivery of Health Care"/
10.	exp Patient Care Team/
12.	or/1-10

Cochrane search terms

#1	MeSH descriptor Rehabilitation explode all trees
#2	MeSH descriptor Rehabilitation Centers explode all trees
#3	MeSH descriptor Rehabilitation Nursing explode all trees
#4	MeSH descriptor Physical Medicine explode all trees
#5	MeSH descriptor Physical Therapy Modalities explode all trees
#6	MeSH descriptor Exercise Therapy explode all trees
#7	MeSH descriptor Occupational Therapy explode all trees
#8	MeSH descriptor Social Work explode all trees
#9	(rehab*):ti,ab,kw
#10	(physiotherap*):ti,ab,kw or (physi* near therap*):ti,ab,kw or (occupational near therap*):ti,ab,kw or (speech or language) near therap*):ti,ab,kw or (social near (work* or service*)):ti,ab,kw
#11	MeSH descriptor Delivery of Health Care explode all trees
#12	MeSH descriptor Patient Care Team explode all trees
#13	(#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13)

Trip database searched 19/12/11 term used 'stroke rehabilitation'
<http://www.tripdatabase.com/search?criteria=stroke+rehabilitation>

In addition Website searches for Stroke guidelines on the following sites using the search terms 'Stroke' or 'Stroke rehabilitation':

http://my.americanheart.org/professional/StatementsGuidelines/ByTopic/TopicsQ-Z/Stroke-Statements-Guidelines_UCM_320600_Article.jsp

American Academy of Neurology
<http://www.aan.com/index.cfm?axon=redirect&&path=/go/home>

European Stroke Initiative
<http://www.eso-stroke.org/>

American College of Cardiology
<http://www.cardiosource.org/acc>

Internet Stroke Centre
<http://www.strokecenter.org/>

American Stroke Association
<http://www.strokeassociation.org/STROKEORG/>

Association of Chartered Physiotherapists in Neurology
<http://www.acpin.net/>

Chartered Physiotherapists Working With Older People: AGILE
<http://agile.csp.org.uk/>

Cochrane Stroke Group

<http://www.dcn.ed.ac.uk/csrg/>

Different Strokes

<http://www.differentstrokes.co.uk/>

Help the Aged now AgeUK

<http://www.ageuk.org.uk/>

New Zealand Clearing House for Health Outcomes and Health Technology Assessment

<http://www.worldcat.org/identities/lccn-n98-801635>

and

<http://www.otago.ac.nz/christchurch/research/nzhta/>

Northern Ireland Multidisciplinary Association for Stroke Teams

<http://www.nimast.org.uk/>

Stroke Association

<http://www.stroke.org.uk/>

Stroke Therapy Evaluation Programme (STEP)

<http://www.dcn.ed.ac.uk/STEP/About.htm>

The National Stroke Foundation (Australia)

<http://www.strokefoundation.com.au/>

Q. In people after stroke does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care or length of hospital stay)?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Units		RCTs and Systematic Reviews [Medline, Embase	2006-05/10/12

Medline search terms

1.	*Hospital Units/
2.	Patient care team/
3.	(stroke adj2 (ward* or team* or unit* or mobile or care or caring or comprehensive)).ti,ab.
4.	exp "Delivery of Health Care"/
5.	exp Interprofessional Relations/
6.	((multi?disciplinary or inter?disciplinary or cross?disciplinary or integrated or multi?modal or multi?professional or inter?professional or cross?professional) adj3 (therap\$ or team\$ or care)).ti,ab.
7.	Or/1-6

Embase search terms

1.	"hospital subdivisions and components"/
2.	health care delivery/
3.	patient care/
4.	teamwork/
5.	(stroke adj2 (ward* or team* or unit* or mobile or care or caring or comprehensive)).ti,ab.
6.	interdisciplinary communication/

7.	*"multidisciplinary team meeting"/
8.	((multi?disciplinary or inter?disciplinary or cross?disciplinary or integrated or multi?modal or multi?professional or inter?professional or cross?professional) adj3 (therap\$ or team\$ or care)).ti,ab.
9.	or/1-8

Cochrane search terms

1.	MeSH descriptor Hospital Units, this term only
2.	MeSH descriptor Patient Care Team explode all trees
3.	(stroke near2 (ward* or team* or unit* or mobile or care or caring or comprehensive)):ti,ab,kw
4.	MeSH descriptor Delivery of Health Care explode all trees
5.	MeSH descriptor Interprofessional Relations explode all trees
6.	(#6 OR #7 OR #8 OR #9 OR #10)

Q. Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?

Update of: A systematic review and synthesis of the quantitative and qualitative evidence behind patient-centred goal setting in stroke rehabilitation *Clin Rehabil* June 2011 25: 501-514, first published on March 25, 2011 doi:10.1177/0269215510394467

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Goal setting			2010-05/10/12

Medline search terms

1.	Patient-Centered Care/
2.	*patient participation/
3.	(patient adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
4.	(client adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
5.	(person adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
6.	Or/1-5
7.	(goal or goals).ti,ab.
8.	goals/
9.	7 or 8
10.	6 and 9

Embase search terms

1.	patient autonomy/ or patient decision making/
2.	*patient participation/
3.	(patient adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
4.	(client adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
5.	(person adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
6.	or/1-5
7.	(goal or goals).ti,ab.
8.	goal attainment/
9.	7 or 8
10.	6 and 9

Cochrane search terms

1.	MeSH descriptor Patient Participation, this term only
2.	MeSH descriptor Patient-Centered Care, this term only
3.	((patient or client or person) NEXT (centr* or center* or focus* or orient*)):ti,ab
4.	#1 or #2 or #3

5.	MeSH descriptor Goals explode all trees
6.	goal or goals:ti,ab
7.	#5 OR #7
8.	#4 and #8

Cinahl search terms

S1.	(patient N1 centr* OR patient N1 center* OR patient N1 focus* OR patient N1 orient*) OR (client N1 centr* OR client N1 center* OR client N1 focus*OR client N1 orient*) OR (person N1 centr* OR person N1 center* OR person N1 focus* OR person N1 orient*)
S2.	(MH "Patient Centered Care") OR (MM "Consumer Participation")
S3.	S1 or S2
S4.	(MH "Goals and Objectives") OR (MH "Goal Attainment") OR (MH "Goal-Setting")
S5.	goal OR goals
S6.	S4 or S5
S7.	S3 and S6

PsychINFO search terms

1.	client centered therapy/
2.	client participation/
3.	(patient adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
4.	(client adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
5.	(person adj1 (centred\$ or centered\$ or focus\$ or orient\$)).ti,ab.
6.	or/1-5
7.	goals/ or goal orientation/ or goal setting/
8.	(goal or goals).ti,ab.
9.	7 or 8
10.	6 and 9

Q. In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language / communication abilities and / or psychological wellbeing?

Update of: Speech and language therapy for aphasia following stroke. Kelly,H. Brady, MC. Enderby,P. *Cochrane Database Syst Rev* 2010 Issue 5 CD000425

Search for Aphasia or speech therapy disorder re-run (see section A.3.4)

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
	Asphasia or speech disorder/therapy		RCTs and Systematic Reviews [Medline and Embase only]	2009-05/10/12

D.5.14.1 Economic searches

Economic searches were run in Medline and Embase by combining the standard population with the economic filter (A.1.4) and limiting by date range (see table below). Economic searches were executed in the NHS EED and HTA (CRD) databases by running a standard population without a date limitation. Search terms for the CRD database are given below.

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke			Economic [only Embase and Medline]	<ul style="list-style-type: none">• 2009-05/10/12 (Medline and Embase)• All years-05/10/12 (CRD)

CRD search terms

1.	(stroke* or cva or "brain attack" or "cerebrovascular accident*" or "cerebrovascular apoplexy") and (acute or rehab* or prevent* or manag*)
----	---

Post consultation searches

The following additional searches were run for Economics

Fitness and rehabilitation

Q. In people after stroke does cardiorespiratory or resistance training improve outcome (fitness, function, quality of life, mood and reduce disability)?

Q. In people after stroke does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Stroke (including brain injury)	Rehabilitation, multidisciplinary teams		Economic [only Embase and Medline]	2009-05/10/12 All years-05/10/12 (CRD & HEED)

Medline search terms

1.	rehabilitation/ or vocational rehabilitation/ or cognitive rehabilitation/ or community based rehabilitation/ or community reintegration/ or functional assessment/ or functional training/ or home rehabilitation/ or muscle training/ or occupational therapy/ or psychosocial rehabilitation/ or recreational therapy/ or exp speech rehabilitation/
2.	rehabilitation center/
3.	rehabilitation nursing/
4.	rehabilitation care/
5.	rehabilitation medicine/
6.	rehabilitation patient/
7.	exp physical medicine/
8.	patient care planning/
9.	exp nursing care delivery system/
10.	social work/
11.	rh.fs.
12.	rehab\$.ti,ab.
13.	(physiotherap\$ or (physi\$ adj therap\$) or (occupational adj therap\$) or ((speech or language) adj3 therap\$) or (social adj2 (work\$ or service\$))).ti,ab.
14.	health care delivery/
15.	patient care/
16.	teamwork/
17.	interdisciplinary communication/
18.	*"multidisciplinary team meeting"/
19.	((multi?disciplinary or inter?disciplinary or cross?disciplinary or integrated or multi?modal or multi?professional or inter?professional or cross?professional) adj3 (therap\$ or team\$ or care)).ti,ab.
20.	or/1-20

Embase search terms

1.	exp Rehabilitation Centers/ or exp Rehabilitation/ or exp Rehabilitation Nursing/
2.	exp Physical Medicine/
3.	exp Physical Therapy Modalities/
4.	exp Exercise Therapy/
5.	exp Occupational Therapy/
6.	exp Social Work/
7.	rh.fs.
8.	rehab\$.ti,ab.
9.	(physiotherap\$ or (physi\$ adj therap\$) or (occupational adj therap\$) or ((speech or language) adj3 therap\$) or (social adj2 (work\$ or service\$))).ti,ab.
10.	exp "Delivery of Health Care"/
11.	exp Patient Care Team/
12.	exp Interprofessional Relations/
13.	((multi?disciplinary or inter?disciplinary or cross?disciplinary or integrated or multi?modal or multi?professional or inter?professional or cross?professional) adj3 (therap\$ or team\$ or care)).ti,ab.
14.	or/1-14

HEED search terms

1.	ax=stroke
2.	ax=brain AND injur*
3.	cs=1 or 2
4.	ax=rehab*
5.	ax=multidisciplin*
6.	ax=service delivery
7.	ax=plan*
8.	cs=4 or 5 or 6 or 7 or 8
9.	cs=3 and 9

CRD search terms

1.	(stroke* OR poststroke* OR CVA OR "brain attack" OR "cerebrovascular accident*" OR "cerebrovascular apoplexy" OR " brain injur*") AND (rehab* OR reintegrat* OR physiotherap* OR "occupational therap*" OR "exercise therap*" OR crossdisciplin* OR cross-disciplin* OR multidisciplin* OR multi-disciplin* OR interdisciplin* OR "speech therap*" OR "language therap*" OR "social service*" OR "social care" OR multiprofessional OR multi-professional OR interprofessional OR cross-professional)
----	---

Q. In people after stroke does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care or length of hospital stay)?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Units		Economic [only Embase and Medline]	2010-05/10/12 All years-05/10/12 (CRD & HEED)

HEED search terms

1.	ax=stroke
2.	ax=ward* or unit* or comprehensive

3.	ax='mobile team' within 2
4.	cs=2 OR 3
5.	cs=1 and 4

CRD search terms

1.	(stroke)
2.	(ward* or unit* or comprehensive)
3.	("mobile team")
4.	#2 OR #3
5.	1 AND #4

Q. Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
Stroke	Goal setting		Economic [only Embase and Medline]	2010-05/10/12 All years-05/10/12 (CRD & HEED)

See terms for Goal setting clinical search

CRD search terms

1.	MeSH DESCRIPTOR Stroke EXPLODE ALL TREES
2.	MeSH DESCRIPTOR Cerebral Hemorrhage EXPLODE ALL TREES
3.	(stroke* or cva or poststroke* or apoplexy or "brain attack*" or "cerebrovascular accident*")
4.	#1 OR #2 OR #3
5.	MeSH DESCRIPTOR patient-centered care EXPLODE ALL TREES
6.	MeSH DESCRIPTOR patient participation EXPLODE ALL TREES
7.	(patient centr* OR patient center* OR patient focus* OR patient orient* OR patient-centr* OR patient-center* OR patient-focus* OR patient-orient*)
8.	(client centr* OR client center* OR client focus* OR client orient* OR client-centr* OR client-center* OR client-focus* OR client-orient*)
9.	(person centr* OR person center* OR person focus* OR person orient* OR client-centr* OR person-center* OR person-focus* OR person-orient*)
10.	#5 OR #6 OR #7 OR #8 OR #9
11.	MeSH DESCRIPTOR goals EXPLODE ALL TREES
12.	(goal or goals)
13.	#11 OR #12

Q. In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language / communication abilities and / or psychological wellbeing?

Search for Aphasia or speech therapy disorder re-run (see section A.3.4)

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention	Comparison	Study filter used	Date parameters
	Asphasia or speech disorder/therapy		Economic [only Embase and Medline]	2009-05/10/12 All years-05/10/12 (CRD &

Population	Intervention	Comparison	Study filter used	Date parameters
				HEED)

CRD search terms

1.	(aphasia*):TI OR (dysphasi*):TI OR (anomia):TI OR (anomic):TI IN NHSEED, HTA
2.	(aphasia*) OR (dysphasi*) OR (anomia) OR (anomic) IN NHSEED, HTA
3.	MeSH DESCRIPTOR Aphasia EXPLODE ALL TREES
4.	MeSH DESCRIPTOR Language Disorders EXPLODE ALL TREES
5.	(language disorder*) OR (language impair*) OR (language problem*) OR (language disfunction) IN NHSEED, HTA
6.	(lingusitic disorder*) OR (lingusitic impair*) OR (lingusitic problem*) OR (lingusitic disfunction) IN NHSEED, HTA
7.	#1 OR #2 OR #3 OR #4 OR #5 OR #6

HEED search terms

1.	ax=aphasia* or anomia or anomic
2.	ax=dysphagi*
3.	ax=language OR linguistic
4.	ax=disorder*
5.	ax=impair*
6.	ax=problem*
7.	ax=disfunction*
8.	cs=4 OR 5 OR 6 OR 7
9.	cs=3 AND 8

Appendix E: Review Protocols

E.1	In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and/or neglect and visual neglect?	104
E.2	In people after stroke what is the clinical and cost-effectiveness of memory strategies versus usual care to improve memory?	105
E.3	In people after stroke what is the clinical and cost-effectiveness of sustained attention training versus usual care to improve attention?	106
E.4	In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?	107
E.5	In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions / usual care to improve swallowing? (dysphagia).....	108
E.6	In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?	109
E.7	What listener advice skills/training or information would help family members/carers improve communication in people with aphasia after stroke?.....	110
E.8	In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?.....	111
E.9	In people after stroke what is the clinical and cost-effectiveness of Functional Electrical Stimulation (FES) for hand function versus usual care?	112
E.10	In people after stroke what is the clinical and cost effectiveness of constraint induced therapy versus usual care on improving function and reducing disability?.....	113
E.11	In people after stroke what is the clinical and cost effectiveness of repetitive task training versus usual care on improving function and reducing disability?	114
E.12	In people after stroke what is the clinical and cost effectiveness of all treadmill versus usual care on improving walking?.....	115
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E.1 In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and/or neglect and visual neglect?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Prisms and goggles Track to left Top down
Comparison	Usual care
Outcomes	MMSE, BIT, drawing tests (clock drawing etc.), Line Bisection tests, all cancellation tests (line cancellation, bell cancellation etc.), sentence reading, target screen examinations (lump together all cancellation tests and drawing tests)
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL , PsycInfo Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SR of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=10 (5 in each arm) Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Time after stroke (anytime) Report of adverse events

E.2 In people after stroke what is the clinical and cost-effectiveness of memory strategies versus usual care to improve memory?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Memory strategy training: (mnemonic strategies 'association' and 'organisation', drill-and-practice, memory aids internal, external or both, errorless learning) (3 groupings – 1. Compensatory strategies – 2.restorative strategies, 3. Rehearsal - drill & practice)
Comparison	Usual care
Outcomes	Wechsler Memory Scale Rivermead behavioural memory assessment. MMSE. Addenbrooks Cognitive Advised Examination abbreviated mental test score.
Exclusions	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL , PsycInfo Studies will be restricted to English language only Databases will be searched from the date of the Cochrane review Compensatory strategy Restoratory Errorless learning
The review strategy	SR of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=10 (5 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Time after stroke (any time after stroke) Report of adverse events

E.3 In people after stroke what is the clinical and cost-effectiveness of sustained attention training versus usual care to improve attention?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Computerised training programme using reaction times and pattern recognition.
Comparison	Usual care
Outcomes	Test of everyday attention, ABMT, MMSE, Addenbrooks Cognitive examination - revised
Exclusions	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL, PsycInfo Studies will be restricted to English language only Databases will be searched from the date of the Cochrane review
The review strategy	SR of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=10 (5 in each arm) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Time after stroke (anytime) Report of adverse events

E.4 In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Eye movement therapy, visual search therapy, visual scanning , scanning compensatory training
Comparison	Usual care (usually nothing), Sham Rehabilitation
Outcomes	Reading (speed and accuracy), Eye movement, Scanning, Letter Cancellation test
Exclusion	Prism therapy, visual restorative therapy, Perimetry, Quality of Life
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=10 (5 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months)

E.5 In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions / usual care to improve swallowing? (dysphagia)

	Clinical methodology
Population:	Adults and young people 16 or older who have had a stroke
Intervention	Carbonated water Frazier free water protocol Swallowing exercises : Specific exercises: a. effortful swallowing technique b. head-positioning c. tongue exercises d. thickening fluids/texture modification e. Mendelsohn's manoeuvre
Comparison	Usual care Thickening fluids Nil by mouth Alternative interventions Naso Gastric feeding
Outcomes	Occurrence of aspiration pneumonia (most important) Occurrence of chest infections Reduction in hospital stay Reduction in re-admission Return to normal diet
Exclusion	No Obstructive Dysphagia
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs , RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events (Adverse events – see above, malnutrition, dehydration, progression to tube feeding, death)

E.6 In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Upper limb strength training and / or Lower limb strength training Trunk and pelvis (Weight Training, Resistance Training, Isometric and Isotonic Exercises, Circuit Training for strength)
Comparison	Usual care
Outcomes	Upper Limb Fugl-meyer Assessment, Action Research Arm test (ARAT), Functional Independence Measure (FIM) /Barthel Index, MRC Scale, Newton/Metres, Lower Limb/Trunk and pelvis Functional Independence Measure (FIM) /Barthel Index, Timed up and go test, any timed walks, distance walks, Newton/Metres,
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL , AHMED Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events (pain, falls and (tone) spasticity)

E.7 What listener advice skills/training or information would help family members/carers improve communication in people with aphasia after stroke?

	Clinical methodology
Population	Families and carers of adults and young people 16 or older who have had a stroke with aphasia
Intervention	Listener advice skills/training or information
Comparison	Usual care or nothing, sham or alternative interventions
Outcomes	Any outcome – quality of life outcomes
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies No restriction on sample size Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 any months / > 12 months any) Report of adverse events

E.8 In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Possibly include 'soft and scotch' casts, All the usual ones, orthoses, orthosis, splint, brace, low temperature splints, palm protector. With or without botulinum toxin, lycra splinting
Comparison	Usual care
Outcomes	Range of movement assessed by goniometry
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL (n.b. Cochrane withdrawn as analysis was incorrect) Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events

E.9 In people after stroke what is the clinical and cost-effectiveness of Functional Electrical Stimulation (FES) for hand function versus usual care?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	FES with or without Robotics, FES with or without Transcranial Magnetic stimulation
Comparison	Usual care
Outcomes	Any outcome reported in the paper. Upper limb outcomes including: Action Research Arm Test (ARAT), Fugl-Meyer Assessment, 9 hole peg test, grip strength
Exclusion	Shoulder, shoulder subluxation and shoulder pain, hand pain
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies No restriction on sample size Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months any) Report of adverse events

E.10 In people after stroke what is the clinical and cost effectiveness of constraint induced therapy versus usual care on improving function and reducing disability?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Constraint induced therapy For upper limb Subgroup analysis – less than 5 hours More than 5 hours Any constraint – e.g slings
Comparison	Usual care
Outcomes	Functional Independence Measure (FIM) /Barthel Index, Fugl-Meyer Assessment, Action Research Arm test (ARAT), Wolfe, 9 hole peg test,
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Length of intervention / study = 5 out of 7 days for 2-3 weeks Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events - Falls

E.11 In people after stroke what is the clinical and cost effectiveness of repetitive task training versus usual care on improving function and reducing disability?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Repetitive task practice Lower limb functional tasks and / or Upper limb functional tasks (purposeful functional tasks with therapist present)
Comparison	Usual care
Outcomes	Lower limb Any timed walk, 6 minute walk test, 5 metre, 10 metre timed walks (lump together), change in walking distance, Rivermead mobility index Upper limb Arm: Fugl Meyer Assessment, ARAT Hand: Any peg hole test, Frenchay Arm Test, MAS (Group together any timed walk and any peg hole test).
Exclusion	Treadmill and Constraint induced movement therapy
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL, AMED Studies will be restricted to English language only Databases will be searched from the date of the Cochrane review.
The review strategy	SR of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Time after stroke (anytime) Report adverse events

E.12 In people after stroke what is the clinical and cost effectiveness of all treadmill versus usual care on improving walking?

E.13 In people after stroke who can walk, what is the clinical and cost effectiveness of treadmill plus body support versus treadmill only on improving walking?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Treadmill with or without body support
Comparison	Usual care (other physiotherapy)
Outcomes	Walking speeds (5 m/ 10 m / 30 m), any timed walk, walking endurance, Functional Independence Measure (FIM)/Barthel Index, Rivermead mobility index
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Time after stroke (anytime) Report of adverse events

E.14 In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Electromechanical gait training Locomat,
Comparison	Usual care
Outcomes	Walking speeds (5 m/ 10 m / 30 m), any timed walk, walking endurance, Functional Independence Measure (FIM) /Barthel Index, Rivermead mobility index
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events

E.15 In people after stroke what is the clinical and cost-effectiveness of ankle-foot orthoses of all types to improve walking function versus usual care?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	'soft and scotch' casts, orthoses, orthosis, splint, brace, low temperature splints, ankle-foot orthoses (AFO), ground reaction ankle-foot orthoses (GRAFO), dynamic ankle-foot orthoses (DAFO)
Comparison	Usual care
Outcomes	Walking speed: 6 min walk test, 10 metre timed walk Lower limb MAS (stairs) Walking endurance, Functional Independence Measure (FIM), Barthel Index, Rivermead mobility index Cadence Gait symmetry (stance time, step length) Quality of Life outcomes
Exclusion	KAFOs (Knee Ankle Foot Orthoses)
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Minimum proportion of participants with stroke: 50% Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events (Pressure sores, falls, pain)

E.16 In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing / others) versus usual care?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Intensive OT - Dressing , grooming, bathing, feeding/eating, washing, toileting
Comparison	Usual care (OT once a week)/no care
Outcomes	Nottingham Extended Activities of Daily Living (NEADL), Extended Activities of Daily Living (EADL), Functional Independence Measure (FIM), Barthel Index, Nottingham dressing assessment, Northwick park nursing dependency scale, Rivermead Mobility Index
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months any Report adverse events

E.17 In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Job retention Return to work (tailored to the impairment of the patient recognising the demands of the job)
Comparison	Usual care Nothing
Outcomes	Same job same employer Same job different employer Different job same employer Different job different employer Unemployment Retired due to ill health Voluntary work Benefit claims
Exclusion	Barriers to returning to work Patient experience studies
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL, PsychInfo Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SR of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events

E.18 What is the effectiveness of supported versus unsupported information provision on mood and depression in people with stroke?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Supported information giving (active information provision, encourage feedback, peer support, interactive computer programme,)
Comparison	Unsupported Information (leaflets, notice board information etc.)
Outcomes	Impact on mood/depression Hospital Anxiety and Depression Scale, General health questionnaire Visual Analogue Mood Scale Stroke Aphasic Depression Questionnaire (SAD-Q) Geriatric Depression Scale Beck Depression Inventory Self-efficacy General Self-Efficacy Scale Stroke Self-Efficacy Questionnaire Locus of Control Scale Extended activities of daily living Nottingham extended activities of daily living Frenchay Activities Index Yale mood scale
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SR of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months) Report of adverse events

E.19 In people after stroke what is the clinical and cost-effectiveness of psychological therapies provided to the family (including the patient)?

	Clinical methodology
Population	Adults and young people over 16 with stroke And family carers (family member or relative, or other unpaid carer support)
Intervention	Family Therapy Cognitive-Behaviour Therapy Relationship counselling (to include Couples therapy) All interventions may include some form of information.
Comparison	Usual care (usually nothing)
Outcomes	Quality of Life (for both carer and patient) – Any QoL and depression outcomes including the following: stroke impact scale, euroQoL, care giver burden scale, caregiver strain index, carer strain index, burden of stroke scale, Stroke and aphasia quality of life scale, ASCOT scale. Occurrence of depression/anxiety/mood in carers – Beck Depression Inventory, Beck Depression Inventory 2, Geriatric Depression Scale, neuropsychiatric inventory, Hospital Anxiety and Depression Scale (HADS), General health questionnaire, Visual Analog Mood Scale, SAD-Q.
Exclusion	Patient experience studies Patient views Cross over studies
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL, Psychinfo Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SR of RCTs or RCTs, SRs of cohort studies No restriction on sample size Only patients with stroke included (100%) Reporting of long/short term outcomes We will not consider the number of therapy sessions given in each study but it will be reported.

E.20 In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke(specify which cohort)
Intervention	Early supported discharge for stroke (specify what this is in extraction)
Comparison	Usual care; stroke hospital units
Outcomes	Barthel Index , length of hospital stay, Functional Independence Measure, Caregiver strain index, falls, readmissions, Hospital Anxiety and Depression Scale (HADS), mortality, Quality Of Life (any outcome), Nottingham Extended Activities of Daily Living (NEADL)
Exclusion	Hospital at home, intermediate care
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Only patients with stroke included (100%) Follow up period (up to 1-2 years) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months= any) Report of adverse events

E.21 In people after stroke what is the clinical and cost-effectiveness of intensive rehabilitation versus standard rehabilitation?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke
Intervention	Intensive rehabilitation (inpatient and outpatient)(hours per day, no of days of treatment, weeks versus months, large versus small dose)
Comparison	Standard rehabilitation or none
Outcomes	Length of stay, Functional Independence Measure (FIM), Barthel Index, Quality of life (any measure), Nottingham activities of daily living (NADL), Rankin, Rivermead Mobility Index
Exclusion	Movement specific interventions
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies Minimum sample size of participants: N=20 (10 in each arm) Minimum proportion of participants with stroke: 50% Follow up period (any) Report of long/short term outcome (< 6 months / < 12 months / > 12 months= any) Rehabilitation starting on acute ward; no Report of adverse events

E.22 In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?

	Clinical methodology
Population	Adults and young people 16 or older who have had a stroke and have communication difficulties
Intervention	Intensive speech therapy, - aphasia therapy, constraint induced aphasia therapy (Any study with more versus less)
Comparison	less speech therapy or nothing
Outcomes	any outcome reported in the paper Asha facts, boston naming test, Western aphasia battery, stroke dysphasia index, McKenna grading naming test,
Exclusion	None
Search strategy	The databases to be searched are Medline, Embase, Cochrane Library, CINAHL Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin Dysarthria, aphasia
The review strategy	SRs of RCTs or RCTs, SRs of cohort studies No restriction on sample size Only patients with stroke included (100%) Follow up period (any) Reporting of long/short term outcome (< 6 months / < 12 months / > 12 months any) Report of adverse events

E.23 Health economic evidence questions

Objectives	To identify economic studies relevant to the review questions set out above.
Criteria	Populations, interventions and comparators as specified in the individual review protocols above. Must be a relevant economic study design (cost-utility analysis, cost-benefit analysis, cost-effectiveness analysis, cost-consequence analysis, comparative cost analysis).
Search strategy	An economic study search was undertaken using population specific terms and an economic study filter – see Appendix D.
Review strategy	<p>Each study is assessed using the NICE economic evaluation checklist – NICE (2009) Guidelines Manual, Appendix H.</p> <p>Inclusion/exclusion criteria</p> <p>If a study is rated as both ‘Directly applicable’ and ‘Minor limitations’ (using the NICE economic evaluation checklist) then it should be included in the guideline. An evidence table should be completed and it should be included in the economic profile.</p> <p>If a study is rated as either ‘Not applicable’ or ‘Very serious limitations’ then it should be excluded from the guideline. It should not be included in the economic profile and there is no need to include an evidence table.</p> <p>If a study is rated as ‘Partially applicable’ and/or ‘Potentially serious limitations’ then there is discretion over whether it should be included. The health economist should make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the GDG if required. The ultimate aim being to include studies that are helpful for decision making in the context of the guideline. Where exclusions occur on this basis, this should be noted in the relevant section of the guideline with references.</p> <p>Also exclude:</p> <ul style="list-style-type: none"> unpublished reports unless submitted as part of the call for evidence abstract-only studies letters editorials reviews of economic evaluations Error! Reference source not found. foreign language articles <p>Where there is discretion The health economist should be guided by the following hierarchies.</p> <p>Setting:</p> <ul style="list-style-type: none"> UK NHS OECD countries with predominantly public health insurance systems (e.g. France, Germany, Sweden) OECD countries with predominantly private health insurance systems (e.g. USA, Switzerland) Non-OECD settings (always ‘Not applicable’) <p>Economic study type:</p> <ul style="list-style-type: none"> Cost-utility analysis Other type of full economic evaluation (cost-benefit analysis, cost-effectiveness analysis, cost-consequence analysis) Comparative cost analysis Non-comparative cost analyses including cost of illness studies (always ‘Not applicable’) <p>Year of analysis:</p> <p>The more recent the study, the more applicable it is</p> <p>Quality and relevance of effectiveness data used in the economic analysis:</p> <p>The more closely the effectiveness data used in the economic analysis matches with the studies included for the clinical review the more useful the analysis will be to decision making for the guideline.</p>

(a) *Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.*

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F.1 Introduction

During consultation on the draft version of the full guideline, stakeholder comments were received which raised a number of significant issues in relation to the guideline scope and recommendations developed in the guideline.

Stakeholders had concerns that because the guideline did not present a complete stroke rehabilitation patient pathway this may lead to services being reduced or even withdrawn. Stakeholders also noted the agreed approach to rehabilitation was a holistic one that reflected individual patient need provided by a multidisciplinary team but this was not considered by the guideline which had focused only on the delivery of interventions.

In light of the comments received from stakeholders, the GDG agreed that additional work would be carried out to address the structure and process of stroke rehabilitation which had not been included in the original draft version (or reference would be made to other NICE guidance). This was done to produce a more complete piece of guidance that would be useful to health professionals who deliver rehabilitation to a stroke population.

The evidence base is weak or absent for many of the areas stakeholders wished the guideline to include, therefore a different methodology was necessary that would provide a robust process to enable the GDG to make further recommendations. Where there was a lack of published evidence the NCGC technical team used a modified Delphi method (anonymous, multi-round, consensus-building technique) based on other available guidelines or expert opinion. This type of survey has been used successfully for generating, analysing and synthesising expert view to reach a group consensus position. The resulting statements will form the basis for the GDG to consider and utilise to develop further recommendations.

Whilst the stakeholder consultation clearly showed a concern that recommendations had not been made for particular areas of the rehabilitation pathway, the results of the Delphi survey have demonstrated that for many of these areas there does not appear to be consensus agreement held by the wider stroke rehabilitation professional body.

A process and protocol framework was drawn up for this additional work which was published on the NICE website (<http://guidance.nice.org.uk/CG/Wave21/4/FinalProtocol/pdf/English>) and is added here as Appendix B.

The modified Delphi process and areas that are covered by it are detailed below.

It is important to emphasise that a search was conducted for systematic reviews on any of the additional topics that were identified by stakeholders. Where there were good quality systematic reviews identified, the evidence was updated (i.e. searches from the cut-off dates of the reviews) and findings were presented to the GDG. The GDG based their recommendations on this evidence. Reviews were identified for goal setting, stroke units, fitness and management of aphasia. Modified Delphi – areas to address

The following areas were identified as additional topics. These were prioritised based on stakeholders' comments received during the consultation period of the guideline:

- Service delivery, multidisciplinary team working
- Assessment for rehabilitation, care planning, goal setting, and ongoing review of patients.
- Transfer of care, discharge planning and interface between health and social care
- Long term health and social support for people after stroke.
- Visual impairment including Diplopia
- Speech and language therapies –dysphasia, dysarthrophonia and articulatory dyspraxia

- Shoulder pain

F.2 Modified Delphi methodology

For review areas where little or no evidence was identified, a modified Delphi survey method^{15,30} was adopted. In NICE processes, little or no evidence for reviews is an exceptional circumstance when formal consensus techniques (such as the Delphi method) can be adopted²². For this guideline a full process and protocol framework was drawn up which can be found in Appendix A. Two external, independent experts were recruited to act as consultants in the development of the survey statements. The consultant experts' role was to provide guidance to the technical team in the formulation and validation of consensus statements at each round of the survey. They neither took part in the survey nor the GDG meeting in which recommendations were drawn up from the Delphi consensus statements.

Delphi statements were distilled from the content of existing national and international stroke rehabilitation guidelines. The identified guidelines were quality assured by two research fellows using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument as described in the Appendix B. In this process the topic 'goal setting' was an exception since a systematic review was identified covering this issue. However, after presenting the evidence from this review to the GDG they came to the conclusion that important aspects of goal setting in clinical practice were not captured. To be able to draw up further recommendations regarding this topic it remained in the Delphi. The relevant sections of the guidelines were summarised and these summaries were used as the basis for draft statements. Statements were then discussed and revised with the recruited experts. Additional statements were drafted by the expert consultants with the technical team for areas where no existing guidance was available (e.g. interface between health and social care). Please see the appendicised table outlining the mapping process.

The Delphi panel comprised of stroke rehabilitation clinicians and other professionals with significant experience in stroke rehabilitation (referred to as the expert panel) covering a wide range of disciplines involved in stroke care. Members of the panel were identified by means of nomination, where each Guideline Development Group member had the option to nominate a maximum of 10 experts (providing name, work setting, discipline, area of expertise and contact details). These nominations were then collated and reviewed by the chair of the GDG and the RCP Intercollegiate Stroke Working Party and, after removal of duplicates, inspected for representativeness. There was an under-representation of social workers and orthoptists and organisations were directly contacted to nominate potential participants. In the first instance 164 experts were contacted and invited to participate. The list comprised:

- 6 geriatricians
- 9 neurologists
- 12 nurses
- 9 occupational therapists
- 8 people from patient representation/organisations: 7 were employees from patient organisations and 1 was a GDG patient representative (3 of those came employed by the Stroke Association, 3 from Different Strokes, one person from Speakability)
- 49 physiotherapists
- 6 psychologists
- 7 research / policy makers
- 9 social workers
- 16 speech and language therapists
- 19 stroke physicians

- 14 'other' health care professionals (e.g. orthoptist, dietician, GP and pharmacists).

A survey, consisting of 68 statements plus 3 demographic questions (profession, setting, and geographic area), was then circulated to the expert panel. This survey included open text options in which panel members could give comments to statements. 116 panel members (69%), with representatives from all professions, responded to the survey. Participants were asked to comment on and rate how much they agreed with statements via an online survey. Comments from round 1 were then used to revise and refine the entire set of Delphi statements as is done in the usual piloting process of survey design. This process was carried out in conjunction with the consultant experts as well as the Chair of the guideline.

The new survey (round 2) was then sent out to the whole panel of 164 experts. In round two 89% (103/116) of panel members who took part in the first round responded, 83% (85/103) took part in round 3 and 86% (75/85) in round 4. Detailed statistics on each round could be found in Delphi Methodology Appendix 3. Throughout this process the group that participated stayed broadly representative of the panel that was originally identified. Details of group membership in each of the rounds can be obtained from the National Clinical Guideline Centre stroke guideline technical team demand. There was an option to decline to participate in Round 1 five members and in Round 2 six panel members declined to take part. The survey included a general set of statements to be rated by all panel members, as well as specialist topics (shoulder pain, speech and language management and visual impairments) targeted at those with particular experience in this field of expertise. These sections could be skipped by panel members without specific experience in these areas. For the majority of all 69 statements (plus demographics), a Likert scale was applied to indicate the level of agreement. Some statements employed multiple choice options. A four option Likert scale was used: strongly disagree, disagree, agree and strongly agree. A rate of 70% or higher of participants 'strongly agreeing' was set for rounds 1 and 2, with this threshold for consensus being reviewed in rounds 3 and 4. In analysing the data, and in understanding the difficulty of reaching consensus in the latter rounds where iteration had featured, a decision was reached by the technical team to accept a rate of 67% 'strongly agree' as consensus as long as the majority of other participant responses were 'agree' and less than 10 of panel members disagreed. This was a pragmatic response by the technical team and meets published criteria that consensus is achieved when at 66.6% of an expert panel agrees. Statements that reached these levels would not feature in the next round. Statements that did not reach this level were reviewed by the technical team with the GDG chair and expert consultants and were amended based on the panel's comments in the survey. This procedure of re-evaluation continued until either the consensus rate was achieved or until the experts no longer modified their previous estimates / responses (or comments). There is not complete agreement about the termination of Delphi and one researcher has stated 'if no consensus emerges, at least a crystallizing of the disparate positions usually becomes apparent' (Gordon, 1971)¹⁶.

When there were low levels of disagreement, some statements were not edited and re-included in the next round. With already low levels of disagreement it was felt that re-inclusion of these statements would encourage panel members to shift from an 'agree' to a 'strongly agree' response. This process led to a survey with eleven statements in round 4. None of them reached the level of agreement specified for consensus, even with revision in previous rounds. A joint meeting of the technical team with the expert advisors and the chair of the guideline the results for the remaining 11 questions were discussed. Due to the fact that despite rephrasing levels of agreement had not changed it was decided that experts no longer modified their responses for this set of questions and that therefore consensus was unlikely to be achieved with further revision. In other words when both the level of agreement and the type of comments no longer changed it was agreed that a further round would not achieve consensus. The comments that illustrated these differences in opinions or comments that showed agreement but no longer changed were then highlighted in the final Delphi report.

How and when consensus was achieved for all statements in rounds 2 to 4 is presented in the appendices.

Since there was an over-representation of physiotherapists in the panel responses were inspected by profession in the analysis. There were no systematic differences in physiotherapists' responses compared to those of other professions. Hence further details of responses per profession were not included in the report.

F.3 Qualitative analysis

A free text box was available for panel comments for each statement. Members of the panel used these text boxes frequently. Rates of comments ranged between 7-20% of for some items gaining early consensus, and up to 60% for items that were more controversial. For some items direct prompts were provided (e.g. 'list the possible role of a MDT co-ordinator') and most panel members commented providing additional items, i.e. with a rate of 60% or higher.

Overall comments fell into several categories:

1. Those highlighting particular issues related to the clarity of the statement.
 - a. Those criticising / or disagreeing with the statement content.
2. Those providing additional options / approaches to those given in the statement (whether or not prompted).
3. Those giving additional or qualifying information to the content of the statement.

Comments in category 1 were discussed after each round to inform possible changes to the statement for the next round. The technical team discussed these with the external consultants and Chair of the guideline and agreed on changes to the statements based.

When additional options were given by panel members (category 2 above), the frequency of comments (e.g. how often people mentioned a particular additional assessment) was inspected and applicability was discussed in the technical team meeting. Sometimes the frequency of mention clearly indicated a missing option which needed to be included in the list for the next round. However, frequency was not regarded as the only indicator for further inclusion the technical team also inspected idiosyncratic responses. Some suggested items were discussed but were deemed not to be a high priority for inclusion in the next round. Suggestions that did not feature in later rounds are provided in the Tables below in the relevant comments section.

Category 3 comments were reviewed using discourse analysis. As a starting point the most frequent keywords were inspected using the survey text analysis feature. The survey software provides a visual representation of keywords with more frequently produced items indicated by larger font size (the so called 'cloud'). It was then checked whether these words / concepts could correspond to identifiable themes. In cases where the cloud was not found to be useful category 3 comments were carefully inspected and thematically interpreted. Representative comments or extracts from comments are frequently provided in the tables of results below. The themes and individual points that were raised by panel members were then discussed in the technical team meeting with the external consultants and Chair of the guideline .

For results of the qualitative analysis please refer to the final column of the consensus and non-consensus statement tables.

F.4 Service delivery - multidisciplinary team working

F.4.1 Consensus protocol

Table 1: What should be the constituency of a multidisciplinary rehabilitation team and how should the team work together to ensure the best outcomes for people who have had a stroke?

Population	Adults and young people 16 or older who have had a stroke
Components	<ul style="list-style-type: none"> Constituency of a multidisciplinary rehabilitation team Working practices, such as communication and co-ordination of services (team and family meetings, co-ordination of care between rehab specialties and other agencies)
Outcomes	<ul style="list-style-type: none"> Patient and carer satisfaction optimised strategies to minimise impairment and maximise activity/participation

F.4.2 Multidisciplinary team working

F.4.2.1 Delphi statements where consensus was achieved

Table 2: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	<p>A core stroke rehabilitation team should comprise of membership from the following disciplines:</p> <ul style="list-style-type: none"> Consultant neurology/stroke medicine Nursing Physiotherapy Occupational therapy Speech and Language Therapy Clinical Neuro Psychology Rehabilitation Assistant Social work 	<p>81.0</p> <p>89.1</p> <p>99.0</p> <p>99.0</p> <p>99.0</p> <p>74.0</p> <p>72.2</p> <p>71.2</p>	<p>28/101 (28%) panel members commented</p> <p>Pharmacists and Nutritionist did not reach consensus</p> <p>Some other 'optional' team members were suggested in comments, for instance:</p> <ul style="list-style-type: none"> Orthoptists Counsellor Family or patient support worker Access to relevant others such as peers with stroke, information navigators, voluntary sector organisations <p>An opinion was expressed that different specialists are required at different stages of rehabilitation ("The core team should be available although it is recognised that at different stages of the rehabilitation pathway and depending on the needs of the patient the level of these inputs may vary.")</p> <p>The importance of voluntary sector involvement was stated with regards to the role of a co-ordinator ("This</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			role could be provided by the voluntary sector, the best example being the Stroke Association's information, advice and support co-ordinators.").
2.	Throughout the care pathway roles and responsibilities of the multi-disciplinary stroke rehabilitation team services should be clearly outlined, documented and communicated to the patient and their family.	72.7	<p>18/99 (18%) panel members commented</p> <p>Information to the family of the person who has had a stroke should only be given with patient's consent</p> <p>Communication was viewed as integral in rehabilitation process</p> <p>Extracts: 'Verbal communication should be supported by clear, unambiguous written information to avoid any subsequent disputes/confusion.' 'I think it helps communication for patients and staff, however the frequency and process of this has to be realistic in its delivery.'</p>
3.	In order to inform and direct further assessment, members of the MDT should screen the person who has had a stroke for a range of impairments and disabilities.	81.0	<p>9/100 (9%) commented: Reliability and validity of screening instruments was highlighted</p> <p>Reason for screening: Screening to inform treatment / further assessment rather than screening for screening's sake</p> <p>Treatment: Some people commented that the focus in stroke rehabilitation should be on treatment rather than measurement.</p>

F.4.2.2 Delphi statement where consensus was not reached

Table 3: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results	Amount and content of panel comments – or themes
1.	The person who has had a stroke is integrated in the stroke rehabilitation team.	62.9	26/100 (26%) panel members commented in round 2; 29/84 (35%) commented in round 3 and 24/70 (34%) commented in round 4:

Number	Statement	Results	Amount and content of panel comments – or themes
			<p>Impairments of the persons who have had a stroke that affect participation should be considered for this statement. (“Some individuals can easily make a very active and substantial contribution to the work of the team whereas others because of the severity of the stroke or of any communication difficulties would be much more limited.”)</p> <p>Patient preference: It may not be the wish of the person who has had a stroke to participate in the team (“When I need care or help I wish to be treated with respect, dignity and as an equal, but I view the MDT as people who support me, advise me and have clinical expertise, they are the team who help me.”).</p> <p>Between rounds 3 and 4 the statement was changed from: ‘is a member of’ to ‘is integrated in’ the stroke rehabilitation team’.</p> <p>Most panel members objected to the concept of team membership.</p> <p>The concept of membership as opposed to partnership was highlighted</p> <p>Two panel members expressed the opinion that this statement was redundant.</p>
2.	A member of the multidisciplinary stroke rehabilitation team should be tasked with coordination and steering (e.g. communication, family liaison and goal planning) of the rehabilitation of the person who has had a stroke at each stage of the care pathway.	62.5	<p>A direct prompt was given for this question (to list the roles). In round 2 61/100 (61%) panel members commented; 48/85(56%) in round 3 and 34/72 (47%) in round 4:</p> <p>There was a list of possible roles for a coordinator:</p> <ul style="list-style-type: none"> • Communication • Goal planning • Family liaison

Number	Statement	Results	Amount and content of panel comments – or themes
			<ul style="list-style-type: none"> • Key working • Discharge planning • Single point of contact <p>“few teams cover the whole of the stroke care pathway and this would not work practically”.</p> <p>“where a member of the team is responsible, the process becomes slowed down.”</p>

F.5 Assessment for rehabilitation, goal setting and care planning

F.5.1 Consensus protocol

Table 4: In planning rehabilitation for a person after stroke what assessments and monitoring should be undertaken to optimise the best outcomes?

Population	Adults and young people 16 or older who have had a stroke
Components	<ul style="list-style-type: none"> • assessment • care plans • monitoring
Outcomes	<ul style="list-style-type: none"> • Patient and carer satisfaction • optimised strategies to minimise impairment and maximise activity/participation

F.5.2 Assessment for rehabilitation

F.5.2.1 Delphi statements where consensus was achieved

Table 5: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	<p>After admission to hospital the person who has had a stroke should have the following assessed as soon as possible:</p> <ul style="list-style-type: none"> • Positioning • Moving and handling • Swallowing • Transfers • Pressure area risk • Continence • Communication • Nutritional status 	<p>82.0</p> <p>92.0</p> <p>94.9</p> <p>79.5</p> <p>90.0</p> <p>86.8</p> <p>80.0</p> <p>77.7</p>	<p>34/100 (34%) panel members commented:</p> <p>A number of additional assessments/measurements were suggested (a lot of these are covered in other sections):</p> <ul style="list-style-type: none"> • Activities of daily living • Mood • Pain • Motor control • Cognition <p>A number of people commented that the terminology 'sensory</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			registration' [the one option that did not reach consensus] was unclear.
2.	<p>Comprehensive assessment takes into account:</p> <ul style="list-style-type: none"> • Previous functional status • Impairment of psychological functioning • Impairment of physiological body functions and structures • Activity limitations due to stroke • Participation restrictions in life are stroke • Environmental factors (social physical and cultural) 	<p>86.1</p> <p>81.1</p> <p>81.1</p> <p>84.1</p> <p>75.2</p> <p>76.2</p>	<p>25/100 (25%) panel members commented:</p> <p>Additional issues to take into account:</p> <ul style="list-style-type: none"> • Patient and carer views • Motivation • Co-morbidities
3.	Family members and/or carers should be informed of their rights for a carers' needs assessment.	71.7	<p>11/99 (11%) panel members commented:</p> <p>This was generally viewed as an important issue.</p> <p>Extracts:</p> <p>'Those carers who are passive need to be informed that this is available and many may be too timid to know they can request this assessment.'</p>
4.	The impact of the stroke on the person's family, friends and/or carers should be considered and if appropriate they can be referred for support.	78.0	<p>11/100 (13%) panel members commented:</p> <p>Comments were divided:</p> <ul style="list-style-type: none"> • Some thought that this was obvious • Others thought that in reality there is a lack of available support mechanisms.
5.	People who have had a stroke should have a full neurological assessment including cognition, vision, hearing, power, sensation and balance.	69.0	<p>19/84(23%) panel members commented:</p> <p>This was a statement that was added in Round 3 based on comments in Round 2.</p> <p>Comments to this statement were – more individual than in themes:</p> <ul style="list-style-type: none"> • The phrase 'full assessment' was queried by one ("If you mean that a full neurological assessment includes a screening process that can lead to a more detailed assessment as needed then I 'strongly agree'")

Number	Statement	Results %	Amount and content of panel comments – or themes
			<ul style="list-style-type: none"> Some people wanted additional assessments (swallow, coordination, movement control, shoulder subluxation for instance) It was mentioned that this should be done according to need and that people should not be over assessed. The need to have a neurologist doing this was questioned.
6.	Experts agreed with screening for the following: <ul style="list-style-type: none"> Mood Pain 	69.8 68.6	In round 2 this was an open text question and 83 people answered; in round 3 this was rephrased into a statement with multiple options format and 18/83 (22%) commented: <p>There was confusion about some of the options and additional screening tools were suggested:</p> <ul style="list-style-type: none"> Dysphagia / Swallow tests Falls Carers Strain Index
7.	Routine collection and analysis of a range of measures should include: <ul style="list-style-type: none"> National Institute of Health Stroke Scale Barthel Index Hospital Anxiety Depression Scale (HADS) 	74.0 (of 50) selected as first option 46.5 (of 43) - as second option 56.3 (of 32) as third option	In round 2 - 40/87 (46%) panel members commented; 26/77(34%) in round 3. This was included in a different format in Round 3 (to select the three main). <p>Those that did not reach consensus were:</p> <ul style="list-style-type: none"> Modified Rankin Berg Balance Scale EQ5D General Health Questionnaire (GHQ) Geriatric Depression Scale <p>Some people disliked the fact that only 3 options could be selected and stated that it depends on the individual patients which measures would be selected.</p> <p>Others panel members highlighted that measures depend on the stage of rehabilitation ("NIHSS is a reasonable baseline whereas the Berg is most useful beyond the acute phase. It also depends on what sort</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			<p>of ‘analysis’ you are expecting to be done. Is the data for understanding the severity of stroke or the outcome of rehab?”)</p> <p>It was questioned whether the statement refers to outcome or baseline measures (“...It depends what you are trying to show? If it’s outcomes and service demands? Maybe rehab complexity scales to show the demands and resources you need. FIM to show functional outcomes perhaps instead of Barthel.”).</p> <p>Additional measures were also suggested:</p> <ul style="list-style-type: none"> • TOM • PHQ • Nottingham Extended Activities of Daily Living Scale

F.5.2.2 Delphi statement where consensus was not reached

Table 6: Table of ‘non-consensus’ statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	<p>The specific list of professional screening tools to be included:</p> <ul style="list-style-type: none"> • Montreal Cognitive Assessment (MOCA) • Frenchay Aphasia Screening Test (FAST) • Malnutrition Universal Screening Tool (MUST) • The Waterlow Pressure score risk assessment tool (pressure ulcers) 	<p>25.4</p> <p>22.5</p> <p>42.6</p> <p>44.9</p>	<p>In round 2 - 48/93 (52%) panel members commented; 40/72(56%) in round 3 – the options changed between rounds 2 and 3:</p> <p>A number of additional scales/tools were mentioned [some of which were already included in other statements]:</p> <ul style="list-style-type: none"> • Berg Balance scale • Modified Rivermead Mobility Index • Mood • Therapy outcome measure • Screen for malnutrition <p>Validity, reliability and training need to be taken into consideration. (“You should state ‘using a recognised tool;”</p> <p>“The tool is not important so long as it is a validated tool. There is no need</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			<p>to direct which tools people should use.”)</p> <p>Concern was raised about possible recommendations being too prescriptive (“These tools should only be suggested tools not prescriptive as the clinician should be able to make the decision as to the most appropriate tool”.</p> <p>“The tool is not important as long as it is a validated tool. There is no need to direct which tools people should use”.)</p> <p>Whether these were screening tools or outcome measures was also questioned.</p>
2.	Data collection should be overseen by a national body.	62.0	<p>In round 2 - 27/97 (28%) panel members commented; 21/81(26%) in round 3 and 16/71 (23%) in round 4:</p> <p>It was highlighted that this is already in existence in some place (such as the RCP audit, the Scottish Stroke Care Audit or the National Sentinel Stroke Audit)</p>

F.5.3 Goal Setting

F.5.3.1 Delphi statements where consensus was achieved

Table 7: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
	Both profession specific as well as multidisciplinary stroke teams' goals should be person focused.	81.8	<p>17/99 (17%) panel members commented</p> <p>This was seen important in the process of goal planning by some panel members (“Absolutely. We don’t do this enough yet and we need to get much better at this to use outcome measures properly and really effectively.”)</p> <p>It was seen as most important that goals should be set by or set collaboratively with the person who has had a stroke (“Goals need to be</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			<p>genuinely person generated.”</p> <p>“Goal setting should be collaborative, set with the patient, and multidisciplinary rather than uni-disciplinary”</p> <p>“There should be one set of patient agreed patient centred goals”)</p> <p>Four people expressed the opinion that this was not a sensible statement.</p>
	Efforts should be made to establish the wishes and expectations of the person who has had a stroke and their carer/family.	86.9	<p>13/99 (13%) panel members commented</p> <p>It was highlighted that these expectations need to be realistic.</p> <p>Some people questioned the term ‘efforts’ and what this would mean in real terms.</p> <p>One person indicated the opinion that this was a redundant statement.</p>
	<p>The following criteria should be used when setting goals with the person who has had a stroke:</p> <p>Meaningful and relevant</p> <p>Should be focused on activities and participation</p> <p>Challenging but achievable</p> <p>Both short and long-term targets</p> <p>May involve one MDT team member or may be multidisciplinary</p> <p>Involve carer / family where possible, with consent of person who has had a stroke</p> <p>Used to guide therapy and treatment</p>	<p>92.0</p> <p>69.7</p> <p>76.0</p> <p>70.1</p> <p>76.0</p> <p>81.0</p>	<p>20/100 (20%) panel members commented</p> <p>Rather than themes individual issues were highlighted:</p> <p>The type of goal depends on the stage and setting of rehabilitation (“Initial goals in the acute setting may be less focussed on activities and participation as the treatment begins to develop a base from which further goals may be set, e.g. increasing the length of treatment that can be tolerated. Not all objectives can be identified within recognised assessment tools in the early stages.”)</p> <p>Some goals might not be easily measurable (“Goals do not have to be measurable as improvement in engagement and motivation can be a goal that will be difficult to quantify.”)</p> <p>Goals should be jargon free.</p> <p>One person indicated the opinion that this was a redundant statement.</p>

F.5.3.2 Delphi statements where consensus was not achieved

Table 8: Table of ‘non-consensus’ statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
	Goals should have predicted dates for completion.	36.5	<p>In round 2 - 24/98 (24%) panel members commented; 19/85(22%) in round 3:</p> <p>Themes:</p> <p>Flexibility – timing of goals should not be too rigid and prescriptive.</p> <p>Type of goals – some goals don’t leant themselves to predict an end point</p> <p>Effect on patients – focus on dates and failure can lead to distress and have an impact on confidence and esteem</p> <p>Progression – Rather than giving one date, regular reviews lead to a feeling of progress</p>
	A review of goals of the person who has had a stroke should be conducted between the person and the multidisciplinary team member delivering the intervention at the expected date of completion.	42.4	<p>In round 2 - 14/99 (14%) panel members commented; 13/85(15%) in round:</p> <p>The panel’s comments have the following themes – some of these are mirroring those for expected dates of goals:</p> <p>Expected date – it was queried whether there would be an expected date (“I don’t agree that goals always need to have an expected date of completion.”)</p> <p>Regular reviews – goals should be regularly reviewed as an ongoing process (“But should be constantly reviewed throughout therapy.”).</p> <p>Flexibility – when and how the review would take place should be flexible (“These people should be involved but there does need to be some flexibility”).</p> <p>Team or individual member - Could involve an individual team member, but sometimes also the whole team (“This should be part of the weekly MDT meeting which the patient should take part in.”).</p> <p>One person objected to this statement since it represents an ideal scenario rather than what can</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			be achieved in clinical practice (“if you did all these things, you’d never have time to do any actual therapy.”).
	The reasons for unattained goals and goals that have been reassessed need to be documented.	56.5	<p>In round 2 - 11/99 (11%) panel members commented; 6/85(7%) in round 3:</p> <p>Generally this was seen as positive, but it was stated that this may be too reflective for some and that it needs to benefit the individual rather than be a measure of outcome.</p> <p>“It is helpful to know why a goal is not being met – to learn about patterns of recovery and what affects progress.”</p>
	Patients should have a written copy of their goals.	52.4	<p>In round 3 (this statement was first introduced in round 3) 17/84 (20%) panel members commented</p> <p>There was a feeling that the format of this documentation would not always be accessible to the person who has had a stroke (cognitive or language impaired persons for instance).</p> <p>“It might be helpful if this stated that these goals should be in language appropriate to the patient (not MDT language) and that where possible, they should reflect the patient’s own words in setting the goals.”</p> <p>“For patients with memory problems this is particularly important but also written goals aid communication between the patient, team and family”.</p>

F.5.4 Care Planning

F.5.4.1 Delphi statements where consensus was achieved

Table 9: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
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Number	Statement	Results %	Amount and content of panel comments – or themes
1.	<p>Documentation related to rehabilitation should be individualised, and contain the following minimum information:</p> <p>Basic demographics including contact details and next of kin</p> <p>Diagnosis and relevant medical information</p> <p>List of current medications including allergies</p> <p>Standardised screening assessments to include those identified in earlier questions</p> <p>Person focused rehabilitation goals</p> <p>Multidisciplinary progress notes</p> <p>Key contact from the stroke rehabilitation team to co-ordinate health and social care needs</p> <p>Discharge planning information</p> <p>Joint health/social care plans if developed</p> <p>Follow up appointments</p>	<p>93.9</p> <p>96.9</p> <p>92.9</p> <p>78.7</p> <p>93.9</p> <p>79.5</p> <p>87.8</p> <p>85.8</p> <p>76.5</p> <p>79.5</p>	<p>17/99 (17%) panel members commented:</p> <p>A number of additional documents were suggested:</p> <p>Return to work information was mentioned most frequently</p> <p>Information on additional support available after discharge (carer support organisations, stroke support groups etc)</p> <p>Stroke education / lifestyle information</p>
2.	<p>In the development of rehabilitation plans, efforts should be made to encourage the person who has had a stroke and carers to be involved and actively participate.</p>	<p>86.9</p>	<p>17/99 (17%) panel members commented:</p> <p>This was seen as important in person centred care.</p> <p>It was mentioned that the wishes of the person who has had a stroke should be taken into consideration. Some people find</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			<p>this a stressful experience.</p> <p>Three people expressed an opinion that this was a redundant statement.</p>
3.	Rehabilitation plans should be reviewed by the multidisciplinary team at least once per week.	71.4	<p>In round 2 - 41/95 (43%) panel members commented; 34/77(44%) in round 3</p> <p>The phase of rehabilitation was commented on. Weekly reviews early on in the acute phase, or when the person who has had a stroke is an inpatient, reducing to longer intervals as the rehabilitation progresses.</p> <p>“not sensible. In first 6 weeks weekly is needed there after two weekly is reasonable – or longer”</p> <p>“in light of the quick throughput of hospital stroke patients the review may need to be undertaken twice a week”.</p> <p>There was a concern not to be too prescriptive about timing.</p> <p>“because each person who has had a stroke is different, the review should take place according to needs of the individual and this will vary”</p> <p>Type of plan and type of goal was also seen as important:</p> <p>“This depends on how you define rehabilitation plans. Are they broad, e.g. to go home independently walking and self</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			care and returning to work or more specific to the moment e.g. to be able to stand for 5 minutes in a standing frame?"

F.5.4.2 Delphi statement where consensus was not reached

Table 10: Table of ‘non-consensus’ statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	When there is a significant change, or when a plateau/potential is reached, or before discharge, a meeting involving the stroke rehabilitation team, with an invitation to the person and their family/carer, should be conducted to discuss these points.	63.4	<p>In round 2 - 22/99 (22%) panel members commented; 16/85(19%) in round 3 and 11/72 (15%) in round 4:</p> <p>There were several themes:</p> <p>MDT – some members of the panel thought that this does not have to involve the whole team (“The meetings should happen but only include the relevant staff, not the whole stroke rehabilitation team”).</p> <p>Before discharge – this was seen as the most important aspect of the statement.</p> <p>Need for an additional meeting – if there are regular reviews then changes / plateau should not come as a surprise</p> <p>Meeting type – this needs to be tailored (formal or informal) to the individual and their carer/family</p> <p>Statement – the statement itself was seen as having too many different components to answer with one response.</p> <p>Several people commented that the terms ‘plateau’ or ‘potential’</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			was unclear. (“What is plateau? One day of no change, one week, one month?”)

F.5.5 Transfer of care, discharge planning and interface with social care

F.5.5.1 Component and consensus protocol

Table 11: What planning and support should be undertaken by the multidisciplinary rehabilitation team before a person who had a stroke is discharged from hospital or transfers to another team/setting to ensure a successful transition of care?

Population	Adults and young people 16 or older who have had a stroke
Components	<ul style="list-style-type: none"> • Discharge planning • Emotional / educational support • Co-ordination and resources of other services/agencies (such as social care)
Outcomes	<ul style="list-style-type: none"> • Patient and carer satisfaction • Successful discharge • Quality of life • optimised strategies to minimise impairment and maximise activity/participation

F.5.6 Transfer of care and discharge planning

F.5.6.1 Delphi statements where consensus was achieved

Table 12: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
	Each patient should have a documented discharge report which has been discussed with the person who has had a stroke and their carer/s prior to transfer of care, including discharges to residential settings.	75.5	14/98 (14%) panel members commented This was seen as important, but it was questioned whether this would be different to the GP report, a copy of which would be given to the person who has had a stroke. This should be written in an accessible way.
	A discharge report (informing ongoing rehabilitation planning) should contain information about the following: Diagnosis and health status Mental capacity Functional abilities Transfers and mobility Care needs for washing, dressing,	86.8 69.7 86.8 82.8 82.8	31/99 (31%) panel members commented A few further suggestions and comments were made: The individual’s named point of contact. Joint health and social care plan.

Number	Statement	Results %	Amount and content of panel comments – or themes
	<p>toileting and feeding</p> <p>Psychological and emotional needs</p> <p>Medication needs</p> <p>Social circumstances</p> <p>Management of risk including the needs of vulnerable adults</p> <p>Ongoing goals</p> <p>Ways of accessing rehabilitation services</p>	<p>77.7</p> <p>84.8</p> <p>76.7</p> <p>74.7</p> <p>76.5</p> <p>74.4</p>	<p>Stroke Association Information</p> <p>Further comments: The terms ‘mental capacity’ was queried – i.e. capacity for what, and whether ‘cognitive status’ may be a better term It was felt not necessary to have all these for all people.</p>
	<p>A home visit (with the person who has had a stroke present) may be required when simulation of the home environment set up in the inpatient setting has been inconclusive or there is an indication for further assessment.</p>	<p>69.8</p>	<p>14/96 (14%) panel members commented</p> <p>A limited number of panel members provided comments for this statement: One person felt that there were limits on staff time and resources Another person stated that this depended on whether an early supported discharge team was available. This could delay discharge from hospital was mentioned. The term ‘may’ was queried.</p>
4.	<p>Local systems with open communication channels and timely exchange of information should be established to ensure that the person who has had a stroke is able to transfer to their place of residence in a well timed manner.</p>	<p>71.7</p>	<p>10/99 (10%) panel members commented</p> <p>Of the ten people who commented on this statement seven indicated that the phrasing of the statement was confusing and contained jargon.</p> <p>Of the other three, one commented on the role of the key worker, another person commented that this should minimise duplication and administration and the third person stated that this should be done as soon as it is safe to do so.</p>
5.	<p>Local health and social care providers should have established standard operating procedures to ensure a safe discharge process.</p>	<p>74.0</p>	<p>11/100 (11%) panel members commented</p> <p>Individual issues were raised in the comments: Any changes to procedures need to be communicated in timely fashion Take into account person’s wishes and be aware of carer stress and vulnerable adult procedures Ideally joint standard procedures</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			A need for flexibility and broad guidance that can be easily individualised, rather than prescriptive procedures.

F.5.6.2 Delphi statement where consensus was not reached

Table 13: Table of ‘non-consensus’ statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	An access visit (without the person present) can ascertain suitability of access to, from and within the property in respect to the person's functional, cognitive status and managing risk.	36.6	<p>In round 2 - 20/98 (20%) panel members commented; 15/84(18%) in round 3 and 13/71 (18%) in round 4:</p> <p>The majority of comments expressed that the statement was unspecific and did not say whether it should be done or in what circumstances (“The issue is when – always, sometimes, why, how to decide.”).</p> <p>Several people expressed the opinion that this statement was too obvious, since it included the word ‘may’ or later the word ‘can’.</p>
2.	A home visit can ascertain a person's potential for managing risk and cognitive/functional impairment within a familiar environment.	56.8	<p>In round 2 - 11/99 (11%) panel members commented; 13/84(15%) in round 3 and 8/70 (11%) in round 4:</p> <p>The majority of comments expressed that the statement was unspecific and did not say whether it should be done or in what circumstances. (“...guidelines should be given guidance about to whom and under what circumstances a visit - either access or with the patient should be done.”)</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			<p>“usually not required if ESD team involved in care”.)</p> <p>Several people expressed the opinion that this statement was too obvious, since it included the word ‘may’ or later the word ‘can’.</p>
3.	Both access and home visits should be coordinated by an occupational therapist and if this is not possible they should have clinical oversight from an occupational therapist.	19.4	<p>In round 2 - 38/95 (40%) panel members commented; 34/83(41%) in round 3 and 15/72 (21%) in round 4:</p> <p>The main point of contention was whether or not an OT should oversee this.</p> <p>“although the OT would usually be involved, this does not need to be the case and it may be appropriate for another member of the team to co-ordinate/conduct this depending on what limitations the pt presented with.”</p>
4.	As part of rehabilitation care planning, both access and home visits can be used separately or sequentially, to ascertain suitability for rehabilitation, management of risk and management of life after stroke within the person’s home environment.	52.1	<p>In round 2 - 9/99 (9%) panel members commented; 9/83(11%) in round 3 and 11/71 (15%) in round 4:</p> <p>It was felt that this statement was vague and did not define the circumstances of when and how this should happen.</p> <p>There was also a comment that this should not delay discharge and that this is something the community stroke team could undertake.</p>

F.5.7 Interface with social care

F.5.7.1 Delphi statements where consensus was achieved

Table 14: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	Where appropriate, social workers should be involved with the stroke rehabilitation team in the assessment of post hospital care needs.	72.0	<p>11/100 (11%) panel members commented</p> <p>The panel assumed that a social worker would be part of the MDT</p> <p>Some people thought that the term 'appropriate' needed to be defined.</p>
2.	The role of social care and any service provision required should be discussed with the person who has had a stroke and documented within the social care plan.	72.7	<p>10/99 (10%) panel members commented</p> <p>A few panel members highlighted the relationship between this statement and the joint care plan and that there should be access to one set of notes.</p> <p>A couple of people thought that this should be discussed fully with the person who has had a stroke and with the carer or nearest relative.</p> <p>In another comment it was stated that it is not necessary to discuss the whole plan with the person who has had a stroke in case the amount of information was overwhelming</p>
3.	When social needs are identified there needs to be timely involvement of social services to ensure seamless transfer from primary to community care.	76.8	<p>11/100 (11%) panel members commented</p> <p>Several panel members commented that a social worker should be part of the MDT.</p> <p>One person commented whether the statement should read 'from secondary to community care' rather than 'from primary to community care'.</p> <p>Another comment was regarding the concepts of 'timely' and 'seamless' which were not defined and the statement should be set out to describe minimum standards.</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
4.	Coordination between health and social care should include a timely, accurate assessment (including documentation and communication) to facilitate the transitional process for admission/return to care or nursing homes.	77.8	<p>10/99 (10%) panel members commented</p> <p>This should also include the management staff of the care home.</p> <p>Social worker should be part of the MDT.</p> <p>There would be no need for this since integrated health and social care teams would deal with this.</p> <p>The term 'timely' was questioned.</p>
5.	Should family members wish to participate in the care of the person who has had a stroke; they should be offered training in assisting the person who has had a stroke in their activities of daily living prior to discharge.	79.8	<p>18/99 (18%) panel members commented</p> <p>There were some comments about the need for consent from the person who has had a stroke.</p> <p>The difficulty of arranging this prior to discharge was mentioned and whether this could be done at the person's home was raised.</p> <p>It was also stated that there should not be an assumption that people are willing to provide high levels of care.</p> <p>Respite care and carer support options should also be identified and put in place.</p>

F.6 Long term health and social support for people after stroke

F.6.1 Component and consensus protocol

Table 15: What ongoing health and social support does the person after stroke and their carer(s) require to maximise social participation and long term recovery?

Population	Adults and young people 16 or older who have had a stroke
Components	<ul style="list-style-type: none"> Continued monitoring and re-access into rehab Long term support/care at home Social participation activities Carer/family support & education
Outcomes	<ul style="list-style-type: none"> Patient and carer satisfaction Quality of life

- optimised strategies to minimise impairment and maximise activity/participation

F.6.2 Long term health and social support for people after stroke

F.6.2.1 Delphi statements where consensus was achieved

Table 16: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
	If there is a new identified need for further stroke rehabilitation services, the person who has had a stroke should be able to self re-refer with the support of a GP or specialist community services.	66.7	<p>In round 2 - 23/99 (23%) panel members commented; 11/81(14%) in round 3:</p> <p>One issue that was highlighted is the demand this may create (“Direct self referral could lead to demand outstripping resources of the stroke rehab service. There does need to be an assessment.”).</p> <p>Other panel members thought that the phrase ‘with the support of’ was unclear since this would not mean self-referral anymore. “we operate self referral for anyone previously known to the stroke service”.</p> <p>“ this is unclear, how can you self refer with the support of a GP, are they still being gatekeepers then?”</p>
	<p>Focus on life after stroke may include:</p> <p>Information and discussion about community access</p> <p>Participation in community activities</p> <p>Social roles</p> <p>Information about driving</p> <p>Opportunities to discuss issues around sexual function</p>	<p>75.2</p> <p>72.9</p> <p>70.2</p> <p>76.4</p> <p>68.2</p>	<p>In round 2 - 10/98 (10%) panel members commented; 37/85(44%) in round 3 (direct prompt given in round 3):</p> <p>A few other areas of focus were suggested.</p> <p>Return to work / training</p> <p>Relationships, childcare issues</p> <p>Secondary prevention – diet, exercise</p> <p>Psychological / emotional adaptation</p> <p>Stroke groups – communication support activities</p> <p>Support for carers</p> <p>Access to welfare benefits and allowances, equipment</p>
	While the person with stroke is in hospital local processes should ensure that referral is made to adult social	67	In round 2 - 19/99 (19%) panel members commented; 21/84(25%) in round 3:

Number	Statement	Results %	Amount and content of panel comments – or themes
	care for an assessment of need (if the person has a need for social care).		<p>It was highlighted that a social worker should be part of the MDT. “at an appropriate time to allow the social worker to work alongside the MDT to fully appreciate the patient’s difficulties and get to know them and their family. This shouldn’t be started right at the end of the inpatient stay, but ‘worked up’ during the inpatient stay”.</p> <p>Some people commented that this should be a joined up process and happen in a timely manner. “yes, prior to discharge so there is not a long gap between services ending and others beginning”.</p> <p>A couple of people commented that the statement was not very clear (e.g. ‘local processes’ was not defined and also, who would be making the assessment is unclear)</p>

F.6.2.2 Delphi statement where consensus was not reached

Table 17: Table of ‘non-consensus’ statements with qualitative themes of panel comments

Number	Statement	Results	Amount and content of panel comments – or themes
1.	Review intervals need to be specified and agreed with the person who has had a stroke in regards to their long term rehabilitation needs.	65.0	<p>In round 2 - 13/100 (13%) panel members commented; 9/80(11%) in round 3:</p> <p>Opinions were divided. Some members suggested that this should be needs based and flexible whereas others said that the 6 and 12 month follow-up was sufficient.</p>
2.	A review of health and social care needs of the person who has had a stroke that is formally reported and / or coordinated or conducted with the GP services should take place at least (options: 6 months, 12 months, unspecified)	44.6	<p>In round 2 - 40/98 (41%) panel members commented; 20/83(24%) in round 3:</p> <p>The majority of comments stated, 6 wks, 6 months and then annually. (“in accordance with the National Stroke Strategy @ 6/52 , 6/12 then annually”).</p> <p>There were some comments recommending a need based system</p>

Number	Statement	Results	Amount and content of panel comments – or themes
			<p>that would allow more frequent intervals if necessary.</p> <p>It was also commented that this would depend on the time post discharge.</p> <p>There was a concern that if it were to be a needs based approach people would not be given an opportunity for a meeting unless they have a need</p> <p>“If left to individual needs it tends to result in crises management meetings. There should be some sort of structure and process to ensure that reviews are frequent enough to monitor the patient longer term safely and reasonably but not too frequent to be unnecessary and possibly devaluing the merit...”</p>
3.	Where the persons who have had a stroke are still making progress likely to lead to functional change, they should be offered a goal-focused enabling care package.	56.9	<p>In round 3 - 21/84 (25%) panel members commented; 15/72(21%) in round 4:</p> <p>Some people commented that this statement was not very clear and that the term enabling care package was not universally understood.</p> <p>Extract: “I suspect there will be some issues as to how you measure functional change and the word likely should there be a timescale put on this as this caveat would suggest that most patients/clients would fall into this category and services will find this very difficult to deliver...”</p> <p>Some comments were made about the term ‘functional change’ and that the statement was unclear about what it may be referring to.</p>
4.	When a person with stroke leaves hospital, there should be a review of the discharge process with the person who has had a stroke together with their family and carers by a member of the community stroke rehabilitation team. The aim of this review is to	56.9	<p>In round 2 - 22/99 (22%) panel members commented; 16/85(19%) in round 3 and 11/72 (15%) in round 4:</p> <p>There were some comments about the amount of reviews that were</p>

Number	Statement	Results	Amount and content of panel comments – or themes
	ensure that the discharge plan was followed and carried out, that their current status and goals are reviewed, and a continuing rehabilitation plan is devised.		<p>suggested.</p> <p>This should be done according to need since some people may be discharged and do not wish or need a post discharge meeting.</p> <p>“Will this apply to every stroke patient or only those discharged with a disability – I agree it should be every stroke patient but that would create a huge workload for the community stroke team ... I feel that this should be reconsidered and reflect the varied post-stroke needs of patients and their carers.”</p>
5.	Self-management and training needs form part of long term health education for the person after stroke.	61.1	<p>In round 2 - 12/98 (12%) panel members commented; 13/84(11%) in round 3 and 9/72 (15%) in round 4:</p> <p>It was stated that there was insufficient evidence to conclude that this works.</p> <p>There is also the issue that it depends on the level of post stroke ability.</p> <p>“in order to support secondary prevention and more independence, education is important.”</p> <p>“self management isn’t just about education, a person may need other interventions to facilitate behaviour change”.</p>

F.7 Shoulder pain

F.7.1 Component and consensus protocol

Table 18: How should people with shoulder pain after stroke be managed to reduce pain?

Population	Adults and young people 16 or older who have had a stroke and have symptoms of shoulder pain
Components	<ul style="list-style-type: none"> • Assessment • Pain management • FES • Physical therapies
Outcomes	<ul style="list-style-type: none"> • Mobility

	<ul style="list-style-type: none"> • Function • pain
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F.7.1.1 Delphi statements where consensus was achieved

Table 19: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	Information should be provided by the healthcare professional on how to prevent pain/trauma to the shoulder.	77.6	<p>7/49 (14%) panel members commented</p> <p>Most panel members who commented on this question queried who to give the information to (patient, carer, other staff) and under which conditions (if there is weakness in the shoulder).</p> <p>It was stated in one comment that there was no information available on this topic.</p>
2.	<p>When managing shoulder pain the following treatments should be considered:</p> <ul style="list-style-type: none"> • Positioning • Analgesics 	<p>70.7</p> <p>64.2</p>	<p>In round 2 - 23/49 (47%) panel members commented; 13/42(31%) in round 3</p> <p>None of the other treatment options gained consensus the options were:</p> <ul style="list-style-type: none"> • Arms slings, • Shoulder support, • High intensity transcutaneous nerve stimulation, and • Functional Electrical Stimulation <p>Comments were divided:</p> <ul style="list-style-type: none"> • A number of panel members stated that shoulder pain has to be treated in a flexible manner and according to individual needs. • Some stated that treatment should be evidence based. • Others stated that the evidence for most of the options was poor

F.7.1.2 Delphi statement where consensus was not reached

Table 20: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	The person who has had a stroke	63.6	In round 2 - 13/48 (27%) panel

Number	Statement	Results %	Amount and content of panel comments – or themes
	should be assessed for shoulder pain		members commented; 7/42(17%) in round 3 There was a general opinion that this should be easily ascertained and therefore a full assessment is not needed .
2.	There is a need for an algorithm to assess and treat shoulder pain	31.0	In round 2 - 23/49 (47%) panel members commented; 13/42(31%) in round 3 Some comments were made that there are algorithms already in existence . Others commented that the evidence for treatments was poor and therefore there is not enough information to create an algorithm. There were also comments that this would be useful .

F.8 Speech and language therapies

F.8.1 Component and consensus protocol

Table 21: What interventions improve communication in people dysphasia, dysarthrophonia and articulatory dyspraxia?

Population	Adults and young people 16 or older who have had a stroke and who have speech and language impairments
Components	<ul style="list-style-type: none"> • Assessment • Speech and language therapies • Communication aids
Outcomes	<ul style="list-style-type: none"> • Quality of life • Communication skills • Social participation

F.8.2 Speech and language therapies for dysphasia, dysarthrophonia and articulatory dyspraxia

F.8.2.1 Delphi statements where consensus was achieved

Table 22: Table of consensus statements, results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	For all people with speech and language impairments the Speech and Language Therapist needs to explain	78.6	3/28 (11%) panel members commented

Number	Statement	Results %	Amount and content of panel comments – or themes
	and discuss the impairment with the person who has had a stroke/family/carers/treatment team and teach them how to manage the condition.		<p>One person commented that this does not need to be carried out by a speech and language therapist as long as it is under the guidance of one.</p> <p>Carer involvement was also highlighted.</p> <p>One person expressed surprise that Communication Support Services were not included in the whole speech and language section.</p>
2.	Early after stroke the person with a speech and language impairment should be facilitated to communicate everyday needs and wishes, and supported to understand and participate in decisions around, for example, medical care, transfer to the community, and housing. This may need alternative and augmentative forms of communication.	93.1	<p>4/29 (14%) panel members commented</p> <p>It was commented that there are interactions with cognition and emotion and therefore input from other MDT members may be needed.</p> <p>It was stated that AAC may be low tech and simple paper and pen or higher tech I-pad apps could be used.</p> <p>One comment was that this depends on the person's individual assessment, readiness to participate and his/her stated goals.</p> <p>Training for some members of the MDT may also be necessary.</p>
3.	People who have had a stroke and who have persisting speech and language deficits should be assessed for alternative means of communication (gesture, drawing, writing, use of communication aids).	73.1	<p>2/26 (8%) panel members commented</p> <p>One person stated that mixing people with language and those with speech impairments together is not appropriate in this statement.</p> <p>The other person thought that this statement was too obvious to be useful.</p>
4.	The impact of speech and language impairments on life roles e.g. family, leisure, work, etc should be assessed and possible environmental barriers (e.g. signs, attitudes), should be addressed, jointly with the MDT.	81.5	<p>3/27 (11%) panel members commented</p> <p>One person pointed out that this would not happen in the acute stage of rehabilitation.</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
			<p>Another person thought that it should also involve family and friends, employers and relevant other agencies</p> <p>A third person indicated that 'addressed' was not clear.</p>

F.8.2.2 Delphi statement where consensus was not reached

Table 23: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	The key aim of speech and language therapy early after stroke should be to minimise the communication impairment.	55.0	<p>In round 2 - 17/27 (63%) panel members commented; 11/20(55%) in round 3</p> <p>Panel members thought that there are many facets to the aims of speech and language therapy that were not captured by this statement. Such as:</p> <ul style="list-style-type: none"> • To deal with the impact of the communication impairment • To assess and educate regarding the extent of the difficulty • To address the person's confidence, • To enhance skills of communication partners • To remove barriers to communication <p>Extract: "This can be very broadly defined. Minimising the communication impairment is not necessarily just reducing the actual impairment. It may be providing advice and information which enhances understanding and indirectly minimises the problem, it may be using strategies to facilitate communication, it may be providing facilitated emotional support to reduce trauma which can enhance communication."</p>
2.	<p>The list of approaches that may be used with a patient who is dysphasic:</p> <ul style="list-style-type: none"> • Picture cards • Drawings 	<p>36.8</p> <p>42.1</p>	<p>In round 2 - 20/27 (74%) panel members commented; 11/19(58%) in round 3</p> <p>Some further approaches were</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
	<ul style="list-style-type: none"> • Sound Boards • Writing • Phonological sound cueing • Modelling words • Sentence completion • Melodic intonation therapy • Neurolinguistic approach • Computerised approach 	<p>12.5</p> <p>33.3</p> <p>27.7</p> <p>22.2</p> <p>33.3</p> <p>5.8</p> <p>27.7</p> <p>38.8</p>	<p>suggested:</p> <ul style="list-style-type: none"> • Talking mats • Semantic cueing • Gesture • Cognitive neuropsychological approaches • Constraint induced therapy (which uses picture cards) • Augmentative and alternative communication <p>One person highlighted that any approach needs to be evidence based.</p> <p>It was also highlighted that the statement implies a focus on language impairment rather than focus on the skills and competence of the person who has dysphasia and those in their communicative environment. This panel member suggested the following approaches to do this:</p> <ul style="list-style-type: none"> • Information and support for the person and their family/friends/service providers (and also about language strengths) • Training of conversation partners • Access to peer support <p>Others specifically favoured impairment-based approaches.</p> <p>It was highlighted that this would vary from person to person (“The Speech and Language Therapist would make a communication book tailored to the individual rather than alphabet chart and/or talking mats to aid discussion”).</p>
3.	<p>The list of approaches that might be used with a patient who is dysarthric:</p> <ul style="list-style-type: none"> • Oral muscular exercises • Monitoring rate of speech production 	<p>21.7</p> <p>34.7</p>	<p>In round 2 - 12/24 (47%) panel members commented; 14 commented in round 3 (free text prompt)</p> <p>The following approaches were</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
	<ul style="list-style-type: none"> Pausing Alphabet supplementation 	<p>26.0</p> <p>27.2</p>	<p>suggested:</p> <ul style="list-style-type: none"> Initiation of vocalisation (exercises for articulation) Coordination between breathing and speech (breathing support exercises) Sustaining voice during speech production Pacing Gesture Advice about condition, and training of conversation partners Computer therapy Writing / drawing Augmentative and alternative communication Compensatory slowing of speech rate with exaggerated articulation <p>One person highlighted that this should be a focused approach based on assessment (“the system that is most compromised would be targeted e.g. respiration, palatal movement, voice, articulation, rate of speech, phrasing, intonation”).</p>
4.	<p>List of approaches that might be used with a patient who has dysarthrophonia:</p> <ul style="list-style-type: none"> Biofeedback Voice amplifier Intense therapy to increase loudness 	<p>12.5</p> <p>11.7</p> <p>0.0</p>	<p>In round 2 - 9/23 (39%) panel members commented; 7/17(41%) in round 3</p> <p>No clear approaches were suggested. It was stated that this depends on the patient’s presentation and severity.</p> <p>It was also highlighted that this is a rare problem and that there is no evidence to support a particular approach.</p>
5.	<p>The list of approaches that might be used with a patient who has articulatory dyspraxia:</p> <ul style="list-style-type: none"> Cognitive linguistic therapy Repetitive drills Auditory input/analysis Automatic speech Singing Phonemic cueing 	<p>20.0</p> <p>41.6</p> <p>33.3</p> <p>38.4</p> <p>8.3</p> <p>16.6</p>	<p>In round 2 - 16 panel members commented (free text prompt); 8/14(57%) in round 3</p> <p>No further approaches were suggested and it was highlighted that any approach needs to be evidence based.</p>

Number	Statement	Results %	Amount and content of panel comments – or themes
	<ul style="list-style-type: none"> • Word imitation • Computer programmes • Varley approach • AAC (Augmentative and Alternative Communication) reading aloud • Distraction practice with feedback • Phoneme manipulation tasks • Segment by Segment approach • SWORD (computer software) • Prosodic therapy 	<p>8.3</p> <p>38.4</p> <p>27.2</p> <p>18.1</p> <p>11.1</p> <p>9.0</p> <p>18.1</p> <p>27.2</p> <p>25.0</p>	
6.	Any patient with severe articulation difficulties (<50% intelligibility) reasonable cognition and language function should be assessed for and provided with alternative or augmentative communication aids.	61.1	<p>In round 2 - 3/25 (12%) panel members commented; 3/18(17%) in round 3</p> <p>It would depend on stage of rehab, success of rehab and prognosis.</p> <p>One person objected to a level (i.e. below 50% intelligibility) being stated (“... as it may be different for each patient and intelligibility may depend on familiarity with the patient.</p>

F.9 Visual impairments

F.9.1 Component and consensus protocol

Table 24: How should people with visual impairments including diplopia be best managed after a stroke?

Population	Adults and young people 16 or older who have had a stroke
Components	<ul style="list-style-type: none"> • Continued monitoring and re-access into rehab • Long term support/care at home • Social participation activities • Carer/family support & education
Outcomes	<ul style="list-style-type: none"> • Patient and carer satisfaction • Quality of life • optimised strategies to minimise impairment and maximise activity/participation

F.9.2 Visual impairments – people with diplopia or other ongoing visual symptoms after stroke

F.9.2.1 Delphi statements where consensus was achieved

Table 25: Table of consensus statements , results and comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	People who have persisting double	70.8	1/24 (4%) panel member

Number	Statement	Results %	Amount and content of panel comments – or themes
	vision after stroke require a formal orthoptic assessment.		commented The person who commented thought that all other forms of visual impairment would also require orthoptic assessment .

F.9.2.2 Delphi statement where consensus was not reached

Table 26: Table of ‘non-consensus’ statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
2.	All people who have impaired acuity, double vision or a visual field defect following a stroke require a formal ophthalmology assessment.	23.8	In round 2 - 7/24 (29%) panel members commented; 7/21(33%) in round 3 It was pointed out that different aspects in the statement require different actions (“Impaired acuity and double vision both require an ophthalmological diagnosis. Visual field defect after stroke is less problematic, and the diagnosis is usually known – in such cases adaptive treatments and education are the priority.”). Other comments also highlighted that this is not always needed .
3.	People who have ongoing visual symptoms after a stroke, should be provided with information on compensatory strategies from: <ul style="list-style-type: none"> • Ophthalmology services • Orthoptic services • Occupational therapy services 	15.7 50.0 31.5	In round 2 - 6/23 (26%) panel members commented; 9/20 (45%) in round 3 It was highlighted that it depends on availability and on the need (“Occupational Therapists are most likely to advise re rehab and application to daily life whereas orthoptists can advise on vision strategies. Ophthalmology will ax and rx eye problems but perhaps not so much advise on strategies.”). One panel member was involved in the development of web-based therapies that work by inducing compensatory eye movements
4.	People who have had a stroke and have visual impairments should be provided with contact details for the RNIB or Stroke Association for further	38.1	In round 2 - 4/23 (17%) panel members commented; 1/21 (5%) in round 3

Number	Statement	Results %	Amount and content of panel comments – or themes
	information on visual impairments after stroke.		<p>People who have persisting double vision after stroke require a formal orthoptic assessment.</p> <p>It was pointed out that this should be done if symptoms persist and not given routinely to everybody.</p>
5.	Assessment and information for registering as sight impaired or severely sight impaired should be provided by referral to an ophthalmologist.	47.6	<p>In round 2 - 2/24 (8%) panel members commented; 5/21 (24%) in round 3</p> <p>It was commented that: “All involved in stroke care should realise that only ophthalmologists can sign the certification of visual impairment form.”</p> <p>Others queried whether an orthoptist could also do this.</p>

F.10 Delphi Methodology Appendix 1: See Process Protocol in Guideline Appendix B

F.11 Delphi Methodology Appendix 2: Appraisal of existing guidelines

F.11.1 Assessment of existing guidelines for consensus statements

For the assessment of guideline quality, we used complete guideline documents including any additional information available, as in Appendices or other supplementary information, on related websites (e.g. evidence table, algorithms or short guides). The evaluation was conducted using the Appraisal of Guidelines for Research and Evaluation (AGREE – by The AGREE Research Trust <http://www.agreetrust.org>) instrument which is specifically designed for the assessment of practice guidelines. It comprises 23 items divided into 6 domains of guideline quality. These 6 domains are:

1. scope and purpose (3 items)
2. stakeholder involvement (3 items)
3. rigour of development (8 items)
4. clarity of presentation (3 items)
5. applicability (4 items)
6. editorial independence (2 items)

There is an additional overall rating of the quality and a statement of whether the guideline would be recommended for use in practice. Each of the 23 items is rated on a scale from 1 (strongly disagree) to 7 (strongly agree). Results are calculated and reported as the 6 domain scores rather than a total overall and expressed as a percentage across appraisers (in this guideline 2 reviewers appraised all guidelines independently using AGREE). There are no pre-specified cut-offs for domain results in the AGREE instrument. However, the overall assessment features an option of not recommending the guideline for use in practice which would mean that the guideline would be excluded. For domain figures of assessed guidelines please see Figure 1.

F.11.2 AGREE assessment of national and international stroke guidelines

Searches were conducted for guidelines that address the management of stroke (for the search strategy see Appendix D). For details of the scopes of each guideline see Table 27. After assessment with the AGREE-II instrument by two reviewers we included 7 guidelines. AGREE figures are appendicised to this report.

Table 27: Overview of included guidelines.

GUIDELINES	SCOPE
Royal College of Physicians ¹⁸	<ul style="list-style-type: none"> • Acute diagnosis and treatment (from NICE guideline) – including organisation of services • All aspects of rehabilitation • Long-term care and support • Secondary prevention • Prevention of complications
SIGN ²⁹	<ul style="list-style-type: none"> • Organisation of services • Rehabilitation • Prevention • Management of complications • Discharge planning

GUIDELINES	SCOPE
Australian ²	<ul style="list-style-type: none"> • Organisation of services • Stroke recognition and pre-hospital care (including early assessment and diagnosis as well as acute medical and surgical management) • Secondary prevention • Rehabilitation • Managing complications • Community participation and long-term recovery • Cost and socioeconomic implications
New Zealand ³	<ul style="list-style-type: none"> • This is the Australian guideline plus a section specific to New Zealand issues (perspectives of people with stroke, Māori and stroke, Pacific people and stroke, younger adults and stroke)
Dutch (Royal Dutch Society for Physical Therapy) ³²	<ul style="list-style-type: none"> • General treatment principles • Immobilization phase • Mobilization phase: walking ability and gait-related abilities • Mobilization phase: dexterity • Mobilization phase: ADL skills • Mobilization phase: Cognitive rehabilitation
Canadian Best Practice ¹	<ul style="list-style-type: none"> • Public awareness of stroke • Prevention of stroke • Hyperacute stroke management • Acute management • Stroke rehabilitation • Managing stroke care transitions • Cross-continuum topics in stroke management
Veterans (American) ⁴	<ul style="list-style-type: none"> • Rehabilitation during the acute phase • Prevention of complications • Medical co-morbidities • Assessment of impairments • Assessment of activity and function • Assessment of support systems • Discharge from rehabilitation • Treatment interventions for rehabilitation after stroke

F.11.3 Overall quality assessment and inter-rater agreement

Two raters assessed the overall quality, the results of which are presented in Table 28. As shown in the table Inter-rater agreement was generally high ranging from the lowest agreement for the Australian guideline (Cronbach's alpha of .40) to the highest agreement (Cronbach's alpha of .91) for the Veterans (American) guideline. Domain scores of all assessed guidelines are graphically presented in Figure 1.

Table 28: Overall assessment of the included guidelines (the higher the rating 1-7 the higher the assessed quality, overall assessments were: 'yes-recommend', 'yes – with modifications' and 'no-would not recommend')

Guidelines and inter-rater agreement (alpha value)	Quality rating (1-7) and assessment – rater 1	Quality rating (1-7) and assessment – rater 2
Royal College of Physicians (.71)	4, yes –with modifications	5, yes – with modifications

Guidelines and inter-rater agreement (alpha value)	Quality rating (1-7) and assessment – rater 1	Quality rating (1-7) and assessment – rater 2
SIGN (.79)	6, yes – with modifications	5, yes – with modifications
Australian (.40)	6, yes – recommend	6, yes – recommend
New Zealand (.53)	6, yes – recommend	5, yes – with modifications
Dutch (Royal Dutch Society for Physical Therapy) (.82)	5, yes –with modifications	6, yes – recommend
Canadian Best Practice (.58)	5, yes – with modifications	5, yes – with modifications
Veterans (American) (.91)	4, yes –with modifications	4, yes –with modifications

F.11.4 Guideline domain profile

Figure 1: AGREE-domain scores for both included (RCP, SIGN, Veterans, Dutch, Australian, Canadian Best Practice and New Zealand) and excluded (European (ESO), Singapore, British Columbian and South African). Scores are given as percentages using both raters' scores with higher percentage indicating better quality.



F.11.5 Delphi statement drafting process - identified guideline content mapped to areas in post-consultation

Table 29: Areas to address and summary of guideline content plus first draft of statements.

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
<p>SERVICE DELIVERY</p> <p>RCP - The whole chapter 3 (Systems underlying stroke services):</p> <p>SIGN – chapter 3 (Organisation of services)</p> <p>New Zealand – Chapter 1 (organisation of services)</p> <p>Australian – Chapter 1.</p> <p>Dutch – Chapter 1.</p> <p>Canadian – sections 5.0</p> <p>Veterans (American) –Chapter 7</p>	<p>RCP - The majority of the recommendations from chapter 3 are stated as ‘following on from other sections of the guideline’ then there are many by ‘consensus’ and some extrapolations from the NICE guideline, a few others are based on qualitative or (i.e. goal setting) or on studies that do not directly address the stroke population. Recommendations with regards to stroke rehabilitation units were based on Stroke units trialists’ collaboration Cochrane review (2007)</p> <p>SIGN – stroke unit research, case control or cohort studies</p> <p>Australian / New Zealand – mainly from the Stroke units trialists’ collaboration 2007 and Foley N, Salter K, et al. (2007) another meta-analysis of acute, combined and rehabilitation units. Early Supported Discharge (ESD) Trialists. Some</p>	<p>RCP – Rehabilitations should be delivered by a specialist stroke service which could be an inpatient unit, day-hospital unit or at home. It should involve a multidisciplinary team with access to specialist equipment and availability of specialist staff training.</p> <p>SIGN – stroke patients should be admitted to a stroke unit staffed by a multidisciplinary team or in exceptional circumstances (when admission is not possible) admitted to a generic rehabilitation unit. Integrated care pathway is not recommended. Patients and carers should be early actively involved in the process.</p> <p>Australian / New Zealand – early active inpatient rehabilitation by a dedicated stroke team and if ongoing inpatient rehabilitation is required patient should be transferred to a dedicated stroke rehabilitation service. Before discharge all patients should be assessed by a specialist stroke rehab team regarding their suitability for ongoing rehabilitation.</p> <p>Dutch – a hospital stroke unit should be in a stroke service with appropriate rehabilitation facilities</p> <p>Canadian- divides by stroke unit care and all settings.</p>	<p>Recommendations with regards to the efficacy of stroke rehab units (and whether combined acute/rehab or specific rehab) will come from the update of the Cochrane review on stroke units.</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
	<p>lower level evidence and some consensus.</p> <p>Dutch – Stroke unit systematic reviews</p> <p>Canadian – rehabilitation stroke unit – Systematic reviews</p> <p>Veterans – organised multidisciplinary rehab – Stroke units trialists’ collaboration 2007 & systematic reviews</p>	<p>all patients treated in comprehensive or rehabilitation stroke unit.</p> <p>Post acute stroke rehabilitation to be delivered in formally co-ordinated setting</p> <p>Veterans – formally organised & coordinated rehab setting with team experienced in stroke services.</p> <p>if service is not available locally then refer patient to other facility.</p> <p>community rehab for patients mild-moderate disability.</p> <p>inpatient rehab for patients requiring daily prof nursing/multiple interventions required.</p>	
<p>MULTIDISCIPLINARY TEAMS</p> <p>RCP – Sections 3.2 recommendation B point 2 and section 3.3 recommendation B</p> <p>SIGN – key recommendation and section 3.3 (membership) and whole chapter 6</p> <p>New Zealand – section 1.8</p> <p>Australian – Multidisciplinary team approach in introduction and section 1.2.1.</p>	<p>RCP – Stroke units trialists’ collaboration 2007</p> <p>SIGN – stroke unit research</p> <p>Australian / New Zealand - Stroke units trialists’ collaboration 2007</p> <p>Dutch – Another earlier systematic review since superseded by SUTC 2007</p> <p>Canadian – interprofessional specialist rehabilitation teams – Stroke unit trialists collaboration;</p> <p>Veterans – stroke unit trialists,</p>	<p>RCP – specifies constituency of a rehab team.</p> <p>SIGN – specifies constituency of a rehab team as well as a description of the roles within such a team.</p> <p>Australian / New Zealand – specifies constituency of rehab team from the outset (i.e. before the review chapters)</p> <p>Dutch – specifies constituency of rehab team.</p> <p>Canadian – specifies the constituency of a rehab team .</p> <p>Veterans- specifies constituency</p>	<p>A core stroke rehabilitation team should comprise of membership from the following disciplines:</p> <p>Consultant neurology/stroke medicine</p> <p>Nursing</p> <p>Physiotherapy</p> <p>Occupational therapy</p> <p>Speech and language therapy</p> <p>Nutrition/Dietetics</p> <p>Clinical/Neuro psychology</p> <p>Social work</p> <p>Pharmacy</p> <p>The stroke rehabilitation team should have a dedicated appropriate professional tasked with</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
<p>Dutch – section C 1.1 Canadian – sections 5.2 Veterans (American) –Chapter 7.1</p>	<p>Evans (1995) cifu (1999) SRs</p>		<p>coordination and steering of the stroke care pathway.</p> <p>The stroke rehabilitation team should have dedicated rehabilitation assistants.</p> <p>The person who has had a stroke is a member of the stroke rehabilitation team.</p>
<p>ASSESSMENT FOR REHAB</p> <p>RCP – Section 3.10: Use of assessment / measures SIGN – not directly described in an extra section New Zealand – section 1.6 as well as chapter 3. Australian – section 1.6. Dutch – section C 1.1 Canadian – sections 5.1 Veterans (American) – Chapters 1-6 all under the main heading of assessment</p>	<p>RCP - All based on consensus (2 articles mentioned but not directly stroke related) SIGN – consensus statement Australian / New Zealand – consensus (chapter 3 concerns rapid assessment in the emergency department) Dutch – a little bit unclear since only a very broad statement is made</p> <p>Canadian – initial assessment by rehab team RCT evidence assessment tools - observational studies Veterans – AHCPR, RCP, SIGN guideline</p>	<p>RCP – Active involvement of specialist rehabilitation services with patients from the time of admission wherever they are admitted. Patients should be seen by at least one member of the specialist rehabilitation team within 24 hours for assessment and by all team members within 5 days for treatment. A rehab assessment service should agree on standard sets of data that should be collected and recorded routinely. Data collection tools should fulfil criteria as much as possible. These are: relevant data covering the require range (valid and fulfil a need); have sufficient sensitivity to detect change within and between patients; of known repeatability; simple to use; have easily understood scores.</p> <p>Services should have protocols determining the collection and use of data and to be able to guide the use of more complex assessment tools</p>	<p>Initial assessment for stroke rehabilitation should take place within: 24 hrs 48 hrs As soon as possible No guidance as to when to assess</p> <p>The person who has had a stroke should be seen by all the appropriate members of the multidisciplinary team individually (tailored to the patient’s needs).</p> <p>Clinicians should have criteria for the type of assessment data or assessment tools that are specific to or an adjunct to stroke rehabilitation.</p> <p>A holistic assessment takes into account a person’s previous body structure and function in terms of participation and activity across</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
		<p>SIGN – Timing of rehab assessment not specified</p> <p>Australian / New Zealand – A national stroke audit from 2009 highlighted that there are only 68 stroke units and 8 rehab units in Australia therefore the timing aspect is not specified. It states that ideally stroke patients should be admitted to a stroke unit within 3 hours, but timing of assessment is not directly stated.</p> <p>Dutch – A fully standardised assessment at admission</p> <p>Canadian – initial assessment by rehab team within first 24-48 hrs. states what assessment should comprise of. assessment on rehab unit – within 24-48 hrs of admission.</p> <p>Use standardised assessment tools</p> <p>Veterans – early screening for rehab, standardised assessments FIM, NOMS, NIHSS. multidisciplinary assessment covering medical stability, rehab needs, impairment & function</p>	<p>personal and environmental contexts prior to the stroke, and determines current body structure and function following the stroke and the impact this has on the person’s ability to participate and be active in their personal and environmental contexts.</p> <p>A holistic assessment should be supported by use of the following standardised clinical tools, measures, scales or data:</p> <ul style="list-style-type: none"> Level-of-consciousness scale Stroke deficit scale Global disability scale Measure(s) of disability/ Measure(s) of activities of daily living Mental status screening Mood/depression Assessment of motor function Balance assessment Mobility assessment Assessment of speech and language function Health status/quality of life measures Family assessment Other (please specify) <p>There should be a minimum set of rehabilitation assessments/markers/outcomes/data which</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
			<p>indicate level of impairment and disability, health and social functional status including behaviour and quality of life perception. These should be able to be tracked across the stroke pathway and longitudinally when focus is targeted towards meaningful life after stroke.</p> <p>At different stages of the care pathway roles and responsibilities of multidisciplinary stroke rehabilitation team services should be clearly specified, documented, and communicated to the patient and their family</p> <p>Service delivery would be improved if clinicians had a standard matrix of outcomes to evaluate and monitor care provision.</p> <p>Data protection and usage should be governed and overseen by a national protocol.</p> <p>The person who has had a stroke should have their mood assessed and monitored as part of a rehabilitation plan.</p> <p>Carers should have their own needs and if appropriate psychological wellbeing assessed prior to discharge of the person who has had a stroke.</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
<p>CARE PLANS</p> <p>See also discharge planning RCP – section 3.11 (goal setting – implies there is a care plan) SIGN – section 5.2.1 New Zealand – section 1.3.1 Australian – section 1.3.1. Dutch – section C 1.1 Canadian – sections 4.3 (advance care planning, palliative and end-of-life care) and section 6.3 (interprofessional</p>	<p>RCP – Consensus SIGN – Consensus Australian / New Zealand – Consensus (some studies with non-conclusive results are mentioned in the research summary) Dutch – unclear since only a bullet point statement is made Canadian- care plans – narratives or consensus -level C evidence. Veterans- unclear consensus?</p>	<p>RCP – See goal setting SIGN – multidisciplinary team meeting at least once a week Australian / New Zealand – Mainly described as part of discharge planning Dutch – formulation of an interdisciplinary care plan as used in stroke units. Canadian - teams should conduct formal interprofessional meeting at least once a week to plan and monitor patient care. comprehensive individualised rehabilitation plans to be developed. care management plans to include pre-discharge needs assessment. careplan to cover medical, rehab, psychosocial</p>	<p>Rehabilitation care plans should be individualised and contain the following minimum information which can be shared in written form with the person who has had a stroke:</p> <ul style="list-style-type: none"> Diagnosis and relevant medical information Person focused rehabilitation goals Assessment data or outcome results Key contact from the stroke rehabilitation team List of current medications Discharge planning information Consent and signature(family member or carer if person is not able to sign)

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
<p>communication) Veterans (American) – section 7.1</p>		<p>and functional needs available to all involved in patient’s care. Veterans – provide information to patient/carer to enable informed decision making. provides content of care plans. document plans and involve family/carers in planning</p>	<p>Rehabilitation care plans should be formally reviewed by the multidisciplinary team at least once a week</p> <p>If appropriate people receiving stroke rehabilitation and their carers could be invited to all care plan reviews.</p> <p>A family meeting involving the stroke rehabilitation team, person who has had a stroke and their family/carer should be conducted when there is a significant change or a point in time requiring review of the rehabilitation plan and care provision.</p> <p>Patients and carers should be involved and actively participating in the development of care plans.</p>
<p>GOAL SETTING</p> <p>RCP Section 3.11 and section 6.2: Goal setting Evaluating and stopping treatment SIGN – section 3.3.1 (part of multidisciplinary care) New Zealand – section 1.7</p>	<p>RCP – Consensus, partially based on two papers by Diane’s research group and other studies more generally goal setting related SIGN – based on RCP guidance Australian / New Zealand – Two consensus recommendations, one recommendation from the STUC Cochrane and one evidence level C.</p>	<p>RCP – During the goal setting process: every patient should have their wishes and expectations established and acknowledged; Participate in the goal setting process; Be given help to understand the nature of goal setting; What goals should be like: meaningful and relevant; challenging but achievable; both short and long-term targets;</p>	<p>For this section most, but possibly not all, recommendations might come from the systematic review.</p> <p>Further statements may include:</p> <p>Both profession specific as well as joint stroke team goals should be patient focused. Patients / carers should be encouraged to be actively involved in the goal setting and</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
<p>Australian – section 1.7 Dutch – C 1.1 mentions care plans which suggests that goals are set - not directly stated. Canadian – 6.3 recommendation II. Veterans (American) – not directly stated, but section 7.1 implies that assessment should be documented which suggests goals will be set.</p>	<p>Dutch – unclear since only a bullet point statement is made Canadian – observational - level B evidence Veterans – unclear. AHCP and consensus</p>	<p>include single clinicians and team; documented with specified time targets and measureable outcomes; involve family if possible; used to guide therapy and treatment Patients should have their progress measured against goals at regular intervals (e.g. goal attainment scaling) When a patient’s goal is not achieved, the reason(s) should be established and: goal should be adjusted or intervention should be adjusted or no further intervention should be given towards the goal SIGN – Goals developed during team meetings and then discussed in ‘family conferences’ between the patient and multidisciplinary team where goals should be discussed with the patient and family / carers. Australian / New Zealand – patients and carers should have their wishes established and acknowledged. They should have the opportunity to participate in the process of goal setting. Goals should be set collaboratively and they should be prescribed, specific and challenging. Stroke survivors should be offered training in self management. Dutch – not specifically described Canadian – consider patient and carer</p>	<p>reviewing process. A weekly review of goals should be conducted. The reasons for unattained goals need to be documented and if appropriate goals could be re-assessed. The wishes and expectations of the person who has had a stroke and their carer should be established and considered in the goal setting process. Please indicate two of the most important criteria for goals: meaningful and relevant; challenging but achievable; both short and long-term targets; include single clinicians and team; documented with specified time targets and measureable outcomes; involve family if possible; used to guide therapy and treatment</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
		<p>preferences and goals</p> <p>Veterans – rehab should be guided by goals developed with team, patient and family.</p>	
<p>TRANSFER OF CARE/DISCHARGE PLANS</p> <p>RCP - Section 3.6 and 3.7 SIGN – chapter 5 New Zealand – section 1.3 Australian – section 1.3 Dutch – not in scope Canadian – section 6.4 Veterans (American) – section 7.6 and 8 Annotation K. (discharge patients from rehabilitation)</p>	<p>RCP – section 3.6 consensus; section 3.7 mainly consensus papers on early supported discharge, one paper that looks relevant (ordered)</p> <p>SIGN – mixture consensus, extrapolated evidence and the early supported discharge Cochrane. Home based care (DOMINO trial and Bradford Community stroke trial, involvement of GP based on consensus and level D evidence. Australian / New Zealand – Consensus and level C-D evidence</p> <p>Canadian – section on transitions in care-observational/consensus level B-C evidence.</p> <p>Veterans – transfer to community – consensus, Discharge plans - consensus</p>	<p>RCP – hospitals should have a locally negotiated protocol detailing: preparation for patients and carers; that GPs, primary healthcare teams and social services are all informed; the availability of equipment and support services; that continuing specialist services are available without delay; the provision of information to patients and carers;</p> <p>patients discharged who remain dependent should be offered transition package; home environment should be assessed; there should be continuing involvement by the specialist stroke service; carers should be trained;</p> <p>patients should continue to have access to specialist stroke services after leaving hospital and know how to contact them.</p> <p>SIGN – prior to discharge there should be a home visit; discharge documents should be sent to all relevant agencies; early supported discharge for patients with mild/moderate stroke; access to specialist therapy based rehabilitation services</p> <p>Australian / New Zealand – prior to discharge patients should be assessed to see whether a home visit is needed.</p>	<p>Each patient should have a documented discharge plan which has been discussed with the person who has had a stroke and their carer/s prior to discharge, including discharges to residential settings.</p> <p>During their stroke rehabilitation, people who remain dependent should be offered an enabling package of care.</p> <p>Prior to discharge carers/family members should be trained in meaningfully assisting the stroke survivor in their activities of daily living to feel empowered about the relevant rehabilitation needs of the person who has had a stroke.</p> <p>Seamless transfer of care requires open communication channels that are free of barriers in terms of advance notice and timely exchange of information that is free from repetition and needless paperwork so as not to hold up discharge from one location to another.</p>

Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
		<p>Before discharge the hospital should ensure: Patients and families have the opportunity to identify and discuss their post-discharge needs General practitioners, primary health care teams and community services are informed All medication, equipment and support services are organised</p> <p>Any continuing specialist treatment is organised A documented post-discharge care plan is developed in collaboration with the patient and family and a copy provided to them.</p> <p>A locally developed protocol may assist in the implementation of a safe discharge process. A discharge planner may be used to coordinate a comprehensive discharge plan.</p> <p>Relevant members of the multidisciplinary team should provide specific and tailored training for carers / family before discharge.</p> <p>After hospital discharge: patients should have access to a multidisciplinary community rehabilitation team. Rehabilitation in the home setting should be offered. Education by trained staff should be offered to patients / carers. A case management model and be used after discharge. A member of the stroke team should review the stroke survivor in first 3 mths, then again at 6 and 12 mths after discharge. Contact information for the specialist stroke service should be provided.</p>	<p>There should be a post-discharge planning meeting coordinated by the rehabilitation team that is providing care for the person who has had a stroke together with their family and carers.</p> <p>Local health care providers should have a protocol to ensure a safe discharge process.</p> <p>Ways of accessing multidisciplinary services need to be outlined to persons who had a stroke and their families/carers and should be included in written form on their joint careplan.</p> <p>Review intervals need to be specified and negotiated with the person who has had a stroke in regards to their long term rehabilitation needs.</p> <p>An access visit (when ongoing needs have been determined) should be scheduled for persons who have had a stroke to assess suitability for rehabilitation or discharge to their home environment depending on their health and social needs.</p> <p>Following the access visit a home visit may be</p>

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		<p>Long term rehabilitation: Stroke survivors should be reviewed annually. Those with residual impairments should receive therapy to set new goals. Stroke survivors with confirmed difficulties should have a documented management plan. Should be encourage to participate in long-term exercise programs.</p> <p>Canadian – support for patients, carers and families in transition between care environments.</p> <p>initiate asap after admission. involve patient and carers. should include needs assessment, caregiver training, family and team meetings etc activities.</p> <p>discharge plans should include action plans, follow-up care and goals – medication, interventions and roles and responsibilities of care provider and caregiver.</p> <p>Veterans –transition to community – assessment of ADL and mobility, preparation of family and carers, information on community services/resources provided</p> <p>discharge- discharge plan complete and all necessary equipment training provided to family/carers before discharge.</p> <p>psychosocial needs of family members</p>	<p>indicated if the individual needs to be assessed within their home environment.</p>

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		provided for.	
<p>INTERFACE WITH SOCIAL CARE</p> <p>RCP – not directly mentioned SIGN – role of the social worker? New Zealand – not explicitly stated Australian – not specifically described Dutch – not in scope Canadian – not described Veterans (American) – sections 7.6 and 7.7 ('transfer to community living' and 'function / social support' - mention case management and health and social services professionals)</p>	SIGN – level 4 evidence relating to multidisciplinary care and planning of discharge		<p>The role of social care should be clearly stated and documented within the care plan.</p> <p>Where appropriate social workers should be involved together with the stroke rehabilitation team in the assessment of post hospital social needs.</p> <p>People who have had a stroke may need specialist social care provision specific to their individual and personal health and well being needs.</p> <p>There is a need for greater and more timely involvement of social services in the transfer from hospital to primary / community care.</p> <p>The coordination between health and social care should be improved, documented and communicated across the relevant settings to facilitate the transitional process for admission / return to care or nursing home.</p>
<p>LONG TERM HEALTH AND SOCIAL SUPPORT</p> <p>RCP – chapter 7 long term</p>	RCP – consensus SIGN – Therapy-based rehabilitation services for stroke patients at home. Cochrane	RCP –patients whose situation changes should be offered further assessment; patients with residual impairments should be offered a formal review (at least every 6 mths); further therapy only given if clear goal identified;	A formal review, that is formally reported and/or coordinated or conducted with the stroke survivor's GP, should take place at least: Once every 6 months

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<p>management after recovery SIGN – sections 5.5, 5.6 and 5.7 New Zealand – Chapter 8 Australian – Chapter 8 Dutch – not in scope Canadian – section 6.6 Veterans (American) – Chapter / section 17 (family / community support)</p>	<p>Australian / New Zealand – Generally based on Consensus and level C evidence. The issue of return to leisure activities was based on a systematic review and RCT. Canadian – rehab services stroke patients at home – cochrane Veterans – assessment of progress consensus; long term management - consensus</p>	<p>encourage social activities and facilitate social participation; identify emotional needs of patients and carers; ensure that patients and carers can access support and advice; patients in nursing homes should be able to receive assessment and treatment from specialist stroke rehab services; staff in nursing homes should be familiar with the common clinical features of stroke. There is a whole section of recommendations concerned with carers' needs SIGN - stroke patients in the community should have access to specialist therapy-based rehabilitation services with self-referral for stroke therapy services to be considered. Return to work should be reviewed early in the rehabilitation pathways. There are several recommendations about driving after stroke (must not drive for at least one month, patients with activity limitations must inform DVLA, clinicians should be vigilant about possible executive function impairments, if in doubt refer to disabled drivers assessment centre) The GP's at the time of discharge into community: The GPs and community staff should receive adequate information Medication changes need to be outlined</p>	<p>Once every 12 months No specified time – arranged according to individual needs. Should there be an identified need to re-access stroke rehabilitation services and self re-referral is not possible, then the GP should be the point of contact to facilitate re-referral. The person who had stroke should be given information about driving post stroke and how to contact the DVLA. Opportunities to discuss issues around sexual function should be provided. Focus on life after stroke should include, if appropriate, sharing of information and discussion about community access, participation in meaningful and person focused community activities and roles which may or may not be specific to stroke. An occupational therapist should be keyworking for the person who had a stroke to discuss return to work and vocational rehabilitation. Self-management and training needs, form part</p>

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		<p>The patient’s physical and emotional wellbeing needs to be monitored.</p> <p>Secondary prevention and lifestyle factors to be monitored</p> <p>Pain to be assessed.</p> <p>Australian / New Zealand – Self-management: patients should be supported to access self-management programs.</p> <p>Stroke specific programs for self-management programs should be provided for those who need more specialist programs.</p> <p>A collaboratively developed self-management care plan can be used to optimise skills</p> <p>Driving:</p> <p>Patients should be asked whether they intend to drive</p> <p>Patients who wish to drive should be assessed should be advised on where they can access information and that they have to report their condition to license authorities and insurance.</p> <p>Should not drive for a months (patients with TIA two wks) and if necessary be assessed</p> <p>If deemed medically fit but required for further testing patient should be referred to occupational therapy driving assessment.</p> <p>Return to work: Targeted occupational therapy programs can be used to increase participation in leisure activities</p>	<p>of the long term health plan.</p>

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		<p>Patients wishing to return to work should be offered assessment and assistance</p> <p>Sexuality: stroke survivors and partners should be offered</p> <p>The opportunity to discuss issues relating to sexuality with an appropriate health professional</p> <p>Written information addressing issues relating to sexuality post stroke</p> <p>Any intervention (related to sexuality) should address psychological aspects as well as physical function.</p> <p>Peer support: stroke survivors and family / carers should be given information about availability and potential benefits of local stroke support groups and other sources for peer support.</p> <p>Carer support:</p> <p>Carers should be provided with tailored information and support during all stages of the recovery process</p> <p>Where it is the wish of the patient the carer should be actively involved in the recovery process (assistance with goal setting, therapy sessions, discharge planning and long-term activities)</p> <p>Carers should be offered support services after the stroke survivors return to the community (problem solving or educational counselling</p>	

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		<p>approach) Assistance should be provided for family / carers to manage stroke survivors who have behavioural problems</p> <p>Canadian- Psychological and social support reviewed regularly. Continued access to appropriate therapy if difficulty with ADL to improve/prevent deterioration declining activity or mobility at 6 mo assess for targeted rehab. veterans – re-evaluate progress during rehab. Review psychosocial and community integration needs, assess when/if further rehab needed. post-discharge telephone followup, patient info on access to community resources, ongoing monitoring and secondary prevention strategies employed.</p>	
<p>cross refer to neuropathic pain GL</p> <p>SHOULDER PAIN</p> <p>RCP – section 6.22 SIGN – sections 4.12</p>	<p>RCP – Three consensus recommendations, two based on SR Ada et al 2002 for FES with additional RCT trials by Griffin et al 2006, Hanger et al 2000 and Kalita et al 2006 SIGN – Prevention based on RCT evidence, SR (hemiplegic</p>	<p>RCP – prevention of pain by handling the weak arm correctly; avoiding arm slings; correct positioning of arm. Every patient should be assessed for shoulder pain. Patients should be offered simple analgesia. When experiencing more severe pain the following should be considered: high-intensity transcutaneous nerve stimulation; shoulder strapping; FES.</p>	<p>The person who has had a stroke should be assessed for shoulder pain.</p> <p>Initial treatment for shoulder pain should be analgesics.</p>

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<p>(prevention) and section 4.13 (management) Australian / New Zealand – section 7.6.1 Dutch – mentioned in F13 Veterans section 2.6 pain</p>	<p>patients) related to biofeedback, Cochrane review on strapping, FES (Ada et al 2002) NMES individual RCT, Botox small N RCTs, steroid injections small N RCT and time series study without control group Australian / New Zealand – Consensus and level B/C evidence Dutch – SR (hemiplegic patients) on glenohumeral subluxation Canadian – assessment, prevention and management of shoulder pain. SR for FES (Ada Foongchomcheay 2002), mobilisation techniques - observational study veterans – FES for shoulder pain RCT (Price & pandyan 2001;Van Peppen 2004)</p>	<p>Patients should not be offered shoulder supports and slings or intra-articular steroid injections. SIGN – Not recommended: shoulder strapping intra-articular steroids without inflammatory disorders Due to the complex nature of shoulder pain an algorithm should be considered (example algorithm for post-stroke shoulder pain provided in an appendix) Australian / New Zealand – Management may include: Strapping and education of staff, carers people with stroke about prevention of trauma. For patients who develop shoulder pain management should be based on interventions for acute musculoskeletal pain. Do not use: corticosteroid injections ultrasound Dutch – mention neuromuscular stimulation to improve motion, but state that it does not lead to a decrease in pain. Canadian –joint protection strategies, FES, stretching and mobilisation, botox recs. veterans – monitor shoulder mobility manage subluxation and pain using FES</p>	<p>Shoulder supports or slings are not effective in managing shoulder pain. High-intensity transcutaneous nerve stimulation or FES can be effective in relieving shoulder pain. Arm slings should be avoided in the treatment for shoulder pain. There is a need for an algorithm to assess and treat shoulder pain.</p>
<p>SPEECH AND LANGUAGE THERAPIES</p>	<p>RCP - Aphasia based on a mixture of consensus and</p>	<p>RCP – Aphasia: Any patient with left hemisphere damage should be screened for</p>	<p>Generally:</p>

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<p>RCP - sections 6.36 (aphasia), 6.37 (dysarthria) and 6.38 (apraxia of speech) SIGN – section 4.6 New Zealand – section 6.5 (aphasia 6.5.1; dyspraxia of speech 6.5.2 and dysarthria 6.5.3) Australian – section 6.5 (aphasia 6.5.1; dyspraxia of speech 6.5.2 and dysarthria 6.5.3) Dutch – not in scope Canadian – not addressed Veterans (American) – section 4.2 (assessment of communication impairments) and section 12 Communication (dysarthria and aphasia – apraxia of speech not mentioned)</p>	<p>evidence; Dysarthria on consensus one review article and 2 non-specific treatment reviews, Apraxia based on consensus only SIGN – expert opinion Australian / New Zealand – Cochranes and SRs as well as consensus recommendations for aphasia, dyspraxia of speech based on consensus and level D evidence, dysarthria based on consensus and level D evidence veterans – Cochrane & SRs for aphasia 1 SR apraxia, 1 SR dysarthria (Wambaugh 2006 Yorkston 2007), assessment of communication impairments – consensus , level II unclear.</p>	<p>aphasia using formal screening tools; patients found to have aphasia should be formally assessed by an SLT; the SLT should: explain the nature of the impairment to patient, family and treating team establish method of communication and inform / train family and treating team re-assess nature and severity at appropriate intervals Patients with aphasia persisting for >2 wks should: be given treatment aimed at reducing identified specific language impairments be considered for early intensive (2-8 hrs/wk) SL therapy be assessed for alternative means of communication (gesture, drawing, writing, use of communication aids) While patient has difficulties with communication: all people interacting regularly with patient should be taught the patient’s mood should be assessed Patients with aphasia persisting for >6 mths should: should be considered for and referred for a further episode of specific treatment (if appropriate)</p>	<p>For all patients with speech and language impairments the SLT needs to explain and discuss impairment with patient/family/carers/treatment team and teach strategies.</p> <p>The persons with speech and language impairments should be assessed for alternative means of communication (gesture, drawing, writing, use of communication aids).</p> <p>The Impact of speech and language impairments on other aspects of life should be assessed and possible environmental barriers should be addressed, jointly with the occupational therapist if appropriate.</p> <p>Aphasia (this will be covered by another new review – and therefore recommendations will be discussed when evidence is presented to the GDG)</p> <p>Dysarthria:</p>

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		<p>have their and their families need for social support assessed formally.</p> <p>Dysarthria: Any patient with unclear / unintelligible speech should be assessed by an SLT to determine nature and cause.</p> <p>Any patient with severe dysarthria should: be taught techniques to improve clarity of speech</p> <p>be assessed for compensatory techniques (letter board, communication aids)</p> <p>The communication partner should be taught how to assist communication.</p> <p>Apraxia of speech: Any patient with difficulty articulating words should be formally assessed. Any patient with severe articulation difficulties but reasonable cognition and language function should be assessed for and provided with alternative or augmentative communication aids.</p> <p>SIGN – Aphasia: Patients should be referred to SL therapy with a minimum of 2 hrs/wk. Treatments for aphasia require a minimum of 6 mths treatment. Referral to volunteer stroke services should be considered.</p> <p>Dysarthria: Patients should be referred to SL therapy services for assessment and management.</p> <p>Apraxia of speech: No recommendation.</p> <p>Australian / New Zealand – Aphasia: All patients</p>	<p>Interventions for persons with dysarthria post stroke may include:</p> <p>Biofeedback or voice amplifier</p> <p>Intense therapy to increase loudness</p> <p>Oral muscular exercises</p> <p>Not enough evidence to make any statement with regards to the use of a particular type of intervention</p> <p>Apraxia of speech:</p> <p>Any patient with severe articulation difficulties but reasonable cognition and language function should be assessed for and provided with alternative or augmentative communication aids.</p> <p>Interventions for persons with apraxia of speech post stroke may include:</p> <p>integral stimulation approach, visual cueing, and articulatory placement cueing</p> <p>principles of motor learning to structure practice sessions</p> <p>PROMPT therapy (which stands for: Prompts for Restructuring Oral and Muscular Phonetic Targets)</p> <p>Not enough evidence to make any statement with regards to the use of a particular type of</p>

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		<p>should be screened with valid and reliable tool. Those with suspected aphasia should be assessed by a specialist clinician. For a patient with aphasia the clinician should:</p> <ul style="list-style-type: none"> document provisional diagnosis explain and discuss impairment with patient/family/carers/treatment team and teach strategies in collaboration with patient identify goals and develop a tailored intervention plan. Goals and plans should be reviewed regularly Alternative means of communication (gesture, drawing, writing, use of communication aids) should be used if necessary All written information should be available in an aphasia friendly format. Individually tailored treatment can include: <ul style="list-style-type: none"> treatment of aspects of language following models derived from cognitive neuropsychology constraint-induced language therapy use of gesture supported conversation techniques therapy programs delivered via computer Group therapy and conversation groups can be used and should be used if aphasia persists. People with chronic aphasia should have their mood monitored. 	<p>intervention</p>

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		<p>Environmental barriers facing people with aphasia should be addressed (negative attitudes, aphasia friendly information, consideration of cultural background)</p> <p>Impact of aphasia on other aspects of life should be assessed.</p> <p>Not recommended: Use of piracetam</p> <p>Dyspraxia of speech: Patients should be comprehensively assessed. Interventions should be individually tailored and can incorporate:</p> <ul style="list-style-type: none"> integral stimulation approach, visual cueing, and articulatory placement cueing principles of motor learning to structure practice sessions <p>PROMPT therapy (which stands for: Prompts for Restructuring Oral and Muscular Phonetic Targets)</p> <p>Augmentative or alternative communication modalities should be used.</p> <p>Dysarthria: Patients should be assessed to determine nature and cause.</p> <p>Interventions can include:</p> <ul style="list-style-type: none"> Biofeedback or voice amplifier Intense therapy to increase loudness (e.g. Lee Silverman voice treatment) Oral muscular exercises <p>People with severe dysarthria should be</p>	

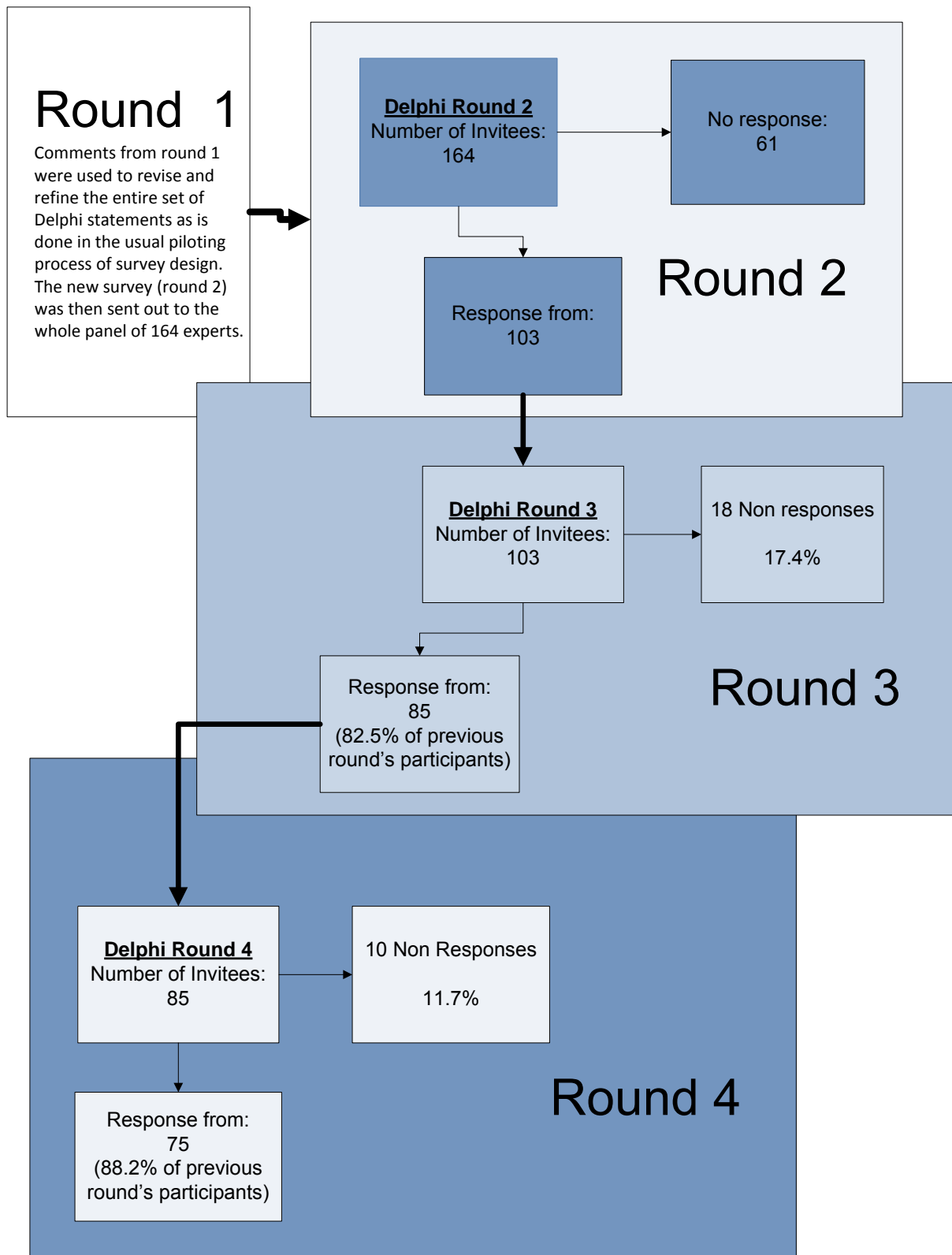
Sections from other guidelines that are relevant to areas need addressing for this guideline	Were sections from other guidelines evidence based or consensus based	Recommendations from other guidelines that were used by the expert consultants to draft the Delphi statements	Statements drafted for the Delphi process
		<p>assessed for alternative or augmentative communication devices.</p> <p>Veterans- dysarthria compensatory treatment prosthesis, writing, gesturing, augmentative communication devices</p> <p>general assessment – carry out assessment use, standardised testing procedures</p>	
diplopia other visual impairments	<p>Veterans – studies small and nonrandomised, majority of evidence in brain injury</p> <p>SIGN – section 4.5 visual problems – cohort study – assessment of visual problems. Limited poor quality evidence for visual scanning /compensatory techniques for visual field defects.</p> <p>section 6.9 (orthoptic care) mentions diplopia and use of prisms occlusion, orthoptic exercises or compensatory head postures</p> <p>New Zealand / Australian – diplopia mentioned in 6.2.4 (vision impairments) eye patching mentioned</p>	<p>Veterans (American) – section 14.2 consider scanning training, visual field stimulation, prisms eye exercises as restorative strategies prisms or patching as compensatory strategies</p> <p>All stroke patients should be screened for visual problems, and referred appropriately</p> <p>Patients with disorders of eye movements should be referred for orthoptic assessment and should receive appropriate advice or interventions from appropriately trained specialists</p>	<p>Already have recommendations for hemianopia</p> <p>All patients with impaired acuity, double vision or a visual field defect following a stroke requires a formal ophthalmology assessment</p> <p>Patients with persisting double vision after stroke require a formal orthoptic assessment</p> <p>Patients with ongoing visual symptoms should be provided with information on compensatory strategies from ophthalmology, orthoptic and occupational therapy services</p> <p>Patients should be provided with contact details for the RNIB or Stroke Association for further information on visual impairments after stroke.</p>

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	<p>A review by Khan et al. (stroke and visual rehabilitation 2008) mentions prisms and patching for diplopia</p> <p>prisms for heminaopia – RCT, Rossi</p> <p>computer based training of stimulus detection study RCT Kasten (brain injury including stroke)</p> <p>RCP – from consensus and systematic review - Riggs 2007 for compensatory strategies</p>	<p>People with stroke who report or appear to have difficulties with vision and/or perception should be screened using specific assessment instruments, and if a deficit is found, referred on for comprehensive assessment by relevant health practitioners.</p> <p>15-diopter Fresnel prism glasses can be used to improve visual function in people with homonymous hemianopia but there is no evidence of benefit in activities of daily living (Rossi et al, 1990).</p> <p>Computer-based visual restitution training can be used to improve visual function in people with visual field deficits (Kasten et al, 1998).</p> <p>Every patient should have:</p> <ul style="list-style-type: none"> • practical assessment of visual acuity wearing their appropriate glasses, checking their ability to see newspaper text and distant 	<p>Assessment and Information for registering as sight impaired or severely sight impaired should be provided by referral to an ophthalmologist</p>

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		<p>objects clearly</p> <p>Any patient who has a visual field deficit should be informed and, if a car driver, should specifically be informed about the consequences for driving (see 6.48).</p> <p>C Any patient whose visual field defect causes practical problems should be taught compensatory techniques.</p> <p>D Treatment for hemianopia using prisms should only be provided if:</p> <ul style="list-style-type: none"> • the treatment is supervised by someone with expertise in this treatment • the effects are evaluated • the patient is aware that it may not have any benefit for them. 	
<p>PATIENT INFORMATION NEEDS</p> <p>cross refer patient exp GL</p>		<p>NOT COVERED WITHIN THE DELPHI PROCESS</p>	
<p>SPASTICITY</p> <p>cross refer to spasticity in child GL and make general rec for assessment by specialist</p>		<p>NOT COVERED WITHIN THE DELPHI PROCESS</p>	
<p>NUTRITION AND DIET</p>		<p>NOT COVERED WITHIN THE DELPHI PROCESS</p>	

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cross refer to nutrition GL			
INCONTINENCE cross refer to incontinence due to neurological disorder GL and faecal incontinence GL		NOT COVERED WITHIN THE DELPHI PROCESS	
MOOD cross refer to depression in adults, depression with a chronic illness, anxiety GLs		NOT COVERED WITHIN THE DELPHI PROCESS	

F.12 Delphi Methodology Appendix 3



	Round 2 Questions and Results		Round 3 Questions and Results		Round 4 Questions and Results																																																																																																		
4	<p>A core stroke rehabilitation team should comprise of membership from the following disciplines/roles:</p> <table border="1"> <thead> <tr> <th>Answer Options</th> <th>Strongly Agree</th> <th>Agree</th> <th>Disagree</th> <th>Strongly Disagree</th> <th>Response Count</th> <th>% Strongly Agree</th> </tr> </thead> <tbody> <tr> <td>Consultant neurology/stroke medicine</td> <td>81</td> <td>17</td> <td>2</td> <td>0</td> <td>100</td> <td>81.00%</td> </tr> <tr> <td>Nursing</td> <td>90</td> <td>11</td> <td>0</td> <td>0</td> <td>101</td> <td>89.11%</td> </tr> <tr> <td>Physiotherapy</td> <td>100</td> <td>1</td> <td>0</td> <td>0</td> <td>101</td> <td>99.01%</td> </tr> <tr> <td>Occupational therapy</td> <td>100</td> <td>1</td> <td>0</td> <td>0</td> <td>101</td> <td>99.01%</td> </tr> <tr> <td>Speech and Language Therapy</td> <td>99</td> <td>1</td> <td>0</td> <td>0</td> <td>100</td> <td>99.00%</td> </tr> <tr> <td>Nutrition/Dietetics</td> <td>63</td> <td>33</td> <td>2</td> <td>0</td> <td>98</td> <td>64.29%</td> </tr> <tr> <td>Clinical/Neuro psychology</td> <td>74</td> <td>26</td> <td>0</td> <td>0</td> <td>100</td> <td>74.00%</td> </tr> <tr> <td>Rehabilitation assistant</td> <td>73</td> <td>26</td> <td>1</td> <td>1</td> <td>101</td> <td>72.28%</td> </tr> <tr> <td>Social work</td> <td>71</td> <td>28</td> <td>0</td> <td>0</td> <td>99</td> <td>71.72%</td> </tr> <tr> <td>Pharmacy</td> <td>33</td> <td>51</td> <td>11</td> <td>0</td> <td>95</td> <td>34.74%</td> </tr> <tr> <td>Other:</td> <td></td> <td></td> <td></td> <td></td> <td>28</td> <td></td> </tr> <tr> <td colspan="5"></td> <td>answered question</td> <td>101</td> </tr> <tr> <td colspan="5"></td> <td>skipped question</td> <td>2</td> </tr> </tbody> </table>	Answer Options	Strongly Agree	Agree	Disagree	Strongly Disagree	Response Count	% Strongly Agree	Consultant neurology/stroke medicine	81	17	2	0	100	81.00%	Nursing	90	11	0	0	101	89.11%	Physiotherapy	100	1	0	0	101	99.01%	Occupational therapy	100	1	0	0	101	99.01%	Speech and Language Therapy	99	1	0	0	100	99.00%	Nutrition/Dietetics	63	33	2	0	98	64.29%	Clinical/Neuro psychology	74	26	0	0	100	74.00%	Rehabilitation assistant	73	26	1	1	101	72.28%	Social work	71	28	0	0	99	71.72%	Pharmacy	33	51	11	0	95	34.74%	Other:					28							answered question	101						skipped question	2		Consensus achieved in last round.		
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12	Routine collection and analysis of a range of measures should include:						9	Routine collection and analysis of a range of measures should include, which three would you pick?						Consensus achieved in previous round.				
	Answer Options	Strongly agree	Agree	Disagree	Strongly disagree	Response Count		% Strongly Agree	Answer Options	1	2	3	Response Count				% Strongly Agree	
	National Institute of Health Stroke Scale/Score (NIHSS)	40	37	3	3	83		48.19%	National Institute of Health Stroke Scale/Score (NIHSS)	40	9	5	54				74.07%	
	Rankin	31	40	10	4	85		36.47%	Modified Rankin Scale	10	10	8	28				35.71%	
	Barthel Index	28	49	6	3	86		32.56%	Barthel Index	17	21	11	49				34.69%	
	Hospital Anxiety Depression Scale (HADS)	28	39	14	2	83		33.73%	Hospital Anxiety Depression Scale (HADS)	5	13	20	38				13.16%	
	Berg Balance Scale	17	39	20	2	78		21.79%	Berg Balance Scale	3	9	5	17				17.65%	
	EQ5D	17	37	16	7	77		22.08%	EQ5D	0	5	12	17				0.00%	
	General Health Questionnaire (GHQ)	15	36	25	4	80		18.75%	General Health Questionnaire (GHQ)	1	4	8	13				7.69%	
	Geriatric Depression Scale	12	35	24	7	78		15.38%	Geriatric Depression Scale	0	4	2	6				0.00%	
	Others (please specify)					40			Others (please specify)				26					
	answered question							87	answered question								77	
skipped question						16	skipped question						8					
14	Throughout the care pathway roles and responsibilities of the multi-disciplinary stroke rehabilitation team services should be clearly outlined, documented and communicated to the patient and their family.						10	Consensus achieved in last round.										
	Answer Options					Response Percent		Response Count	Answer Options								Response Percent	Response Count
	Strongly agree					72.7%		72	Strongly Agree								53.1%	43
	Agree					24.2%		24	Agree								39.5%	32
	Disagree					2.0%		2	Disagree								6.2%	5
	Strongly disagree					1.0%		1	Strongly Disagree								1.2%	1
Comment:						18	Comment:						21					
answered question						99	answered question						81					
skipped question						4	skipped question						4					
13	Local and National data collection should be overseen by a national body.						10	Data collection should be overseen by a National Body:						6				
	Answer Options					Response Percent		Response Count	Answer Options								Response Percent	Response Count
	Strongly agree					60.8%		59	Strongly Agree								62.0%	44
	Agree					34.0%		33	Agree								32.4%	23
	Disagree					4.1%		4	Disagree								4.2%	3
	Strongly disagree					1.0%		1	Strongly Disagree								1.4%	1
Comment:						27	Comment:						16					
answered question						97	answered question						71					
skipped question						6	skipped question						2					

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67	Do you have the relevant experience to answer questions regarding visual impairments?			41	Do you have the relevant experience to answer questions regarding visual impairments?			N/A			
	Answer Options	Response Percent	Response Count		Answer Options	Response Percent	Response Count				
	Yes (you will automatically be directed to the visual impairments section)	25.5%	25		Yes (Click 'next' and you will automatically be directed to the visual impairments section)	25.9%	22				
	No (you will be automatically redirected to the end of the survey)	74.5%	73		No (Click 'next' and you will be automatically redirected to the end of the survey)	74.1%	63				
			<i>answered question</i>				85				
			<i>skipped question</i>				0				
68	All people who have impaired acuity, double vision or a visual field defect following a stroke require a formal ophthalmology assessment.			42	All people who have impaired acuity, double vision or a visual field defect following a stroke require a formal ophthalmology assessment.			Statement not included in further round as consensus unlikely to be achieved.			
	Answer Options	Response Percent	Response Count		Answer Options	Response Percent	Response Count				
	Strongly Agree	45.8%	11		Strongly Agree	23.8%	5				
	Agree	20.8%	5		Agree	33.3%	7				
	Disagree	33.3%	8		Disagree	38.1%	8				
	Strongly disagree	0.0%	0		Strongly disagree	4.8%	1				
	Comment:		7		Comment:		7				
			<i>answered question</i>				21				
			<i>skipped question</i>				64				
69	People who have persisting double vision after stroke require a formal orthoptic assessment.			Consensus achieved in last round.							
	Answer Options	Response Percent	Response Count								
	Strongly Agree	70.8%	17								
	Agree	25.0%	6								
	Disagree	4.2%	1								
	Strongly disagree	0.0%	0								
	Comment:		1								
			<i>answered question</i>								
			<i>skipped question</i>								
70	People who have ongoing visual symptoms after a stroke, should be provided with information on compensatory strategies from ophthalmology, orthoptic and occupational therapy services.			43	People who have ongoing visual symptoms after a stroke, should be provided with information on compensatory strategies from:			Statement not included in further round as consensus unlikely to be achieved.			
	Answer Options	Response Percent	Response Count		Answer Options	Strongly Agree	Agree		Disagree	Strongly disagree	Response Count
	Strongly Agree	56.5%	13		Ophthalmology services	3	12	3	1	19	15.79%
	Agree	39.1%	9		Orthoptic services	10	9	1	0	20	50.00%
	Disagree	0.0%	0		Occupational therapy services	6	12	1	0	19	31.58%
	Strongly disagree	4.3%	1		Comment:				9		
	Comment:		6						<i>answered question</i>	20	
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Appendix G: Flow charts of selected studies

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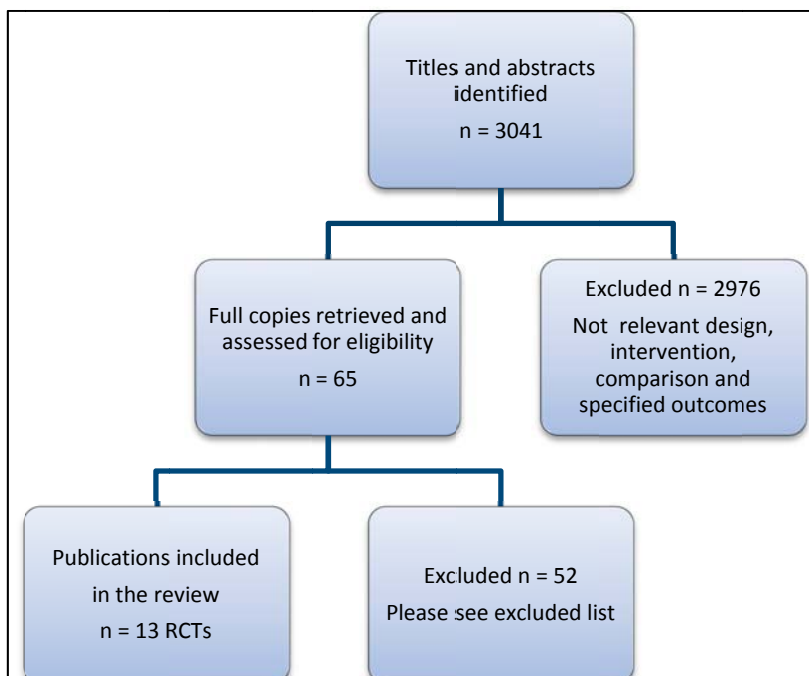
12 RCTs were included for this review

G.1.2 In people after stroke what is the clinical and cost-effectiveness of memory strategies versus usual care to improve memory?

2 RCTs were included for this review

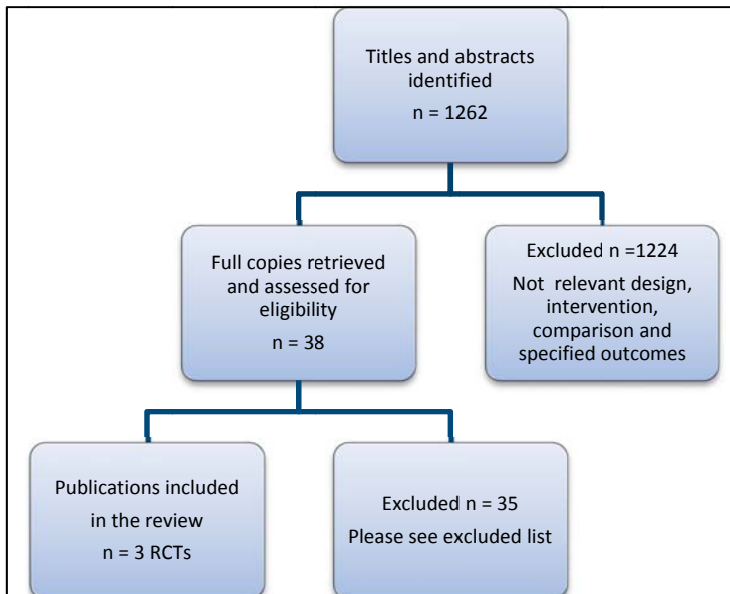
G.1.3 In people after stroke what is the clinical and cost-effectiveness of sustained attention training versus usual care to improve attention?

One randomised control trial included for this review



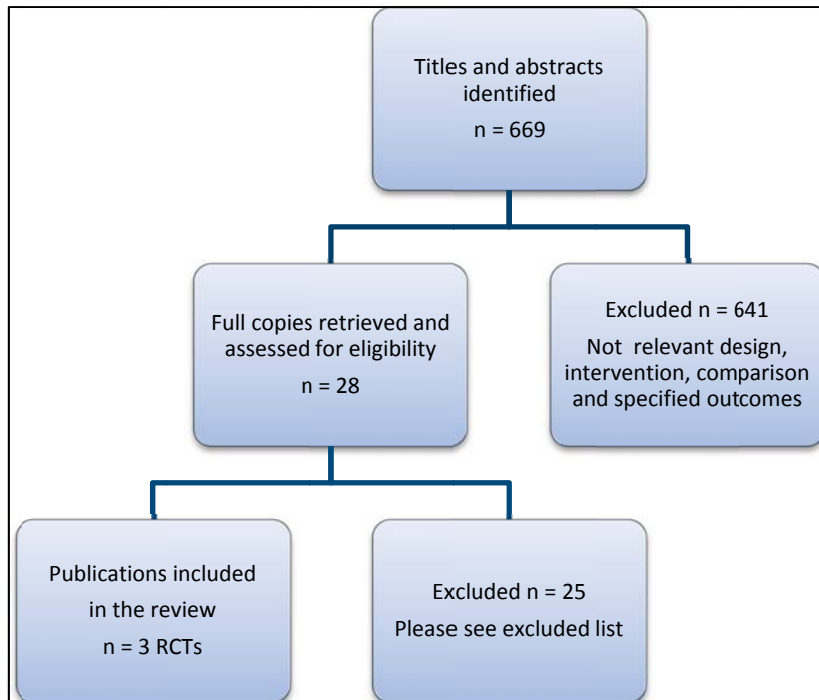
G.1.4 In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?

2 RCTs were included for this review



G.1.5 In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions / usual care to improve swallowing? (Dysphagia).

3 RCTs were included for this review



G.1.6 In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?

6 RCTs were included for this review

G.1.7 In people after stroke what is the clinical and cost effectiveness of constraint induced therapy versus usual care on improving function and reducing disability?

15 RCTs were included for this review

G.1.8 In people after stroke what is the clinical and cost effectiveness of repetitive task training versus usual care on improving function and reducing disability?

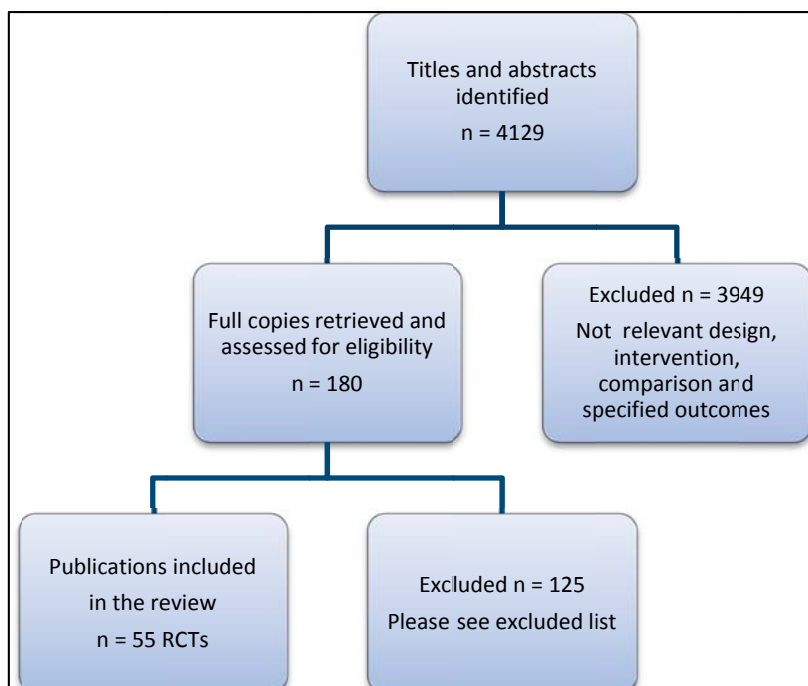
5 RCTs were included for this review

G.1.9 In people after stroke what is the clinical and cost effectiveness of all treadmill versus usual care on improving walking? In people after stroke who can walk, what is the clinical and cost effectiveness of treadmill plus body support versus treadmill only on improving walking?

13 RCTs were included for this review

G.1.10 In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?

10 RCTs were included for this review

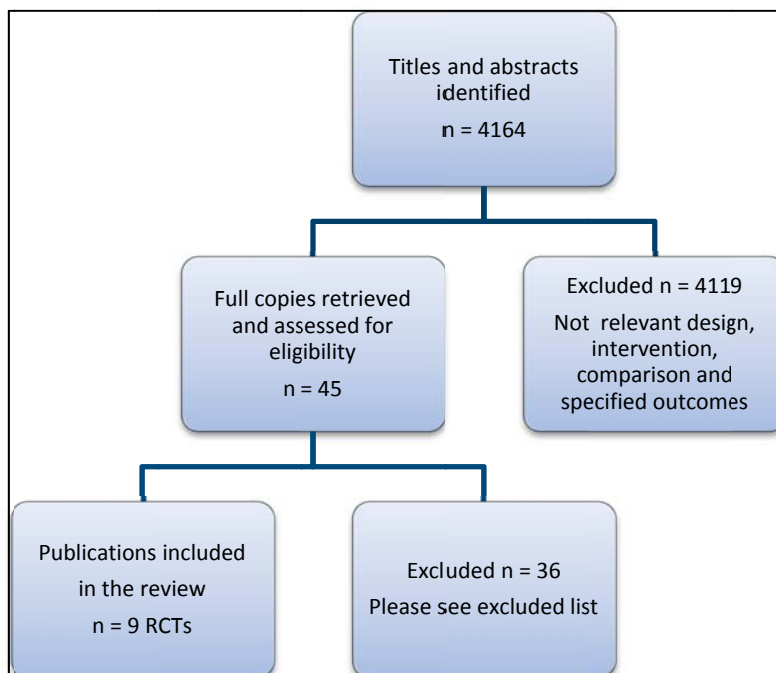


G.1.11 What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?

2 RCTs were included for this review

G.1.12 In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?

7 RCTs were included for this review

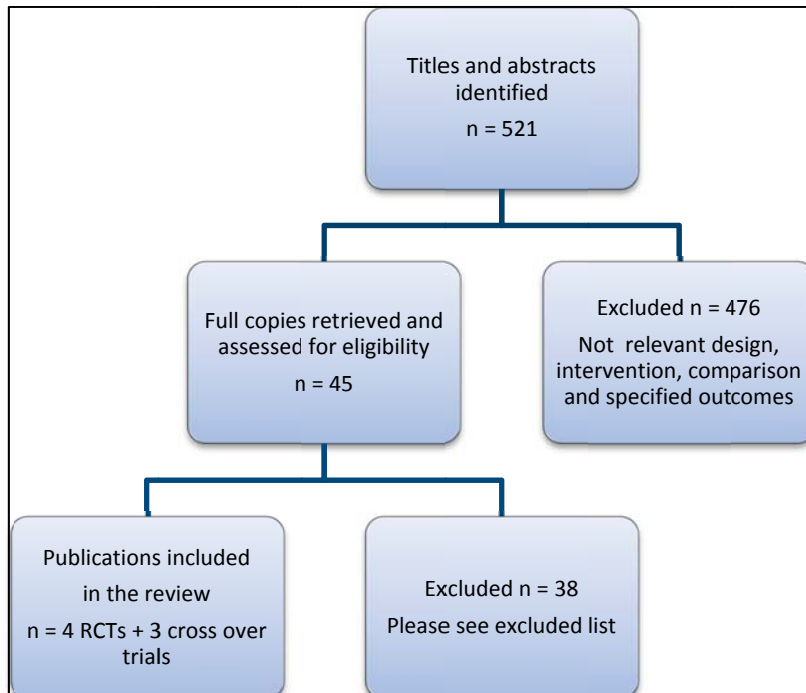


G.1.13 In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?

One RCT was included for this review

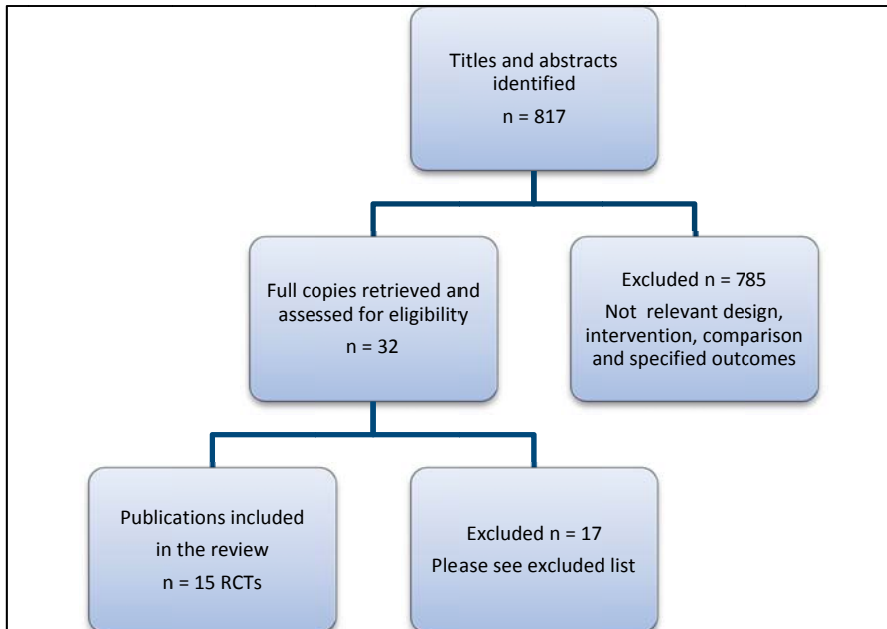
G.1.14 In people after stroke what is the clinical and cost-effectiveness of ankle-foot orthoses of all types to improve walking function versus usual care?

2 RCTs and 3 cross-over trials were included for this review



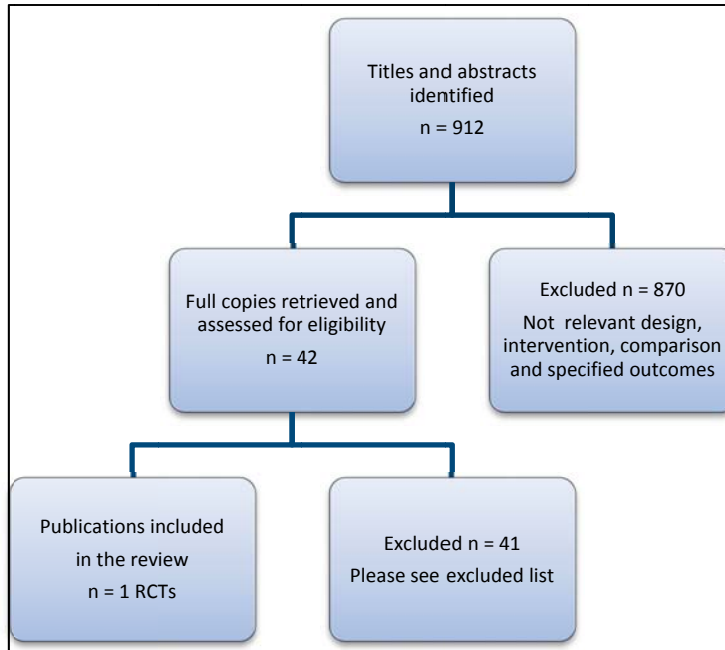
G.1.15 In people after stroke what is the clinical and cost-effectiveness of Functional Electrical Stimulation for hand function versus usual care?

13 RCTs were included for this review



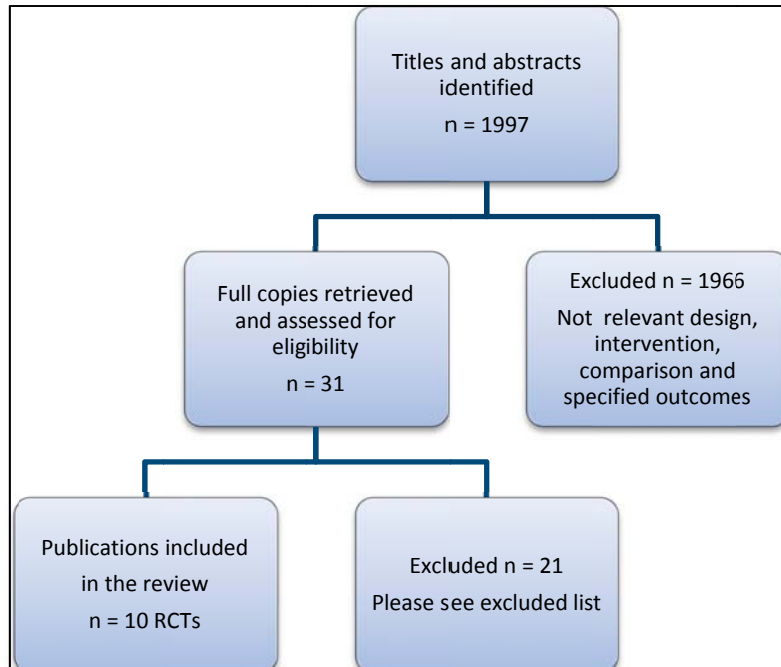
G.1.16 In people after stroke what is the clinical and cost-effectiveness of psychological therapies provided to the family (including the patient)?

No studies were included for this review



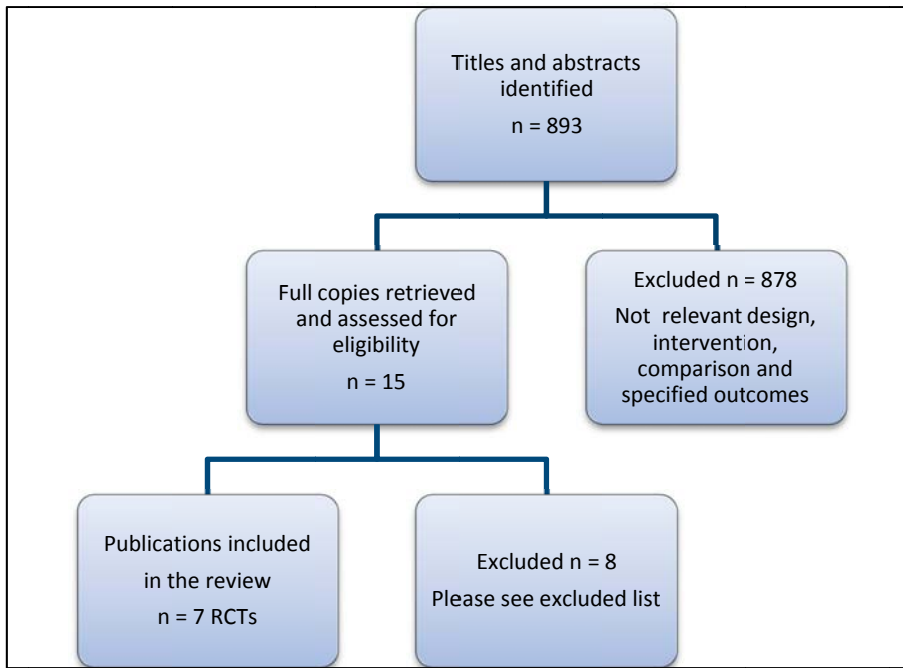
G.1.17 In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?

10 RCTs were included for this review



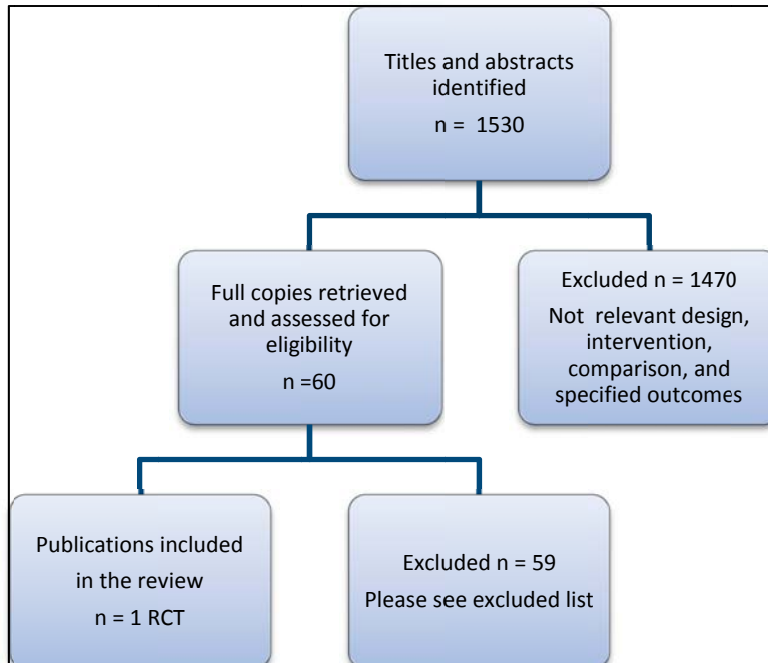
G.1.18 In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing / others) versus usual care?

7 RCTs were included for this review



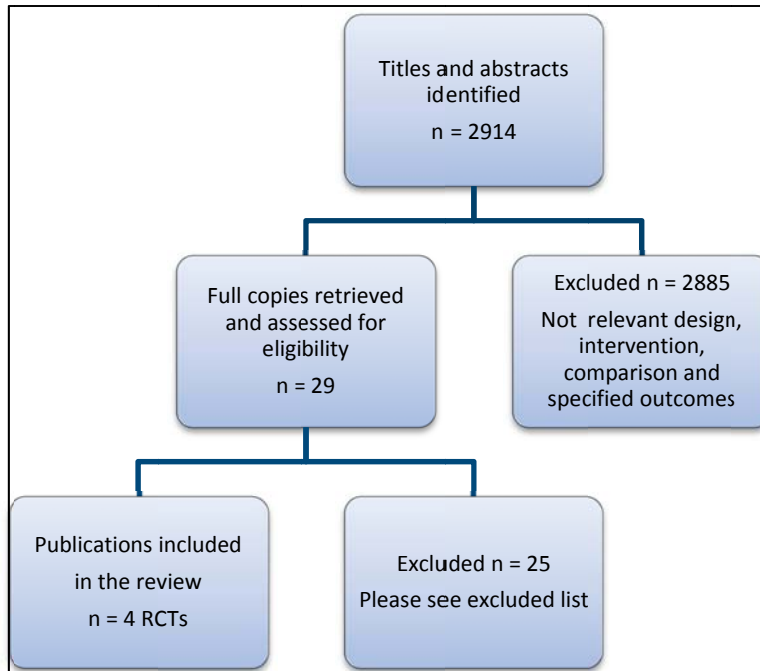
G.1.19 In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?

One RCT was included for this review



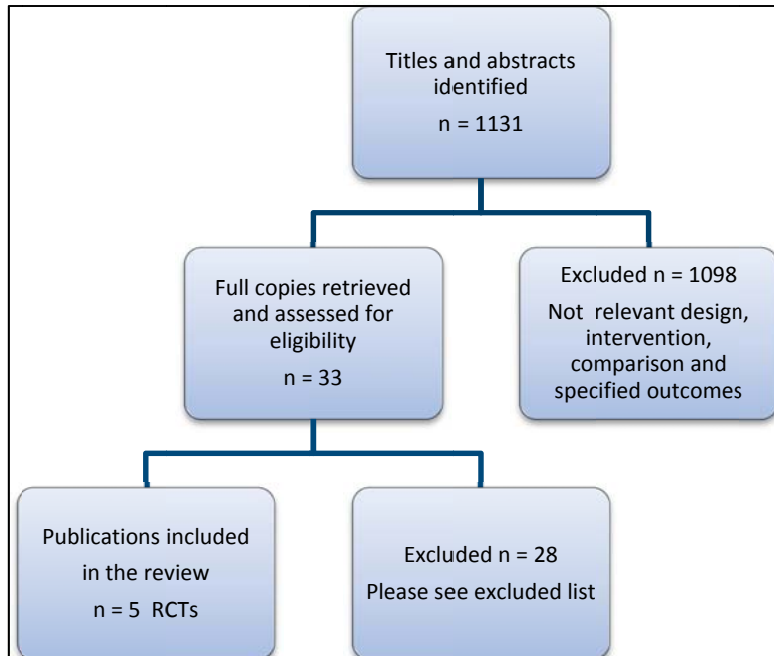
G.1.20 In people after stroke what is the clinical and cost-effectiveness of intensive rehabilitation versus standard rehabilitation?

4 RCTs were included for this review

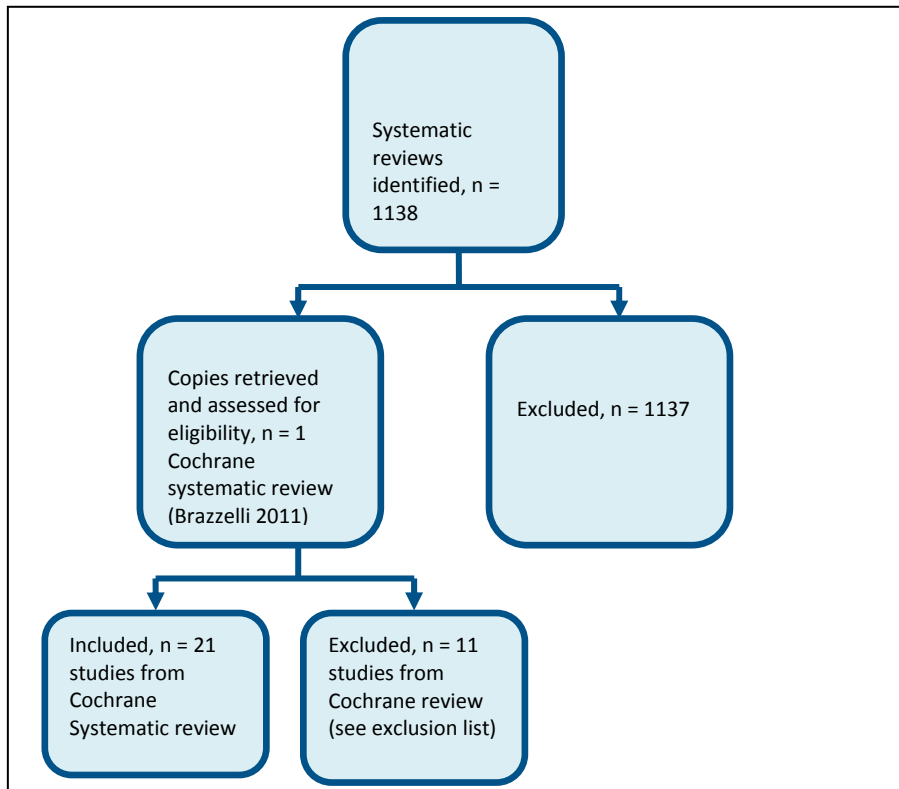


G.1.21 What the effectiveness is of supported versus unsupported information provision on mood and depression in people with stroke?

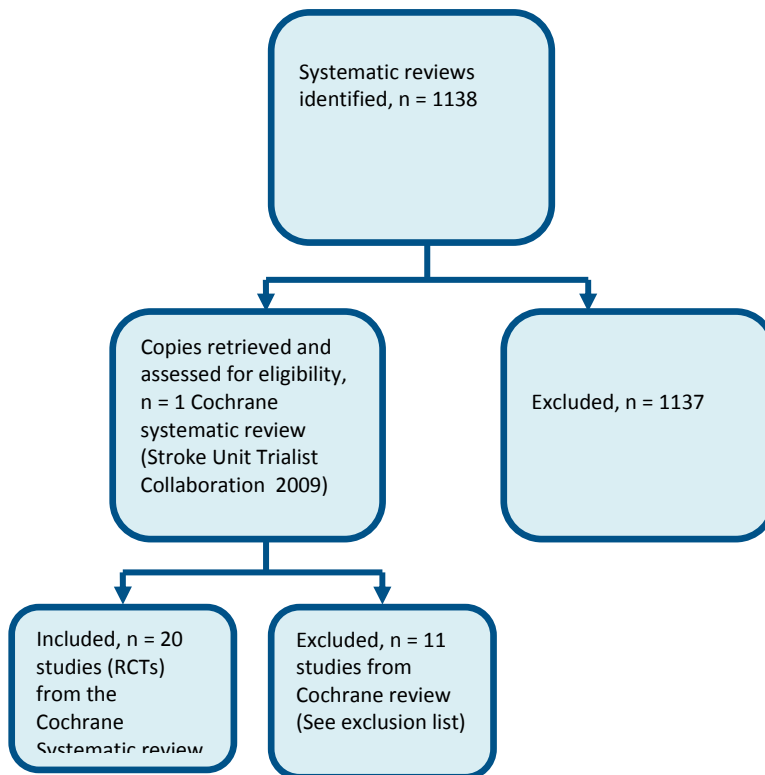
5 RCTs were included for this review



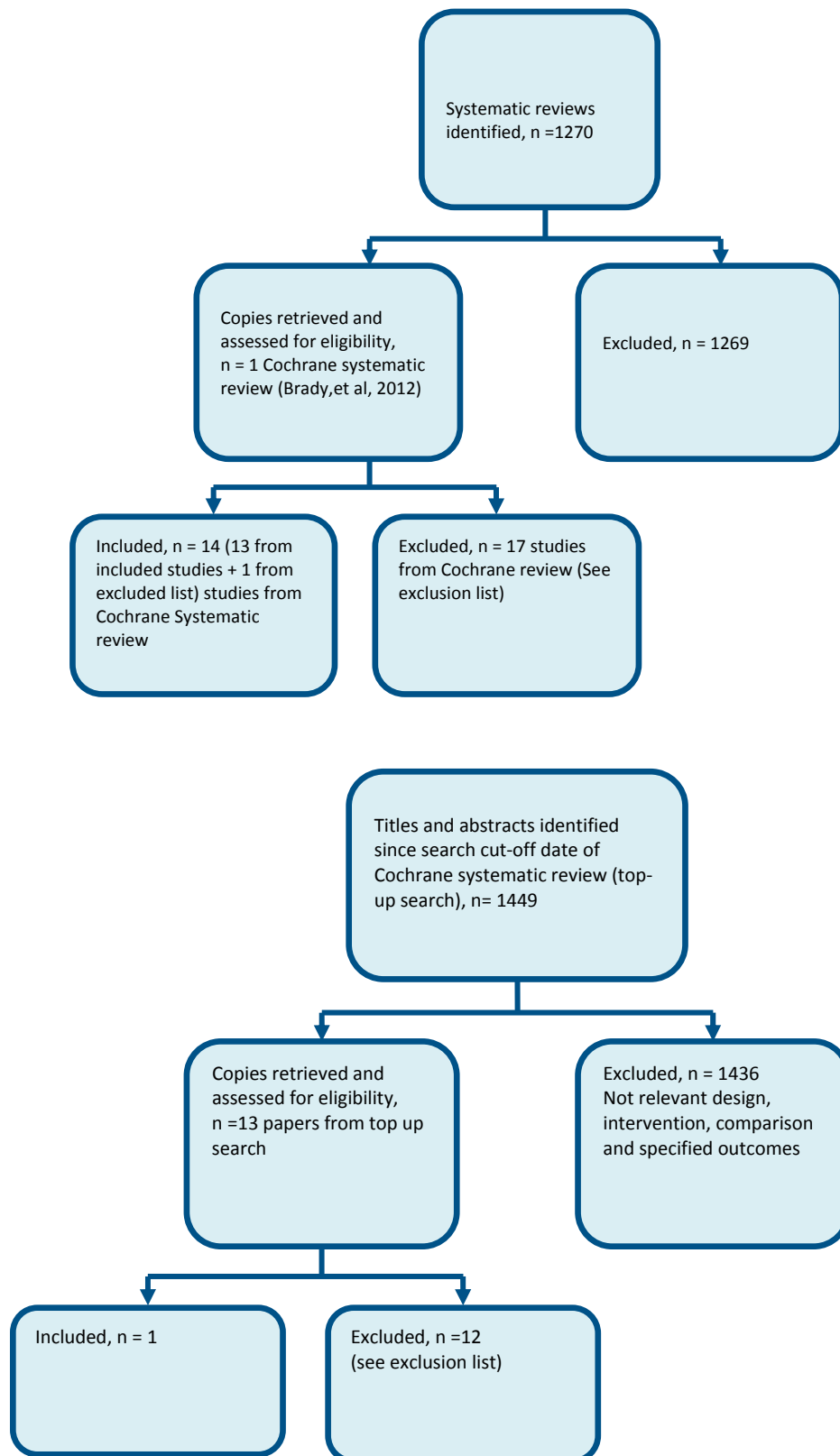
G.1.22 In people after stroke, does cardiorespiratory or resistance training improve outcome (fitness, function, quality of life, mood) and reduce disability?



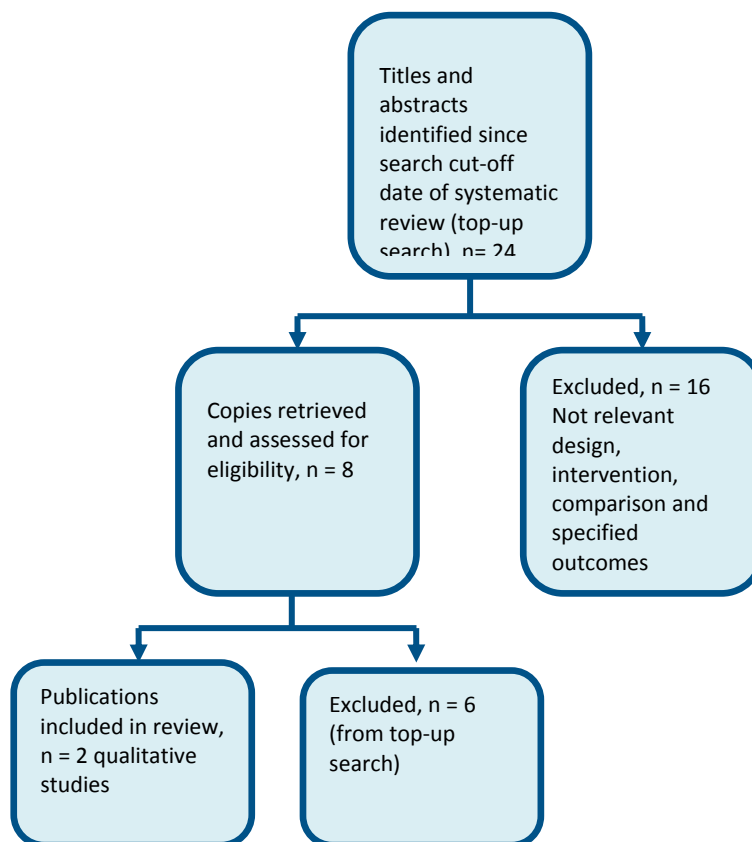
G.1.23 In people after stroke, does organised rehabilitation care (comprehensive, rehabilitation and mixed rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?



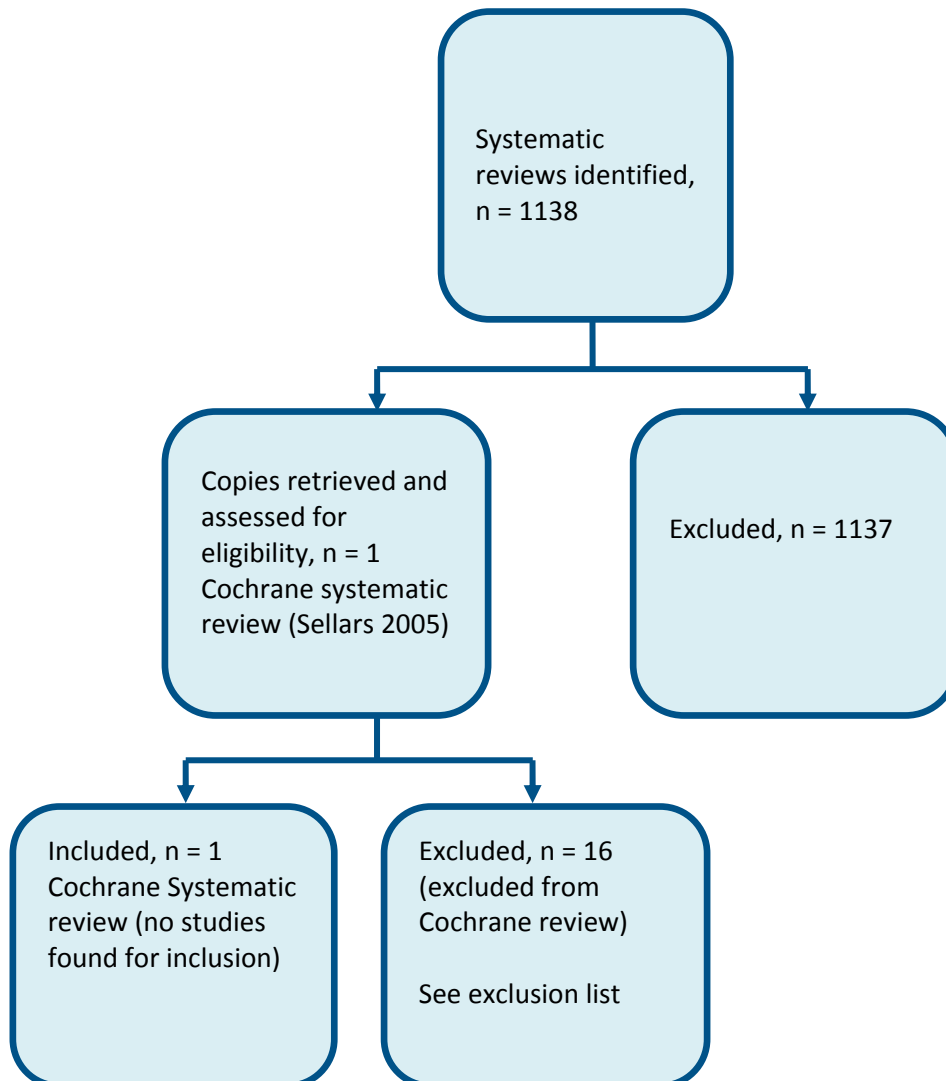
G.1.24 In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language/communication abilities and/or psychological wellbeing?



G.1.25 Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?



G.1.26 In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language/communication abilities and/or psychological wellbeing?



Appendix H: Clinical evidence tables

1. In people after stroke does cardiorespiratory or resistance training improve outcome (fitness, function, QOL, mood and reduce disability)?	237
2. In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and visual neglect?	263
3. In people after stroke what is the clinical and cost effectiveness of memory strategies versus usual care to improve memory?	287
4. In people after stroke what is the clinical and cost effectiveness of sustained attention training versus usual care to improve attention?	294
5. In people after stroke what is the clinical and cost effectiveness of eye movement therapy for visual field loss versus usual care?	297
6. In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions/usual care to improve swallowing? (Dysphagia)	303
7. In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?	310
8. What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?	330
9. In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?	333
10. In people after stroke what is the clinical and cost-effectiveness of functional Electrical Stimulation for hand function versus usual care?	340
11. In people after stroke what is the clinical and cost effectiveness of constraint induced therapy versus usual care on improving function and reducing disability?	375
12. In people after stroke what is the clinical and cost-effectiveness of repetitive task training versus usual care on improving function and disability?	405
13. In people after stroke who can walk, what is the clinical and cost effectiveness of treadmill plus body support versus treadmill only on improving walking?	431
14. In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?	456
15. In people after stroke what is the clinical and cost effectiveness of ankle/foot orthoses of all types to improve walking function versus usual care?	478
16. In people after stroke what is the clinical and cost effectiveness of interventions to aid return to work versus usual care?	505
17. What is the clinical and cost effectiveness of supported information provision versus unsupported information provision on mood and depression in people with stroke?	507
18. In people after stroke what is the clinical and cost effectiveness of psychological therapies provided to the family (including patients)?	518
19. In people after stroke what is the clinical and cost effectiveness of early supported discharge versus usual care?	521
20. In people after stroke what is the clinical and cost effectiveness of intensive rehabilitation versus standard rehabilitation?	541
21. In people after stroke with communication difficulties what is the clinical and cost effectiveness of intensive speech therapy versus standard speech therapy?	549
22. Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological well being, functioning and activity?	563

Evidence Table

Question: In people after stroke does cardiorespiratory or resistance training improve outcome (fitness, function, QOL, mood and reduce disability)?

Study Type	Systematic Review
-------------------	-------------------

Brazzelli M;Saunders DH;Greig CA;Mead GE;

Physical fitness training for stroke patients

Ref ID 16154 **RID:** 879 2011

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Direction =

Overall Study Quality -Strengths and Weaknesses:

Clear and focussed objectives; criteria for considering studies for the review were clearly described abd detailed; relevant databases searched; Data collection analysis well described and detailed; methodological quality assessment was appropriate, detailed and reproducible

DETAILS

of patients: 21 trials, involving 910 participants, which comprised cardiorespiratory (14 trials, 718 participants), and resistance training (7 trials, 192 participants)

Prevalence (Diagnostic):

Patient Characteristics	Stroke survivors. Mean age was approximately 64 years. Mean time since onset of symptoms ranged from 8.8 days in trials assessing participants before discharge from hospital to 7.7 years in trials assessing participants after hospital discharge
Interventions/ Test/ Factor being investigated	Cardiorespiratory training; Resistance training
Comparisons	Usual care
Length of Study/ Follow-up	End of follow up ranged from 12-36 weeks
Outcome measures studied	Mortality rate; Dependence or level of disability; Physical fitness; Mobility; Physical function; Quality of life; Mood
Results	See guideline for results
Effect Size	
Source of funding:	Funded by the Department of Health
Does the study answer the question?/Further Comments	Authors' concluded that there is sufficient evidence to incorporate cardiorespiratory training involving walking within post-stroke rehabilitation programmes to improve speed, tolerance, and independence during walking

Kelly H;Brady MC;Enderby P;

Speech and language therapy for aphasia following stroke

Ref ID 4915

RID:

909

2010

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Direction =

Overall Study Quality -Strengths and Weaknesses:

DETAILS

# of patients:	Thirteen trials comprising 1205 participants comparing Speech and Language therapy (SLT) to no SLT, and to placebo (social support and communicative
Prevalence (Diagnostic):	
Patient Characteristics	Study participants included people with aphasia as a result of stroke
Interventions/ Test/ Factor being investigated	Speech and Language Therapies (SLTs)
Comparisons	No SLT, and placebo (social support and communicative stimulation)
Length of Study/ Follow-up	No general statement made about follow up
Outcome measures studied	Functional communication, receptive language skills, expressive language skills, severity of aphasia, psychological or social wellbeing, patient satisfaction / carer and family views, compliance / drop-out
Results	See guideline
Effect Size	
Source of funding:	Department of Health
Does the study answer the question?/Further Comments	Authors observed a consistency in the direction of results which favoured intensive SLT over conventional SLT, though significantly more people withdrew from intensive SLT than conventional SLT

Stroke Unit Trialists' Collaboration;

Organised inpatient (stroke unit) care for stroke

Ref ID 318

RID:

908

2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Direction =

Overall Study Quality -Strengths and Weaknesses:

Clear and focussed objectives; criteria for considering studies for the review were clearly described and detailed; relevant databases searched; Data collection analysis well described and detailed; methodological quality assessment was appropriate

DETAILS

of patients:

Tewnty trials involving 6936 participants, compared organised stroke unit care (comprehensive stroke unit; mixed rehabilitation stroke unit; rehabilitation stroke

Prevalence (Diagnostic):

Patient Characteristics

Any patient admitted to hospital who had suffered a stroke

Interventions/ Test/ Factor being investigated

Organised stroke units

Comparisons	General medical wards
Length of Study/ Follow-up	Median 12 months; range 6 to 12 months
Outcome measures studied	Death, death or dependency, death or institutional care, duration of stay in hospital or institution or both, quality of life, patient and carer satisfaction
Results	See guideline for results
Effect Size	
Source of funding:	Funded by the Department of Health
Does the study answer the question?/Further Comments	Authors' conclude that stroke patients who receive organised inpatient care in a stroke unit are more likely to be alive, independent, and living at home.

Study Type	Randomised Controlled Trial
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Bowen A;Hesketh A;Patchick E;Young A;Davies L;Vail A;Long A;Watkins C;Wilkinson M;Pearl G;Lambon RM;Tyrrell P;

Clinical effectiveness, cost-effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke: a randomised controlled trial (the ACT NoW Study)

Ref ID 16253

RID:

949

2012 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Multi-centre, parallel-group randomised controlled trial (RCT) (12 English NHS hospital and community stroke services). Randomisation was by an external, independent, web-based randomisation service from the York Trials Unit (University of York) to ensure concealment of allocation. Randomisation was stratified. Participants were randomised using a 1:1 allocation ratio and block sizes of two, four and six with differing combinations. Variable block sizes were used to reduce the likelihood of selection bias through predictable allocation sequences. Attempts were made to ensure that research assistants who collected data on outcome assessments were blinded to the randomisation group. However, it was anticipated that research assistants could become unblinded. Outcome assessor did not know the patients and were blinded as to allocation. Intention- to- treat approach used.

DETAILS

of patients: 170 participants. Allocated to control n = 85 (primary analysis n = 72); allocated to therapy n = 85 (primary analysis n = 81)

Prevalence (Diagnostic):

Patient Characteristics

Participants ranged in age from 32 to 97 years (mean 70 years) and 56% were men. Almost all had aphasia (90%), 39% had dysarthria and 29% had both. Half were classified as having a severe activity restriction (disability) in terms of their baseline communication. Half had dysphagia (impaired swallowing).

Baseline characteristics by allocation group

Characteristic	AC (n = 85)	SL therapy (n = 85)
Mean age, years (range)	70 (40–92)	70 (32–97)
Male	46 (54%)	49 (58%)
Diagnosis		
Aphasia only	53 (62%)	51 (60%)
Dysarthria only	8 (9%)	9 (11%)
Both	24 (28%)	25 (29%)
Aphasia impairment, mean (SD)	1.9 (1.1), n = 77	1.9 (1.2), n = 76
Dysarthria impairment, mean (SD)	2.5 (1.1), n = 32	2.2 (1.2), n = 34
Either impairment* severe (0–2)	58 (68%)	58 (68%)
Communication activity		
Mean (SD)	2.2 (1.2)	2.3 (1.3)
Severe	47 (55%)	40 (47%)
Dysphagia present	47 (55%)	41 (48%)
BI		
Mean (SD)	10.7 (7.3)	12.7 (7.2)
Mild (18–20)	22 (26%)	36 (42%)
Moderate (11–17)	22 (26%)	17 (20%)
Severe (0–10)	41 (48%)	32 (38%)

*Stratification factor in the randomisation routine

Interventions/ Test/ Factor being investigated

On average started 2 weeks after stroke, involved an average of 22 ACT NoW (Assessing the effectiveness of Communication Therapy in the North West) speech and language therapy contacts, for 18 hours (mean), delivered over 13 weeks in both hospital and community settings.

Comparisons

Attention Control (AC): an average of 19 ACT NoW visitor contacts, for a mean of 15 hours. Visitors did not provide therapy or any communication strategies. Visitors had excellent social skills and general competency and were trained to deliver social attention absent of any intuitive form of communication therapy or strategy

Length of Study/ Follow-up

Six months

Outcome measures studied

Functional communicative ability on the Therapy Outcome Measure activity subscale (TOM)

Results

Scale	AC: mean (SD), n	SL therapy: mean (SD), n
TOM	3.1 (1.7), 27	3.1 (1.4), 33

TOM, Therapy Outcome Measure activity subscale

Effect Size

Source of funding:	Project was funded by the NIHR Health Technology Assessment programme. The stroke association funded part of the treatment costs
Does the study answer the question?/Further Comments	Authors concluded that functional communicative ability at 6 months had improved by a clinically meaningful amount for people in both groups. However, there was no evidence of an added benefit of early communication therapy from SL therapists for people with communication disability or their carers over and above that from AC and natural recovery, when both were provided at a higher level than in typical standard practice.

Bowen A;Hesketh A;Patchick E;Young A;Davies L;Vail A;Long A;Watkins C;Wilkinson M;Pearl G;Lambon RM;Tyrrell P;

Clinical effectiveness, cost-effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke: a randomised controlled trial (the ACT NoW Study)

Ref ID 16253 **RID:** 948 2012 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Multi-centre, parallel-group randomised controlled trial (RCT) (12 English NHS hospital and community stroke services). Randomisation was by an external, independent, web-based randomisation service from the York Trials Unit (University of York) to ensure concealment of allocation. Randomisation was stratified. Participants were randomised using a 1:1 allocation ratio and block sizes of two, four and six with differing combinations. Variable block sizes were used to reduce the likelihood of selection bias through predictable allocation sequences. Attempts were made to ensure that research assistants who collected data on outcome assessments were blinded to the randomisation group. However, it was anticipated that research assistants could become unblinded. Outcome assessor did not know the patients and were blinded as to allocation. Intention- to- treat approach used.

DETAILS

of patients:

170 participants. Allocated to control n = 85 (primary analysis n = 72) ; allocated to therapy n = 85 (primary analysis n = 81)

Prevalence (Diagnostic):

Patient Characteristics

Participants ranged in age from 32 to 97 years (mean 70 years) and 56% were men. Almost all had aphasia (90%), 39% had dysarthria and 29% had both. Half were classified as having a severe activity restriction (disability) in terms of their baseline communication. Half had dysphagia (impaired swallowing).

Baseline characteristics by allocation group

Characteristic	AC (n = 85)	SL therapy (n = 85)
Mean age, years (range)	70 (40–92)	70 (32–97)
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Either impairment* severe (0–2)	58 (68%)	58 (68%)
Communication activity		
Mean (SD)	2.2 (1.2)	2.3 (1.3)
Severe	47 (55%)	40 (47%)
Dysphagia present	47 (55%)	41 (48%)
BI		
Mean (SD)	10.7 (7.3)	12.7 (7.2)
Mild (18–20)	22 (26%)	36 (42%)
Moderate (11–17)	22 (26%)	17 (20%)
Severe (0–10)	41 (48%)	32 (38%)

*Stratification factor in the randomisation routine

Interventions/ Test/ Factor being investigated

On average started 2 weeks after stroke, involved an average of 22 ACT NoW (Assessing the effectiveness of Communication Therapy in the North West) speech and language therapy contacts, for 18 hours (mean), delivered over 13 weeks in both hospital and community settings.

Comparisons

Attention Control (AC): an average of 19 ACT NoW visitor contacts, for a mean of 15 hours. Visitors did not provide therapy or any communication strategies. Visitors had excellent social skills and general competency and were trained to deliver social attention absent of any intuitive form of communication therapy or strategy

Length of Study/ Follow-up

Six months

Outcome measures studied Functional communicative ability on the Therapy Outcome Measure activity subscale (TOM); participants' perceptions on the Communication Outcomes After Stroke scale (COAST); carers' perceptions of participants (carer COAST); serious adverse events

Results	Scale	AC: mean (SD), n	SL therapy: mean (SD), n
	TOM	3.0 (1.6), 72	3.3 (1.4), 81
	COAST	73 (18), 50	71 (18), 67
	Carer COAST	62 (18), 59	62 (21), 70
	COPE		
	Negative	23 (3.2), 58	24 (3.5), 67
	Positive	13 (2.4), 57	13 (2.5), 68
	Support	11 (3.2), 57	12 (3.3), 65

TOM, Therapy Outcome Measure activity subscale; COAST, Communication Outcomes After Stroke scale; COPE, Carers of Older People in Europe Index; AC, Attention control; SL, Speech Language.

Serious adverse events		
Worst SAE	AC (n = 85)	SL therapy (n = 85)
Hospitalisation	3 (4%)	1 (1%)
Stroke	4 (5%)	2 (2%)
Death	8 (9%)	4 (5%)
Any	15 (18%)	7 (8%)

Effect Size

Source of funding: Project was funded by the NIHR Health Technology Assessment programme. The stroke association funded part of the treatment costs

Does the study answer the question?/Further Comments Authors concluded that functional communicative ability at 6 months had improved by a clinically meaningful amount for people in both groups. However, there was no evidence of an added benefit of early communication therapy from SL therapists for people with communication disability or their carers over and above that from AC and natural recovery, when both were provided at a higher level than in typical standard practice.

Globas C;Becker C;Cerny J;Lam JM;Lindemann U;Forrester LW;Macko RF;Luft AR;

Chronic stroke survivors benefit from high-intensity aerobic treadmill exercise: a randomized control trial

Ref ID 186 **RID:** 1080 2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = computer-based random number generator by study-independent staff

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear risk of bias

Direction = assessment at end of intervention period only; outcome assessment blinding not stated; could bias in favour of intervention
computer-based random number generator by study-independent staff; blinding of outcome assessment not stated; could bias in favour of intervention; sample size calculation: 15 subjects per group required to detect a significant difference in VO₂peak (2.4mL/kg/min) with a power of 0.8 at p<0.05

Overall Study Quality -Strengths and Weaknesses:

DETAILS

of patients:

n=38 randomised, TAEX 20, control 18

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Chronic (>6 months) stroke survivors aged >60 years with residual hemiparetic gait (at least 1 clinical sign for paresis, spasticity or circumduction of affected leg while walking; ability to walk on treadmill at ≥0.3km/hr for 3 minutes with handrail support. Exclusion: Unstable angina pectoris, heart failure NYHA >II°, haemodynamically significant valvular dysfunction, peripheral arterial occlusive disease, dementia (Mini-Mental State Examination <20), aphasia (unable to follow 2 commands) major depression (CES-D >16) and other medical conditions precluding participation in aerobic exercise; patients already performing aerobic exercise for >20 min/day and >1 day/week. Gender: 29 male, 7 female. Mean (SD) age (years): 68.7 (6.3) range 60-84 years. Time since stroke onset: 65.1 (57.3) months

Interventions/ Test/ Factor being investigated

High-intensity aerobic treadmill exercise (TAEX) for 3 months (39 sessions) starting with 10-20 minutes at 40-50% heart rate reserve (HRR) building up to 30-50 minutes at 60-80% HRR

Comparisons	TAEX versus Conventional Care Physiotherapy (1-3 sessions of 1 hour each/week) including passive muscle tone-regulating exercises for upper and lower extremity, balance training
Length of Study/ Follow-up	Crossover trial but only results for first period extracted (at end of 3 months intervention) as intervention changed for second period
Outcome measures studied	Primary: Body-mass adjusted peak VO ₂ ; sustained walking ability (6 minute walk). 2ry: 10m timed walk at comfortable and maximal speeds; 5 chair rise test; Berg balance scale; Rivermead Index; SF-12
Results	Maximum walking speed in 10 minute walk increased in TAEX by 0.12 (0.12)m/s and decreased non-significantly in controls -0.02 (0.02)m/s, p<0.001. Comfortable walking speed increased in TAEX by 0.07 (0.02) m/s and remained unchanged in controls (0.0 (0.2)m/s, NS. Berg Balance Scale improved 1.7 (3) points in TAEX and decreased in controls -0.9 (3.2) p<0.05. 5 chair rise test (leg strength) improved in TAEX by 2.4 (0.9) s and in controls 0.1 (0.9) s NS. RMI improved in TAEX 13.2 (1.7) to 13.3 (1.7) and declined in controls (12.1 (2.5) to 11.3 (2.5), p=0.02. Mental score of SF-12: improved in TAEX by 2.2 (1.2) points more than controls -1.8 (1.5), p=0.006. Other subscores of SF-12 did not differ
Effect Size	Body-mass adjusted peak VO ₂ improved by 5.5 (1.0)mL/kg/min in TAEX and non-significantly deteriorated in control -0.8 [0.8]ml/kg/min; ITT p<0.001. Distance walked in 6 minutes: increased in TAEX by 57.7 (44.6) m and in controls by 4.7 (5.9) m p<0.001
Source of funding:	grant of the "Forschungskolleg Geriatrie" of the Robert Bosch Foundation
Does the study answer the question?/Further Comments	TAEX effectively improves cardiovascular fitness and gait in people with chronic stroke

Hartman J;Landau WM;

Comparison of formal language therapy with supportive counseling for aphasia due to acute vascular accident

Ref ID 871

RID:

287

1987 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Inadequate randomisation and allocation concealment; 50/60 randomised dropped out (16.67%); blinded assessment of outcome.

DETAILS

of patients:

60 randomised (30 to speech therapy and 30 to counselling).

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: 1st stroke affecting left hemisphere; native speakers of American English; functionally normal hearing and vision; right-handed.
Exclusion: multiple vascular lesions; other serious pathology; inadequate current history; left-handed; too ill to participate.
Age range: speech therapy: 30-86 years (mean 65.8 years); counselling group: 32-91 years (mean 63.7 years).
Speech therapy: 18 men and 12 women; counselling: 10 men and 20 women.

Interventions/ Test/ Factor being investigated

Conventional speech therapy: language drills; home practice; auditory stimulation at single-word and phrase level; follow spoken commands; reading; repetition, sentence completion, cueing strategies, twice weekly for 6 months.

Comparisons

Conventional speech therapy vs. unstructured conversation-based counselling/support focused on problems of everyday life; encouraging independent problem-solving by patient/family, twice weekly for 6 months.

Length of Study/ Follow-up

post-treatment and 3 months`

Outcome measures studied	Primary: Porch Index of Communicative Ability (PICA) change 1 month (baseline) to month 7 (post-treatment) and month 10 (3-month follow up) analysis of covariance with month 1 as covariate
Results	Pre-treatment: speech therapy: 8.79 (3.36), n=30; counselling 8.85 (3.72), n=30. Post-treatment: speech therapy: 10.52 (3.24), n=30; counselling 10.65 (3.78), n=30. 3-month follow up: speech therapy: 11.22 (2.88), n=24; counselling 10.86 (4.02), n=26. All differences non-significant.
Effect Size	
Source of funding:	not stated
Does the study answer the question?/Further Comments	This was a small study with a high drop-out rate comparing standard speech therapy with counselling (each twice weekly for 6 months) and showing no difference between the groups at post-treatment or at 3-month follow-up.

Holmgren E;Gosman-Hedstrom G;Lindstrom B;Wester P;

What is the benefit of a high-intensive exercise program on health-related quality of life and depression after stroke? A randomized controlled trial

Ref ID 16123

RID:

837

2010 Sep

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Single centre, single blinded, randomised controlled trial; randomisation conducted with a minimization software program, MiniM to avoid imbalances at baseline between the two groups; nurses and physiotherapist who performed the clinical test assessments were blinded to group allocation; participants were instructed not to reveal anything from their 5 weeks in the study at the different assessment times; all participants were blinded as for the content of the two different groups before randomisation

DETAILS

of patients:

34 patients with stroke included in the study; 15 allocated to intervention and 19 allocated to control.

Prevalence (Diagnostic):

Patient Characteristics

Inclusion to the study was done 3-6 months after stroke onset.

Baseline characteristics of the participants

	Intervention grp n=15	Control grp n=19
Sex (M/F)	9/6	12/7
Age	77.7±7.6	79.2±7.5
Inpatient rehabilitation		
Days at stroke unit	12.5±5.0	10.9±5.3
Days from stroke		
Onset to study start	139.7± 37.3	126.8±28.2
Diagnosis of depression	3	2
Use of medication		
SSRI or other anti-depressant	6	4
Use of sleeping pills	4	6
MMSE	26.3±3.5	25.5±4.4
Fall risk index (19, 37)		
No	14	16
Low	1	0
Medium	0	3
High	0	0

Interventions/ Test/ Factor being investigated

Seven sessions a week divided over 3 days with individualized group training, supervised by a physiotherapist (PT) plus one session a week for 1hr with educational group discussions about fall risk and security aspects led by a PT and an OT

Comparisons

One session a week for 1hr each during the 5-week period. Session was an educational group discussion session led by one occupational therapist (OT)

Length of Study/ Follow-up

Post-Intervention; 3 months post-intervention; 6 months post-intervention

Outcome measures studied

Health Related Quality of Life (HRQoL) as measured by the SF-36 and symptoms of depression as measured by the gds-15.

Results

Baseline
Outcome: study population (n=34); IG (n=15); CG (n=19)
SF-36
PCS 30.8±9.6; 30.9±8.3; 30.8±10.7
MCS 53.2±9.4; 53.6±10.0; 52.8±9.2
SF-36
PF 45.8±20.8; 45.7±21.7; 45.8±20.6
RE 81.4±35.0; 73.3±42.2; 87.7±27.7
MH 77.2±17.3; 82.1±13.6; 73.3±19.2
GDS-15 3.0±2.1; 2.5±1.7; 3.4±2.3

Post-Intervention
Outcome: study population (n=33); IG (n=14); CG (n=19)
SF-36
PCS 32.8±11.3; 32.2±10.6; 33.2±12.0
MCS 54.6±10.0; 54.4±10.3; 54.8±10.0
SF-36
PF 48.5±24.6; 52.1±22.2; 45.8±26.6
RE 79.8±35.3; 71.4±38.9; 86.0±32.0
MH 81.6±17.7; 84.6±12.4; 79.4±20.8
GDS-15 4.2±2.7; 3.1±2.1; 5.0±2.8

6 months post-intervention
Outcome: study population (n=33); IG (n=14); CG (n=19)
SF-36
PCS 35.3±12.8; 35.3±13.3; 35.4±12.9
MCS 53.3±12.0; 50.4±15.0; 55.4±9.3
SF-36
PF 48.7±23.6; 51.5±18.6; 46.7±26.9
RE 83.0±34.3; 71.8±40.5; 90.7±27.6
MH 79.0±17.8; 81.2±11.9; 77.3±21.2
GDS-15 3.4±2.4; 3.0±1.5; 3.7±2.9

Results are presented as mean±SD. GDS-15, Geriatric Depression Scale; SF-36, Short Form 36; IG, Intervention Group; CG, Control Group; PCS, Physical Component Scale; MCS, Mental Component Scale; PF, Physical Functioning; RE, Role Functioning-emotional; MH, Mental Health.

Effect Size

Source of funding:

Study supported by grants from the Swedish Institute for Health Sciences, Swedish Stroke Foundation, Swedish Heart and Lung Foundation, Northern

Does the study answer the question?/Further Comments

Authors concluded that high-intensive functional exercises implemented in real-life situations should also include education on hidden dysfunctions after stroke instead of solely focus on falls and safety aspects to have a favourable impact on Health Related Quality of Life (HRQoL).

Jin H;Jiang Y;Wei Q;Wang B;Ma G;

Intensive aerobic cycling training with lower limb weights in Chinese patients with chronic stroke: discordance between improved cardiovascular fitness and walking ability

Ref ID 16304

RID:

996

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = randomisation by drawing lots

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind intervention;
stated to be single blind

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

randomisationand allocation concealment inadequate; no sample size calculation

DETAILS

of patients:

n=133: 68 intervention and 65 control

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: age 50 or more; Chinese Han; single stroke >6 months ago; independent in ambulation with or without walking aid. Exclusion: heart failure, unstable angina, peripheral arterial occlusive disease, aphasia, dementia, untreated major depression, other medical conditions precluding participation. Gender: intervention 48 male, 20 female, control 46 male, 19 female. Mean (SD) age (years): intervention 57 (6), control 56 (7). Time since stroke onset: intervention 18.5 (5.2) months, control 17.9 (4.8). Admitted to rehabilitation centre.

Interventions/ Test/ Factor being investigated

Cycling exercise group: 8-week aerobic cycling training + paretic lower limb weights 40 mins/day 5 times a week, target aerobic intensity 50-70% heart rate reserve

Comparisons

Cycling exercise versus Control: low-intensity overground walking training 20-30% heart rate reserve. Both groups had balance exercise 30 minutes and supervised stretching 20 minutes

Length of Study/ Follow-up

assessment at end of 8-week intervention, no follow up

Outcome measures studied	Primary outcome measure: 6 minute walking distance, Rivermead Mobility Index. Secondary outcome measures: knee muscle strength (dynamometer); balance (Berg scale); spasticity (Modified Ashworth Scale)
Results	6 minute walking distance (m) intervention 218.5 (63.7), control 213.5 (50.6), p<0.001. Rivermead Mobility Index intervention 10.5 (1.7), control 10.4 (1.6) NS. Berg balance scale intervention 48.6 (2.9), control 48.3 (3.9) NS. Modified Ashworth Scale median 1 (IQR 0-1), control median 1 (IQR 0-1), NS. Paretic knee muscle strength intervention 72.4 (10) control 60.1 (6.3) p<0.001. Non-paretic knee muscle strength intervention 118.8 (11.7) control 102.6 (6.6) p<0.001
Effect Size	Cardiovascular fitness: post treatment peak VO2 (L/min) intervention 1.13 (0.17), control 0.89 (0.14), p<0.001
Source of funding:	none
Does the study answer the question?/Further Comments	The enhanced cardiovascular fitness after aerobic cycling training was not associated with increased walking ability.

Palmer R;Enderby P;Cooper C;Latimer N;Julious S;Paterson G;Dimairo M;Dixon S;Mortley J;Hilton R;Delaney A;Hughes H;

Computer therapy compared with usual care for people with long-standing aphasia poststroke: a pilot randomized controlled trial

Ref ID 16928 **RID:** 1001 2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** web-based randomisation system

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** impossible to blind intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction = Single blind (outcome assessor blinded to training type)

Overall Study Quality -Strengths and Weaknesses:

Adequate randomisation and allocation concealment; of 17 control group: 17 completed baseline; 13 (76.5%) completed 5 months and 11 (64.7%) 8 months (3 withdrew due to ill health and 3 declined to continue); of 17 intervention group: 16 baseline (1 became ineligible due to further stroke); 15 (88.2%) 5 months and 13 (76.5%) 8 months (withdrawals due to ill health and change in family circumstances; none declined to continue). Intention to treat analysis. Sample size calculation: no large RCTs on which to base sample size calculation; authors aimed to recruit 30 patients to have at least 12 evaluable per group

DETAILS

of patients:

n=34, intervention = 17; control = 17

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: participants with stroke and aphasia with word-finding difficulties as one of the predominant features; ability to repeat spoken words; no longer receiving speech and language therapy. Exclusion: severe visual or cognitive difficulties reducing ability to use computer program. Gender: control 12 male, 5 female; intervention 9 male, 7 female. Mean (SD) age (years): control 66.2 (12.3) n=17, intervention 69.5 (12.2), n=16. Time since stroke onset: control 6.6 years (range 1.8 to 12); intervention 6.2 years (range 1-29). Community

Interventions/ Test/ Factor being investigated

Computer treatment: Usual language activities as for control group plus speech and language therapy delivered through independent use of computer program (StepbyStep; library of over 13000 language exercises) supported by a volunteer; work through exercises for at least 20 minutes 3 days a week for 5 months

Comparisons

Computer treatment versus Usual care: participation in activities that provide general language stimulation: attendance at communication support groups and conversation, reading and writing activities that are part of daily life

Length of Study/ Follow-up

Treatment duration 5 months; follow up at 8 months

Outcome measures studied

Primary: this was a pilot study; main outcome feasibility of carrying out trial. Secondary: clinical effectiveness (mean difference in % improvement in word retrieval ability from Object and Action Naming Battery), cost-effectiveness

Results

% words named correctly at 8 months (follow up 3 months after end of intervention): intervention 67.9 (n=12), control 56.6 (n=11), mean difference in change from baseline 11.3% (95% CI -7.4% to +29.9%), p=0.221

Effect Size

% words named correctly at 5 months (end of intervention): intervention 67.2 (n=15), control 47.4 (n=13), mean difference in change from baseline 19.8% (95% CI 4.4% to 35.2%), p=0.014

Source of funding:

National Institute for Health Research; Stroke and Telehealth themes of South Yorkshire Collaboration for Leadership in applied health research and care; North

Does the study answer the question?/Further Comments

The difference in percentage of words named correctly at 5 months (end of intervention) favoured the intervention but was non-significant at 8 months follow up in this small pilot study.

Van De Port IGL;Wevers LEG;Lindeman E;Kwakkel G;

Effects of circuit training as alternative to usual physiotherapy after stroke: Randomised controlled trial

Ref ID 246

RID:

1024

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = baseline differences accounted for in analysis so low risk of bias

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind participants or those administering care but outcome assessment blinded

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Adequate randomisation, allocation concealment, sample size. Baseline characteristics similar except time from onset of stroke, baseline strength, baseline leg motricity index and six minute walk test; all analyses adjusted for these baseline covariates. Single blind (outcome assessment blinded)

DETAILS

# of patients:	250: 125 circuit training; 125 usual physiotherapy
Prevalence (Diagnostic):	
Patient Characteristics	Inclusion: patients with verified stroke who had completed inpatient rehabilitation (discharged home) as soon as they were able to start outpatient rehabilitation; able to walk a minimum of 10m without physical assistance; need to continue physiotherapy to improve walking competency or physical condition or both; able to give informed consent; motivated to participate in 12 week intensive physiotherapy programme. Exclusion: cognitive defects determined by Mini-Mental State Examination Score <24 points; unable to communicate; lived more than 30km from rehabilitation centre. Gender: Task-oriented circuit training: 82/126 male, 44 female; Usual physiotherapy care 80/124 male, 44 female. Mean (SD) age (years): Task-oriented circuit training: 56 (10) n=126, Usual physiotherapy care: 58 (10) n=124. Time since stroke onset: Task-oriented circuit training: 91 (42) days; Usual physiotherapy care: 103 (51) days. Outpatients
Interventions/ Test/ Factor being investigated	Task-oriented circuit training: 90 minute graded task-oriented circuit training twice a week for 12 weeks aimed at improving walking competency (warm up 5 minutes; circuit training 60 minutes; evaluation/break 10 minutes; group game 15 minutes)
Comparisons	Task-oriented circuit training versus Usual physiotherapy care for 12 weeks according to guidelines; no restrictions on content, time or duration
Length of Study/ Follow-up	12 weeks (end of intervention) and 24 weeks (12 weeks after end of intervention)
Outcome measures studied	1ry: Stroke Impact Scale Mobility 2ry: Other domains SIS; RMI, falls efficacy, NEADL, HADS, fatigue severity, Motricity Index, functional ambulation, 6 min walk, 5m comfortable walk, timed balance, timed up and go, modified stairs, letter cancellation
Results	SIS: Strength: 12 wk CT 62.70 (21.49); control 56.30 (23.81); NS btwn gps; 24 wk CT 63.85 (22.20); control 57.52 (24.56); NS. Memory and thinking: 12 wk CT 85.49 (16.75); control 87.12 (15.32); p=0.024 btwn gps; 24 wk CT 87.23 (15.92); control 87.08 (15.92); NS. Mood and emotions: 12 wk CT 81.91 (14.81); control 81.86 (14.25); NS; 24 wk CT 82.02 (14.87); control 82.18 (16.02); NS. Communication with others: 12 wk CT 85.97 (18.84); control 87.09 (17.14); NS; 24 wk CT 86.74 (16.67); control 87.32 (17.23); NS. ADLs during typical day: 12 wk CT 78.70 (16.30); control 76.07 (16.82); NS; 24 wk CT 79.34 (16.12); control 77.37 (17.89); NS. Ability to use most affected hand: 12 wk CT 58.60 (37.36); control 52.56 (37.94); NS; 24 wk CT 60.64 (36.55); control 55.51 (37.94); NS. Social participation in ADLs: 12 wk CT 70.90 (20.78); control 73.05 (18.25); NS; 24 wk CT 71.78 (21.18); control 75.74 (16.44); NS. Stroke recovery: 12 wk CT 63.09 (17.60); control 64.07 (17.13); NS; 24 wk CT 67.08 (16.57); control 66.63 (18.94); NS. Fatigue severity scale: 12 wk CT 4.25 (1.74); control 4.22 (1.66); NS; 24 wk CT 4.23 (1.72); control 4.03 (1.67); NS. Falls efficacy scales: 12 wk CT 102.70 (21.11); control 102.15 (20.68); NS; 24 wk CT 104.45 (20.38); control 104.03 (22.19); NS. Hospital anxiety and depression scale (HADS): Depression: 12 wk CT 4.92 (3.62); control 4.42 (3.69); NS; 24 wk CT 4.52 (3.52); control 4.28 (4.00); NS. HADS Anxiety: 12 wk CT 3.80 (3.40); control 4.01 (3.60); NS; 24 wk CT 3.65 (3.13); control 3.66 (3.55); NS. Nottingham extended activities of daily living (NEADL): Mobility: 12 wk CT 13.90 (3.77); control 12.97 (4.31); NS; 24 wk CT 14.17 (3.75); control 13.62 (4.14); NS. Kitchen: 12 wk CT 12.76 (3.33); control 12.08 (3.71); NS; 24 wk CT 13.18 (2.89); control 12.45 (3.53); NS. Domestic: 12 wk CT 8.19 (4.45); control 7.20 (3.95); NS; 24 wk CT 8.39 (4.56); control 7.95 (4.08); NS. Leisure: 12 wk CT 9.45 (3.16); control 9.46 (2.90); p=0.04 btwn gps; 24 wk CT 10.50 (3.79); control 10.39 (3.60); NS. Rivermead Mobility Index (RMI): 12 wk CT 13.47 (1.44); control 12.82 (1.90); NS; 24 wk CT 13.50 (1.42); control 13.03 (1.82); NS. Timed balance test: 12 wk CT 4.06 (1.02); control 3.74 (1.06); NS; 24 wk CT 3.82 (1.45); control 3.36 (1.52); NS. Motricity Index (arm): 12 wk CT 68.30 (25.12); control 62.20 (27.21); NS; 24 wk CT 69.88 (24.44); control 65.04 (27.49); NS. MI leg: 12 wk CT 76.41 (19.18); control 69.20 (21.20); NS; 24 wk CT 75.18 (19.64); control 69.68 (21.09); NS. Letter cancellation task: time to accomplish (sec): 12 wk CT 148 (64); control 146 (89); NS; 24 wk CT 151 (69); control 149 (86); NS; omissions (left): 12 wk CT 0.69 (1.43); control 0.76 (1.61); NS; 24 wk CT 0.81 (1.72); control 0.68 (1.56); NS. omissions (right): 12 wk CT 0.44 (1.06); control 0.41 (1.12); NS; 24 wk CT 0.47 (1.19); control 0.57 (1.13); NS. Functional

ambulation: 12 wk CT 4.87 (0.36); control 4.74 (0.55); NS; 24 wk CT 4.89 (0.36); control 4.78 (0.49); NS Six minute walk test (m): 12 wk CT 412 (117); control 354 (145); p=0.01 btwn gps; 24 wk CT 416 (118); control 366 (151); NS. Timed up and go (sec): 12 wk CT 11 (7); control 15 (16); NS; 24 wk CT 11 (8); control 14.60 (13.79); NS Modified stairs test (sec): 12 wk CT 1 (8); control 17 (10); NS; 14 (9); control 16.78 (9.82); NS.

Effect Size

Mobility SIS: 12wk CT 87.27 (12.38) control 83.73 (13.25) NS; 24wk CT 86.56 (13.19) control 84.42 (14.48) NS Gait speed (m/sec): 12 wk CT 1.1 (0.3); control 0.89 (0.36); p<0.001; 24 wk CT 1.1 (0.3); control 0.94 (0.39); p=0.04

Source of funding:

none stated

Does the study answer the question?/Further Comments

No differences between groups on mobility stroke impact scale; circuit training associated with higher scores on gait speed, walking distance and modified stairs test; few other differences in secondary outcomes; only gait speed still significant at follow up

Study Type	Cohort
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Sellars C;Hughes T;Langhorne P;

Speech and language therapy for dysarthria due to non-progressive brain damage

Ref ID 4918 **RID:** 950 2005

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Direction =

Overall Study Quality -Strengths and Weaknesses:

DETAILS

of patients:

Prevalence (Diagnostic):

Patient Characteristics

Interventions/ Test/ Factor being investigated

Comparisons

**Length of Study/
Follow-up**

Outcome measures studied

Results

Effect Size

Source of funding:

Does the study answer the question?/Further Comments

Study Type	Qualitative
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Worrall L;Sherratt S;Rogers P;Howe T;Hersh D;Ferguson A;Davidson B;

What people with aphasia want: Their goals according to the ICF

Ref ID 16189 **RID:** 904 2011

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Direction =

Overall Study Quality -Strengths and Weaknesses:

A combination of face to face and telephone interviews was used in this study. Using only face-to-face in-depth interviews may have yielded richer data than the combination of face-to-face and telephone interviews. Telephone interviews lack the personal contact made in face-to-face interviews and lose verbal cues. A further limitation to the study is that only one researcher interviewed and analysed the data. Methods well described. No baseline data

DETAILS

of patients: 50 participants (24 males, 26 females; mean age 63.9 ± 10.8 years) with aphasia post stroke (mean duration 54.9± 43.6 months) were recruited through an aphasia

Prevalence (Diagnostic):

Patient Characteristics

Interventions/ Test/ Factor being investigated

Comparisons

**Length of Study/
Follow-up**

Outcome measures studied

Results

Effect Size

Source of funding:

Does the study answer the question?/Further Comments

Question: In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and visual neglect?

Study Type	Randomised Controlled Trial
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Fanthome Y;Lincoln NB;Drummond A;Walker MF;

The treatment of visual neglect using feedback of eye movements: a pilot study

Ref ID 722 **RID:** 40 1995

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Direction of effect uncertain as small sample size of 18 patients

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Direction of effect uncertain as small sample size of 18 patients

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Direction of effect uncertain as small sample size of 18 patients

Overall Study Quality -Strengths and Weaknesses:

Strengths: no attrition bias, appropriate intervention and outcome measures
Weaknesses: unclear if study was randomised, small sample size of 18 patients, unclear if assessors were blind to treatment arms

DETAILS

of patients: 9 patients in intervention arm, 9 in control arm

Prevalence (Diagnostic): N/A

Patient Characteristics UK study. Intervention group: mean age(SD) = 66(11), mean(SD) time post stroke(months) = 1(1), 6 men and 3 women
Control group: mean age(SD) = 71(8), mean(SD) time post stroke(months) = 1(1),

6 men and 3 women

The inclusion criteria for entry into the study were: subjects were not blind; they were under 80 years of age; had no history of dementia or psychiatric problems; were not too ill to be assessed; were right-handed; had a score of more than 6 on the Abbreviated Mental Test; had a right hemisphere stroke and scored less than 130 on the Behavioural Inattention Test (BIT). None had received any specific previous treatment for their visual neglect, although all patients were in hospital and receiving physiotherapy and occupational therapy

Interventions/ Test/ Factor being investigated

Intervention group were required to wear the feedback glasses for 2h and 40min a week for 4 weeks. This was divided into 40min a day for 4 days. Subjects usually wore the glasses for 20min in the morning and 20min in the afternoon. The glasses were calibrated at the beginning of each session. During the first two sessions the experimenter remained with subjects throughout the treatment time to ensure that they understood the principle of the glasses and responded to the auditory signal each time it came on. At subsequent sessions the experimenter calibrated the glasses and then left the subject. Subjects wore the glasses while sitting in the hospital day-room or beside their beds.

Subjects' eye movements were recorded while looking at slides. Subjects sat in front of a table with the chin resting on a fixed chin rest. The eye movement glasses were put on and if subjects were short-sighted they wore their own glasses over these. Slides were projected onto a screen, 171cm in front of them. Subjects were first required to look at a calibration slide which consisted of a central cross (0.5 x 0.5cm) and two letters, one on either side of the cross, equidistant from it.

The projected size of the slides were 48.2 x 36cm and the size of each letter as projected was 11 x 9cm with letters separated by a 1cm gap. A line of 25 upper-case letters was presented on three slides. The first was a practice slide and contained three letter A's. The eye movements from this slide were not recorded. The second and third slides each contained six letter A's. The subject was instructed to count the number of A's. The fourth slide was a picture taken from the Western Aphasia Battery which was reversed so that most of the activity was taking place on the left. The fifth and sixth slides were two short passages.

Comparisons

The control group did not receive any treatment for their visual inattention or other perceptual deficits for 4 weeks

Length of Study/ Follow-up

At end of treatment and follow-up at 4 weeks

Outcome measures studied

Recording of eye movements and BIT

Results

For both assessment at 4 weeks (end of study) and 4 week follow-up No significant differences were found between intervention group versus control group for BIT or eye movement outcomes.

Effect Size

Source of funding:

Chest, Heart and Stroke Association

Does the study answer the question?/Further Comments

Use of glasses providing a reminder bleep if patients failed to move eyes to the left in a 15 second interval had no significant effect on eye movements or on BIT at end of study and at 4 weeks follow-up.

Harvey M;Hood B;North A;Robertson IH;

The effects of visuomotor feedback training on the recovery of hemispatial neglect symptoms:

assessment of a 2-week and follow-up intervention

Ref ID 667

RID:

63

2003

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain due to small sample size of 14 patients

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain due to small sample size of 14 patients

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Yes

Direction = Investigators may have been biased in favour of intervention

Overall Study Quality -Strengths and Weaknesses:

Strengths: no attrition bias, relevant intervention and outcome
Weakness: no description of randomisation, single blind study, small sample size of 14 patients, wide range post stroke (range 5 to 25 month), small sample size of apparently 14 patients, 3 day intervention lead by experimenter but this was succeeded by 10 day intervention over 14 days which patients performed on their own (although it was stated 'HCP often controlled execution of the training'). Unlear if assessors of the study were blinded.

DETAILS

of patients:

Intervention: 17 patients, Control 17 patients

Prevalence (Diagnostic):

N/A

Patient Characteristics

UK study. Study stated no difference found between intervention and control groups with respect to age, time since stroke, and screening of hemispatial neglect. Mean age (SD) = 69(9.3), 8 male, 4 female, 2 unspecified in paper. CVA attack range 5 to 25 months. Assessment for neglect assessed on Balloons test, and the BIT. Not all patients fell below cut-offs on both tests (< 10% Ballons, 129

Interventions/ Test/ Factor being investigated	<p>BIT), but each intervention and control group contained either 3 or 4 very impaired (<10% Balloons, <70 BIT) and two only mildly impaired when results of both taken into account.</p> <p>Rehabilitation of rod lifting exercise, administered on 3 consecutive daily sessions, lasting approximately 1 hour. 3 step process using. Step 1- line bisection, landmark and reaching for real objects, Step 2- Step 1-repeat of step 1. Three wooden rods 1.1cm diameter, 0.63 g/cm in weight and either 50, 75, 100cm in length were used. Each rod was presented horizontally on a test mat in front of the patient, with the middle of the rod in line with the patient's body midline.</p> <p>The intervention group patients tried to reach, lift and balance the rods at the centre, readjusting until satisfied with the judged central grip, whilst patients in the control group reached and lifted the right-hand side of the rod only. The intervention group therefore received proprioceptive as well as visual feedback as the rod would tilt if not grasped in the centre, however both groups received a comparable amount of motoric experience of reaching and lifting rods. The rods varied in length and spatial location and reaches were repeated eight times in each session creating 72-rod lifts. All patients used their right hand only.</p> <p>In addition to the immediate experimenter-led intervention, a 6-week extended rod lifting intervention was run assessing the effects with a larger test battery that was performed at baseline (before any intervention) and re-administered in part after the 3-day experimenter present session and in full, following a further 10 days of home-based intervention.</p>
Comparisons	As for intervention group, however, control group reached and lifted the right hand side of the rod only.
Length of Study/ Follow-up	Immediately after intervention and 1 month follow-up
Outcome measures studied	BIT convention scores, BIT behavioural scores.
Results	<p>BIT conventional scores (pre-post analysis) No significant main effect of time was found on the 2 x 4 mixed ANOVA although there was a significant time by group interaction ($F [3,30] = 4.367, P = 0.01$). Paired t-tests indicated a significant effect between the end of the home-based training and the 1-month follow-up: the intervention group scores improved significantly, whereas the scores of the control group did not differ between the end of the training and the follow-up (presented graphically).</p> <p>BIT behavioural scores In contrast to the conventional scores, no simple main effect of time nor a time by group interaction was found for the 2 x 3 ANOVA run on the BIT behavioural scores.</p> <p>Balloon test No simple main effect of time nor a time by group interaction was found following the 2 x 4 ANOVA of the laterality bias of the Balloons test.</p>
Effect Size	
Source of funding:	James S McDonnell grant to M Harvey, B Hood and IH Robertson. A North was solely funded by James S McDonnell
Does the study answer the question?/Further Comments	Reported significant time by group interaction on BIT conventional subscores at month indicating improvement in intervention group, but no improvement on 6 behavioural sub-tests and Balloons Test.

Kalra L;Perez I;Gupta S;Wittink M;

The influence of visual neglect on stroke rehabilitation

Ref ID 31

RID:

25

1997

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain as small sample size of 50 patients

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain as small sample size of 50 patients

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: no attrition bias, appropriate intervention and outcomes, assessors were blind to intervention
Weaknesses: single blind study, small sample size of 50 patients

DETAILS

of patients:

Intervention: 25 patients, Control: 25 patients

Prevalence (Diagnostic):

N/A

Patient Characteristics

UK study. The median duration between the acute episode and randomization was 6 days (range, 2 to 14 days). Intervention group mean(SD) age = 78(9), men(%) = 44, mean Rivermead Perceptual Assessment Battery (RPAB) overall 16 subsets(SD) = 177(53), Median Barthel(range) = 4(2-12). Control group mean(SD) age = 76(10), men(%) = 36, mean Rivermead Perceptual Assessment Battery (RPAB) overall 16 subsets(SD) = 185(44), Median Barthel Index of ADL(BADL) (range) = 4(2-7). Criterion for neglect = < 2 SD below normative mean

	on RPAD.
Interventions/ Test/ Factor being investigated	Intervention Modified approach to conventional therapy involving spatiomotor cueing based on the "attentional-motor integration" model and early emphasis on restoration of function. The principle behind this approach was that movements of the affected limb in the deficit hemisphere led to a summation of activation of the affected receptive fields of two distinct, but linked, spatial systems for personal and extrapersonal space, resulting in improvements in attentional skills and appreciation of spatial relationships on the affected side.
Comparisons	Conventional therapy input concentrating on restoration of normal tone, movement patterns, and motor activity before addressing skilled functional activity
Length of Study/ Follow-up	12 weeks
Outcome measures studied	Mean RPAB scores; overall (16 subsets), body image subset, cancellation subset. BADL in survivors, mortality, median length of stay in hospital, physiotherapy and OT time per patient(hours), mortality, discharge home, institutional care
Results	Mean RPAB scores-overall (16 subsets) (SD) intervention versus control = 224.32 (55.38) versus 199.44(64.87) (not significant), body image subset(SD) intervention versus control = 13.19 (1.47) versus 9.72 (1.33) (p<0.01), cancellation subset (SD) intervention versus control = 37.19(13.10) versus 30.12 (18.45). BADL in survivors- Median at discharge(range) intervention versus control = 14 (9-18) versus 12.5 (4-16) (not significant). Median change(range) intervention versus control = 10 (6-15) versus 8 (3-14) (not significant). No difference found for intervention versus control group for; mortality, median length of stay in hospital, physiotherapy time per patient(hours), mortality, discharge home, institutional care, occupational therapy time per patient(hours)
Effect Size	
Source of funding:	Not stated
Does the study answer the question?/Further Comments	Study indicates that perceptual training may improve spatial neglect

Mancuso M;Pacini M;Gemignani P;Bartalini B;Agostini B;Ferroni L;Caputo M;Capitani D;Mondin E;Cantagallo A;

Clinical application of prismatic lenses in the rehabilitation of neglect patients. A randomized controlled trial

Ref ID 16285

RID:

1037

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Possibly overestimation of effect size for experimental group

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Over-estimation of effect

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear **Direction =**

Overall Study Quality -Strengths and Weaknesses:

This study is small scale and has a short follow-up time. It is only single blinded (blinding otherwise not stated) with very little description of methodology (method of randomisation or allocation concealment). Many useful outcome measures were collected.

DETAILS

of patients: N=13 experimental N=9 control

Prevalence (Diagnostic):

Patient Characteristics

	Experimental	Control
Age m (sd)	70 (9)	62 (13)
Years in education m (sd)	8 (5)	11 (4)
Days from onset m (sd)	180 (301)	129 (132)

All patients were selected in accordance with tests for neglect and those who had abnormal scores in at least two tests were enrolled. No patient had visual field deficits which could preclude the proper performance of tests or exercises or severe symptoms of cognitive impairment

Interventions/ Test/ Factor being investigated

Pointing exercise with prismatic lenses producing optical shift of 5 degrees to the right
Each group (intervention and control) was treated with 5 rehabilitation sessions lasting about 30 minutes each, from Monday to Friday in the morning by the same investigator in each center.

Comparisons

Pointing exercise with neutral lenses

**Length of Study/
Follow-up** 5 days

Outcome measures studied Albert test, Bells test, Bit drawing test, Line orientation test, line bisection test, Dealing playing cards test

Results Participants were tested at T0 (baseline) and T1 (after 5 days). Three p-values are provided: Within refers to whether subjects got better over time. Between refers to whether one group was overall better than the other on the outcome measure and Interaction means whether the rate of improvement or deterioration was dependent on the type of intervention that was received (i.e. taking the baseline into account).

Group	Experimental group		Control		Within p
	T0	T1	T0	T1	
Albert R	17.77	17.92	16.22	17.67	0.016
0.038	0.75				
Albert L	14.69	16.54	12.22	15.89	0.083
0.510	0.4				
Bells R	13.75	13.08	12.11	14.89	0.148
0.011	0.759				
Bells L	7.83	10.08	4.56	9.11	0.009
0.174	0.508				
BIT draw	1.00	1.58	1.44	1.89	0.030
0.771	0.400				
LINE Ori	9.36	12.82	9.89	14.63	0.001
0.345	0.583				
LINE Bi	20.12	25.24	14.66	41.57	0.006
0.147	0.453				
Deal R	13.92	12.83	13.13	13.00	0.010
0.283	0.150				

Effect Size Please see above

Source of funding: Not stated

Does the study answer the question?/Further Comments The results showed that the prismatic lenses of only five degrees, used for the study, did not contribute to the variation in performance. Thus this deviation of the fixation point of the visual field to the right is not sufficient to create a therapeutic effect.

Nys GM;de Haan EH;Kunneman A;de Kort PL;Dijkerman HC;

Acute neglect rehabilitation using repetitive prism adaptation: a randomized placebo-controlled trial

Ref ID 177

RID:

53

2008

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Likely effect in favour of intervention

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Likely to favour intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Yes

Direction = Favour intervention

Overall Study Quality -Strengths and Weaknesses:

Strengths: no attrition bias, appropriate intervention and relevant outcomes
Weaknesses: unclear randomisation, patients recruited from 3 hospitals but no further information given, single blinded study, small sample size of 16 patients, unclear if assessment at 1 month follow up was blinded, unclear description of the control intervention

DETAILS

of patients:

Treatment arm: 10 patients, Control arm: 6 patients

Prevalence (Diagnostic):

N/A

Patient Characteristics

Dutch Study. Experimental group: mean age(SD) = 64(14), male sex = 70%, days since stroke onset(SD) = 9(5), short BIT score at baseline = 27(17)
Control: mean age(SD) = 62(11), male sex = 50%, days since stroke onset(SD) = 11(6), short BIT score at baseline = 25(22)
Patients were screened for the presence of neglect using four subtasks of the Behavioural Inattention Test. Patients who performed \leq cut off on at least two of the four tasks were included in the study.

Interventions/ Test/ Factor being investigated

Four-day-in-a-row experimental treatment with 10 degree rightward deviating prisms. Prism exposure- 100 fast pointing movements to 2 visual targets presented 10 degrees to left and right of the body midline, with 50 to each in a random order.

Comparisons

Four-day-in-a-row experimental treatment without prism.

Length of Study/ Follow-up

Immediate assessment and 1 month follow-up

Outcome measures studied	Line bisection, letter cancellation, scene copying, four letter conventional tests, full BIT
Results	<p>Schenkenberg Line Bisection: intervention group showed better performance than control group [$F(2,13) = 3.25, p=0.035$ one-tailed]. The interaction between group and treatment session was not significant but the interaction was significant when considering line deviation separately [$F(7,98) = 1.73, p=0.05$ one-tailed]. One-sample t-tests for each group separately demonstrated that different scores of line bisection performance (post-treatment minus pre-treatment performance) were not significantly different from zero.</p> <p>Letter cancellation: Significant interaction found between group and session [$F(7,8) = 2.7; p=0.045$ one-tailed], indicating intervention group improved faster than control group. No other significant effects found. One-sample t-tests for each group separately demonstrated that difference scores of letter cancellation performance (post-treatment minus pre-treatment performance) were not significantly different from zero.</p> <p>Scene copying: significant interaction was found between group and session, in which the pattern of improvement of sessions was different for control group versus intervention group [$F(7,8) = 7.7, p=0.003$]. One-sample t-tests for each group separately demonstrated that difference scores of scene copying performance (post-treatment minus pre-treatment performance) were not significantly different from zero.</p> <p>Results at one month follow-up, improvement compared with baseline Repeated measure analysis comparing performance on the four BIT tasks administered both in the screening and the long term assessment for the intervention group versus control group (Star Cancellation, Figure Copying, Representational Drawing and Line Bisection). Overall, the patients performed better at the second assessment indicating a significant recovery [$F(4,11) = 5.6, p=0.01$] as is to be expected during the first weeks post-stroke. Statistical improvement was observed in three of the four tasks (Star Cancellation [$F(1,14) = 23.3; p < 0.001$]) Line Bisection [$F(1,14) = 12.8; p = 0.003$] and Representational Drawing [$F(1,14) = 18.5; p < 0.001$]). Patients demonstrated a smaller non-significant improvement on Figure Copying [$F(1,14) = 3.3; p = 0.09$]). There was neither a main effect of group nor any interaction effect between task and group, indicating EG demonstrated similar outcome at one month post-treatment versus control group.</p> <p>Full BIT at 1 month follow-up No main effect of group (neither for conventional BIT or the ecological BIT), indicating no long-lasting effect of the intervention. Three of the 6 patients in the control group and 5 of the 10 patients intervention group still Intervention may improve acute neglect.</p>
Effect Size	
Source of funding:	Dutch Brain Foundation
Does the study answer the question?/Further Comments	At 1 month follow up, there was no difference in neglects outcomes for intervention group (prisms) versus control.

Robertson IH; Gray JM; Pentland B; Waite LJ;

Microcomputer-based rehabilitation for unilateral left visual neglect: a randomized controlled trial

Ref ID 723

RID:

27

1990

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Uncertain due to small sample size of 36 patients

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain due to small sample size of 36 patients

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = Intention to treat analysis

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: no attrition bias, assessor at end of study and at 6 months blind to intervention, intention to treat analysis, appropriate intervention and outcomes
Weaknesses: single blind study, small sample size of 36 patients

DETAILS

of patients:

Intervention: 20 patients, Control: 16 patients

Prevalence (Diagnostic):

N/A

Patient Characteristics

UK study. Significant unilateral left field visual neglect according to BIT; failure in 3 out of 9 tests. 33 patients sustained CVA's, 2 sustained head injuries, 1 surgery brain tumour. Intervention: mean(SD) age = 64(13), mean(SD) onset of neglect (weeks) = 19(21), men/women = 9/11. Control mean(SD) age = 63(03), mean(SD) onset of neglect (weeks) = 11(6) men/women = 10/6.

Interventions/ Test/ Factor being investigated

Computerised scanning and attention training, 14 sessions of 75 minutes each, usually 2 times per week. Mean(SD) hours = 15.5(1.8). Training procedure: Shapes were presented on the screen, and all of them were identical except one. The subject identified the one which was different and identified it by touching the screen where feedback was given. The nature of the shapes could be varied and

combined with different odd shapes, and the total number of shapes could be 4, 16 or 64. A voice synthesizer cued the subject to "look left" and subjects were encouraged to verbalize this. A flashing left-pointing arrow with the words "Look Left" prominently displayed also appeared with the other cues before presentation of each task.

Also in the program, a horizontal and vertical line bisection task enabled the subject to create four screen quadrants. Subjects then underwent an automated training procedure to scan the screen, using a scanning window, by touching each of the screen quadrants in a predetermined order. This scanned procedure owes much to the "systematic clockwise scanning" procedure used by Weinberg and colleagues. Subjects were first given an assessment version of the scanning program. Next the quadrant creation and quadrant scanning procedures were carried out. Once these had been successfully accomplished, the scanning task was presented again, although this time with the scanning box superimposed on the "odd one out" task. In this final stage, the person carried out this task using the scanning box as an aid.

The second main suite of programs consisted of a combined scanning and attention program. The program was one where an infinite number of tasks could be programmed into one basic framework. This framework was a target presented at the top of the screen and a series of matching targets and distractors presented. The task was for the person to locate and touch the targets as quickly as possible, and the responses were recorded via touch-sensitive screen. Feedback as to accurate detection was given by the computer in the form of auditory and visual rewards, and this was related to the speed of response. Before each response, the subject touched a red band at the far left of the screen, which immediately turned green. Failure to do this resulted in the computer flashing a message across the screen to "touch left" along with a flashing arrow. The flashing message and arrow continued until the person touched the red band.

Comparisons

Exposure to plausible computer activities that were considered not to improve cognitive function (word games, quizzes and simple logical games such as 'reds and greens'). Mean(SD) hours = 11.4(5.2)

**Length of Study/
Follow-up**

End of study and at 6 months follow-up

Outcome measures studied

Primary BIT. Others revised Weschsler Adult Intelligence Scale (WAIS = R), Neale Reading Teast, letter cancellation test, Rey-Osterreith Test

Results

At end of study: There was no difference for intervention versus control the following outcomes; BIT(SD) (intervention 52.0(24.0) versus 59.9(20.2) for control), Rey-Osterreith complex figure copy (intervention 25.9(13.4) versus 20.7(11.6) for control), Neale Reading Test(SD) (intervention 20.1(26.1) versus 9.2(16.5) for control), Letter cancellation test (intervention 43.4(30.4) versus 43.2(28.3) for control), WAIS-R block design (intervention 4.9(2.0) versus 5.3(2.0) for control). There was a significant (p=0.02) difference for WAIS-R picture completion (intervention 7.5(2.8) versus 5.1(2.5) for control). At 6 months follow up there were no significant differences between intervention versus control for any outcome. BIT(SD) (intervention 60.1(18.6) versus 61.8(21.5) for control), Rey-Osterreith complex figure copy (intervention 29.7(11.3)) versus 26.8(11.8) for control), Neale Reading Test(SD) (intervention 6.2(9.1) versus 14.9(23.0) for control), Letter cancellation test (intervention 20.0(16.4) versus 23.1(14.5) for control), WAIS-R block design (intervention 4.9(3.2) versus 4.4(1.8) for control). WAIS-R picture completion (intervention 7.2(2.9) versus 5.9(1.5) for control).

Effect Size

Source of funding:

Scottish Home and Health Department

Does the study answer the question?/Further Comments

Study indicated computerised training for neglect did not improve outcomes compared with control group.

Robertson IH;McMillan TM;Macleod E;Edgeworth J;Brock D;

Rehabilitation by limb activation training reduces left-sided motor impairment in unilateral neglect patients: a single randomised control trial

Ref ID 731

RID:

28

2002

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

strengths: randomised, long follow up

weaknesses: unclear randomisation, allocation concealment.
Attrition bias

DETAILS

of patients:

N=40 (n=19 Perceptual training +Limb Activating Device; n=21 to Perceptual training + "dummy" Limb activating Device)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria

Diagnosis of right hemisphere stroke according to WHO criteria ; no history of major psychiatric problems or organic disorder (other than stroke) likely to influence cerebral function ; no other coexisting disease or disability preventing testing ; willingness to provide informed consent to participate in the study ; presence of unilateral left visual neglect as defined by a score of 51 or less on the Star Cancellation Test of the Behavioural Inattention Test (BIT) or a score of 7 or less on the Line Bisection Test of the BIT, with at least 2 of the 3 lines in this test bisected to the right of centre ; sensory physical and cognitive capacities at a level sufficient to carry out all the assessment procedures ; age 20-75; no other disability or disease likely to prevent or contaminate assessment or follow-up ; right-handed ; score of 7 or above on the Hodkinson Mental Test for dementia

Patients' characteristics

Variable	LAT+PT	Control group (PT)	
Sex (M: F)	13:6	16:5	ns
Age mean (SD)	69.3 (9)	67 (9.47)	ns
Time post stroke			
Mean (SD)	152.8 (142.4)	152.1 (117.9)	ns
Lesion type			
Infarct: Hemorrhage*	18:1	16:4	ns
First: Recurrent stroke	15:4	19:2	ns
Destination on discharge from hospital			
Home: RU:NH**	9:8:2	11:9:1	
Barthel index	13.3 (5.7)	11.4(6.5)	ns
Motricity index			
Left arm leg	52.4 (31.1)	44.5(34.1)	ns
Tactile Sensory Detections			
Left	8.8 (2.4)	7.6(3.5)	ns
Frenchay Arm Test	2.2 (2.4)	1.5 (2)	ns
BIT score***	107.8 (29.9)	108.7(32)	ns
Verbal memory (Immediate recall)	17.3 (7.5)	25.2(9.3)	p<0.006
Test of Everyday Attention			
Elevator counting	11.1 (4.4)	11 (3.5)	ns
Stimuli detected in			
lower left visual field	4.3 (1.6)	4 (1.9)	ns
Stimuli detected in			
upper left visual field	4.4 (1.4)	4.3 (1.6)	ns
Depression (HADS)	7.3 (3.6)	8.3 (3.9)	ns

*1 subject not classified; RU – Rehabilitation Unit; Nursing Home; BIT score – Behavioural Inattention Test score.

Interventions/ Test/ Factor being investigated

Experimental group: Perceptual training + Limb Activating Device
Both groups received training of 12 sessions of 45 minutes duration over a 12 week period

Comparisons

Control group: Perceptual training + “dummy” Limb activating Device. Both groups received training of 12 sessions of 45 minutes duration over a 12 week period

Length of Study/ Follow-up

Follow up 6 months for BIT, Landmark Test, Comb and Razor tests ; up to 18-24 months for Barthel index, CB rating Scale of Neglect and Motricity Index

Outcome measures studied

Barthel Index, CB rating Scale of Neglect, Motricity Index, BIT Behavioural Tests, Landmark Test, Comb and razor test

Results

Outcome	Experimental	Control
Barthel index		
Posttraining	13.1 (5.5)	12.6 (5.1)
3 months	14.6 (4.6)	12.5 (4.7)
6 months	13.6 (14.5)	12.3 (5.1)
18-24 months	25.1 (21.3)*	24.3 (15.2)*
*at final follow up ceiling effects dictated Barthel to be replaced by the Nottingham Extended ADL score		
CB Rating Scale of Neglect		
Posttraining	9.4 (9.1)	12.6 (8.8)

3 months	9.9 (8.4)	11.9 (8.3)
6 months	11.9 (8.6)	13.8 (10.5)
18-24 months	7.6 (6.2)	9.5 (6.8)
Motricity Index (total, left side)		
Posttraining	62 (31.5)	48.4 (36.9)
3 months	66.1 (30.6)	51 (35.3)
6 months	67.3 (32.6)	49.6 (35.6)
18-24 months	67.3 (33.3)	44.9 (33.4)

Outcome	Experimental	Control
BIT Behavioural Test		
Posttraining	30.2 (11.9)	31.2 (11.9)
3 months	30.1 (11.5)	32.8 (11.9)
6months	30.1 (13.2)	33.5 (12.6)
Landmark Test		
Posttraining	4 (1.7)	3.4 (2)
3 months	3.3 (1.4)	4 (2.1)
6 months	4.2 (1.6)	3.7 (1.8)
Comb and razor test		
Posttraining	0.27 (0.15)	0.25 (0.13)
3 months	0.22 (0.14)	0.22 (0.14)
6 months	0.25 (0.16)	0.24 (0.11)

2 factor ANCOVA performed on each of the 3 outcome measures, with one between-subject factor and one within-subject factor. Only Motricity Index showed significant time by treatment effect p=0.009

Effect Size

Source of funding:

UK NHS National R&D Programme; 24months follow up was funded by the University of Surrey Small Grants Scheme

Does the study answer the question?/Further Comments

LAT treatment was associated with significantly improved left sided motor function, with effects lasting up to 18-24 months. No significance was reached for time by condition interactions for all other outcomes.

Due to unclear reporting of randomisation and allocation concealment methodology the level of risk of bias remains unclear and so cannot be ruled out

Rossi PW;Kheyfets S;Reding MJ;

Fresnel prisms improve visual perception in stroke patients with homonymous hemianopia or unilateral visual neglect

Ref ID 57

RID:

29

1990

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Prism group patients significantly older than control group $p < 0.01$

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

strength: randomised, no attrition

weaknesses: small sample size, unclear randomisation and allocation concealment, no blinding, outcome data missing for the Tangent Screen examination outcome

DETAILS

of patients:

N=39 (n=18 in prism group ; n=21 in control group)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: free of disabling cardiac pulmonary or rheumatologic problems that might have precluded rehabilitation efforts.
Exclusion: best-corrected visual acuity worse than 20-200 and those unable to comprehend and cooperate with visual field assessment

Characteristics Variable	Control (N=21)	Prism (N=18)	P value
Age (SEM)	63.3 (2.5)	72.6 (1.8)	<0.01
Sex: M/F	9/12	10/8	ns
Interval poststroke (wks) (SEM)	4.7(0.6)	4.4(0.3)	ns
Lesion type:			
Infarct/haemorrhage	18/3	15/3	ns
Side of stroke: R/L	13/8	16/2	ns
Deficit type			
HHA/VN	15/6	12/6	ns

	Modified MMS (SEM)	10.3 (1.1)	12.8 (0.9)	ns
Interventions/ Test/ Factor being investigated	15-diopter plastic press-on Fresnel prisms: cut to shape of half circle overlaying only affected hemifield, with base of prism towards affected field. Both groups receive routine rehabilitation programme (physical, occupational, speech therapy)			
Comparisons	Routine rehabilitation programme (physical, occupational, speech therapy)			
Length of Study/ Follow-up	4 weeks			
Outcome measures studied	Modified Mini Mental Status Examination, Motor Free Visual Perception Test, Line bisection task, Line cancellation Task, Harrington Flocks Visual Screener, Tangent Screen Examination, Barthel ADL-Mobility Score			
Results	Results are only reported in text:			
	MVPT response:	Prism	Control	P-value
	Baseline	53.2 (8)	47.7 (6)	ns
	4 weeks	80.8 (4)	56.9 (6)	<0.01
	LB* error scores:	Prism	Control	P-value
	Baseline	2.3 (0.7)	2.2 (0.5)	ns
	4 weeks	0.68 (0.2)	2.2(0.5)	<0.01
	*Line Bisection			
	LC** Task errors:	Prism	Control	P-value
	Baseline	15 (3)	12.8(3)	ns
	4 weeks	2.4 (1)	9.8(2)	<0.02
	**Line cancellation			
	HFVS error scores:	Prism	Control	P-value
	Baseline	17.5 (2)	21.2 (2)	ns
	4 weeks	5.8 (1)	14.2 (2)	<0.01
	*** Harrington Flocks Visual Screener			
	Tangent Screen Examination: 15/16 prism-treated patients showed expansion of their visual field at 4 weeks relative to baseline compared with 7/17 control patients (chi squared=8.02, p<0.01). The 2 prism patients and 5 controls for which data was missing were not retested due to scheduling problems.			
	Modified MMS: not reported post treatment Barthel ADL: no significant difference in scores was found between groups at any study interval.			
		Prism	Control	P-value
	Baseline	37 (5)	42 (6)	ns
	4 weeks	50 (5)	54 (5)	ns
	Number of falls: similar during study interval: 4/18 in prism and 4/21 in control			
Effect Size				
Source of funding:	not reported			
Does the study answer the question?/Further Comments	After 4 weeks, the prism-treated group performed significantly better than controls on the MFVPT, line bisection task, line cancellation task, Harrington Flocks Visual Field Screener and Tangent screen examination. There was no significant difference in Barthel ADL between groups. Thus treatment with 15-diopter Fresnel prisms improves visual perception test scores but not ADL function in stroke patients with homonymous hemianopia or unilateral visual neglect. Due to unclear reporting of randomisation allocation concealment and other methodological weaknesses the risk of bias is high for this study			

Tsang MH;Sze KH;Fong KN;

Occupational therapy treatment with right half-field eye-patching for patients with subacute stroke and unilateral neglect: a randomised controlled trial

Ref ID 84

RID:

46

2009

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Small sample size of 16 patients makes this difficult to estimate

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Small sample size of 16 patients makes this difficult to estimate

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Yes

Direction = Assessment after intervention was done by an independent assessor, but at 1 month follow-up this is unclear. Likelv direction of bias uncertain due

Overall Study Quality -Strengths and Weaknesses:

Strengths: no attrition bias, appropriate intervention and outcomes
Weaknesses: single blind study, no follow-up, small sample size of 34 patients

DETAILS

of patients:

17 patients in intervention, 17 patients in control

Prevalence (Diagnostic):

N/A

Patient Characteristics	Stroke patients with partial anterior circulation infarction determined according to clinical and radiological criteria were included in the study. The “middle group” of patients was objectively defined on the basis of impairments in power, balance, proprioception, and cognition, using a validated scale, which ranged from 1.6 (no deficits) to 6.4 (maximum deficit). Patients with hemianopsia or severe dysphasia (restricting communication) were excluded from the study.
Interventions/ Test/ Factor being investigated	Intervention group received 4 weeks of conventional occupational therapy with right half-field eye patching glasses, which were worn throughout the occupational therapy treatment sessions. Five occupational therapy sessions of 60 min each per week.
Comparisons	4 weeks of conventional occupational therapy without eye-patching. Five occupational therapy sessions of 60 min each per week
Length of Study/ Follow-up	Studied at end of treatment, no follow up
Outcome measures studied	Conventional BIT, FIM
Results	<p>The t test was used to compare the initial BIT-conventional and FIM scores between the two groups before the treatment (Table II). At the baseline, control and intervention groups were comparable in all important prognostic characteristics. There were no significant differences in the initial scores of BIT-conventional (p=0.394) and FIM (p=0.099) between the two groups. Both the control and intervention groups showed significant within-group improvements in BIT-conventional (control mean = 8.29), p=0.004; intervention mean = 25.06, p=0.004) and FIM (control mean = 12.41, p=0.002; intervention mean = 16, p=0.000 after 1 month. There were no group differences in the variable MMSE (p=0.6; control mean=15.94; intervention mean= 17.18).</p> <p>There was a significant difference between the subjects in the control and intervention groups in the BIT gain (p=0.046). Stroke patients treated with right half-field eye-patching had a significantly higher BIT gain (mean =25.06) than stroke patients treated with conventional method (mean =8.29).</p> <p>For intervention versus control, there was no significant difference (p=0.467) in FIM Comparing the items in FIM, only eating (p=0.027), bathing (p=0.047), and dressing the lower body (p=0.045) were significantly different between the two groups.</p>
Effect Size	
Source of funding:	Not stated
Does the study answer the question?/Further Comments	Study may indicate benefit of right half eye patching , however study had no follow-up.

Turton AJ;O'Leary K;Gabb J;Woodward R;Gilchrist ID;

A single blinded randomised controlled pilot trial of prism adaptation for improving self-care in stroke patients with neglect

Ref ID 3354

RID:

119

2010

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Uncertain

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Uncertain

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

No detection bias present

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: clear description of appropriate randomisation, 2 assessors blinded to patient treatment arm and wherever possible assessors were carried out by same assessors, all patients allocated to treatment arms were accounted for in study and drop out explained, clearly explained intervention and sham intervention, no attrition bias, appropriate and clearly described outcomes.
Weakness: single blind study as healthcare professional conducting overseeing treatment and sham was not blinded to intervention.

DETAILS

of patients: 36 patients randomised: 19 to sham treatment and 17 patients to prism treatment

Prevalence (Diagnostic): N/A

Patient Characteristics
Control group: mean age(SD) = 71(14), male to female = 11.7, mean(SD) days since stroke = 47(39), median (IQR) BIT = 109(60), frequency hemianopia = 4, mean(SD) Motricity score = 50(30), meadian(IQR) Sensory score = 9(6-10), mean (IQR) Barthel score = 45(35-63).
Experimental group: mean age(SD) =72(14), male to female = 8.8, mean(SD) days since stroke = 45(23), median (IQR) BIT = 88(72), frequency hemianopia = 3, mean(SD) Motricity score = 54(37), meadian(IQR) Sensory score = 9(4-10), mean (IQR) Barthel score = 43(20-76).
Eligibility criteria: right hemisphere stroke occurring at least 20 days before study, self-care problems due to neglect (OT identified), ability to sit and point with the unaffected hand, ability to understand and follow instructions and medical fitness to participate.
Presence of neglect confirmed by star cancellation task and/or line bisection test from the BIT.

Interventions/ Test/ Factor being investigated	<p>The treatment procedure involved repeated pointing movements to targets, using the right “unaffected” hand while wearing the prism glasses. Ten dioptre prisms that shifted the field of view 6 degrees to the right were held in optician’s trial frames (fitted with felt blinkers to prevent interference from peripheral vision)</p> <p>The participant, positioned directly in front of a box containing a touch-screen, was required to use the index finger to touch a bold vertical line (width 15mm), which appeared either directly in the centre of 100mm to the left or right of centre on the screen. Target lines were presented in an unpredictable sequence with each block comprising 10 central, 10 right and 10 left of centre targets, in three blocks of 30 trials. The pointing arm was screened from view with the starting position for each movement marked by a Velcro disc, under the screen. The participant was able to see only the terminal part of each pointing movement to allow visuomotor adaptation.</p> <p>Before wearing the glasses, participants were given some pointing practice, with vision of the terminal part of the movement, to ensure they understood the task.</p>
Comparisons	Sham treatment using plain glasses
Length of Study/ Follow-up	4 days and 8 weeks
Outcome measures studied	<p>Primary outcome measure: CBS (Azouvi et al., 1996, 2003). Neglect in 10 self-care behaviours are rated to give a total score out of 30 points.</p> <p>Secondary outcome measure: conventional pencil and paper tests from the BIT</p>
Results	<p>At 4 days follow up</p> <p>Both groups significantly improved their performances on both the CBS and the BIT; two factor repeated measures analysis of variance: assessment sessions CBS $F(1,32)= 49.6, p <0.001$; BIT $F(1, 32)= 17.0, p <0.001$; but there was no difference between groups. Mean (SD) change scores for the CBS were similar for both groups: experimental group -3.5 (3.1), control group – 3.3 (2.5). Mean (SD) change scores for BIT assessments, were 14.8 (18.7) and 9.7(15.9), respectively. The results of the analysis of variance using logits instead of raw CBS score were similar with no significant difference between groups.</p> <p>At 8 weeks follow-up</p> <p>No significant difference between groups in CBS or BIT test performances.</p>
Effect Size	
Source of funding:	Stroke Association
Does the study answer the question?/Further Comments	For intervention versus control group at 4 days and 8 weeks follow-up no effect on BIT or self care (CBS).

Wiat L;Come AB;Debelleix X;Petit H;Joseph PA;Mazaux JM;Barat M;

Unilateral neglect syndrome rehabilitation by trunk rotation and scanning training

Ref ID 34

RID:

35

1997

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain as small sample size of 22 patients

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain as small sample size of 22 patients

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk

Direction = Uncertain as small sample size of 22 patients

Overall Study Quality -Strengths and Weaknesses:

Strengths: appropriate outcomes, specified in study that control group received standard rehabilitation for same amount of time as intervention group, no attrition bias
Weaknesses: single blind study, inadequate description of randomisation, unclear if assessors were blind to intervention and control groups, small sample size of 22 patients, control group significantly older in control group ($p < 0.02$), FIM score significantly lower in control group ($p < 0.01$).

DETAILS

of patients:

Intervention: 11 patients, Control: 11 patients

Prevalence (Diagnostic):

N/A

Patient Characteristics

French study. Inclusion criteria: stroke < 3 months, MMSR cut-off score 74/100, FIM cut-off score 90/126, line cancellation of 40 standardised lines (cut-off score: more than 2 left omissions). Experimental group: sex F/M = 5/6, age(SD) = 66(8), days after stroke(SD) = 35(9), MMSR/100(SD) = 84(6), Schekenberg,%RD (SD) = 50(22), Bells/18(SD) = 13(2), Albert/20(SD) = 14(6), FIM/126(SD) = 66(18). Controll group: sex F/M = 5/6, age(SD) = 72(6), days after stroke(SD) = 30(4), MMSR/100(SD) = 81(4), Schekenberg,%RD (SD) = 53(27), Bells/18(SD) = 14(3), Albert/20(SD) = 16(4), FIM/126(SD) = 54(10). Exclusion criteria: history of stroke, alteration of general status, or cognitive difficulties incompatible with rehabilitation.

Interventions/ Test/ Factor being investigated

Every day for 20 days intervention group received 1 hour of the experimental treatment (Bon Saint Come's Device), followed by 2-3 hours of traditional rehabilitation (1 to 2 hours of physiotherapy, 1 hour of occupational therapy).
Intervention
The first part of the system was a polysar thoracolumbar vest and an attachment

of a vertical metal bar that projects forward horizontally just above the apex of the subject's head. The extremity of the bar, or pointer, was situated 1.5m in front of the patient, who was forced to make an axial rotation of the trunk under visual control to displace the pointer laterally and explore the visual field.

The second part of the device consisted of a series of targets attached to a mobile wooden panel placed in front of the patient. The targets, of different geometric form, housed an electrical circuit connected to a light bulb and to a buzzer. When the pointer was brought into contact with the target, audible and luminous signals are elicited, producing a biofeedback effect.

The patient had to learn how to use the device, visualizing the pointer and moving it by trunk rotation. The patient had to detect the visual and audible signals and touch the corresponding target with the pointer. If the patient succeeded, the same signals were emitted, providing positive feedback. An incorrect manoeuvre provoked no response and the patient was asked to try again.

Comparisons

Control group 3 to 4 hours of traditional rehabilitation each day for 20 days.

**Length of Study/
Follow-up**

End of study (day 30) and day 60

Outcome measures studied

Line bisection (Albert test, cutoff score of 2 left omissions), Schekenberg test (cutoff score 11% of right deviation), line cancellation, Bells test (cutoff score of 6 left omissions).

Results

Results at end of study

Control group: the Schekenberg test score went from 53% (SD22) of right deviation (RD) at day 0 to 45% (SD25) at end of study, the bell test score from 14(3) left omissions to 13(4) left omissions, and the Albert test score from 16 (4) left omissions to 12(7) left omissions.

Intervention: Schekenberg test score went from 50% (27) of RD at day 0 to 17% (SD 14) at end of study, the bell test score from 14(2) left omissions to 6(4) left omissions, and the Albert test score from 14 (5) left omissions to 4 (4) left omissions.

Intervention versus control group: Schekeberg test 45% (25) in control versus 17% (14) of RD in intervention group (p <0 .01); bell test 13 (4) left omissions in control versus 6(4) left omissions in intervention group (p <0 .02); Albert test 12(7) left omissions in control versus 4(4) left omissions in intervention group (p <0.05).

Results at 60 day follow-up

Study stated that at day 60, the quantitative improvements found at day 30 were slightly improved in both groups maintaining the same differences between the control and experimental groups. These results were presented graphically.

Effect Size

Source of funding:

None stated

Does the study answer the question?/Further Comments

Study may indicate that Bon Saint Come's Device / method may improve spatial awareness

Question: In people after stroke what is the clinical and cost effectiveness of memory strategies versus usual care to

improve memory?

Study Type	Randomised Controlled Trial
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Aben L;Heijenbrok-Kal MH;Van Loon EMP;Groet E;Ponds RWHM;Busschbach JJV;Ribbers GM;

Training memory self-efficacy in the chronic stage after stroke: A randomized controlled trial

Ref ID 16288

RID:

981

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Likely to overestimate intervention effect

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: It is a relatively large study with baseline adjusted outcome analysis. Study quality is relatively good with relevant outcome measures.
Weaknesses: It is unclear whether data was imputed for the ITT analysis. Participants were analysed regardless of whether they finished the trial or not in the group they were allocated to.

DETAILS

of patients:

N=77 intervention N=76 control

Prevalence (Diagnostic):

Patient Characteristics

Patients were included in the study if 18 months or more had elapsed since their first and only stroke, if they were between 18 and 80 years old and were living independently and if they reported subjective memory complaints. Subjective memory complaints were assessed using a semistructured telephone interview. Patients who reported memory deficits but nevertheless were able to adequately deal with these deficits by using memory aids were excluded.

	Experimental	Control
Age m (sd)	58 (10)	58 (9)
Time postonset months (sd)	52 (39)	55 (35)
Memory self-efficacy (MSE)	8.5 (1.76)	8.39 (1.62)
Delayed recall AVLT	7.58 (3.68)	6.43 (3.51)
Delayed recall RBMT	13.02 (7.73)	11.30 (5.70)

Note AVLT=Auditory Verbal Learning Test; RBMT = Rivermead Behavioural Memory Test

Interventions/ Test/ Factor being investigated

Memory self efficiency training which consists of 4 parts: (1) general introduction on memory and stroke, including the consequences of actual memory deficits and how to cope with these; (2) a training in internal and external memory strategies to improve compensating abilities (e.g. visualization, diary use, and taking notes); (3) psycho-education on the influence of beliefs, anxiety, memory-related worries, and motivation on memory performance and (4) realistic goal setting regarding memory-demanding tasks, using cognitive behavioural therapeutic aspects. 9 twice-weekly group sessions of 1 hour

Comparisons

Peer support group in which general education on causes and consequences of stroke was provided. Patients were invited to share problems experienced in their daily life. No active therapeutic interventions were performed. A psychologist was present to provide basic information on stroke and to moderate the sessions.

Length of Study/ Follow-up

All patients were assessed at home within 3 weeks prior to the intervention (T0) then there were 4.5 weeks of intervention (9 twice weekly sessions) then they were assessed within 10 days after the intervention (T1)

Outcome measures studied

Memory Self-Efficacy (MSE), Delayed recall AVLT, Delayed recall RBMT, EQ5D

Results

Group	Intervention Group			Control		
	Group comparison			T1-		
T0	Change score T1-T0a			T1-		
value	Mean	SE	p-value	Mean	SE	p-
MSE	0.48	0.14	.001	0.12	0.12	
.314	0.40	0.17	.019			
Delayed recall AVLT	1.01	0.26	.000	1.22	0.29	
.000	-0.11	0.42	.802			
Delayed recall RBMT	-0.01	0.49	.978	0.97	0.46	
.040	-0.63	0.71	.378			

a A positive (or negative) number means an increase (or decrease) in outcome score over the intervention period.

b A positive (or negative) number means that the intervention group scored higher (or lower) than the control group at T1 adjusted for baseline.

Effect Size

See above

Source of funding:

Kinder Fonds Adriaanstichting (The Dutch Children's fund Adriaanstichting)

Does the study answer the question?/Further Comments

The MSE may be used to improve memory function in a chronic stroke population.

Doornhein K;De Haan EHF;

Cognitive Training for Memory Deficits in Stroke Patients

Ref ID 727

RID:

39

1998

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: randomised

Weaknesses: very small sample, number and flow of participants throughout trial not mentioned, no follow up after treatment

DETAILS

of patients:

N=12 n=6 training programme n=6 pseudo treatment “drill and practice” control group

Prevalence (Diagnostic):

Patient Characteristics

	Age	Education
Treatment	51.3 (18.3)	4.3 (0.9)
Control	51.7 (10.8)	4 (1.6)

Exclusion: patients with severe aphasia, apraxia or agnosia

Interventions/ Test/ Factor being investigated	Memory training: twice a week for 4 weeks ; subjective memory problems assessed; mnemonic strategies taught were "association" and "organisation". Homework books used. Control group: "drill and practice" exercises, spend more time repeating material		
Comparisons	memory training vs pseudo training		
Length of Study/ Follow-up	no real follow up after intervention		
Outcome measures studied	(1) for target memory tasks: Name-Face Paired Associated Memory Test, Stylus Maze test (2) For Control memory task: 15 Words Test, Oxford Recurring Faces Test, Memory Questionnaire		
Results		Treatment	Control
	Target tasks		
	Name-face	9.7(5.9)	5.8(5.3)
	Stylus Maze	18.9(0.4)	14.4(2.6)
	Control tasks		
	15 Words	39.2(11.7)	29(4.7)
	Recurring Faces	50(3.5)	46.5(3.5)
	Memory Questionnaire	93(53.5)	85.3(11.1)
Effect Size			
Source of funding:	no details reported		
Does the study answer the question?/Further Comments	<p>Participants who received the training programme appeared to perform significantly better than those on the pseudo treatment group on the trained memory tasks but not on the control memory tasks; and no differences were observed on subjective ratings of everyday memory functions between both groups.</p> <p>There were substantial limitations to the study quality (small sample size, unclear randomisation, allocation concealment, and no follow up</p>		

Westerberg H;Jacobaeus H;Hirvikoski T;Clevberger P;Ostensson ML;Bartfai A;Klingberg T;

Computerized working memory training after stroke--a pilot study

Ref ID 54 **RID:** 34 2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/Unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

strength: randomised

weaknesses: very small sample size, no details on randomisation, allocation concealment or blinding methods, no follow up. The methodological quality of the study is unclear, and the risk of bias is either unclear or high.

DETAILS

of patients:

N=18 (n=9 treatment ; n=9 control)

Prevalence (Diagnostic):

Patient Characteristics

Setting: Sweden

Inclusion: stroke 12-36 months ago; stroke documented by PET, MR or CT; age 30-65; daily access to a PC with internet connection at home; self reported deficits in attention

Exclusion: IQ<70 (IQ was based on the age-normalised results from the WAIS-R test). All participants were assessed with the WAIS-R test within 6 months before entering the study; motor or perceptual handicap that would prevent use of the computer programme; changing medication during study period ; fulfilling criteria for major depressive-disorder diagnosis as per the DSM-IV diagnosis code ; known history of abuse of alcohol or illicit drugs

Participants' characteristics

Variable	Control (n=9)	Treatment (n=9)	All
Age	53.6 (8)	55 (8)	54 (7.7)
IQ	101 (13)	103 (11)	102 (12)

Male/female	4/5	8/1	
Education (yrs)	12.1 (1.8)	12.4 (1.7)	12.3 (1.7)
First ever stroke	8	8	
Time since stroke			
Months	20.8(6.2)	19.3(6.2)	20.1(6)
Type of stroke			
Haemorrhagic	23	6	
Infarction	3	7	
Severity (1 mild; 3 severe)			
	1.9 (0.8)	2.1(0.6)	2(0.7)
No of training days	-	23(2.2)	

Interventions/ Test/ Factor being investigated

The training method was implemented with a software product used at home on a PC. All tasks involved maintenance of multiple stimuli at the same time, short delays during which the representation of stimuli should be held in WM, unique sequencing of stimuli order in each trail, the difficulty adapting as a function of individual performance. The training plan specified that participants must complete 90 trials each day (taking about 40 minutes), 5 days a week for 5 weeks. The software directly included reinforcement, which was implemented via scores and positive verbal feedback on performance. The participants completed their training on a PC at home and reported their daily results via the internet to a server at the hospital. A certified psychologist provided feedback once a week via telephone.

The control group condition was passive: the participants only performed the neuropsychological test battery and completed the CFQ twice – with no training in between – at the same time points as the training group. The control group did not receive phone calls during the 5 weeks between test and retest.

Comparisons

Working memory training vs no training

Length of Study/ Follow-up

no follow up, just pre and post-training tests

Outcome measures studied

Wechsler Adult Intelligence Scale : Span board ; digit span
Word list learning: number of repetitions ; delayed recall
CFQ

Results

	Pre training		Post training	
	Control	Treatment	Control	Treatment
CFQ total	41 (14)	36.9 (10.2)	43 (13.8)	29.2 (12.1)
WAIS Span board	5.7(1.4)	5.2 (1)	5.7(1.8)	6.2 (1)
WAIS Digit span	5.7 (0.9)	5.8 (1)	5.7(1.3)	7.3 (1)
Word list learning:				
No of repetitions	6.9 (2.9)	6.3 (2.7)	7.4 (2.79)	6 (2.5)
Delayed recall	5.6 (2)	6 (1.9)	5.9 (2.1)	6.4 (1.7)

Effect Size

Source of funding:

Swedish Stroke Foundation

Does the study answer the question?/Further Comments

The study results suggest significant differences between groups for WAIS Span board and digit span. Significant reduction of cognitive symptoms as measured by the CFQ. However the methodological quality of the study put doubt into the results: very small (mainly male) sample size, unclear randomisation and allocation concealment methods, no follow up

Question: In people after stroke what is the clinical and cost effectiveness of sustained attention training versus usual

care to improve attention?

Study Type	Randomised Controlled Trial
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Barker CS;Feigin VL;Lawes CM;Parag V;Senior H;Rodgers A;

Reducing attention deficits after stroke using attention process training: a randomized controlled trial

Ref ID 3356 **RID:** 121 2009

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** randomisation, blinding and allocation concealment well described

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =** nature of intervention means blinding of participants not possible

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** no information on which groups the different participants who did not complete the study belonged to

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk **Direction =** the person carrying out the intervention was the only team member who was unblinded to randomisation status. The named

Overall Study Quality -Strengths and Weaknesses:

Strengths: well randomised, allocation concealment appropriate and blinding well carried out. Reasonable sample size, very low attrition rate

Weaknesses: nature of intervention made blinding of the treating neuropsychologist not possible.

Overall good quality recent study set in New Zealand

DETAILS

of patients: N=78 (n=38 in Attention Process Training [APT], n=40 in control)

Prevalence (Diagnostic):

Patient Characteristics

Setting: New Zealand
Participants were stroke survivors admitted to 2 New Zealand hospitals over 18 months who experienced an attention deficit as determined during neuropsychological screening assessment. Stroke survivors were approached within 2 weeks after stroke.
Excluded if they could not give informed consent, experienced severe cognitive deficits precluding participation, were medically unstable, not fluent in English as required for standardisation assessment, or had another condition that could impact results.

Parameter	APT (n=38)	Standard care (n=40)
Age (mean(SD))	70.2 (15.6)	67.7 (15.6)
Gender N(%)		
Male	23 (60.5)	24 (60)
Female	15 (39.5)	16 (40)
Barthel Index		
mean(SD)	14.9 (5.3)	14 (5.9)
MMSE mean(SD)	26.5 (2.8)	26.7 (2.6)
Stroke type		
Ischemic	31 (81.6)	37 (92.5)
Intracerebral hemorrhage		
	3 (7.9)	1 (2.5)
Unknown	2 (5.3)	2 (5)
Hemisphere of lesion		
Left	14 (43.8)	25 (58.1)
Right	15 (46.9)	17 (39.5)
Other	3 (9.1)	1 (2.3)
Time after stroke		
mean (SD)	18.48 (11.95)	18.58 (7.62)

Interventions/ Test/ Factor being investigated

In addition to standard care, participants in the APT group received up to 30 hours of individual APT conducted for 1 hour on weekdays for 4 weeks (mean 13.5hours, SD 9.44). Because of issues such as fatigue, a 30hour maximum was set and hours of APT treatment received were recorded. Participants discharged from hospital before 30 hours was achieved continued to receive APT sessions in the community. All APT sessions were administered by a registered clinical neuropsychologist, who was the only member of the study team who did not remain blinded to randomization status throughout the study.
Control group received standard care alone

Comparisons

standard care + APT vs standard care alone

Length of Study/ Follow-up

5 weeks after randomisation and 6 months

Outcome measures studied

Primary outcome: IVA-CPT Full Scale Attention Quotient (FSAQ) combining auditory and visual scores
Other outcomes: 1/ Attention measures: Trail Making , PASAT , Bell . 2/ Broader outcomes: SF-36, MRS total score, GHQ-28

Results

Parameter	Baseline		diff. btwn grps at 5 wks mean(95%CI)	diff btwn grps at 6 months mean(95%CI)
	APT Mean(SD)	SC mean(SD)		
1/ Attention measures:				
IVA-CPT(z score)				
Full attention*	-4.93(3.44)	-3.52(2.99)	2.76(1.31 - 4.21)	2.49(1.24 - 3.74)
Auditory attention	-4.01(3.17)	-3.35(2.79)	1.96(0.48 - 3.45)	0.83(-0.47 - 2.13)
Visual attention	-4.44(3.78)	-3.44(3.43)	1.56(-0.01 - 3.12)	1.41(0.02 - 2.8)
Trail-making (z score)				
A	-2.6(3.85)	-3.97(5.53)	0.01(-1.64 - 1.65)	0.55(-1.17 - 2.28)
B	-2.41(3.04)	-3.01(3.70)	-0.29(-1.84 - 1.26)	0.12(-1.50 - 1.75)
PASAT (z score)^				
2.4sec	-1.63(0.90)	-1.58(0.54)	0.46(-0.05 - 0.97)	0.74(-0.04 - 0.98)
2.0sec	-1.24(0.8)	-1.3(1.05)	0.54(-0.08 - 1.17)	0.15(-0.45 - 0.74)

Bell (raw)	
Left	11.94(4.77) ; 12.35(4.79) ; 0.92(-0.38 – 2.21) 1.59(-0.02 – 3.2)
Centre	4.31(1.11) ; 4.30(1.49) ; -0.18(-0.76 – 0.40) 0.016(-0.36 – 0.69)
Right	13.49(2.87) ; 13.3(2.83) ; -0.54(-1.82 – 0.75) 0.47(-0.68 – 1.62)

2/ Broader outcomes

SF-36	
PCS	32.3(10.11) ; 33.59(10.7) ; 1.84(-2.4 – 6.08) 3.21(-2.43 – 8.84)
MCS	46.22(11.3) ; 42.48(11.34) ; -3.14(-8.53 – 2.25) 0.31(-5.38 – 5.99)
MRS total score	2.58(1.24) ; 2.55(1.34) ; ... (... - ...) ; -0.29(-0.75 – 0.17)
CFQ total score	23.5(13.07) ; 28(10.81) ; ... (... - ...) ; 6.14(-0.5 – 12.78)
GHQ-28	6.53(4.58) ; 7.95(4.91) ; ... (... - ...) ; -0.27(-2.78 – 2.25)

* Primary outcome

^ baseline n=21 in APT and n=18 in SC

Difference in change: positive values favour APT except for MRS and GHQ-28

... indicates not administered at 5 weeks

CFQ: Cognitive Function Questionnaire ; MRS modified Rankin Scale ; SC: standard care ; MCS: Mental component score ; PCS: physical component score

Effect Size

Source of funding:

New Zealand Health Research Council ; National Heart Foundation (New Zealand) Fellowship

Does the study answer the question?/Further Comments

Yes. This well conducted, high quality study showed that APT resulted in significantly greater improvement on the primary outcome (IVA-CPT Full Score Attention Quotient) than standard care. APT is a viable and effective means of improving attention deficits after incident stroke.

Question: In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?

Study Type	Randomised Controlled Trial
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Carter LT;Howard BE;O'Neil WA;

Effectiveness of cognitive skill remediation in acute stroke patients

Ref ID 1046 **RID:** 554 1983

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Randomization not clear; patients characteristics were compared between experimental and control groups to check for homogeneity; to help protect against experimental bias, pre-test scores were not disclosed to the tester or the patient until after the post-test was completed; allocation concealment done; testers were blinded; experimental blind testing procedure was used; due to the layout of the stroke unit, at times it was possible for the tester to see which patients were given training by the other assistant

DETAILS

of patients: 33 acute stroke patients. Treatment (n =16) and control (n = 17). Randomization (pretest - posttest)

Prevalence (Diagnostic):

Patient Characteristics

Means (Standard Deviations) for Subject Variables and Control Patients

Variable	Experimental Group	Control Group	P Value
Age	70.5 (±11.4)	73.4 (±9.2)	>.20
Sex	M=7 F=9	M=9 F=8	>.50
Barthel Score*	25.2 (±8.6)	22.9 (±11.7)	>.20
Neurological Severity Score**	29.4 (±3.9)	28.5 (±6.4)	>.20
Pre-test Score***	54.2 (±24.3)	48.9 (±24.1)	>.10
No. Days – from Admittance to Stroke Program to Pre-test	4.81 (±1.6)	4.6 (±2.6)	>.20
No. Days from Pre-test to Post-test	22.1 (±7.1)	22.2 (±6.3)	>.20

*Scale of 100; **Scale of 60; ***Of 100

Interventions/ Test/ Factor being investigated

Cognitive skill retraining which involved:

- Visual scanning
- Visual-Spatial
- Time estimation

Letter cancellation test: patient was visually and verbally instructed to find and cross out the target letter each time it appeared among other letters on the page.

Visual-Spatial task: First part required patient to match an object that was identical to the sample. 2nd part, the correct match was the same as the sample but in a different spatial orientation.

Time –Judgement task: each patient was asked to estimate a 1-minute time period.

Retraining was on a one-to-one basis for 30 to 40 minutes per day, 3 days per week, for 3 weeks. Intervention continued for as long as patient was on the stroke program, an average of 3 to 4 weeks.

Comparisons

Routine stroke program: Social worker interviews, physical therapy, speech therapy, occupational therapy, family visits, and constant interaction with the rehabilitation nursing staff.

Length of Study/ Follow-up

Not mentioned

Outcome measures studied

Letter cancellation; Visual-Spatial matching to sample (identifying objects)

Results

Mean Improvement Scores * and SDs for Each Skill Area

Task	Experimental Grp			Control Grp			P Values
	Mean	SD	n	Mean	SD	n	
Scanning	35.9	21.3	9	3.8	13.2	10	<.005
V-S**	31.0	22.8	14	-3.3	18.0	15	<.005

*Based on a 100-pt scale; **Visual-Spatial, SDs: Standard deviations
Both treatment and non-treatment patients were post-tested for performance on the different skills before discharge from the stroke program.

Visual scanning is needed for reading and looking at objects in the entire visual field. Scanning is necessary for many activities in a rehabilitation setting, such as accurately perceiving and locating objects in space, operating a wheelchair and for transferring to and from a wheel-chair.

V-S orientation is needed for identifying and perceiving objects with different forms and in various positions (object constancy).

Effect Size

Source of funding: Research was supported by a grant awarded to the first author by Southern New England Long Term Care Gerontology Centre, Brown University

Does the study answer the question?/Further Comments Patients receiving treatment had overall and separate skill improvement scores that were significantly higher than those for control patients.

Modden C;Behrens M;Damke I;Eilers N;Kastrup A;Hildebrandt H;

A randomized controlled trial comparing 2 interventions for visual field loss with standard occupational therapy during inpatient stroke rehabilitation

Ref ID 16286 **RID:** 979 2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Randomisation by throwing dice; could bias in either direction

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** impossible to blind individuals administering care

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

high risk of bias **Direction =** in favour of intervention

Overall Study Quality -Strengths and Weaknesses:

Single blind (outcome assessor not blinded to training type). Sample size calculation: expansion of 1° over whole visual field defined as a meaningful effect; with SD 5.9, α and β error of 0.05, this gives sample size 15 per group. Baseline characteristics similar. Randomisation by throwing dice - inadequate randomisation and allocation concealment. Assessment at end of 3 week treatment period only no follow up

DETAILS

of patients:

n=47 randomised of whom two unable to receive intervention due to health impairment, 45 completers presented. Restorative computer training (RT) 15

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: patients with posterior cerebral artery stroke and visual field defect (homonymous hemianopia) admitted for inpatient rehabilitation. Exclusion: Patients with visual neglect, eye movement disorders, neuropsychological disorders like aphasia, dysexecutive syndromes, memory deficits or higher order motor impairments like apraxia. Gender: RT 10 male, 5 female; CT 9 male, 6 female; OT 7 male, 8 female. Mean (SD) age (years): RT 58.3 (11.4); CT 57.1 (8.3); OT 59.0 (11.1). Time since stroke onset: RT: 4.7 weeks; CT 4.9 weeks; OT 4.3 weeks. Inpatients

Interventions/ Test/ Factor being investigated

Restorative computer training (RT) using computer-based stimulation of border areas of visual field defects (eye movements not allowed), Computer-based compensatory therapy teaching visual search strategy (CT) – eyes taught to explore hemianopic field. 15 single sessions of 30 minutes over 3 weeks

Comparisons

RT and CT versus Standard occupational therapy (OT) using different compensatory strategies to train for activities of daily living (active control) e.g. using eye, head and body movements. All patients had standard inpatient rehabilitation including physiotherapy, speech therapy and health education

Length of Study/ Follow-up

at end of 3-week intervention only no follow up

Outcome measures studied

Primary: visual field expansion, visual search performance, reading performance. Secondary: visual conjunction search, alertness, Barthel Index

Results

Reduction in reading errors: RT: 0.9 (SD 2.4) n=15, NS vs. baseline; CT: 0.9 (1.1) n=15, p=0.016 vs. baseline; OT: 0.7 (1.0) n=15, NS vs. baseline; NS between groups Improved alertness: RT: 28.5 (SD 56.9) n=15, p=0.33 vs. baseline; CT: 77.8 (SD 112.9) n=15, p=0.001 vs. baseline; OT: -13.3 (SD 112.7) n=15, NS vs. baseline; NS between groups Visual conjunction search (visual scanning): RT: 2.7 (SD 5.1) n=15, NS vs. baseline; CT: 7.0 (SD 5.0) n=15, p=0.001 vs. baseline; OT: 3.5 (SD 6.8) n=15, NS vs. baseline; NS between groups Activities of daily living (Extended Barthel Index): RT: 1.5 (SD 2.8) n=15, p=0.027 vs. baseline; CT: 3.3 (SD 3.6) n=15, p=0.005 vs. baseline; OT: 1.8 (SD 2.0) n=15, p=0.003 vs. baseline; NS groups

Effect Size

Vis field enlarge RT3.9(4.9)n=15 p=0.003vs. baseline (t1) CT2.9(4.0)n=15 p=0.013vs. t1 OT1.3(4.7)n=15 p=0.316vs. t1; NS btwn gps. search perform: RT5.3(10.5)p=0.005vs. t1 CT5.4(5.2) p=0.003vs. t1 OT2.3(5.0)NS CTvs. OT p=0.048 RT/OT, RT/CT NS

Source of funding:

none

Does the study answer the question?/Further Comments

Compared with OT, CT gave better visual search performance; RT did not give larger expansion of visual field; larger trial with longer follow up needed

Spitzyna GA;Wise RJ;McDonald SA;Plant GT;Kidd D;Crewes H;Leff AP;

Optokinetic therapy improves text reading in patients with hemianopic alexia: a controlled trial

Ref ID 313

RID:

517

2007 May 29

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Small cross over trial (n=22). Treatment blocks lasted 4 weeks each. Allocation concealment unclear. Baseline comparisons reported. N=3 drop-out. Intention to treat analysis not used.

DETAILS

of patients:

N=22 participated in the study.
N=19 completed the study and were included in the analyses (n=11 in MT and

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Patients with a right sided homonymous hemianopia that interfered with reading were included.

In the majority of cases the hemianopia was secondary to a posterior cerebral artery territory stroke (infarct or haemorrhage), but head injury and tumours were among the causative lesions. All the patients had a fixed homonymous field

defect that had been present for at least 3 months.

There was no significant difference between the groups for the following variables: degrees of sparing (with respect to vertical meridian); single word reading speed; text reading speed. There was a significant difference between the groups for age at onset of hemianopia although these data were skewed by an outlier who had his hemianopia age 5 years old.

General neurological assessment:

All patients were tested once on a battery of neurological tests including: a test of general intellectual function, the Wechsler Abbreviated Scale of Intelligence (WASI); a test of visuo-spatial function, the visual Object and space perception battery (VOASP); a graded test of spelling; and Warrington's recognition memory test for words and faces. There was no significant differences between the groups on all of the variables.

Interventions/ Test/ Factor being investigated

Moving text (MT) daily for two 4 week blocks.
The tapes were made by animating freely available text from a variety of Sherlock Holmes stories across a computer screen from right to left, so called Times Square presentation. Patients were instructed to read the story on the tapes and try to follow it, although no tests of comprehension were made to check this. Patients were asked to keep diaries of how many minutes they spent each day on both the therapies. The aim was to achieve a minimum of 400 minutes of rehab (20 sessionsx20 min) over approximately 4 weeks.

Comparisons

Sham visual rehabilitation therapy (spot-the –difference) for 4 weeks and then crossed over to MT for the second.
Spot the difference tests were taken from a children's puzzle book –let. The number of differences on each page varied between 8 and 12. Patients were instructed to look for as many differences as possible between the two pictures, but were not told how many to expect, completing at least 2 cartoons over 20 mins.

Length of Study/ Follow-up

baseline (2-4 weeks), 5 weeks , 6 weeks, 8 weeks

Outcome measures studied

Text reading speeds ; single word reading speeds ; recording and analysis of eye movements ; recording and analysis of visual field perimetry.

Results

Text reading speeds: (using passages 3,4,5 of the Neale analysis of reading)
Between group effects: There was a main effect of time across both treatment groups: $F(1,17)=15.40, P<0.001$, but no interaction between treatment group and time , either comparing data from the three time points that spanned both blocks of therapy (baseline, 5 weeks, 6 weeks): $F(2,16)=0.97, p<0.388$, or over the two that spanned just the first block (baseline, 5 weeks): $F(1,17)=1.27, p<0.275$.
Within group effects: MT – Results from MT revealed an overall effect of time: $F(2,9)=23.91, P<0.001$, with patients improving from a speed of 95 wpm at baseline to 103 at 5 weeks and 114 at 6 weeks .
Within group effects: spot-the-difference- results from this group revealed that an overall effect of time: $F(2,9)=19.39, p<0.001$, with patients improving from a mean speed of 82 wpm at baseline to 86 at 5 weeks and 101 at 6 weeks.
Post-rehabilitation effects (6 weeks- 8 weeks): Reading times for both groups decreased after therapy stopped, but not significantly for spot-the-difference group: reduction in mean at 6 weeks from 101 wpm to 97 at 8 weeks, $t(7)=1.43, p=0.196$; and at marginal significance for MT, reduction in mean at 6 weeks from 118 wpm to 107 at 8 weeks, $t(10)=2.17, p=0.055$.
Single word reading speeds:(using 25 examples of 3,4,5 7 and 9 letter words taken from the MRC psycholinguistic battery)
There was no significant effect of therapy on the single word reading slopes (a planned analysis); however patients reads single words of all lengths (3,5,7, 9 letters long) significantly quicker post-rehabilitation, although some of these effects were marginally significant.
Eye movement data: (patients silently read 3 out of a corpus of 10 short text passages extracted from a newspaper, eye movements recorded with SR eye-link II video based head mounted eye tracking system);
Three spatial and 4 temporal measures were analysed.
Spatial characteristics:
a)Saccadic amplitudes (progressive and regressive): comparison was made on the effect of therapy between progressive (rightward) and regressive (leftward) saccades. Both groups increased the size of their progressive saccades with main

effect of time: $F(2,34)=15.93$, $p<0.001$. Again there was also a group by time interaction at both 5 weeks: $F(1,17)=7.38$, $P=0.015$ and 6 weeks: $F(2,34)=4.46$, $p=0.016$. There was no main effect of time on regressive saccades: $F(2,34)=0.84$, $P=0.44$

b) Incoming saccadic amplitude: There was both a main effect of time across both groups: $F(2,34)=7.87$, $p=0.002$, and a group by time interaction which was marginal at 5 weeks: $F(1,17)=3.98$, $P=0.06$, and significant at 6 weeks: $F(2,34)=3.88$, $p=0.03$.

c) Landing position: There was a non significant trend for landing position to increase with time across both groups : $F(2,34)=2.41$, $p=0.105$.

Temporal characteristics: Patients in both groups improved over the therapy as judged by the number of fixations per 100 words, with a main effect of time across both groups: $F(2,34)=29.78$, $p<0.001$, with a group by time interaction at both 5 weeks: $F(1,17)=33.45$, $p<0.001$ and 6 weeks: $F(2,34)=17.94$, $p<0.001$.

Analysis of perimetry:(static fields were measured using the automated Humphrey field analyser , dynamic fields using a Goldmann perimeter).

Only one of the 19 patients visual fields changed between baseline and 6 weeks, from 0 to 2 degrees of sparing. There was no change across the group: Wilcoxon Signed ranks test, $Z=-1.00$, $p=0.317$.

Effect Size

Source of funding:

Not reported.

Does the study answer the question?/Further Comments

Yes. Moving text (MT) therapy showed significant improvements in static text reading speed over both therapy blocks (18% improvement), while spot-the-difference group did not significantly improve over the first block (5% improvement) but did when they crossed over to the MT block (23% improvement) MT therapy was associated with a direction-specific effect on saccadic amplitude for rightward but not leftward reading saccades.

Question: In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions / usual care to improve swallowing? (dysphagia)

Study Type	Randomised Controlled Trial
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Carnaby G;Hankey GJ;Pizzi J;

Behavioural intervention for dysphagia in acute stroke: a randomised controlled trial

Ref ID 5045

RID:

579

2006

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Large study; randomisation and allocation concealment adequate; baseline characteristics comparable between groups; outcome assessor blinded; analysis were by intention to treat; minimal loss to follow up; patient and treating therapist were aware of the treatment allocation; small number of patients and outcome events making way for imprecision with wide confidence intervals; study was undertaken in a single centre making generalisability uncertain. Primary outcome measure was return to normal diet and differences in achieving certain diets strongly affected by care practices (e.g. perceptions of staff or involvement of swallowing clinician) rather than patient's functional feeding ability alone. Trial not powered to compare low-intensity versus high-intensity intervention; 3 randomised groups (low, high and usual care).

DETAILS

of patients: 306: 102 to each of high-intensity treatment, low-intensity treatment and usual care.

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Stroke within previous 7 days; dysphagia; consent
Exclusion: swallowing treatment; surgery to head and neck

	High intensity	Low intensity	Usual care
Mean (SD) age (yr)	69.8 (12.5)	72.0 (12.4)	71.4 (12.7)
Male (n, %)	60 (59%)	59 (58%)	59 (58%)
Barthel Index <15 (n, %)	80 (78%)	80 (78%)	81 (79%)
Rankin score <3 (n, %)	15 (15%)	21 (21%)	17 (17%)

Interventions/ Test/ Factor being investigated

Standard low-intensity treatment (swallowing compensation strategies: environmental e.g. upright position; safe swallowing advice e.g. slowed rate of eating; dietary modification) 3 times per week for a month or duration of hospital stay. Standard high-intensity treatment (direct swallowing exercises e.g. effortful swallowing, supraglottic swallow technique; dietary modification) every working day per week for a month or duration of hospital stay.

Comparisons

High and low-intensity treatment (combined in some analyses) versus usual care (at physician's discretion; treatment if offered mainly comprised supervision of feeding and precautions for safe swallowing e.g. positioning, slowed rate of feeding)

Length of Study/ Follow-up

6 months

Outcome measures studied

1ry: return to pre-stroke diet in 6 months. 2ry: time to normal diet; recovering functional swallowing or developing dysphagia-related complication (e.g. chest infection, dehydration, calorie-nitrogen deficient); died; institutionalised; dependent in ADL

Results

	High intensity	Low intensity	Usual care
Normal diet at 6 mth:	71 (70%)	65 (64%)	57 (56%)
Functional swallowing:	49 (48%)	44 (43%)	33 (32%)
Dysphagia complication:	50 (49%)	44 (43%)	64 (63%)
Chest infection:	28 (27%)	26 (25%)	48 (47%)
Death:	17 (17%)	20 (20%)	23 (23%)
Institutionalisation:	19 (19%)	17 (17%)	26 (25%)
Dependency (Rankin ≥3)	69 (68%)	68 (67%)	72 (71%)

Effect Size

Source of funding:

Royal Perth Hospital Medical Research Foundation, Australia.

Does the study answer the question?/Further Comments

The authors concluded that the intervention helped patients to achieve functional swallowing, return to a normal diet and avoid chest infections. However, they acknowledged that the patients and therapist were aware of treatment allocation, which introduces the possibility of bias. . The primary outcome measure was return to normal diet and differences in achieving certain diets strongly affected by care practices (e.g. perceptions of staff o r involvement of swallowing clinician) rather than patient's functional feeding ability alone. Trial not powered to compare low-intensity versus high-intensity intervention; 3 randomised groups (low, high and usual care).

DePippo KL;Holas MA;Reding MJ;Mandel FS;Lesser ML;

Dysphagia therapy following stroke: a controlled trial

Ref ID 5041

RID:

575

1994 Sep

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Patients randomised to 3 levels of intervention as no-intervention control deemed unethical; randomisation and allocation concealment adequate; not blinded; no sample size calculation; low numbers of events so study may have been underpowered.

DETAILS

of patients:

115 (38 in group A; 38 in group B and 39 in group C)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Admitted to inpatient rehabilitation unit for stroke; age 20-90 years inclusive; laboratory values below endpoint criteria; dysphagia (failure on Burke Dysphagia Screening Test and modified barium swallow [MBS] evidence)
Exclusion: known significant oral or pharyngeal anomaly; severe dysphagia (aspiration of over 50% of all consistencies presented even after use of compensatory swallowing techniques)

	Group A	Group B	Group C
Median age (yr) (IQR)	76 (66-80)	74.5 (64-80)	73 (66-80)
Male/Female	22/16	19/19	27/12
Mean MMSE (SD)	16 (12)	17 (10)	18 (10)
Barthel score	37 (23)	48 (20)	46 (38)
Median (IQR) weeks post-stroke	4.6 (3.6-6.1)	4.5 (3.4-5.6)	4.9 (3.7-6.6)

Interventions/ Test/ Factor being investigated	Group C: Dysphagia therapist prescribed diet consistency based on the MBS evaluation but seen daily in mealtime dysphagia management group where additional instructions and reinforcement of techniques given.																								
Comparisons	Group A: one formal dysphagia treatment session; dysphagia therapist recommended an appropriate diet consistency based on the Modified Barium Swallow results; patient/family chose diet consistency they thought appropriate (could change during stay on request); recommendation and training in compensatory techniques with no daily reinforcement by a dysphagia therapist (additional rehearsal of techniques during rehabilitation given only if patient/family requested) Group B: As group A, but patient/family did not choose diet; dysphagia therapist prescribed diet consistency based on the MBS evaluation; group re-evaluated by dysphagia therapist every 2 weeks.																								
Length of Study/ Follow-up	1 year post stroke																								
Outcome measures studied	Pneumonia, dehydration, calorie-nitrogen deficient, recurrent upper airway obstruction, death.																								
Results	<table border="0" style="margin-left: 40px;"> <thead> <tr> <th></th> <th style="text-align: center;">Group A (n=38)</th> <th style="text-align: center;">Group B(n=38)</th> <th style="text-align: center;">Group C (n=39)</th> </tr> </thead> <tbody> <tr> <td>Pneumonia</td> <td style="text-align: center;">1</td> <td style="text-align: center;">5</td> <td style="text-align: center;">2</td> </tr> <tr> <td>Dehydration</td> <td style="text-align: center;">3</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1</td> </tr> <tr> <td>Calorie-nitrogen deficient</td> <td style="text-align: center;">2</td> <td style="text-align: center;">2</td> <td style="text-align: center;">3</td> </tr> <tr> <td>Recurrent upper airway obstruction</td> <td style="text-align: center;">1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Death</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> </tbody> </table> <p>37% of patients in group C independent in compensatory swallowing techniques compared with 19% in groups A and B</p>		Group A (n=38)	Group B(n=38)	Group C (n=39)	Pneumonia	1	5	2	Dehydration	3	0	1	Calorie-nitrogen deficient	2	2	3	Recurrent upper airway obstruction	1	0	0	Death	0	0	0
	Group A (n=38)	Group B(n=38)	Group C (n=39)																						
Pneumonia	1	5	2																						
Dehydration	3	0	1																						
Calorie-nitrogen deficient	2	2	3																						
Recurrent upper airway obstruction	1	0	0																						
Death	0	0	0																						
Effect Size																									
Source of funding:	US Public Health Service grant																								
Does the study answer the question?/Further Comments	No significant difference between the groups on any outcome up to 1 year post-stroke; small number of events so study likely underpowered; authors suggest that a majority of patients also had language or cognitive deficits that might have impaired their ability to learn and implement the techniques regardless of daily reinforcement																								

Garon BR;Engle M;Ormiston C;

A randomized control study to determine the effects of unlimited oral intake of water in patients with identified aspiration

Ref ID 5040

RID:

574

1997

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Small study; randomisation and allocation concealment unclear; groups comparable at baseline; follow-up swallowing evaluations not at set times but based on patients' neurological improvement

DETAILS

of patients: 20 (10 in each group)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Recent stroke in last 3 weeks; aspiration of thin liquids.
Exclusion: Previous stroke, degenerative neurological dysfunction, pneumonia, multiple medical diagnoses, reflux or oesophageal disorders, unable to understand study, poor cognition, severe cough reflex to aspiration, unable to rinse and expectorate, unable to hold a cup and self-feed, impulsive patients, concern about hydration status.

	Intervention group	Comparison group
Mean age:	77.5 years	76.1 years
Male:	8/10	6/10
Consistent aspiration (>50% swallows):	5/10	2/10
Inconsistent aspiration (10-50% swallows):	4/10	2/10
Infrequent aspiration (<10% of swallows):	1/10	6/10
Cough reflex absent:	7/10	5/10

Interventions/ Test/ Factor being investigated

Free access to water (amount measured) in addition to thickened liquids but not with meals or for an hour after meals. No compensatory swallow techniques, direct or indirect swallow therapy or cues given.

Comparisons	Thickened liquids only (with meals or as requested) and no access to water. No compensatory swallow techniques, direct or indirect swallow therapy or cues given.		
Length of Study/ Follow-up	Followed up until no thin liquid aspiration on follow-up videofluoroscopic evaluation (but this was not at a set time interval). Intervention group range 7-35 days; control group 8-64 days.Plus 30 days follow up.		
Outcome measures studied	Aspiration pneumonia, dehydration, need for intravenous fluids, amounts of liquids consumed, time from aspiration to no aspiration on follow up assessment, patient satisfaction.		
Results		Intervention group	Comparison group
	Pneumonia:	0	0
	Dehydration:	0	0
	Mean (range) time to no aspiration:	19.1 days (7-35)	27.2 days (8-64)
	Mean (range) total liquid intake:	1318 cc/day (800-1900)	1210cc/day (400-1800)
	Satisfaction with thickened liquid:	0	1
	Satisfaction with water:	10	NA
Effect Size			
Source of funding:	None stated		
Does the study answer the question?/Further Comments	The study was too small to demonstrate any difference between groups.		

Question: In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?

Study Type	Randomised Controlled Trial
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Cooke EV;Tallis RC;Clark A;Pomeroy VM;

Efficacy of functional strength training on restoration of lower-limb motor function early after stroke: phase I randomized controlled trial

Ref ID 78

RID:

241

2010 Jan

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Multicentre trial - Some differences in 4th centre added later (VICON movement analysis system also used).
For those unable to walk, investigators imputed a value of 0 for both walking speed and step length, but treated step time as missing data. At baseline all measures were balanced across groups with the exception of hemiplegic side and number able to walk at 0.8m/s or more.
Mean duration of additional therapy received by 2 experimental groups was equal (15.7 for CPT and 14.8 for FST)

DETAILS

of patients:

n=109, Control=38, CPT=35, CPT+FST=35

Prevalence (Diagnostic):

Patient Characteristics

Inpatients older than 18 yrs, between 1&3 weeks after anterior circulatory stroke (haemorrhage or infarction). Some voluntary muscle contraction in the paretic lower limb (score of at least 28/100 on the lower limb section of the motricity index) with potential for clinically important improvement. Able to follow a 1-stage command. Independently mobile, with or without aids, prior to the index stroke. No orthopaedic surgery and no trauma affecting the lower limb in the last 8 weeks. No previous history of neurological disease other than stroke.

Variable	Control	CPT	CPT + FST
Gender:	55%M 45%F	63%M 37%F	61%M 39%F.
Hemisphere:	55%L,45%R	62%L,37%R	67%L,33%R.
Age yrs(SD):	66.37(13.7)	67.46(11.3)	71.17(10.6).
Days since stroke:	36.76(22.41)	32.43(21.29)	33.86(16.5).
Walking speed:	0.17(0.24)	0.27(0.36)	0.23(0.29).
Number unable to perform walk measure(%)	57.9	57.1	58.3

Interventions/ Test/ Factor being investigated

All participants received routine CPT from their clinical physiotherapists using a treatment schedule. Content & duration of each session recorded. It included soft tissue mobilization, facilitation of muscle activity, facilitation of coordinated multijoint movement, tactile and proprioceptive input, resistive exercise and functional retraining. All additional therapy was delivered using standardized treatment schedules for up to 1 hour, 4days/week for 6 weeks (24 hours) by research physios independent of clinical team. One physio at each of 4 centres performed both CPT and FST for consistency. To ensure adherence to protocol they were supervised throughout the trial. Control did not receive any additional therapy to their standard physio. Treatment 1 was additional CPT (conventional physiotherapy). Experimental CPT focussed on interventions in the treatment schedule that emphasized control/quality of movement and gave prominence to sensory stimulation and preparation of joint and muscle alignment prior to activating muscle or a functional task. Strongly physio hands-on, with provision of passive movements, active assisted exercise and/or hands-on intervention to facilitate muscle activity or functional ability. Some active exercise and repetitive practice of functional tasks was included but without systematic progression in resistance or repetition. 2nd treatment group was CPT+functional strength training (FST). FST directed patients' attention to the exercise/activity being performed, appropriate verbal feedback on performance and repetition (therapist hands-off). Content of FST focussed on repetitive, progressive resistive exercise during goal-directed functional activity. Emphasis on producing appropriate muscle force for the functional activity being practiced. Treatment progressed systematically using repetition and increase in resistance by, for example, changing the limb's relationship to gravity, increasing the range of movement or distance over which bodyweight was transported and changing the weight of external objects used to provide resistance. Treatment activities progressed systematically from light to heavy loads and from few to many repetitions. Participants performed repetitive exercise of functional tasks such as sit-to-stand-to-sit, stair climbing/step ups, inside and outside walking, transfer training, bed mobility and treadmill training with and without the use of a bodyweight support system.

Comparisons

Control vs CPT vs CPT+FST

Length of Study/ Follow-up

post-test after 6 week intervention and 12 weeks after completion

Outcome measures studied

Primary: Walking speed (m/s) over 10m. VICON movement analysis system used for participants in clinical centers within a 30min taxi-journey of the gait lab.
Secondary: ability to walk at 0.8m/s or more, knee torque, Rivermead mobility index, gait, Euroqol

Results

Outcome: Control ; CTP ; CPT + FST
Walking speed m/s – mean (SD)
Post treatment: 0.3(0.35); 0.55(0.49); 0.42(0.39)
Follow up: 0.44 (0.39) ; 0.59 (0.48) ; 0.46 (0.37)

Knee flexion peak torque- mean (SD)
Post-treatment: 19.0 (17.8);34.0 (23.1); 25.4 (20.3)
Follow-up:25.2 (22.9); 41.7 (28.8); 29.4 (21.2)

Knee extension peak torque- mean (SD)
Post-treatment: 27.8 (26.3); 45.3 (33.2); 35.9 (28.5)
Follow-up: 37.9 (27.8); 56.4 (36.3); 42.1 (27.5)

EuroQuol Health state – Median (IQR)
Post-treatment: 0.47 (0.31); 0.54 (0.30); 0.59 (0.32)
Follow up: 0.60 (0.29); 0.56 (0.27) 0.64 (0.29)

EuroQuol Self-perceived health – Mean (SD)
Post-treatment: 60.8 (19.6); 66.0 (19.3); 69.9 (18.9)
Follow up: 66.2 (18.9); 61.4 (19.5); 69.6 (19.3)

Modified Rivermead mobility index – Mean (SD)
Post-treatment: 34.6 (10.8); 36.6 (10.4); 37.7 (8.6)
Follow up: 39.7 (5.7); 36.6 (9.8); 39.9 (7.2)

Effect Size

Source of funding: The Healthcare Foundation and the Dowager Countess Eleanor Peel Trust

Does the study answer the question?/Further Comments This phase I trial has provided sufficient evidence to justify and inform the design of subsequent trials of CPT and CPT+FST. Attention now needs to be given to identification of the most appropriate dose of both experimental CPT and FST and how adherence can be increased. Combining data from these further investigations will inform the dose and delivery of CPT and CPT+FST for the determination of definitive clinical effectiveness in a subsequent phase II trial.

Donaldson C;Tallis R;Miller S;Sunderland A;Lemon R;Pomeroy V;

Effects of conventional physical therapy and functional strength training on upper limb motor recovery after stroke: a randomized phase II study

Ref ID 216

RID:

266

2009 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Study was observer blind, but those administering treatment were not blinded. The authors did attempt to blind patients to treatment as much as was possible i.e. did not tell them what treatment group they were in.
There was a trend for baseline measures in the CPT+FST group to be lower in all measures, but not statistically significant.
There was a difference in the total hours of therapy received but the 2 experimental groups compared to control (2.81(3.7)hrs for control, 13.8(7.1)hrs for CPT and 17.7(7.5) hrs for CPT+FST. Study underpowered (pilot for subsequent phase III trial).
Strength measurements were in N rather than Nm, still relevant?
All results given as median(IQR).

DETAILS

of patients:

n=30. Control=10, conventional physical therapy (CPT)=10, conventional+functional strength training (FST)=10

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: Infarction of anterior cerebral circulations (diagnosed through neuroimaging) between 1wk and 3months after stroke; some voluntary muscle activity in paretic upper limb, scoring 4+/57 on the ARAT but unable to complete 9 hole peg test in 50 seconds or less; no obvious unilateral visuospatial neglect on clinical observation of subject's ability to orientate toward objects and people in their environment; able, prior to stroke to use paretic upper limb to lift a cup and drink from it, able to follow a one-stage command (touch your nose with your stronger hand)' able to participate in routine therapy.

	Control	CPT	FST
Mean age:	72.6	73.3	72.6
Gender (M:F)	5:5	5:5	5:7
Days since stroke (mean)	13.4	25.6	21.7
ARAT (mean(SD)):	30.5(13.07)	33.70(15.52)	26(9.8)

Interventions/ Test/ Factor being investigated

All subjects received conventional physiotherapy (CPT) by clinical physios. Extra physio (CPT and FST) delivered by research physio. Control=CPT given by physio in clinical center using standardized treatment schedule. Including soft tissue mobilization, facilitation of muscle activity/movement, positioning and education for patient/carer. Emphasises interventions facilitating and guiding movement (therapist hands-on) to provide sensory input to optimize joint alignment in preparation for voluntary movement. Experimental condition 1 was CPT+extraCPT by research physio. Additional CPT recorded by treatment schedule. Condition 2 was CPT+functional strength training (FST).

Comparisons

Control vs CPT vs CPT+FST Change scores, baseline to outcome and baseline to follow up compared between groups

Length of Study/ Follow-up

3 months

Outcome measures studied Primary: Action Research Arm Test (ARAT) score. Secondary: Dexterity: 9 hole peg test, upper limb strength (measured in Newtons): Hand Grip strength (N), pinch grip (N), Isometric elbow flexion force (N), Isometric elbow extension force (N).

Results	Outcome:	Control;	CPTI;	FST
	ARAT [Mean (SD)]:	45.00 (13.93);	41.80 (17.83);	43.60 (18.90)
	9 hole peg test [Mean (SD)] :	0.15(0.14) ;	0.16(0.15) ;	0.17(0.15)
	Grip force (N) [Mean (SD)]:	64.75 (39.25);	71.90 (49.45);	58.50 (60.18)
	Pinch Force (N) [Mean (SD)]:	24.50 (19.70);	31.50 (23.11);	25.80 (21.26)
	Elbow flexion force (N) [Mean (SD)]:	75.0 (38.67);	76.10 (58.73);	59.50 (44.69)
	Elbow extension force (N) [Mean (SD)]:	68.63 (39.61);	64.50 (44.56);	49.20 (34.19)

Effect Size

Source of funding: The Wellcome Trust

Does the study answer the question?/Further Comments Further work toward a phase III clinical trial appears justifiable

Flansbjerg UB;Miller M;Downham D;Lexell J;

Progressive resistance training after stroke: effects on muscle strength, muscle tone, gait performance and perceived participation

Ref ID 4896 **RID:** 261 2008 Jan

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Subjects are randomised but after being stratified by sex - randomization kept in non-sealed envelopes. Assessors only were blinded.

DETAILS

of patients: N=25 Control=9, Training=16

Prevalence (Diagnostic):

Patient Characteristics

Community dwelling subjects who had been treated in 1 of the 2 university hospitals in South Sweden between 2002-05, identified from a database. Inclusion criteria: Age between 40-70yrs, minimum of 6 months post-stroke (cortical/subcortical), able to perform isolated extension and flexion movements of the knee, at least 15% reduction in muscle strength in the paretic limb (mean isokinetic peak torque at 60deg/sec) to assure a real weakness in the paretic lower limb, able to walk without supervision at least 200m with or without a walking aid, no medication, physical cognitive or mental dysfunction that could impact upon knee muscle strength, gait performance or perceived participation, and able to understand verbal and written information.

Patients characteristics

Variable	Training gp	Control gp
Mean age(SD)	61(5)	60(5)
Time since stroke onset mean months(SD)	18.9(7.9)	20(11.6)
Sex (M/F)	9/6	5/4
Paretic side (R/L)	7/8	1/8
Type of stroke (Ischaemic/haemorrhagic)	12/3	6/3

Interventions/ Test/ Factor being investigated

Control = encouraged to continue usual daily activities and training but not to engage in any progressive resistance training (PRT). Asked to record details of activities at end of 10weeks. Training: participated in 10 weeks of PRT twice weekly using Leg Extension/Curl Rehab exercise machine with pneumatic resistance (pressure resistance 10 bar, HUR Ltd). All exercise was performed individually and supervised by the responsible physio. Each session started with a warm-up of 5min of stationary cycling, 5 reps without resistance and 5 reps at 25% of their max load. Then 6-8 reps in 2 sets at a low speed (30-40 sec/set) with about 80% of their max load and with a 2-min rest between each set. Subjects performed as many reps as possible on each occasion and every 2 weeks the load was adjusted to remain at 80% of their max load. Extensors in non-paretic lower limb were trained followed by the extensors in the paretic lower limb. After 10min rest, the same procedure was repeated with the flexors in the non-paretic and paretic lower limbs. After each session, knee extensors and flexors were passively stretched using a static technique. Each session lasted about 90min, actual PRT time was less than 6min. Between each session, subjects continued their usual daily activities and other forms of training but were not engaged in any PRT.

Comparisons	Changes between baseline and after intervention and differences between groups after intervention.																																
Length of Study/ Follow-up	5 months after end of 10 weeks treatment																																
Outcome measures studied	Gait performance including Timed up and go (at a comfortable speed) carried out twice, 1min between each, mean time recorded. Fast gait speed (timed over middle 10m of a 14m walk) Done 3 times with 30 second rest between each, mean recorded. 6min walk (m)																																
Results	<p>Training group:</p> <table border="0"> <thead> <tr> <th></th> <th>pre treatment</th> <th>post treatment</th> <th>follow up</th> </tr> </thead> <tbody> <tr> <td>Timed up and go(sec):</td> <td>28.6(13.9)</td> <td>23.1(10.3)</td> <td>23.6 (11.1)</td> </tr> <tr> <td>Fast gait speed(10m;sec):</td> <td>18(10.3)</td> <td>15.4(8.8)</td> <td>16.1 (9.9)</td> </tr> <tr> <td>6min walk(m):</td> <td>228(137)</td> <td>250(131)</td> <td>251 (144)</td> </tr> </tbody> </table> <p>Control group:</p> <table border="0"> <thead> <tr> <th></th> <th>pre treatment</th> <th>post treatment</th> <th>follow up</th> </tr> </thead> <tbody> <tr> <td>Timed up and go(sec):</td> <td>26.9(15.2)</td> <td>24.3 (14.2)</td> <td>26.7 (18.9)</td> </tr> <tr> <td>Fast gait speed(10m;sec):</td> <td>18.7(15.4)</td> <td>17.9(15.3)</td> <td>19.4 (17.8)</td> </tr> <tr> <td>6min walk(m) :</td> <td>234(134)</td> <td>247(142)</td> <td>240 (140)</td> </tr> </tbody> </table> <p>TUG: Difference between groups before vs. after treatment: 2.9(1.4), NS; before vs. follow up 4.9 (2.0), p<0.05. Fast gait speed: Difference before-after 1.9(1.2), NS; before-follow up 2.7 (2.0), NS. 6MWT: Difference before-after 9(10), NS; before-follow up 17 (14), NS. For the treated group, all gait performance tests improved significantly after intervention (p<0.05) and for timed-up-and-go and 6min walk, at follow up. For the control group, only timed-up-and-go improved significantly (p<0.05). No injuries occurred during the training sessions and the subjects described very low or no discomfort during or after the sessions.</p>		pre treatment	post treatment	follow up	Timed up and go(sec):	28.6(13.9)	23.1(10.3)	23.6 (11.1)	Fast gait speed(10m;sec):	18(10.3)	15.4(8.8)	16.1 (9.9)	6min walk(m):	228(137)	250(131)	251 (144)		pre treatment	post treatment	follow up	Timed up and go(sec):	26.9(15.2)	24.3 (14.2)	26.7 (18.9)	Fast gait speed(10m;sec):	18.7(15.4)	17.9(15.3)	19.4 (17.8)	6min walk(m) :	234(134)	247(142)	240 (140)
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Effect Size																																	
Source of funding:	Swedish Stroke Association, Swedish Association of Neurologically Disabled, amongst other grants																																
Does the study answer the question?/Further Comments	Progressive resistance training is an effective intervention to improve muscle strength in chronic stroke. There appear to be long-term benefits, but further studies are needed to clarify the effects, specifically of progressive resistance training on gait performance and participation.																																

Galvin R;Cusack T;O'Grady E;Murphy TB;Stokes E;

Family-mediated exercise intervention (FAME): evaluation of a novel form of exercise delivery after stroke

Ref ID 16945

RID:

1081

2011 Mar

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = People in the control group were slightly olde, there were fewer men (which might impact on a strength outcome)

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = There is a high risk of bias here, but it was decided to focus more on assessor blinding in this guideline

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = It is a little unclear, but the three people in the control group that were loss to follow-up would affect the

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strength: The study is methodologically well conducted with good randomisation and assessor blinding.
Weakness: Interventional procedure is not clearly enough described. Allocation concealment is unclear. Quite a small scale study.

DETAILS

of patients:

N=40 Control N=20 Family Mediated Exercise Intervention (FAME) N=20

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: participants were assessed at 2 weeks after stroke and were those with a confirmed diagnosis of a first unilateral stroke (MRI or CT), no impairment of cognition (≥ 24 of 30 on the Mini Mental State Examination), participating in a physiotherapy program and a family member willing to participate in the program. To control for heterogeneity individuals who scored from 3.2 to 5.2 on the Orpington Prognostic Scale were recruited. The family member had to be medically stable and physically able to assist in the delivery of exercises. Suitability was determined after consultation with the individual, their family, and the physiotherapist in charge of the patient's routine care.

	Control group (N=20)	FAME group (N=20)
Age m(SD)	70 (12)	63.(13)
Male	7	13
Left / right side stroke	14/6	9/11
Time from stroke onset m days (SD)	20 (3)	19 (3)
Barthel Index (0-100)	66 (28)	56 (27)
Motor Assessment Scale (0-48)	30 (13)	24 (11)
Berg Balance Scale (0-56)	27 (18)	22 (18)

Interventions/ Test/ Factor being investigated

Comparisons

FAME intervention versus usual care ('routine' physiotherapy)

Length of Study/ Follow-up

8 weeks intervention and 3 months follow-up

Outcome measures studied

Primary outcome: Lower limb section of the Fugle-Meyer Assessment (LL-FMA).
Secondary outcomes: Motor assessment Scale (MAS), Berg Balance Scale (BBS), 6-MWT and the Barthel Index (BI)

Results

Mean change scores are reported here. For the post intervention mean change scores it is change from baseline that is reported and for the 3 months follow-up it is mean change from post intervention. Means will be added to the GRADE tables. *p<0.05 FAME group vs. control

	Control Group (n=20)		FAME Group
	Post intervention (n=20)	3 months follow-up	Post intervention
LL-FMA	1.75 (6.3)	1.3 (5.2)	
9.5(9.9)*	1.6 (2.4)		
MAS	4.75 (6.2)	0.7 (2.6)	11.9
(7.8)*	1.8 (3.8)		
BBS	9 (9)	1.8 (8.5)	22.8
(18.1)*	0.9 (2.5)		
6-MWT (metres)	47.2 (50.6)	-3.5 (32.7)	164.1
(128.7)*	39.8 (55.4)*		
BI	16.3 (14.2)	1.5 (11.6)	32.3
(24)*	3.8 (8.3)		

Effect Size

See above

Source of funding:

No declarations of interest reported. It was funded by the Irish Heart Foundation and the Medical Research Charities Group and an unrestricted grant from the

Does the study answer the question?/Further Comments

It did not fully answer the review question. It is the family added part that this study is focusing on rather than the Additional family-mediated exercise therapy has a significant impact on recovery after acute stroke.

Kim CM;Eng JJ;MacIntyre DL;Dawson AS;

Effects of isokinetic strength training on walking in persons with stroke: a double-blind controlled pilot study

Ref ID 1609

RID:

806

2001 Nov

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Double blind (subject and researcher) study; stratified randomisation; unclear allocation concealment; intention-to-treat analysis not mentioned

DETAILS

of patients:

20 participants included in the study; 10 in each group

Prevalence (Diagnostic):

Patient Characteristics

community-dwelling chronic stroke survivors, with residual unilateral weakness; aged 50 years or older; history of a single stroke at least 6 months before participating in the study; ability to walk independently for a minimum of 40 metres with rest intervals with or without assistive device; achievement of a minimum of stage 3 for the leg and foot on the Chedoke-McMaster Stroke Assessment.

	Experimental	Control
	Mean (SD)	Mean (SD)
Age (yr)	60.4 (9.5)	61.9 (7.5)
Time since stroke (yr)	4.9	3.3
Gender (M/F)	7/3	7/3
Mobility aid (cane/none)	3/7	4/6
Chedoke-McMaster (stage range)	3-6	3-6
MAS* (grade range)	0-2	0-2

*Modified Ashworth Scale

Interventions/ Test/ Factor being investigated	Maximal isokinetic strengthening with an isokinetic dynamometer consisting of three 45-minute sessions per week for 6 consecutive weeks for a total of 18 sessions									
Comparisons	The same as intervention except the resisted contractions replaced with passive range of motion movements.									
Length of Study/ Follow-up										
Outcome measures studied	Self-selected gait speed (m/s); Maximal gait speed (m/s)									
Results	<p>Mean change scores for the experimental and control groups (N=10 per group)</p> <table border="0" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th style="text-align: center;">Experimental grp</th> <th style="text-align: center;">Control group</th> </tr> </thead> <tbody> <tr> <td>Self-selected gait speed (m/s)</td> <td style="text-align: center;">0.04±0.13</td> <td style="text-align: center;">0.09±0.07</td> </tr> <tr> <td>Maximal gait speed (m/s)</td> <td style="text-align: center;">0.05±0.09</td> <td style="text-align: center;">0.07±0.08</td> </tr> </tbody> </table> <p>Values reported as mean±1 standard deviation.</p>		Experimental grp	Control group	Self-selected gait speed (m/s)	0.04±0.13	0.09±0.07	Maximal gait speed (m/s)	0.05±0.09	0.07±0.08
	Experimental grp	Control group								
Self-selected gait speed (m/s)	0.04±0.13	0.09±0.07								
Maximal gait speed (m/s)	0.05±0.09	0.07±0.08								
Effect Size										
Source of funding:	Not stated									
Does the study answer the question?/Further Comments	Authors concluded that the intervention aimed at increasing strength did not result in improvement in walking. Strength training in conjunction with other task-related training may be indicated.									

Langhammer B;Lindmark B;Stanghelle JK;

Stroke patients and long-term training: Is it worthwhile? A randomized comparison of two different training strategies after rehabilitation

Ref ID 615

RID:

276

2007 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation done by a die (odd numbers to intensive exercise and even to regular exercise groups); intensive group had 22 days in hospital versus control group 16 days ($p=0.03$) which could bias in favour of the intervention
Patients informed that some would get intensive physical therapy and others routine physical therapy but all were encouraged to maintain a high activity level and were tested at discharge and at 3, 6 and 12 months
3/35 did not complete intensive exercise in hospital; 5/40 did not complete regular exercise in hospital. Intensive group: no further dropouts; regular group: 2/35 dropped out by 3 months and further 2/33 by 6 months; no more by 12 months
3/35 (8.6%) in intensive group and 9/40 (22.5%) in regular group. Possibility that more dropouts in regular group (6 died, 3 withdrew compared with 1 dead and 1 withdrawal in intensive group) could have biased in favour of intervention

Inadequate randomisation/allocation concealment by die; baseline differences between groups, e.g. duration of hospital stay longer in intensive treatment group ($p=0.03$); all participants told about the importance of exercise and tested at discharge, 3, 6 and 12 months (regular exercise group engaged in higher than expected levels of self-directed exercise, possibly due to test occasions and regular contact with physiotherapists); power calculation and adequate sample size

DETAILS

of patients:

35 in intensive exercise group; 40 in regular exercise group

Prevalence (Diagnostic):

Patient Characteristics	Variable	Intensive exercise	Regular exercise	P
	Mean age	76 (12.7)	72 (13.6)	
	Lesion side R/L	19/16	19/21	
	Mean days in hospital	22	16	0.03
Interventions/ Test/ Factor being investigated	intensive physical therapy with special emphasis on endurance (e.g. treadmill, stationary bike), strength (e.g. sit ups, push ups, weight lifting, stairs) and balance (e.g. walking on uneven surface, dancing, Tai Chi); total treatment period at least 80 hours (minimum 20 hours every third month for the first year after discharge; 2-3 times per week if at home or attending private physio practice or daily if in rehabilitation ward) aiming to improve and maintain motor function, activities of daily living and grip strength			
Comparisons	regular exercise in accordance with routine in the community if required (i.e. some patients would have no follow up treatment) assessed by staff at stroke unit/rehabilitation department or rehabilitation team in the community			
Length of Study/ Follow-up	1 year			
Outcome measures studied	Motor Assessment Scale, Barthel Index of Activities of Daily Living (BI), grip strength using Martin vigormeter (primary or secondary outcome not stated)			
Results	<p>Intensive exercise group:</p> <p>Outcome: post-treatment ; 3months ; 6months ; 1yr</p> <p>Barthel Index: 75.5 (30.6) ; 82.96(26.4) ; 84.5 (23.9) ; 80.8 (29.5)</p> <p>Grip strength paretic hand: 0.40 (0.34) ; 0.46 (0.34); 0.55 (0.42); 0.63 (0.46)</p> <p>Grip strength non-paretic hand: 0.62 (0.28); 0.68 (0.29); 0.77 (0.35); 0.87 (0.40)</p> <p>Control group:</p> <p>Outcome: post-treatment ; 3months ; 6months ; 1yr</p> <p>Barthel Index : 75.8 (30.4) ;87.6 (21.5) ; 91.2 (19.9); 87.7 (27.8)</p> <p>Grip strength paretic hand: 0.48 (0.29); 0.54 (0.39); 0.55 (0.41); 0.67 (0.43)</p> <p>Grip strength non-paretic hand: 0.73 (0.27); 0.79 (0.31); 0.81 (0.31); 0.99 (0.32)</p>			
Effect Size				
Source of funding:	not stated			
Does the study answer the question?/Further Comments	control group (unexpectedly) undertook the same amount of exercise as intervention group and no differences found on any measures after discharge			

Moreland JD;Goldsmith CH;Huijbregts MP;Anderson RE;Prentice DM;Brunton KB;O'Brien MA;Torresin WD;

Progressive resistance strengthening exercises after stroke: a single-blind randomized controlled trial

Ref ID 4899

RID:

263

2003 Oct

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

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Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Appropriate randomisation and allocation concealment; power calculation and adequate sample size; stratification for major confounder (admission Disability Inventory) and stage of recovery of the foot; groups comparable at baseline apart from control group patients more likely to have had prior stroke (34% vs. 15%); 93% data at 4 weeks; 89% at discharge (mean around 7 weeks) and 80% at 6 months; intention to treat analysis; intervention exercises equivalent apart from use of weights in intervention group.

DETAILS

of patients: 68 intervention + 65 control

Prevalence (Diagnostic):

Patient Characteristics

Patient characteristics:

	Intervention	Control
mean age	69.1 (14.8)	72.0 (12.1)
male: female	39:29	42:23
left:right: bilateral	27:35:5	31:27:6
previous stroke	10 (15%)	22 (34%);
days from stroke to admission	36.8 (27.8)	38.1 (25.6)
CMSADI*	47.2 (14.6)	50.5 (14.7)
FIM	72.6 (21.9)	76.3 (21.9)

*Chedoke-McMaster Stroke Assessment Disability Inventory

Interventions/ Test/ Factor being investigated	Strength training: Progressive resistance exercises with weights at waist or on lower extremities; use of ankle exerciser to which variable weights applied; 30 minute exercise sessions (2 sets of 10 repetitions) 3 times a week. Control group exercises same as for experimental group but without the weights. Both in addition to multidisciplinary treatment including conventional physical therapy without weights or other resistance equipment																																								
Comparisons	Strength training vs. control																																								
Length of Study/ Follow-up	4 weeks; at discharge (mean 6.6 weeks, range 0.3-20.3 weeks for intervention group and 6.9 weeks, range 1.3-27.0 weeks for controls); and at 6 months																																								
Outcome measures studied	1ry: rate of change of gross motor function and walking at discharge (CMSADI, 2 Min Walk Test). 2ry: 4 weeks: same + muscle tone (Modified Ashworth Scale); discharge: adverse effects; 6 mo: gross motor function, walking, residence																																								
Results	<p>Intervention group:</p> <table border="0"> <tr> <td></td> <td>4wk</td> <td>discharge</td> <td>6mths</td> </tr> <tr> <td>2MWT (m):</td> <td>41.19 (40.37)</td> <td>46.63 (38.20)</td> <td>58.57 (52.74)</td> </tr> <tr> <td>CMSADI(points):</td> <td>60.17 (15.08)</td> <td>63.92 (16.90)</td> <td>69.85 (20.52)</td> </tr> </table> <p>Percentage of sessions reporting adverse effects:</p> <table border="0"> <tr> <td>pain or stiffness (mean)</td> <td>4.44</td> </tr> <tr> <td>other adverse effects</td> <td>2.72</td> </tr> </table> <p>Adverse effects dichotomised:</p> <table border="0"> <tr> <td>pain or stiffness</td> <td>14/68</td> </tr> <tr> <td>other adverse effects:</td> <td>8/68</td> </tr> </table> <p>Control group:</p> <table border="0"> <tr> <td></td> <td>4wks</td> <td>discharge</td> <td>6months</td> </tr> <tr> <td>2MWT(m)</td> <td>45.35 (38.76)</td> <td>51.72 (41.35)</td> <td>63.18 (49.07)</td> </tr> <tr> <td>CMSADI(points):</td> <td>61.95 (17.09)</td> <td>65.53 (17.27)</td> <td>70.56 (21.30)</td> </tr> </table> <p>Percentage of sessions reporting adverse effects:</p> <table border="0"> <tr> <td>pain or stiffness</td> <td>1.63</td> </tr> <tr> <td>other adverse effects</td> <td>0.83</td> </tr> </table> <p>Adverse effects dichotomised:</p> <table border="0"> <tr> <td>pain or stiffness</td> <td>8/65</td> </tr> <tr> <td>other adverse effects:</td> <td>3/65</td> </tr> </table> <p>No statistically significant between-group differences</p>		4wk	discharge	6mths	2MWT (m):	41.19 (40.37)	46.63 (38.20)	58.57 (52.74)	CMSADI(points):	60.17 (15.08)	63.92 (16.90)	69.85 (20.52)	pain or stiffness (mean)	4.44	other adverse effects	2.72	pain or stiffness	14/68	other adverse effects:	8/68		4wks	discharge	6months	2MWT(m)	45.35 (38.76)	51.72 (41.35)	63.18 (49.07)	CMSADI(points):	61.95 (17.09)	65.53 (17.27)	70.56 (21.30)	pain or stiffness	1.63	other adverse effects	0.83	pain or stiffness	8/65	other adverse effects:	3/65
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Effect Size																																									
Source of funding:	Heart and Stroke Foundation of Ontario																																								
Does the study answer the question?/Further Comments	Progressive resistance exercises as applied in this study, to patients less than 6 months post-stroke and stages 3-5 on leg recovery on the CMSA, for 30 minutes 3 times a week for around 7 weeks, was no more effective than control exercises (for the same duration but without weights) on gross motor function (CMSA Disability Inventory) or walking (2 minute walk test), or secondary outcomes at 4 weeks, discharge or 6 months follow up.																																								

Ouellette MM;LeBrasseur NK;Bean JF;Phillips E;Stein J;Frontera WR;Fielding RA;

High-intensity resistance training improves muscle strength, self-reported function, and disability in long-term stroke survivors

Ref ID 1161

RID:

805

2004 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Patients recruited through local newspaper advertisements and through referrals from a local volunteer database and stroke support network; unclear randomisation; unclear allocation concealment; unclear blinding; no significant differences between groups at baseline; 5 (12%) loss to follow-up

DETAILS

of patients:

A total of 42 patients; 21 in the Progressive Resistance Training (PRT); 21 in the control group

Prevalence (Diagnostic):

Patient Characteristics

Patients aged ≥ 50 years; 6 months to 6 years following a single unilateral mild to moderate stroke with residual lower extremity hemiparesis, community dwelling; independent ambulation with or without an assistive device; report of 2 or more limitations on the physical function subscale (PF 10) of the Medical Outcomes Survey Short-Form and ability to travel to exercise laboratory.

Baseline characteristics

Variables	PRT (n=21)	Control (n=21)
Age (y)	65.8 (2.5)	66.1 (2.1)
Time since stroke (mo)	31.8 (8.3)	25.6 (4.0)
Range	6-60	7-71
Stroke severity*	2.95 (0.1)	2.97 (0.2)

Range	2-4.4	2-4.4
Assisstive device use	12	14

Data represent mean (SE); *Orpington Prognostic Scale: mild, <3.2; moderate, 3.2 to 5.2.

Interventions/ Test/ Factor being investigated

Progressive Resistance Training: Subjects performed seated bilateral leg press (LP), unilateral paretic and non-paretic limb knee extension (KE), unilateral ankle dorsiflexion (DF), and planterflexion (PF) 3 times per week for 12 weeks.

Comparisons

Bilateral range of motion (ROM) and upper body flexibility exercises performed 3 times per week

Length of Study/ Follow-up

Outcome measures studied

Six-minute walk (min); Habitual Gait Velocity (m/sec); Maximal Gait Velocity (m/sec)

Results

Physical Performance	Baseline	Week 12
Six-Minute Walk (min)		
PRT (n=21)	217.1 (30.5)	239.1 (30.3)
Control (n=21)	221.0 (34.0)	234.8 (36.9)
HGV* (m/sec)		
PRT (n=21)	0.65 (0.08)	0.64 (0.08)
Control (n=21)	0.59 (0.08)	0.64 (0.09)
MGV** (m/sec)		
PRT (n=21)	0.84 (0.10)	0.86 (0.11)
Control (n=21)	0.81 (0.11)	0.87 (0.12)

*Habitual Gait Velocity; **Maximal Gait Velocity

Effect Size

Source of funding:

Funding from The Jacob and Valeria Langeloth Foundation

Does the study answer the question?/Further Comments

Authors concluded that high-intensity PRT improves both paretic and nonparetic lower extremity strength after stroke, and results in reductions in functional limitations and disability.

Winstein CJ;Rose DK;Tan SM;Lewthwaite R;Chui HC;Azen SP;

A randomized controlled comparison of upper-extremity rehabilitation strategies in acute stroke: A pilot study of immediate and long-term outcomes

Ref ID 746

RID:

282

2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: randomised, adequate allocation concealment

Weaknesses: unblinded, loss to follow up

DETAILS

of patients:

N=64 N=21 to standard care ; N=22 to Functional-Task Practice ; N=21 to Strength training

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: 1st time stroke from infarction in the anterior circulation confirmed by MRI or computed axial tomography scan; onset of stroke from 2 to 35 days before study entry; FIM total score at admission of 40-80

Exclusions: peripheral nerve or orthopaedic conditions that interfered with arm movement; cardiac disease that limited function by exertional dyspnea, angina or severe fatigue; subarachnoid hemorrhage without evidence of infarction, progressive hydrocephalus, previous history of brain injury, severe aphasia, neglect, agitation or depression that could limit participation.

Baseline characteristics:

Parameter standard care ; functional training ; strength training

Gender

Men 12(60) ; 9(45) ; 12(60)

Women 8(40) ; 11(55) ; 8(40)

Age group

<35 2(10); 0(0) ; 0(0)

35-75 18(90) ; 19(95) ; 20(100)

>=75	0(0)	; 1(5)	; 0(0)
Type of stroke			
Ischemic	16(84)	; 16(84)	; 19(100)
Intracerebral hemorrhage	3(169)	; 3(16)	; 0(0)
Subarachnoid hemorrhage	0(0)	; 0(0)	; 0(0)
Time since onset (d)	15.4(5.5)	; 15.5(6)	; 17.3(10.6)
Orpington Prognostic Scale			
Less severe (1.6-4.1)	14(70)	; 12(60)	; 14(70)
More severe (4.2-6.8)	6(30)	; 8(40)	; 6(80)
Upper extremity Fugl-Meyer			
ROM	23.25(1.21)	; 23.6(0.82)	; 22.55(2.39)
Pain	22.4(2.5)	; 22.4(2.09)	; 21.65(3.33)
Sensory	9.95(3.65)	; 8.6(4.1)	; 9.6(3.72)
Motor function	23.55(22.31)	; 18.7(16.4)	; 19.85(49.56)

Interventions/ Test/ Factor being investigated

Standard care: delivered primarily by an occupational therapist and could include muscle facilitation exercises emphasising the neurodevelopmental treatment approach, neuromuscular electric stimulation applied primarily for shoulder subluxation, stretching exercises, activities of daily living including self-care where the upper limb was used as an assist if appropriate, and caregiver training. Task-specific functional training focused on the systematic and repetitive practice of tasks that could be performed within the level of available voluntary motion. Tasks were progressively arranged and customised to account for any unique proximal-to-distal recovery patterns of reaching and grasping actions. All tasks were designed to be standard, repeatable and to have some functional goal. The principle of motor learning were applied as the physical therapists systematically provided knowledge of results and progressed task difficulty to keep the participants challenged, motivated and engaged. Doable tasks were ordered randomly during practice to facilitate learning and to mini real-world activities. Strength training group: strengthening and motor control training using resistance to available arm motion to increase strength. This program was implemented on alternate days for 3 days a week; on other days, the same exercises were performed with less resistance and at greater speeds.

Comparisons

strength training and functional task practice interventions vs standard care

Length of Study/ Follow-up

posttreatment (4-6weeks post randomisation) and 9 months post randomisation

Outcome measures studied

Primary: upper extremity portion of Fugl-Meyer score (FM); isometric torque at shoulder, elbow, wrist; grip and pinch force; Functional Test of the Hemiparetic Upper Extremity (FTHUE). Secondary: self-care and mobility portions of FIM

Results

Results
Posttreatment change from baseline scores: All evaluable patients
Characteristics ; SC ; ST; Overall gp differences P value
Upper extremity Fugl-Meyer
ROM -0.6 ±1.93 ; -0.75±2.00; 0.14
Pain -0.6±1.79 ; -0.70±2.30; 0.36
Sensory 0.75±1.33 ; 1.30±2.23; 0.35
Motor Function^ 9.05±7.6 ; 18.20±13.54; 0.08
FIM Mobility 14.40±7.58; 15.00±7.14; 0.86
FIM self-care 17.00±5.17; 16.15±5.81; 0.74
^normalising log-transformations

Subgroup analysis: Posttreatment change from baseline scores: less severe Orpington Prognostic Scale (OPS) score
Characterisitcs SC ; ST; p value
Upper extremity Fugl-Meyer
ROM -0.29±1.33 ; -0.43±1.40; 0.16
Pain -0.36±1.86 ; -0.29±2.27; 0.55
Sensory 0.43±1.09 ; 0.50±1.09; 0.61
Motor function^ 9.36±8.05 ; 21.71±14.44; 0.02 (each intervention p<0.05 vs. control)
^normalising log-transformations
FIM Mobility 15.79±7.11; 15.64±4.63;

	0.79		
FIM self-care	17.00±4.37;	17.50±5.73;	0.50
Long term change from posttreatment to 9 months scores: all evaluable patients			
Characterisitcs	; SC	; ST	; p value
Upper extremity Fugl-Meyer			
ROM	-0.33±1.45	-2.13±2.96	0.10
Pain	-1.0±2.88	-1.19±4.00	0.83
Sensory	0.07±1.03	0.25±0.68	0.66
Motor function	8.33±11.26	5.38±9.11	0.30
FIM mobility	5.67±5.47	2.44±1.82	
	0.61		
FIM self-care	6.07±4.62	2.75±4.34	0.39
Long term change from posttreatment to 9 months scores: less severe OPS scores			
Characterisitcs	; SC	; ST	; p value
Upper extremity Fugl-Meyer			
ROM	-0.64±1.29	-1.58±3.06	
	0.44		
Pain	-1.0±2.86	-1.42±4.06	0.83
Sensory	-0.18±0.75	0.17±0.58	0.52
Motor function	4.82±6.93	2.08±3.70	
	0.07		
FIM mobility	4.18±5.42	2.92±1.38	
	0.92		
FIM self care	6.00±4.34	2.92±3.58	0.21

Effect Size

Source of funding:

National institute of Child Health and Human Development, Foundation for Physical Therapy

Does the study answer the question?/Further Comments

Compared with standard care participants, those in the functional task practice and strength training groups had significantly greater increases in Fugl-Meyer motor scores (p=0.04) posttreatment. Treatment benefit was primarily in the less severe participants, where improvement in FT and ST group Fugle-Meyer motor scores more than doubled that of the SC group. The authors concluded that task specificity and stroke severity are important factors for rehabilitation of arm use in stroke. An additional 20 hours of therapy specific to the upper extremity and distributed over 4 to 6 weeks positively influenced both immediate and long term outcomes only for the less evere cohort. The immediate benefits of a functional task approach were similar to those of a resistance-strength approach, however the former was more beneficial in the long term.

Question: What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?

Study Type	Randomised Controlled Trial
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Kagan A;Black SE;Duchan FJ;Simmons-Mackie N;Square P;

Training volunteers as conversation partners using 'Supported Conversation for Adults with Aphasia' (SCA): a controlled trial

Ref ID 563

RID:

296

2001 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Intervention group had more severe aphasia; aphasia quotient used as covariate in analysis

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction = post-treatment only; no follow up. Some caveats about the reliability/validity of the assessment tool

Overall Study Quality -Strengths and Weaknesses:

Block randomisation of 10 volunteers at a time to experimental or control groups. Patients in intervention group had more severe aphasia; aphasia quotient used as covariate in analysis. Post-treatment only; no follow up. Some caveats about the reliability/validity of the assessment tool

DETAILS

of patients:

40 patients with aphasia + 40 volunteers (i.e. 40 dyads, 20 in experimental and 20 in control group)

Prevalence (Diagnostic):

Patient Characteristics	Volunteers recruited from applicants accepted for training at Aphasia Centre; inclusion: proficient English speakers; exclusion: previous experience with neurogenic population or programmes similar to study programme. 87% female, 75% less than 30 years old, 70% students. Participants with aphasia: inclusion: moderate-to-severe (preferably severe) aphasia; ability to engage in conversation at some level (using some or all of verbal, gestural, written, drawn modalities); at least 1 year post-stroke; clinically verified focal lesion(s); premorbidly competent in English; exclusion: deteriorating neurogenic disorder (e.g. dementia), severe behavioural or psychiatric problems, progressive aphasia. 63% male, mean age 70 (SD 11) years, mean time post onset 58 (SD 40) months, range 12-178 months.
Interventions/ Test/ Factor being investigated	"Supported Conversation for Adults with Aphasia": how to acknowledge and reveal the competence of adults with aphasia, e.g. keeping talk as natural as possible, avoiding being patronising, ensuring understanding, allowing person to express knowledge, thoughts and feelings, verifying, using gesture, writing and drawing
Comparisons	Intervention group (volunteers had training in SCA techniques) versus control (volunteers without such training)
Length of Study/ Follow-up	Post-test only
Outcome measures studied	Measure of Skill in Providing Supported Conversation for Adults with Aphasia (MSCA); Measure of Participation in Conversation for Adults with Aphasia (MPCA)
Results	MSCA acknowledge competence: pre: intervention: 1.9 (0.6); control 1.7 (0.8) post: intervention: 2.6 (0.7); control: 1.5 (0.8) MSCA reveal competence: pre: intervention: 0.7 (0.4); control: 0.6 (0.3) post: intervention: 2.7 (0.6); control: 0.7 (0.4) MPCA interaction: pre: intervention: 2.2 (0.9); control: 2.3 (0.9) post: intervention: 2.6 (0.9); control: 2.2 (0.9) MPCA transaction: pre: intervention: 1.9 (0.9); control 2.0 (0.8) post: intervention: 2.7 (0.8); control: 2.0 (0.8)
Effect Size	
Source of funding:	Health Canada grant
Does the study answer the question?/Further Comments	Training volunteers as conversational partners improved ratings of both the volunteers' acknowledgement and revelation of competence of patients with aphasia, and also improved ratings of patients' participation in the conversation in terms of interaction (social connection) and transaction (exchange of content: information, opinions or feelings) even though they had not had any direct intervention.

Worrall L;Yiu E;

Effectiveness of functional communication therapy by volunteers for people with aphasia following stroke

Ref ID 1491

RID:

327

2000

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = differential attrition meant that groups not comparable on aphasia severity (group A better)

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

10 patient pairs matched for aphasia quotient, then randomised to group A or B, however, differential attrition meant that groups at baseline not comparable on aphasia quotient and only 6 and 8 patients in groups A and B respectively. Randomisation and allocation concealment not stated. Blinded assessment of outcomes.

DETAILS

of patients: 20 randomised

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: chronic aphasia due to stroke in language dominant hemisphere; at least 12 months post-onset; discontinued speech therapy at least 1 month before study, living at home, in retirement village or hostel; difficulty in daily communication; had a spouse, relative or friend as a carer; spoke English.
Exclusion: dementia, severe hearing or visual loss or other neurological disease.
Mean age: group A: 59.3 years, group B: 67.9 years
Mean months post-onset: group A: 60, group B 36.5
Mean Aphasia Quotient: group A: 60.1, group B: 45.6

Interventions/ Test/ Factor being investigated

Functional communication therapy programme (Speaking Out) delivered by trained volunteers in patient's home, focusing on strategies to improve communication activities (more about getting task done than speech therapy as such, e.g. paying bills directly from bank account, using multi-trip bus tickets).

Comparisons

Compared to non-verbal recreation programme

Length of Study/ Follow-up	Crossover study: 10 weeks Speaking out or recreation; 10 weeks washout; 10 weeks alternative programme; 10 weeks washout
Outcome measures studied	Western Aphasia Battery (WAB), American Speech-Language Hearing Association Functional Assessment of Communication Skills (ASHA FACS), Communication Effectiveness Index (CETI), Functional Communication Therapy Planner (FCTP), Short Form-36 (SF-36).
Results	Mann-Whitney U test showed no significant differences between groups comparing Speaking Out period versus recreational period on any measure except 1 subscale of the 8 subscales of the SF-36 at $p=0.03$ (authors state that SF-36 not a good indicator of change in this population)
Effect Size	
Source of funding:	Australian National Heart Foundation
Does the study answer the question?/Further Comments	The programme appeared to be more focused on strategies to achieve activities than on speech therapy as such (e.g. paying bills directly from bank account, using multi-trip bus tickets). Only 14 patients completed the study and differential attrition meant the groups may not have been comparable despite paired randomisation. There were no differences between the groups on measures specific to aphasia comparing periods when they received the programme or a non-verbal recreational activity; means and standard deviations were not provided.

Question: In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?

Study Type	Randomised Controlled Trial
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Barry JG;Ross SA;Woehrlé J;

Therapy incorporating a dynamic wrist-hand orthosis versus manual assistance in chronic stroke: a pilot study

Ref ID 16934 **RID:** 1006 2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** 3 pieces of paper for each group in an opaque envelope for participant to select: could bias in either direction

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** impossible to blind to intervention; single blind (testers blind to group assignment)

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias **Direction =** assessment at end of 6-week intervention only; no follow up

Overall Study Quality -Strengths and Weaknesses:

Inadequate randomisation and allocation concealment;assessment at end of 6-week intervention only; no follow up; no sample size calculation (small sample size, underpowered)

DETAILS

of patients: n=22 randomised: 11 dynamic wrist-hand orthosis (WHO) group and 11 manual assisted therapy (usual care)

Prevalence (Diagnostic):

Patient Characteristics	Inclusion: 6 or more months post-stroke; age 21 years or older; 15 or more degrees of active shoulder elevation, 15 or more degrees of active elbow flexion, 15 or more degrees of passive wrist extension with relative finger extension, ability to actively flex digits into 25% of fist position. Exclusion: ability to grasp and release a 7.6cm diameter ball, botulinum toxin injections to paretic upper limb in previous 12 weeks, swan neck deformities of the fingers of the hemiparetic upper extremity, history of frequent or current skin breakdown on the hemiparetic upper extremity, severe aphasia, cognitive impairment determined by Mini-Mental State Examination Score <17/30. Gender: WHO group: 4 male, 6 female; MAT group: 6 male, 3 female. Mean (SD) age (years): WHO group: 52.7 (16.1) range 23-79 years; MAT group: 50.3 (7.5) range 40-60 years. Time since stroke onset: WHO group: 4.1 (2.3) range 1.25 to 7.25 years; MAT group: 5.1 (5.7) range 0.67 to 15 years. Community
Interventions/ Test/ Factor being investigated	Wrist-hand orthosis (WHO) group: SaebFlex dynamic wrist-hand orthosis (WHO) worn for most of the session grasping and releasing 7.6cm balls
Comparisons	WHO versus Manual-assisted therapy (MAT) group: Manual assistance given by therapist for grasp and release. Both groups received therapy for 1 hour once a week for 6 weeks (passive stretching and weight-bearing, then 45 minutes on reaching toward targets while grasping and releasing balls) and were instructed to perform a home exercise program (HEP) 2 times per day on 4 days per week for 6 weeks (upper extremity weight bearing and grasp and release tasks)
Length of Study/ Follow-up	Assessment at end of 6 week intervention; no follow up
Outcome measures studied	Outcome measures (none defined as primary): grip strength (dynamometer), Box and Blocks (B&B) test, Action Research Arm Test, Stroke Impact Scale
Results	Mean (SD) change grip (kg): WHO -1.1 (1.7) NS vs. t1; MAT 0.0 (2.7) NS vs. t1; NS Mean (SD) change in SIS (strength) score: WHO group: 2.1 (9.5) n=10, NS vs. baseline; MAT group: 9.3 (17.1) n=9, NS vs. baseline; not significantly different between groups. Mean (SD) change in SIS (arm use) score: WHO group: 9.3 (18.2) n=10, NS vs. baseline; MAT group: 4.4 (8.5) n=9, NS vs. baseline; NS SIS (% recovery) score: WHO group: 2.0 (14.4) n=10, NS vs. baseline; MAT group: 15.6 (17.8) n=9, NS vs. baseline; NS
Effect Size	Mean (SD) change ARAT: WHO 2.2 (3.3) n=10, p=0.04 vs. baseline (t1); MAT 1.4 (2.5), n=9, p=0.08 vs. t1; NS btwn gps. Mean (SD) change B&B: WHO 1.6 (3.7) NS vs. t1; MAT 1.0 (2.7) n=9, NS vs. t1; NS
Source of funding:	Missouri Physical Therapy Association, Greater St, Louis Health Foundation
Does the study answer the question?/Further Comments	no significant difference between the groups on any of the measures; study underpowered

Basaran A;Emre U;Karadavut K;Balbaloglu O;Bulmus N;

Hand splinting for poststroke spasticity: A randomized controlled trial

Ref ID 16936

RID:

1008

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = Computer-generated random numbers; Independent randomisation and group assignment

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction = Single blind (measurements of electroneuromyography blinded but other measurements not)

Overall Study Quality -Strengths and Weaknesses:

Adequate randomisation and group assignment; single blind (measurements of electroneuromyography blinded but other measurements not); sample size calculation: 33 patients (11 per group) calculated to achieve 81% power and 5% significance level to detect a 0.5 point difference among groups with 1 point SD on the MAS; baseline characteristics similar

DETAILS

of patients:

n=39; dorsal splint 13; volar splint 13, control 12

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: history of single stroke and wrist MAS score $\geq 1+$; if taking antispasticity drugs, dosage had to be stable during previous month. Exclusion: cognitive impairment determined by Mini-Mental State Examination, behavioural disturbances, severe chronic disease likely to interfere with cooperation, cutaneous or joint pathologies in upper limb preventing splinting, previous splinting for upper limb in last 8 weeks. Gender: Dorsal splint: 8 male, 5 female; Volar splint: 7 male, 6 female; No splint (control group) 7 male, 5 female. Mean (SD) age (years): Dorsal splint: 52.0 (11.2) range 35-81; Volar splint: 54.9 (12.3) range 26-68; No splint (control group): 59.9 (10.1) range 49-76. Time since stroke onset: Dorsal splint: 33.5 (19.1) months range 5-72; Volar splint: 39.8 (21.2) months range 11-84; No splint (control group): 40.5 (34.7) months range 6-120. Inpatients

Interventions/ Test/ Factor being investigated

Dorsal splint worn for up to 10 hours overnight for 5 weeks or Volar splint worn for up to 10 hours overnight for 5 weeks

Comparisons	Dorsal or volar splint versus control (no splint). All patients had home exercise program including motor training and stretching, reaching and grasping 3 times a day and advised to use hands as much as possible during the day for 5 weeks
Length of Study/ Follow-up	assessment at end of 5-week intervention; no follow up
Outcome measures studied	Primary: spasticity assessed clinically by Modified Ashworth Scale and electrophysiologically (H latency and Hmax:Mmax ratio of flexor carpi radialis) Secondary: passive range of motion (PROM) of wrist extension (goniometer)
Results	Mean (SD) change in H latency pre-treatment to 5 weeks: Dorsal splint 0.26 (2.05) n=13 NS vs. baseline; Volar splint: 0.13 (2.51) n=13 NS vs. baseline; No splint (control group): 0.05 (0.73) n=12 NS vs. baseline; NS between groups. Mean (SD) change in Hmax:Mmax ratio pre-treatment to 5 weeks: Dorsal splint -0.05 (0.08) n=13 NS vs. baseline; Volar splint: -0.035 (0.07) n=13 NS vs. baseline; No splint (control group): -0.01 (0.03) n=12 NS vs. baseline; NS between groups. Mean (SD) change in wrist extension PROM pre-treatment to 5 weeks: Dorsal splint 2.31 (8.07) n=13 NS vs. baseline; Volar splint: 3.46 (7.18) n=13 NS vs. baseline; No splint (control group): 0.42 (4.5) n=12 NS vs. baseline; NS between groups
Effect Size	Mean (SD) change in MAS score pre-treatment to 5 weeks: Dorsal splint -0.15 (0.55) n=13 NS vs. baseline; Volar splint: -0.15 (0.69) n=13 NS vs. baseline; No splint (control group): -0.17 (0.58) n=12 NS vs. baseline; NS between groups
Source of funding:	not stated
Does the study answer the question?/Further Comments	The study failed to demonstrate any significant differences in spasticity or passive range of motion between dorsal or volar splints and no splints.

Lannin NA;Cusick A;McCluskey A;Herbert RD;

Effects of splinting on wrist contracture after stroke: a randomized controlled trial

Ref ID 5010 **RID:** 503 2007 Jan

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Likely that the risk of performance bias is high.

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction = The follow up was 6 weeks. The investigators were blinded to participant's exposure.

Overall Study Quality -Strengths and Weaknesses:

The risk of selection bias was low (RCT with adequate sequence generation and allocation concealment). The risk of attrition and detection bias was also low, however the risk of performance bias was high as the study was unblinded (only outcome assessors were blinded), Participants were randomized in 3 equally sized groups; adequate allocation concealment (computer generated and concealed in opaque, consecutively numbered envelopes by a person not involved in the study). The three groups were comparable at the baseline.

DETAILS

of patients:

63 participants were randomized to 3 groups; 23 in each arm (prior calculation of sample size based on the statistical power of a sufficient sample to demonstrate a

Prevalence (Diagnostic):

Patient Characteristics

Adults who had a stroke within the previous 8 weeks and had no active wrist extension were included in the study. Mean age (sd) was 75.4 (11) for the control group, 70.3 (12.6) for the neutral splint group and 68.7 (12.1) for the extension splint group. In the sample women accounted for 57% of the control group, 52.3% for the neutral splint group and 42.8% for the extension splint group. The mean number of days poststroke to randomization ranged from 25 to extension splint group and 27.8 in neutral group to 30 days in the control group. The wrist extensibility in degrees (mean, sd): 56.2 (15) in the control group, 62.1 (16.4) in the neutral splint group and 56.8 (12.4) in the extension group.

Interventions/ Test/ Factor being investigated

2 interventions: two types of splints for 4 week period
1st intervention :neutral splint; participants wore a hand splint which positioned the wrist in 00 to 100 extension.
2nd intervention: extension splint: participants wore a hand splint, which positioned the wrist in a comfortable end-of-range position (>450 wrist extension) with the metacarpophalangeal and interphalangeal joints extended.
In both groups, custom made, static, palmar mitt splints for up to 12 hours overnight were used

Comparisons

Control group did not wear a hand splint for the study period.

Length of Study/ Follow-up

6 weeks

Outcome measures studied

- Primary outcome: Extensibility of the wrist and finger flexor muscles. Secondary measures (not specified in our protocol): upper limb function, spasticity, self reported disability and symptoms

Results

	Wrist extensibility in degrees (values are given as mean (sd))		
	Control (N=21)	Neutral splint (N=20)	Extended splint (N=21)
Baseline	56.2 (15)	62.1 (16.4)	56.8 (12.4)
4 weeks	47.3 (16.9)	53.1 (14.9)	45.5 (15.4)

6 weeks	39.4 (17.8)	48.8 (14.5)	42.5 (14.9)
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Effect Size

	Ancova adjusted estimates of effects (adjusted for baseline scores)		
	Control vs neutral	Control vs extended	
4 weeks	1.4 (-5.4 to 8.2)	-1.3 (-4.9 to 2.4)	
6 weeks	4.2 (-3.2 to 11.7)	0.8 (-3.4 to 5.1)	

Source of funding:

University of Western Sydney Postgraduate Research Award.

Does the study answer the question?/Further Comments

Yes, the population and intervention/control groups and outcomes were appropriate for our question. Results of this study showed that 4 weeks of overnight splinting in either neutral or extended wrist position does not prevent significantly loss of range of motion (measured by the angle or wrist extension) compared to control (no use of splint group) at 4 and 6 weeks after introducing the intervention.

Question: In people after stroke what is the clinical and cost-effectiveness of Functional Electrical Stimulation for hand function versus usual care?

Study Type	Randomised Controlled Trial
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Alon G;Levitt AF;McCarthy PA;

Functional electrical stimulation (FES) may modify the poor prognosis of stroke survivors with severe motor loss of the upper extremity: a preliminary study

Ref ID 4965

RID:

444

2008

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment not stated; small sample size; baseline characteristics similar; tested after intervention but no follow up.

DETAILS

of patients:

26 (FES 13, control 13)

Prevalence (Diagnostic):

Patient Characteristics	<p>Inclusion: Unilateral stroke 2-4 weeks ago; medically stable; paralysis/paresis of upper limb; Fugl-Meyer score 2-10; no limited range of passive motion; age 20-90; admitted for at least 1 week and actively engaged in rehab; forearm/hand size compatible with FES system; at least 60% finger flexion/extension with stimulation; understand and respond to commands.</p> <p>Exclusion: Implanted pacing/defibrillator device; unstable vital signs; potentially fatal arrhythmia; motor weakness due to lower motor neurone lesions of upper extremity; inability to sit in chair for 30 mins; receptive aphasia; comorbid neurological disease; shoulder subluxation; caregiver unable to help with training protocol; declined to be videotaped; MMSE 21 or lower.</p> <p>Baseline characteristics:</p> <table border="0"> <thead> <tr> <th></th> <th>FES</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Male:Female</td> <td>9:4</td> <td>5:8</td> </tr> <tr> <td>Side affected right:left</td> <td>9:4</td> <td>7:6</td> </tr> <tr> <td>Mean (SD) days since stroke onset</td> <td>17.4 (7.6)</td> <td>23.8 (10.9)</td> </tr> <tr> <td>Upper extremity Fugl-Meyer score</td> <td>4.0 (2.4)</td> <td>3.9 (2.6)</td> </tr> </tbody> </table>				FES	Control	Male:Female	9:4	5:8	Side affected right:left	9:4	7:6	Mean (SD) days since stroke onset	17.4 (7.6)	23.8 (10.9)	Upper extremity Fugl-Meyer score	4.0 (2.4)	3.9 (2.6)
	FES	Control																
Male:Female	9:4	5:8																
Side affected right:left	9:4	7:6																
Mean (SD) days since stroke onset	17.4 (7.6)	23.8 (10.9)																
Upper extremity Fugl-Meyer score	4.0 (2.4)	3.9 (2.6)																
Interventions/ Test/ Factor being investigated	<p>FES + individually tailored exercise regimen 30 minute sessions twice daily 5 days a week during hospitalisation; after discharge 30 mins twice daily without supervision; OT/physio 1-2 per week. Starts stimulation with 10 min sessions repeated 4 times (2 with exercise and 2 without); increased by 5 mins a day to 1 hour 4 times a day</p>																	
Comparisons	<p>Individually tailored exercise regimen 30 minute sessions twice daily 5 days a week during hospitalisation; after discharge 30 mins twice daily without supervision; OT/physio 1-2 per week.</p>																	
Length of Study/ Follow-up	<p>At end of 12 weeks of training only, no follow up</p>																	
Outcome measures studied	<p>Box & Blocks, light object subset of Jebsen-Taylor test; video-based modified Fugl-Meyer score</p>																	
Results		FES	Control	p value														
	Box & Blocks	10.5 (12.0)	2.5 (4.9)	0.058														
	Upper extremity Fugl-Meyer score	24.2 (13.7)	14.5 (10.3)	0.05														
	Jebsen-Taylor light object test (s)	40.5 (22.8)	52.9 (17.3)	0.012 (n=6 and 2)														
Effect Size																		
Source of funding:	<p>Bioness, Inc., Santa Clarita, CA.</p>																	
Does the study answer the question?/Further Comments	<p>These patients with a slow recovery profile showed a small benefit with FES on motor control, but all patients remained severely deficient in using their paretic hand. However, the study was small and had no follow up.</p>																	

Alon G;Levitt AF;McCarthy PA;

Functional electrical stimulation enhancement of upper extremity functional recovery during stroke rehabilitation: a pilot study

Ref ID 4966

RID:

445

2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Very small sample size; randomisation method and allocation concealment unclear; comparability of baseline characteristics unclear (e.g. ages of patients not given); tested at end of 12-week intervention but no follow up; amount of time patients exercised at home not monitored so compliance unknown.

DETAILS

of patients: total 15: 7 FES and 8 control

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Unilateral stroke 2-4 weeks ago (medically stable); paresis of upper limb; Fugl-Meyer score 11-40; no limited range of passive motion; age 20-90; admitted for at least 1 week and actively engaged in rehab; forearm/hand size compatible with FES system; at least 60% finger flexion/extension with stimulation; understand and respond to commands.
Exclusion: Implanted pacing/defibrillator device; unstable vital signs; potentially fatal arrhythmia; active reflex sympathetic dystrophy or motor weakness due to lower motor neurone lesions of upper extremity; inability to sit in chair for 30 mins; comorbid neurological disease; shoulder subluxation; caregiver unable to help with training protocol; declined to be videotaped; MMSE 21 or lower.
Baseline characteristics:

	FES	Control
Gender M:F	3:4	5:3
Affected side R:L	5:2	6:2
Stroke to study start (days)	18.0 (8.7)	15.6 (5.3)
Initial Fugl-Meyer	23.9 (7.4)	21.9 (7.5)

Interventions/ Test/ Factor being investigated	FES group had standard training (as for control) synchronised with electrical stimulation and induced contraction of wrist/finger extensors. Started with 10 mins 4 times daily with 2 sessions as part of exercise time and 2 not; duration increased by 5 mins per day to 1 hour sessions 4 times daily (2 x 30 mins synchronised with exercise and the rest not)
Comparisons	standard rehab: 3 hours physical, occupational (30 mins twice daily 5 days a week during hospitalisation) and speech therapy within 1-2 days of admission. After discharge, practised 30 mins twice daily unsupervised + 1-2 visits per week
Length of Study/ Follow-up	12 week intervention period only; no follow up
Outcome measures studied	Box and Blocks; light object lift subset of Jebsen-Taylor test; video-based modified Fugl-Meyer test; relative residual deficit in each outcome for paretic limb: Rd=100-(paretic/nonparetic x 100)

Results	FES	Control	p value	
	Box and Blocks (number of blocks):			
	Baseline	5.9 (6.0)	5.3 (6.2)	
	12 weeks	42.3 (16.6)	26.3 (11.0)	0.049
	Residual deficit (%)	27% (17%)	48% (18%)	0.06
	Effect size FES vs. control	1.18 (i.e. 18% more than control)		
	Jebsen-Taylor light object(s)			
	Baseline	47.5 (21.3)	50.9 (17.6)	
	12 weeks	6.7 (2.9)	11.8 (5.4)	0.049
	Rd (times paretic hand slower)	1.6 (0.6)	2.2 (0.9)	0.037
	Effect size FES vs. control	1.17 (i.e. 17% more than control)		
	Modified Fugl-Meyer:			
	Baseline	23.9 (7.4)	21.9 (7.5)	
	12 weeks	49.0 (5.1)	40.6 (8.2)	0.042
	Residual deficit (%)	7.7% (9.4%)	27.0% (15.2%)	0.042
	Effect size FES vs. control	1.23 (i.e. 23% more than control)		

Effect Size

Source of funding: Bioness, Inc Santa Clarita, CA.

Does the study answer the question?/Further Comments FES resulted in better functional recovery than task-related training alone, but sample size very small and other methodological weaknesses including no follow up after end of intervention so not known if effect sustained.

Cauraugh J;Light K;Kim S;Thigpen M;Behrman A;

Chronic motor dysfunction after stroke: recovering wrist and finger extension by electromyography-triggered neuromuscular stimulation

Ref ID 2068

RID:

442

2000

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment not stated; baseline characteristics not stated by group so cannot assess baseline comparability; very small sample size (total 11; 7 intervention + 4 control); outcomes measured at end of 2 week intervention (no follow up); outcome data not reported for several outcomes and only means shown graphically for others; no SDs given.

DETAILS

of patients:

total 11; 7 intervention + 4 control

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: 1 year or more post stroke; chronic upper extremity impairment. Upper limit cut-off of 75% motor recovery; lower limit: subjects had to be capable of voluntarily extending the wrist 20° against gravity from a 90° flexion position. Exclusion: Other neurological deficits; currently enrolled in rehabilitation. Baseline characteristics: 6 women + 5 men; mean age 61.64 years (SD 9.57); mean time after stroke 3.49 (2.56) years; 10 subjects had right hemisphere stroke. Not shown by group.

Interventions/ Test/ Factor being investigated

FES: subjects were instructed to initiate finger/wrist extension so that a target threshold of EMG activity was voluntarily achieved, which triggered the neuromuscular electrical stimulation to assist the muscles to reach a full range of motion. 2 treatment sessions of 30 movement trials (around 60 minutes) 3 days a week for 2 weeks.

Comparisons

The control group followed the same procedure as the experimental group except that they did not receive the neuromuscular electrical stimulation.

Length of Study/ Follow-up	Outcomes at end of 2 week intervention; no follow up.
Outcome measures studied	Box and Block test, Motor Assessment Scale, Fugl-Meyer test; 2 force-generation tasks: reaction time and sustained muscle contraction.
Results	<p>Box and blocks test: intervention group increased number of blocks moved (around 6.5 at baseline to 16 post-intervention) while control group remained the same (around 3.5 at baseline to 5 post-intervention), $p < 0.05$ (test session x group interaction accounted for 6% of the total variance). Data only shown graphically; no SDs.</p> <p>Motor Assessment Scale and Fugl-Meyer test reported as non-significant but no data reported.</p> <p>Reaction time not significant.</p> <p>Sustained muscle contraction task: intervention group increased mean impulse from around 3.4 to around 4.05; control group decreased from around 4.5 to around 2.2, $p < 0.04$ (test session x group interaction accounted for 7% of the total variance). Data only shown graphically; no SDs.</p>
Effect Size	
Source of funding:	Interdisciplinary Grant Award, Foundation for Physical Therapy
Does the study answer the question?/Further Comments	The authors suggest that FES for people with chronic stroke improved their ability to grasp small objects and sustain extensor contractions. However, this is a very small study with inadequate methodological quality and no usable data.

Cauraugh JH;Kim S;

Two coupled motor recovery protocols are better than one: electromyogram-triggered neuromuscular stimulation and bilateral movements

Ref ID 4974

RID:

452

2002

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment unclear; baseline characteristics not shown by treatment group so cannot assess baseline comparability; sample size too small (10 in each of 2 treatment groups + 5 controls); data not normally distributed so transformed and medians presented (with SDs which is inappropriate); outliers excluded which could introduce bias; some measures not equivalent at baseline (pre-test data used as covariate in ANCOVA analysis); results presented graphically with no SDs.

DETAILS

of patients:

25 in total: 10 in each of 2 treatment groups + 5 controls

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: At least one cerebrovascular accident and no more than 2 CVAs on the same side of the brain; upper limit cut-off of 80% motor recovery; lower limit: subjects had to be capable of voluntarily extending the fingers/wrist 10° against gravity from a 90° flexion position.
Exclusion: : Other neurological deficits or pacemaker; use of drugs for spasticity; currently enrolled in another motor recovery rehabilitation protocol.
Baseline characteristics: 21 men + 4 women; 13 left hemisphere and 12 right hemisphere stroke; mean length of time since stroke 39.1 months; mean age 63.7 years.

Interventions/ Test/ Factor being investigated

Unilateral training group: EMG-triggered stimulation to assist wrist and finger extension (unilateral movement).

Bilateral training group: EMG-triggered stimulation plus assistance from unimpaired limb as wrist/finger extension executed simultaneously on both limbs (bilateral movement).

3 sets of 30 successful EMG-triggered trials (around 1.5 hours); total of 6 hours of training on 4 days during 2 weeks.

Comparisons

Control group:
No FES but subjects tried to voluntarily extend wrist/fingers for 5 seconds followed by 25 seconds rest, repeatedly for 90 minutes per session.

Length of Study/ Follow-up

Tested at end of 2 weeks intervention only; no follow up.

Outcome measures studied

Box and Block test; reaction times; sustained muscle contraction.

Results Box and Block: control increased from 16 blocks at baseline to 17 blocks; unilateral 18 to 22 blocks; bilateral 20.5 to 27 blocks; all values read off graph; no SDs. Group x test session interaction $p < 0.04$.
Reaction time: Premotor component: bilateral: median 227ms (SD 34) faster than unilateral: median 255ms (SD 35) and control: 269ms (SD 35.2), $p < 0.01$. Motor component: bilateral: median 57ms (SD 25.9) and unilateral: median 63ms (SD 25.8); both faster than control: 95ms (SD 26), $p < 0.003$.
Sustained muscle contraction: transformed using median root mean square error and shown graphically only.

Effect Size

Source of funding: American Heart Foundation, Florida/Puerto Rico Affiliate.

Does the study answer the question?/Further Comments The authors concluded that bilateral and unilateral training improved motor function in patients with chronic stroke, with bilateral training being better. However, this is a very small study with serious methodological limitations and no usable data.

Chae J;Bethoux F;Bohine T;Dobos L;Davis T;Friedl A;

Neuromuscular stimulation for upper extremity motor and functional recovery in acute hemiplegia

Ref ID 16053 **RID:** 808 1998 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Patients were assigned to the treatment or placebo group by a computer generated random number table; 28 patients (39%) out of 46 stroke survivors completed the study; The treatment and control groups had comparable baseline characteristics; patients who were discharged before completing the treatment continued to receive the treatment at home under the supervision of a trained family member; Blinded evaluations of upper extremity-related motor function and disability were performed before treatment, after treatment, and at 4 and 12 weeks after treatment by trained physical and occupational therapists; high dropout rate (39%); intention-to-treat analysis not mentioned

DETAILS

of patients:

46 patients were randomised. 28 patients completed the study. 14 in the neuromuscular stimulation; 14 in the control group.

Prevalence (Diagnostic):

Patient Characteristics

Patients were 18yrs old or older with moderate to severe upper extremity paresis (Fugl-Meyer score less than 44).

Baseline Characteristics of Control and Neuromuscular Stimulation (NS) Groups

Variable	Control	NS	P
n	14	14	
Age (SD)	60yrs (15.1)	59.4yrs (11.1)	0.91
Stroke onset to trtmnt (SD)	17.8dys (5.9)	13.6dys (7.1)	0.10
Female (%)	8 (57.1)	7 (50)	0.71
Coronary artery disease (%)	5 (35.7)	2 (14.3)	0.19
Hypertention (%)	9 (64.3)	10 (71.4)	0.69
First stroke (%)	11 (78.6)	10 (71.4)	0.66
Sensory impairment (%)	6 (42.9)	5 (35.7)	0.69
U-E Fugl-Meyer (SD)	8.3 (8.8)	11.1 (10.4)	0.45
Self-care FIM (SD)	19.3 (5.5)	21.4 (6.5)	0.36

SD indicates standard deviation; FIM, Functional Independence Measure; U-E, Upper-Extremity

Interventions/ Test/ Factor being investigated

15 sessions of stimulating the extensor digitorum communis and the extensor carpi radialis (ECR) through circular 2.5-cm surface electrodes in addition to standard physical, occupational, and speech therapy interventions. The stimulation current intensity was set to produce full wrist and finger extension with a duty cycle of 10 seconds on and 10 seconds off.

Comparisons

15 sessions of surface stimulation, but the electrodes were placed away from all motor points, producing only cutaneous stimulation just beyond sensory threshold and without motor activation in addition to standard physical, occupational, and speech therapy interventions.

Length of Study/ Follow-up

12 weeks

Outcome measures studied

Motor function was assessed with the upper extremity motor subscore of the Fugl-Meyer Motor Assessment; upper extremity-related disability was assessed with the self-care component of the FIM.

Results

Gains in the Upper-Extremity Fugl-Meyer and Self-care FIM Scores after Treatment and at Follow-up Periods

Neuromuscular

	Stimulation (SD)	Control (SD)	Difference (SE)	95% CI
N	14	14		
Fugl-Meyer gain*				
After treatment	13.1 (10.3)	6.5 (6.1)	6.6 (3.2)	13.2, 0.1
4 weeks	17.8 (12.6)	9.7 (7.7)	8.1 (3.9)	16.2, 0.0
12 weeks	20.6 (15.1)	11.2 (8.7)	9.4 (4.7)	18.9, -0.2
FIM gain**				
After treatment	11.3 (3)	10.6 (5.9)	0.6 (1.8)	4.3, -3.0
4 weeks	13.9 (5.5)	13.6 (6.5)	0.3 (2.3)	5.0, -4.4
12 weeks	15.8 (5.8)	16.1 (6.7)	-0.3 (2.4)	4.6, -5.1

SD indicates standard deviation; SE, standard error; and FIM, Functional Independence Measure.

*Upper extremity motor component

**Self-care component

Effect Size

Source of funding:

Supported in part by the Rehabilitation Medicine Scientist Development Program and the Physical Medicine and Rehabilitation Education and Research Foundation

Does the study answer the question?/Further Comments

Authors suggest that neuromuscular stimulation enhances the upper extremity motor recovery of acute stroke survivors. However sample size in this study was too small to detect any significant effect of neuromuscular stimulation on self function.

Chan MK;Tong RK;Chung KY;

Bilateral upper limb training with functional electric stimulation in patients with chronic stroke

Ref ID 4976

RID:

454

2009 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment not stated; small sample size; post-intervention assessment by blinded outcome assessors; no follow up; means and SDs given although data not normally distributed; ANCOVA test used "to adjust for baseline imbalances".

DETAILS

of patients: 20 (10 FES + 10 control)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: no skin allergy to electric stimulation/electrodes; score of 0 on finger mass extension subitem of Fugl-Meyer Assessment; able to follow simple commands; 6 weeks after onset of stroke; 1st stroke; Glasgow Coma Scale 15/15
Exclusion: Severe dysphasia (expressive or comprehensive) with inadequate communication; additional medical or psychological condition affecting ability to comply with protocol; history of neurological diseases and psychiatric disorder including alcoholism and substance abuse.

Baseline characteristics:

	FES	Control
Age (years)	46 (17)	45 (16)
Male:female	5:5	6:4
Side affected right:left	4:6	5:5
Time after stroke onset (months)	18.1 (16.1)	12.1 (11.9)
Years of education	10.8 (4.2)	9.7 (3.6)
MMSE score	27.3 (2.8)	27.4 (1.5)

Interventions/ Test/ Factor being investigated

10 minutes stretching/passive mobilization activities to facilitate active movement + 20 minutes FES with muscle movement + 60 minutes conventional occupational therapy training.
Each FES session lasted 20 minutes, with 2 training activities out of 4 tasks.

Comparisons

10 minutes stretching/passive mobilization activities to facilitate active movement + 20 minutes placebo electrical stimulation with sensation only + 60 minutes conventional occupational therapy training.

Length of Study/ Follow-up

Post-intervention only, no follow up

Outcome measures studied

1ry: Functional Test for the Hemiplegic Upper Extremity, Fugl-Meyer, forward reach, grip, active ROM.

Results

	FES		Control		p (ES)
	Pre	Post	Pre	Post	
Fugl-Meyer	18.2 (7.7)	25.9 (8.9)	20.0 (10.3)	22.1 (9.0)	0.039 (0.57)
FTHUE	2.4 (0.8)	3.7 (0.5)	2.8 (0.6)	3.1 (0.6)	0.001 (1.52)
Forward reach (cm)	12.7 (7.5)	20.4 (9.8)	7.7 (9.6)	11.9 (12.4)	0.220 (0.41)
AROM wrist ext (°)	4.0 (12.6)	21.0 (28.5)	3.0 (9.5)	6.5 (18.9)	0.020 (0.52)
Grip power (kg)	1.2 (1.9)	2.2 (2.0)	1.1 (1.6)	2.0 (2.1)	0.915 (0.14)
FIM	76.8 (12.0)	80.2 (6.8)	77.3 (12.0)	77.6 (12.0)	0.199 (0.30)
MAS of shoulder	0.5 (0.7)	0.3 (0.5)	0.5 (0.6)	0.5 (0.6)	0.342 (0.33)
MAS of elbow	1.2 (0.9)	1.3 (0.8)	1.4 (1.2)	1.6 (1.1)	0.570 (0.22)

MAS of wrist 1.3 (1.2) 0.9 (0.9) 1.6 (1.2) 1.4 (1.0) 0.355 (0.32)
 FTHUE, Functional Test for the Hemiplegic Upper Extremity; AROM, Active Range
 Of Motion; MAS, Modified Ashworth scale; FES, Functional Electrical Stimulation;
 (ES), Effect Size

Effect Size

Source of funding: none stated

Does the study answer the question?/Further Comments The authors conclude that FES with bilateral upper limb training can improve motor function in patients with chronic stroke. However, the sample size was small and there was no follow up.

Hara Y;Ogawa S;Tsujiuchi K;Muraoka Y;

A home-based rehabilitation program for the hemiplegic upper extremity by power-assisted functional electrical stimulation

Ref ID 105 **RID:** 426 2008

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Small sample size; randomisation method adequate; allocation concealment not stated; data only given for completers; assessment at end of 5 month intervention but no follow up; data only shown graphically.

DETAILS

of patients:

20 included; 12 FES (10 completed programme; 2 dropped out); 10 controls

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Patients with stroke (1 or 2 strokes on same side of brain) and chronic spastic upper extremity impairments (Stroke Impairment Assessment Set [SIAS] scores 0-5); >1 year post-stroke; absence of neurological deficits other than hemiplegia; cognitive function sufficient to understand and follow directions; passive range of motion is wrist extension to 45° from neutral and shoulder flexion to 140°.

Exclusion: Inability of FES to open the impaired hand or flex the shoulder or intolerance of FES by subject; no voluntary movements of wrist, finger or shoulder; Mini Mental State Examination score <20; visual hemineglect; severe depression; pacemaker or other implanted stimulator; excessive pain in affected upper limb, wrist or shoulder.

Baseline characteristics: 2 sub-groups: group A: partial paralysis of wrist/finger movements; group B: partial active shoulder flexion movement

FES: 8 men + 2 women; mean age 56.0 years, range 24-77 years; mean time since stroke 13 months (range 12-16 months)

Control: 6 men + 4 women; mean age 60.5 years (range not given); mean time since stroke 13 months (range not given).

Interventions/ Test/ Factor being investigated

FES for wrist extension during coordinated movement (triggered by voluntary movement by patient). 30 minute FES session 5 days a week at home; increased over 10 days to maximum of 1 hour per session. Supervision 40 minutes once a week for 5 months (OT directed to patient goals).

Comparisons

Supervision by a rehabilitation trainer in extending the impaired wrists and fingers during rehabilitation sessions once a week for about 5 months. Each session lasted approximately 40 min.

Length of Study/ Follow-up

post-intervention at 5 months but no further follow up

Outcome measures studied

Active Range Of Movement, electromyographic measures (maximum isometric contraction); 10 cup moving test; 9 hole peg test

Results

Data shown graphically. Active Range of Movement: FES improved compared to control (p<0.05 at wrist and metacarpophalangeal joints);

10 cup moving test: FES vs. control; p<0.01.

9 hole peg test FES vs. control; p<0.01.

Significant increases in root mean squares of target muscle electromyographic data (p<0.05)

Effect Size

Source of funding:

Grant in aid for Scientific Research from the Japan Society for the Promotion of Science

Does the study answer the question?/Further Comments

The authors state that FES seems to be useful in improving impairment and function. However, the sample was small and data were only shown graphically; the clinical relevance of changes in outcome measures is unclear.

Hsu SS;Hu MH;Wang YH;Yip PK;Chiu JW;Hsieh CL;

Dose-Response Relation Between Neuromuscular Electrical Stimulation and Upper-Extremity Function in Patients With Stroke

Ref ID 16062

RID:

826

2010 Apr 1

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/Unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Assessor-blinded; Block randomisation; Patients recruited from 2 academic medical centres; Intention-to-treat method for dealing with missing data; Baseline characteristics compared and no significant difference found ; 12 patients (18%) lost to follow-up; Allocation concealment not mentioned

DETAILS

of patients:

Sixty-six acute stroke patients were randomised to 3 groups: high Neuromuscular Electrical Stimulation (NMES), low NMES, or control. Twenty-two patients in each

Prevalence (Diagnostic):

Patient Characteristics	Acute stroke patients with unilateral stroke, onset within 3 months, Brunnstrom stage \leq IV with no contraindication for NMES																																																								
	Subject Characteristics at Baseline																																																								
	<table border="1"> <thead> <tr> <th>Grp</th> <th>Control (n =22)</th> <th>Low-NMES Grp (n =22)</th> <th>High-NMES (n =22)</th> </tr> </thead> <tbody> <tr> <td>Age, mean\pmSD (range), y</td> <td>65.6\pm12.2 (36-84)</td> <td>62\pm10.2 (50-81)</td> <td>60.2\pm10.9 (44-81)</td> </tr> <tr> <td>Male, n (%)</td> <td>12 (54.5)</td> <td>15 (68.1)</td> <td>15 (68.1)</td> </tr> <tr> <td>Stroke onset to treatment interval, mean\pmSD (range), d</td> <td>17.4\pm14.1 (4-70)</td> <td>21\pm19.1 (4-86)</td> <td>23.3\pm17.9 (6-90)</td> </tr> <tr> <td>Type of stroke, n (%)</td> <td></td> <td></td> <td></td> </tr> <tr> <td> Infarction</td> <td>12 (54.5)</td> <td>13 (59.1)</td> <td>8 (36.4)</td> </tr> <tr> <td> Hemorrhage</td> <td>10 (45.5)</td> <td>9 (40.9)</td> <td>14 (63.6)</td> </tr> <tr> <td>Brunnstrom stage, n (%)</td> <td></td> <td></td> <td></td> </tr> <tr> <td> Mean stage</td> <td>1.6\pm0.8</td> <td>1.7\pm0.9</td> <td>1.9\pm1</td> </tr> <tr> <td> I-II</td> <td>20 (91)</td> <td>19 (86)</td> <td>17 (77)</td> </tr> <tr> <td> III-IV</td> <td>2 (9)</td> <td>3 (14)</td> <td>5 (23)</td> </tr> </tbody> </table>	Grp	Control (n =22)	Low-NMES Grp (n =22)	High-NMES (n =22)	Age, mean \pm SD (range), y	65.6 \pm 12.2 (36-84)	62 \pm 10.2 (50-81)	60.2 \pm 10.9 (44-81)	Male, n (%)	12 (54.5)	15 (68.1)	15 (68.1)	Stroke onset to treatment interval, mean \pm SD (range), d	17.4 \pm 14.1 (4-70)	21 \pm 19.1 (4-86)	23.3 \pm 17.9 (6-90)	Type of stroke, n (%)				Infarction	12 (54.5)	13 (59.1)	8 (36.4)	Hemorrhage	10 (45.5)	9 (40.9)	14 (63.6)	Brunnstrom stage, n (%)				Mean stage	1.6 \pm 0.8	1.7 \pm 0.9	1.9 \pm 1	I-II	20 (91)	19 (86)	17 (77)	III-IV	2 (9)	3 (14)	5 (23)												
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Interventions/ Test/ Factor being investigated	4 weeks of NMES, 5 times per week in addition to regular inpatient rehabilitation. 30 minutes per session was chosen as the low dose and 60 minutes as the high dose.																																																								
Comparisons	Regular inpatient rehabilitation																																																								
Length of Study/ Follow-up	12 weeks																																																								
Outcome measures studied	Fugl-Meyer Motor Assessment Scale, Action Research Arm Test and Motor Activity Log																																																								
Results	Comparison of Outcome Measure among Groups																																																								
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Effect Size																																																									
Source of funding:	Study was partially supported by the Bureau of Health Promotion, Department of Health, ROC (Taiwan), through grants																																																								
Does the study answer the question?/Further Comments	Authors concluded that higher and lower doses of NMES led to similar improvements in motor function. A minimum of 10 hours of NMES in combination with regular rehabilitation may improve recovery of arm function in stroke patients during the acute stage.																																																								

Electrical stimulation driving functional improvements and cortical changes in subjects with stroke

Ref ID 256

RID:

431

2004 Feb

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

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Direction =

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C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation method and allocation concealment not stated; sample size small (16 in total; 8 FES and 8 sham treatment); post-test at 3 weeks at end of intervention only - no follow up.

DETAILS

of patients:

16 in total; 8 FES and 8 sham treatment

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: At least 6 months post-stroke; at least 10° active flexion/extension at metacarpophalangeal joint of index finger; Mini-Mental State Examination score 25 or more out of possible 30.

Exclusion: none stated

Baseline characteristics: Mean age 60.1 (14.5) years, range 33-78 years; mean time since stroke 35.5 (25.1) months. Treatment group: 5 males + 3 females; 4 right and 4 left hemisphere. Control group: 6 males + 2 females; 4 right and 4 left

hemisphere.

Interventions/ Test/ Factor being investigated	Intensive home use of FES: 60 hours total use; 6 hours per day for 10 days over 3 weeks; half of the time using active effort by subject to trigger stimulated response then FES contracting muscles; other half machine automatically stimulating muscles to contract cyclically without trigger from patient.
Comparisons	FES versus sham treatment (light came on but no current delivered by machine)
Length of Study/ Follow-up	Post-intervention at 3 weeks only
Outcome measures studied	Box and Block Test; Motor Activity Log: Amount of use and How well used; Jebsen Taylor Hand Function Test; Strength of finger extension; Finger tracking task; Functional MRI scan of brain

Results

	Intervention			Control		
	Pre	Post	p	Pre	Post	p
Box and Block Test	23.7 (4.0)	27.0 (4.8)	0.039	23.0 (6.1)	24.3 (6.1)	NS
Strength (Newtons)	9.2 (1.7)	12.9 (7.9)	0.006	7.05 (2.5)	8.9 (2.3)	0.01
MAL Amount use*	1.5 (0.27)	1.9 (0.82)	<0.001	1.4 (0.7)	1.3 (0.71)	NS
MAL How well used*	1.6 (0.97)	2.1 (0.84)	0.003	1.3 (0.62)	1.4 (0.73)	NS
JTHFT (s) page turn	31.1 (12.7)	17.1 (5.7)	NS	28.0 (9.2)	19.5 (4.3)	NS
small objects	41.9 (13.0)	25.0 (5.3)	0.43	49.3 (16.5)	41.4 (12.6)	NS
feeding	6.9 (2.62)	6.7 (2.52)	NS	32.8 (8.5)	27.9 (6.9)	NS
stacking	43.7 (15.9)	25.3 (7.6)	0.01	42.5 (15.6)	56.7 (26.6)	NS
light cans	35.7 (25.2)	34.9 (25.8)	NS	14.4 (5.7)	10.8 (2.1)	NS
heavy cans	45.1 (35.0)	42.4 (35.0)	0.002	37.8 (27.0)	30.8 (21.0)	NS
Tracking accuracy (%)	-23.0 (17)	-30.0 (21)	NS	-17.1 (16)	-6.2 (16)	NS

*changes small and clinical significance unclear
MRI data: no change in voxel count (active brain areas) from pre-to post-test in any designated areas in either hemisphere for either group. In intervention group, there was a significant increase in the intensity index (a measure of neural activity) from pre- to post-test (p=0.046) in the gyrus postcentralis area in the hemisphere ipsilateral to the treated hand but not in the ipsilateral gyrus precentralis or either area on the contralateral side. The intensity index did not change in any area in the sham control group.

Effect Size

Source of funding: National Institute on Disability and Rehabilitation Research.

Does the study answer the question?/Further Comments The authors concluded that FES could be effectively self-administered at home in an intensive manner (60 hours over 3 weeks) and was associated with improvements in hand function, together with stimulation of the sensory cortex. However, the study was small and tested patients immediately after the intervention only; there was no follow up.

Lin Z;Yan T;

Long-term effectiveness of neuromuscular electrical stimulation for promoting motor recovery of the upper extremity after stroke¹²²

Ref ID 16005

RID:

797

2011

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Single centre trial; randomised single-blinded control trial; outcome assessment were assessed by a physiotherapist, who did not know which group each patient belonged; of the 46 patients initially included, 37 completed the study.
Randomisation unclear; allocation concealment not mentioned; Intention to treat analysis not mentioned

DETAILS

of patients:

46 patients randomised; 23 to the NES group and 23 to the control group

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: First stroke; within 3 months post-onset; diagnosed with either cerebral infarction or cerebral haemorrhage using either computed tomography (CT) or magnetic resonance (MR) imaging; fulfilling the diagnostic and classification criteria for stroke established by the Chinese Neuroscience and Neurosurgery Institute.

Exclusion criteria: Progressive stroke; subarachnoid haemorrhage; shoulder muscle strength \geq grade 3; severe heart, liver, kidney or infectious disease; head injury; tumour; a score $<$ 7 on the abbreviated mental test; or if they were younger than 44 years, older than 80 years, or were not willing to sign the consent form.

Participants were in the age range 44-80 years, with hemiplegia of one upper limb. Shoulder flexor strength before treatment was grade 3 or less (out of 5). They were required to have no severe cognitive dysfunction (with a score of 7 or better on the abbreviated mental test).

Demographic data.

	Group	
	NES (n = 19)	Controls (n = 18)
Age, years Mean (SD)	62.2 (8.7)	66.0 (9.6)
Male/Female (n)	11/8	11/7
Time post stroke		
Mean (SD)	43.5 (25.2)	41.3 (26.5)
Stroke type		
Infarction/haemorrhage	13/6	12/6
Hemi-paresis		
Right/left	8/11	7/11
Right-handed	16	16
Left handed	3	2

No significant difference was found between groups before treatment. NES: neuromuscular electrical stimulation; SD: standard deviation

Interventions/ Test/ Factor being investigated	Standard treatment + Neuromuscular Electrical Stimulation (NES) lasting for 30 mins, 5 days per week for 3 weeks. The 2-channel Respond Select II stimulator (Texas, USA) was used. The stimulation was at a frequency of 30Hz, with a pulse width of 300µs, and ramp up and down times of 1s each
Comparisons	Standard treatment, including physical therapy and occupational therapy, for 30 mins on 5 days each week for 3 weeks
Length of Study/ Follow-up	6 months
Outcome measures studied	Modified Ashworth Scale (MAS); Upper limb section of the Fugl-Meyer Assessment (FMA-U); Modified Barthel Index (MBI)

Results Comparison of Fugl-Meyer motor assessment (FMA-U) scores between groups

Group	Before treatment	3 weeks	1 month
	Mean (SD)	Mean (SD)	Mean (SD)
NES (n=19)			
Total	8.4 (2.5)	20.3 (5.4)	22.6 (5.7)
Proximal arm	4.0 (2.8)	11.4 (4.4)	13.1 (5.0)
Wrist	0.7 (0.3)	1.8 (1.9)	2.2 (1.8)
Hand	2.3 (1.2)	3.6 (3.8)	4.0(3.2)
Controls (n=18)			
Total	8.2 (3.4)	14.5 (5.8)	17.7 (6.2)
Proximal arm	4.3 (2.9)	9.4 (3.5)	10.1 (5.5)
Wrist	0.8 (0.5)	1.3 (1.7)	1.6 (1.8)
Hand	2.0 (1.3)	3.2 (3.2)	3.0 (3.6)

Group	3 months	6 months
	Mean (SD)	Mean (SD)
NES (n=19)		
Total	26.0 (5.1)	29.8 (3.6)
Proximal arm	14.6 (4.3)	15.0 (5.1)
Wrist	3.0 (2.1)	3.7 (2.4)
Hand	4.8 (3.7)	5.3 (4.0)
Controls (n=18)		
Total	18.5 (6.7)	20.3 (12.3)
Proximal arm	10.6 (4.3)	12.0 (5.0)
Wrist	2.2 (2.1)	2.5 (2.2)
Hand	4.1 (3.6)	4.3 (4.1)

Comparison of Modified Ashworth Scale for spasticity scores between groups

Group	Before treatment	3 weeks	1 month
	Mean (SD)	Mean (SD)	Mean (SD)
NES (n=19)	0.53 (0.5)	1.16 (0.50)	1.42 (0.51)
Control (n=18)	0.5 (0.51)	0.78 (0.55)	1.11 (0.32)

Group	3 months	6 months
	Mean (SD)	Mean (SD)
NES (n=19)	1.56 (0.53)	1.67 (0.52)
Control (n=18)	1.50 (0.53)	1.86 (0.38)

Comparison of Modified Barthel Index scores between groups

Group	Before treatment	3 weeks	1 month
	Mean (SD)	Mean (SD)	Mean (SD)
NES (n=19)	31 (10.1)	57 (10.7)	64.5 (10.4)
Control (n=18)	30.3 (8.7)	49.7 (11.4)	55.7 (12.1)

Group	3 months	6 months
	Mean (SD)	Mean (SD)
NES (n=19)	72.4 (8.5)	79.2 (5.2)
Control (n=18)	59.3 (12.0)	66.1 (11.3)

Effect Size

Source of funding:

Study funded by projects of GDSTC (No. 2007B031502005, 2010A040302002)

Does the study answer the question?/Further Comments

NES combined with standard rehabilitation treatment promotes muscle strength and motor function in the upper extremities, and thus improves ability in activities of daily living of patients after a first stroke. Its effect persist for at least 6 months

Mangold S;Schuster C;Keller T;Zimmermann-Schlatter A;Ettlin T;

Motor training of upper extremity with functional electrical stimulation in early stroke rehabilitation

Ref ID 68

RID:

425

2009 Feb

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = FES group better on Extended Barthel Index upper extremity subscore at baseline

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Small sample size; randomisation adequate; allocation concealment not stated; groups not comparable at baseline; outcomes reported as medians and quartiles not means and standard deviations; authors reported that follow up was planned for 6 months but no follow up data reported in this paper.

DETAILS

of patients: 23 (12 FES, 11 control)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: first time stroke (2-18 weeks ago; infarct or haemorrhage localised from cortex to brainstem); admitted to rehabilitation centre; 18 years or older; severe hemiparesis to total hemiplegia of arm and/or hand (maximum value of Chedoke McMaster Stroke Assessment [CMSA] for arm and hand 3 points); able to understand study and consent; ability to sit in chair without back rest
Exclusion: pacemaker or other stimulation device; pregnancy; epilepsy; prosthesis of bones or joints in local region of electrical treatment; skin injuries at site of stimulation; prior stroke or other brain impairments; severe impairment of sensitivity and proprioception; shoulder-hand syndrome on affected side; constant strong pain in shoulder (CMSA 1-3 for shoulder pain) or considerable subluxation of affected shoulder joint.
Baseline characteristics:

	Control	FES
n	11	12
Age (yr)	62 (16.2)	57.5 (16.7)
Female n (%)	4 (36%)	2 (17%)
Median (IQR) time post-stroke (weeks)	7.3 (5.8, 8.2)	6.7 (6.4, 7.3)
Non-haemorrhagic stroke n (%)	9 (82%)	10 (83%)
Right hemiparesis n (%)	4 (36%)	3 (25%)
Dominant arm affected n (%)	7 (64%)	4 (40%)
Neglect n (%)	2 (18%)	6 (50%)
Median (IQR) Extended Barthel Index	25 (21, 32)	32 (26, 35)
Median (IQR) EBI upper extremity subscore	5 (4, 5.5)	6 (6, 7) p=0.013

Interventions/ Test/ Factor being investigated

FES replaced conventional therapy in 3 sessions per week 45 minute sessions including 15-20 mins donning / treating spasticity / doffing and 25-30 mins functional training; (included proximal muscles e.g. deltoid, triceps as well as distal muscles, i.e. finger flexors and extensors). If necessary, therapists treated spasticity and provided manual assistance. FES triggered by patient or therapist

Comparisons

Control (conventional training; 3-5 x 45-minute OT sessions per week; mobilisation and exercises supported by therapist or performed bimanually)

Length of Study/ Follow-up

Post-treatment at the end of the 4 week programme only. Authors state that follow up planned at 6 months but no data shown.

Outcome measures studied

ADL assessed by the Extended Barthel Index upper extremity subscore, Chedoke McMaster Stroke Assessment, Modified Ashworth Scale.

Results

	Control	FES	p value
Median (quartiles for gain pre-post)			
EBI upper extremity subscore	3 (1.0, 3.3)	1.5 (0.8, 2.0)	0.19
CSMA hand	0 (0, 1)	0.3 (0, 0.5)	1.0

MAS finger flexors	0 (-0.5, 0.8)	0.5 (0, 1.1)	0.17
MAS wrist flexors	0.5 (0, 1.3)	0.5 (0, 1.1)	0.68

Effect Size

Source of funding: National Center of Competence NCCR: Plasticity and Repair

Does the study answer the question?/Further Comments FES was not superior to conventional therapy but the sample size was too small and there were imbalances between the groups at baseline. Data reported as medians and IQRs not means and SDs so not usable.

Mann GE;Burrige JH;Malone LJ;Strike PW;

A pilot study to investigate the effects of electrical stimulation on recovery of hand function and sensation in subacute stroke patients

Ref ID 2001 **RID:** 441 2005

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Mean time since stroke less in intervention group (5.7 vs. 8.5 months)

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Likely bias in favour of either group

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment adequate; small sample size; mean time since stroke 3 months less in intervention than control group (5.7 vs. 8.5 months) which could bias in favour of intervention group due to natural recovery; patients had other therapy additional to study intervention/control that was not standardised which could bias in favour of either group; data only presented for completers; follow up at 12 weeks post-intervention; no SDs given.

DETAILS

of patients:

24 randomised; data given for 22 completers (11 in each group)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: 1-12 months post first stroke resulting in hemiplegia; medically stable; at least 18 years old; able to take hemiplegic hand to mouth; sensory impairment in paretic hand; no previous pathology to upper limb; no cardiac pacemaker; able to comply with assessment and treatment; able to consent.

Exclusion: Cognitive or psychiatric problems affecting ability to comply with assessment or treatment; cardiac problems; pacemaker

Baseline characteristics:

	FES	Control
Mean (range) age (years)	68 (57-86)	71 (57-87)
Male: female	5:6	5:6
Mean time since stroke (months)	5.7 (1-12)	8.5 (2-12)
Side affected right:left	5:6	5:6
Infarct:haemorrhage	10:1	11:0

Interventions/ Test/ Factor being investigated

FES: stimulation to give full elbow, wrist and finger extension without discomfort; increased from 10 to 30 min twice a day over around 1 week.

Comparisons

FES vs. control: passive extension exercises of elbow, wrist and fingers to be practised for the same period each day. On discharge, continued with help of caregiver or independently.

Length of Study/ Follow-up

Post-intervention after 12 weeks of treatment and follow up at 12 weeks after that (i.e. week 24).

Outcome measures studied

Action Research Arm Test; Sensation using static 2-point discrimination using blunt pins

Results

	FES	Control	ANCOVA difference in means	p value
Action Research Arm Test				
Baseline	20.0	14.3		0.43
12 weeks	34.4	24.4	diff 10.0 (95% CI 3.8 to 16.3)	0.003
24 weeks	34.4	24.7	diff 9.7 (95% CI 2.4 to 17.1)	0.012
Sensation				
Baseline	36	47		0.28
12 weeks	49	47	diff 2 (95% CI -7 to +10)	0.700
24 weeks	51	47	diff 4 (95% CI -6 to +13)	0.396

Effect Size

Source of funding:

The Chartered Society of Physiotherapy Research Foundation UK

Does the study answer the question?/Further Comments

The authors concluded that FES produced a benefit in a functional outcome measure at post-intervention that was maintained at follow up at 12 weeks post intervention. However, the sample size was small, there were differences between the groups at baseline; additional therapy received by the patients was not standardised and no assessment was made as to whether the improved performance on the ARAT measure resulted in meaningful functional improvement in activities of daily living. Also, no SDs were given for the outcome measures so data are not usable.

Popovic MB;Popovic DB;Sinkjaer T;Stefanovic A;Schwirllich L;

Clinical evaluation of Functional Electrical Therapy in acute hemiplegic subjects

Ref ID 258

RID:

432

2003 Sep

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

41 patients considered for the study; random generator used to select 28 subjects for the study (unclear why not all eligible patients studied); random generator used to randomise; allocation concealment not stated; sample size small.

DETAILS

# of patients:	28 (High functioning FES 8; control 8; low functioning FES 6; control 6).																																																																																																															
Prevalence (Diagnostic):																																																																																																																
Patient Characteristics	<p>Inclusion: Between 2 weeks and 6 months post first CVA; age over 18 years; able to understand how to apply FES to control grasp.</p> <p>Exclusion: Dependent on care prior to stroke for activities of daily living; severe medical condition in any arm or hand that precluded participation; previous disease or injury or contracture affecting paretic or non-paretic arm or hand; electrical life support devices (e.g. pacemaker).</p> <p>Baseline characteristics: Lower functioning group (n=12; mean age 58.6 (12.4) years): could extend paretic wrist 10 to 20° and extend metacarpophalangeal and interphalangeal joints of thumb and minimum of 2 other digits between 10 and 20°. Randomised to FES (n=6; 5 right + 1 left sided strokes) or control (n=6; 4 right + 2 left).</p> <p>Higher functioning group (n=16; mean age 60.6 (5.8) years): active extension of wrist more than 20° and extend metacarpophalangeal and interphalangeal joints of all digits more than 20° (no upper functioning limit). Randomised to FES (n=8; 5 right + 3 left sided strokes) or control (n=8; 7 right + 1 left).</p> <p>Gender not stated.</p>																																																																																																															
Interventions/ Test/ Factor being investigated	For the 1st 3 weeks, FES group had 30-minute long treatment sessions of exercise with stimulation 7 days a week; reaching, grasping and using objects and returning them to their places.																																																																																																															
Comparisons	FES versus control group. All had conventional daily therapy for 26 weeks. For the 1st 3 weeks, control group had 30-minute long treatment sessions of exercise only; same tasks as intervention group but without FES.																																																																																																															
Length of Study/ Follow-up	Post-treatment at 3 weeks; follow up at 6, 13 and 26 weeks.																																																																																																															
Outcome measures studied	Upper Extremity Functioning Test (number of repetitions of typical daily activities in 2 min); Drawing Test (% of area of square correctly captured); modified Ashworth muscle spasticity scale; Reduced Upper Extremity Motor Activity Log (RUE/MAL)																																																																																																															
Results	<p>UEFT (no. of successful repetitions)</p> <table border="0"> <thead> <tr> <th rowspan="2">Time (weeks)</th> <th rowspan="2"></th> <th colspan="2">Low function group</th> <th colspan="2">High function group</th> </tr> <tr> <th>Number</th> <th>p value</th> <th>Number</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td rowspan="2">0</td> <td>Intervention</td> <td>0</td> <td>-</td> <td>5.8 (4.3)</td> <td rowspan="2">0.6</td> </tr> <tr> <td>Control</td> <td>0</td> <td>-</td> <td>4.9 (1.3)</td> </tr> <tr> <td rowspan="2">3</td> <td>Intervention</td> <td>1.9 (1.1)</td> <td rowspan="2">0.01</td> <td>18.8 (10.9)</td> <td rowspan="2">0.04</td> </tr> <tr> <td>Control</td> <td>0.2 (0.1)</td> <td>9.6 (6.3)</td> </tr> <tr> <td rowspan="2">6</td> <td>Intervention</td> <td>4.1 (2.6)</td> <td rowspan="2">0.01</td> <td>28.1 (10.4)</td> <td rowspan="2">0.01</td> </tr> <tr> <td>Control</td> <td>0.4 (0.3)</td> <td>12.6 (9.2)</td> </tr> <tr> <td rowspan="2">13</td> <td>Intervention</td> <td>4.5 (3.1)</td> <td rowspan="2">0.03</td> <td>29.2 (10.9)</td> <td rowspan="2">0.01</td> </tr> <tr> <td>Control</td> <td>1.2 (0.6)</td> <td>14.1 (9.7)</td> </tr> <tr> <td rowspan="2">26</td> <td>Intervention</td> <td>4.9 (3.1)</td> <td rowspan="2">0.04</td> <td>29.9 (9.7)</td> <td rowspan="2">0.01</td> </tr> <tr> <td>Control</td> <td>1.5 (0.9)</td> <td>15.4 (7.6)</td> </tr> </tbody> </table> <p>Drawing test (% area compared with target square)</p> <table border="0"> <thead> <tr> <th rowspan="2">Time (weeks)</th> <th rowspan="2"></th> <th colspan="2">Low function group</th> <th colspan="2">High function group</th> </tr> <tr> <th>Area (%)</th> <th>p value</th> <th>Area (%)</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td rowspan="2">0</td> <td>Intervention</td> <td>16.2 (9.5)</td> <td rowspan="2">0.33</td> <td>43.9 (10.3)</td> <td rowspan="2">0.85</td> </tr> <tr> <td>Control</td> <td>14.2 (6.8)</td> <td>42.8 (7.9)</td> </tr> <tr> <td rowspan="2">3</td> <td>Intervention</td> <td>24.0 (9.9)</td> <td rowspan="2">0.11</td> <td>70.5 (11.0)</td> <td rowspan="2">0.01</td> </tr> <tr> <td>Control</td> <td>16.0 (2.8)</td> <td>52.9 (11.6)</td> </tr> <tr> <td rowspan="2">6</td> <td>Intervention</td> <td>34.8 (12.2)</td> <td rowspan="2">0.06</td> <td>77.1 (9.9)</td> <td rowspan="2">0.01</td> </tr> <tr> <td>Control</td> <td>23.2 (3.2)</td> <td>60.9 (12.7)</td> </tr> <tr> <td rowspan="2">13</td> <td>Intervention</td> <td>41.8 (11.5)</td> <td rowspan="2">0.04</td> <td>80.5 (8.4)</td> <td rowspan="2">0.01</td> </tr> <tr> <td>Control</td> <td>28.9 (4.2)</td> <td>64.3 (13.3)</td> </tr> <tr> <td rowspan="2">26</td> <td>Intervention</td> <td>49.8 (9.6)</td> <td rowspan="2">0.06</td> <td>83.8 (5.6)</td> <td rowspan="2">0.02</td> </tr> <tr> <td>Control</td> <td>36.7 (6.9)</td> <td>68.7 (11.7)</td> </tr> </tbody> </table> <p>Ashworth grade</p>	Time (weeks)		Low function group		High function group		Number	p value	Number	p value	0	Intervention	0	-	5.8 (4.3)	0.6	Control	0	-	4.9 (1.3)	3	Intervention	1.9 (1.1)	0.01	18.8 (10.9)	0.04	Control	0.2 (0.1)	9.6 (6.3)	6	Intervention	4.1 (2.6)	0.01	28.1 (10.4)	0.01	Control	0.4 (0.3)	12.6 (9.2)	13	Intervention	4.5 (3.1)	0.03	29.2 (10.9)	0.01	Control	1.2 (0.6)	14.1 (9.7)	26	Intervention	4.9 (3.1)	0.04	29.9 (9.7)	0.01	Control	1.5 (0.9)	15.4 (7.6)	Time (weeks)		Low function group		High function group		Area (%)	p value	Area (%)	p value	0	Intervention	16.2 (9.5)	0.33	43.9 (10.3)	0.85	Control	14.2 (6.8)	42.8 (7.9)	3	Intervention	24.0 (9.9)	0.11	70.5 (11.0)	0.01	Control	16.0 (2.8)	52.9 (11.6)	6	Intervention	34.8 (12.2)	0.06	77.1 (9.9)	0.01	Control	23.2 (3.2)	60.9 (12.7)	13	Intervention	41.8 (11.5)	0.04	80.5 (8.4)	0.01	Control	28.9 (4.2)	64.3 (13.3)	26	Intervention	49.8 (9.6)	0.06	83.8 (5.6)	0.02	Control	36.7 (6.9)	68.7 (11.7)
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3	Intervention	24.0 (9.9)	0.11	70.5 (11.0)	0.01																																																																																																											
	Control	16.0 (2.8)		52.9 (11.6)																																																																																																												
6	Intervention	34.8 (12.2)	0.06	77.1 (9.9)	0.01																																																																																																											
	Control	23.2 (3.2)		60.9 (12.7)																																																																																																												
13	Intervention	41.8 (11.5)	0.04	80.5 (8.4)	0.01																																																																																																											
	Control	28.9 (4.2)		64.3 (13.3)																																																																																																												
26	Intervention	49.8 (9.6)	0.06	83.8 (5.6)	0.02																																																																																																											
	Control	36.7 (6.9)		68.7 (11.7)																																																																																																												

Time (weeks)	FES (low)	Control (low)	FES (high)	Control (high)
0	2.75 (0.5)	2.5 (0.75)	2.25 (1.0)	2.5 (1.0)
26	2.5 (0.75)	2.25 (0.75)	1.25 (0.5)	2.25 (0.75)
p value	NS	NS	<0.05	NS

RUE/MAL: % of maximum score of Amount Scale

Time (weeks)	FES (low)	Control (low)	FES (high)	Control (high)
0	0	0	13.1 (4.5)	12.6 (6.5)
26	16.7 (8.3)	3.3 (1.7)	59.7 (12.5)	28.7 (11.7)
p value	NS	<0.03	<0.01	<0.04

RUE/MAL: % of maximum score of How well Scale

Time (weeks)	FES (low)	Control (low)	FES (high)	Control (high)
0	0	0	16.5 (5.5)	9.6 (6.6)
26	11.5 (6.1)	2.3 (1.2)	66.7 (11.4)	32.5 (10.6)
p value	NS	<0.03	<0.01	<0.04

Effect Size

Source of funding: Danish National Research Foundation; Ministry for Science and Tech. of Serbia

Does the study answer the question?/Further Comments The authors concluded that the gains in the FES groups were much larger than those in the control groups, although the lower functioning groups showed less improvement than the higher functioning groups. However, the study was small and had methodological limitations; use of the percentage of maximal score rather than absolute scores on Motor Activity Log limits comparison with other studies.

Powell J;Pandyan AD;Granat M;Cameron M;Stott DJ;

Electrical stimulation of wrist extensors in poststroke hemiplegia

Ref ID 321 **RID:** 434 1999 Jul

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Appropriate randomisation; inadequate allocation concealment; appropriate sample size; groups comparable at baseline; blinded outcome assessment; most data medians with interquartile ranges not mean (SD).

DETAILS

of patients: 60 (30 intervention + 30 control)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Hemiparesis due to acute stroke with Medical Research Council power of wrist extension grade 4/5 or worse at 2-4 weeks after stroke onset.
Exclusion: Previous wrist problem (e.g. previous hemiplegia or arthritis); unable to understand the study (impaired conscious level, dysphasia or cognitive impairment)

Baseline characteristics:

	Intervention	Control
Male:Female	14:16	14:16
Age (years)	69.0 (10.8)	66.4 (12.2)
Pre-stroke Barthel Index median (range)	20 (13-20)	20 (16-20)
Time after stroke (days)	23.9 (7.7)	22.9 (5.5)
AMT score median (range)	9 (6-10)	9 (6-10)
Left:right side	18:12	20:10

Interventions/ Test/ Factor being investigated

FES: 3 half-hour periods daily (total 90 minutes daily) for 8 weeks

Comparisons

FES versus control. Both groups received standard physiotherapy; control group had visit of up to 10 minutes 3 times weekly to discuss progress in rehabilitation to control for similar contact before and after FES sessions.

Length of Study/ Follow-up

post-intervention at week 8 and follow up week 32

Outcome measures studied

Strength wrist extension/grip; active and passive range of motion; muscle tone during passive extension (modified Ashworth Scale); Action Research Arm Test; 9 hole peg test; local discomfort; Rankin; Barthel

Results

Wrist extension (median, IQR) moment

	Baseline		Change 0-8 weeks		Change 0-32 weeks	
	FES	Control	FES	Control	FES	Control
0°	0.1(0,1.0)	0.7(0,0.2)	0.9(0,1.5)	0.0(-0.1,0.75)*	1.1(0,2.9)	0(-0.1,0.9)\$
15°	0(0,0.3)	0.1(0.0,1.3)	0.6(0.0,1.2)	0(0,0.8)	0.9(0.9,2.2)	0(0,0.06)^
30°	0(0,0.1)	0(0,0.4)	0(0,0.7)	0(0,0.4)	0(0.0,1.25)	0(0,0.6)

* p=0.004; \$ p=0.014; ^ p=0.009

All median (interquartile range):

	Baseline		Change 0-8 weeks		Change 0-32 weeks	
	FES	Control	FES	Control	FES	Control
Grip (kg)	2 (0, 5)	0 (0, 8.5)	2 (0, 3)	1 (0, 4)	2 (0, 8)	4 (0, 10)

Ashworth score	0 (0, 1)	1 (0, 2)	0 (0, 1)	0 (0, 1)	1 (0, 1.5)	1 (0, 1)
ARAT (grasp)	0 (0, 6)	0 (0, 15)	4 (0, 11)	0 (0, 2)**	2 (0, 11)	0 (0, 3)
ARAT (grip)	0 (0, 3)	0 (0, 8)	2 (0, 8)	0 (0, 2)\$\$	0 (0, 8)	0 (0, 5)
ARAT (pinch)	0 (0, 1)	0 (0, 4)	1 (0, 9)	0 (0, 5)	0 (0, 8)	0 (0, 6)
ARAT (gross mov't)	0 (0, 8)	0 (0, 9)	1 (0, 3)	0 (0, 2)	0 (0, 4)	0 (0, 1)
ARAT (total)	6 (0, 18)	0 (0, 39)	10 (0, 29)	2 (0, 14)	6 (0, 31)	1 (0, 16)
No. pegs/sec	0 (0, 0.01)	0 (0, 0.35)	0 (0, 0.13)	0 (0, 0.08)	0 (0, 0.16)	0 (0, 0.11)
Barthel Index	7.5 (6, 11)	7.5 (7, 14)	5 (3, 7)	4 (1, 6)	7 (5, 10)	4 (2, 9)
Rankin Scale	4 (4, 5)	4 (4, 5)	-1 (-1, 0)	-1 (-1, 0)	-1 (-2, 0)	-1 (-1, 0)

** p=0.013; \$\$ p=0.02

Effect Size

Source of funding: Scottish Office Home and Health Department.

Does the study answer the question?/Further Comments

The authors concluded that in carefully selected patients with acute stroke (e.g. highly motivated patients with moderate motor deficit persisting beyond 2 weeks), FES enhanced motor recovery and reduced upper limb disability; it is unlikely to be beneficial in patients with very mild deficits or in those with profound weakness in whom there is little prospect of useful functional recovery. However, the data presented were all medians with interquartile ranges (apart from the star cancellation test which gave the mean (SD) numbers of starts cancelled, a measure of visuospatial neglect) so there are few usable data.

Rosewilliam S;Malhotra S;Roffe C;Jones P;Pandyan AD;

Can surface neuromuscular electrical stimulation of the wrist and hand combined with routine therapy facilitate recovery of arm function in patients with stroke?

Ref ID 16931 **RID:** 1004 2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** Computer-generated randomisation, codes stored independently

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =** no sham treatment used; could bias in favour of intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = large drop out overall reduced power of study

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Computer-generated randomisation, codes stored independently; no sham treatment used; could bias in favour of intervention; large drop out overall reduced power of study; Sample size calculation: 72 participants (36 each arm) required with 80% power and $p=0.05$ to detect a 9-point improvement in ARAT score (SD 8 and 17 in control and treatment arms). Allowing for attrition, 45 patients recruited each arm but full data only available for 66 (31 treatment and 35 control).

DETAILS

of patients:

n=90 randomised; 45 each group

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: adult patients with a first stroke who had no arm function (score 0 in the Grasp subsection of the Action Research Arm Test) within 6 weeks of onset; no contraindications to surface neuromuscular electrical stimulation (sNMES).
Exclusion: medically unstable, history of osteoarthritis, rheumatoid arthritis or soft tissue injuries resulting in contractures or a reduced range of movement in the wrist and fingers. Gender: 44 male, 46 female. Mean (SD) age (years): 74.6 (11.0)
Time since stroke onset: <6 weeks

Interventions/ Test/ Factor being investigated

sNMES for 6 weeks: electrical stimulators to wrist and finger extensors at least twice a day for 30-minute sessions for 5 days a week plus a defined module of upper limb physiotherapy for 6 weeks in addition to routine treatment on the stroke unit

Comparisons

sNMES versus a defined module of upper limb physiotherapy for 6 weeks in addition to routine treatment on the stroke unit only

Length of Study/ Follow-up

Assessments at baseline, end of treatment (6 weeks) and at 3, 6 and 9 months after stopping treatment

Outcome measures studied

Primary outcome measure: Recovery of arm function (ARAT score). Secondary outcome measures: independent in ADL (Barthel Index), active ROM wrist flexion and extension, wrist flexor and extensor strength, grip strength

Results

Mean difference Barthel Index: 6 weeks: -0.2 (-0.5 to 0.1), 36 weeks 0.01 (-0.1 to 0.1). Wrist flexion (degrees) mean difference 6 weeks 0.5 (-0.8 to 1.8), 36 weeks -0.1 (-0.3 to 0.2). Wrist extension (degrees) mean difference 6 weeks 1.1 (0.03 to 2.2) $p=0.04$, 36 weeks 0.04 (-0.2 to 0.3) NS. Wrist flexor strength: 6 weeks 0.1 (-0.03 to 0.3), 36 weeks -0.01 (-0.03 to 0.02) NS. Extensor strength 6 weeks: 0.11 (0.03 to 0.2), 36 weeks 0.01 (-0.01 to 0.03). Grip strength 0.12 (-0.02 to 0.3), 36 weeks 0 (-0.1 to 0.1) NS.

Effect Size

ARAT NS at 6 weeks or 36 weeks (mean difference between groups 0.7 (-0.2 to 1.6) at 6 weeks, 0.2 (-0.1 to 0.4) 36 weeks

Source of funding:

Action Medical Research and Barnwood House Trust

Does the study answer the question?/Further Comments

In patients with severe stroke, with no functional arm movement, electrical stimulation of wrist extensors improves muscle strength for wrist extension and grip; larger studies are required to study its influence on arm function. Electrical stimulation was limited to a cyclical movement of one single limb segment(wrist) which may not be functionally relevant.

Sahin N;Ugurlu H;Albayrak I;

The efficacy of electrical stimulation in reducing the post-stroke spasticity: a randomized controlled study

Ref ID 16247

RID:

922

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation was by electronically randomised numbers using the sealed opaque envelopes. An investigator who was not involved in the selection and allocation of patients, prepared the envelopes. Two patients (4.5%) dropped out of the study.

DETAILS

of patients: Forty-four patients were randomised. Twenty one to the control arm and another twenty one to the intervention arm

Prevalence (Diagnostic):

Patient Characteristics Forty-four patients between 45-65 years of age, who had developed forearm flexor spasticity following a stroke. Hemiplegia was longer than one year, score 2 or 3 spasticity according to Modified Ashworth Scale (MAS) and a stable neurological state.

Characteristic properties of the patients

	CTG (n: 21)	PG (n: 21)
Age (years)	60.2 (6.2)	59.3 (9.3)
Sex (F:M)	10:11	09:12
Duration (months)	25 (14.6)	35.1 (24.4)
Wrist spasticity (MAS)	3	2.8
Wrist extension (ROM) (degrees)	8.5 (4.1)	7.9 (4.6)
Brunnstrom motor scale (upper)	3.1	3
FIM total	107.7 (18.9)	101.7 (19.6)
Fmax/ Mmax (%)	8.2 (3.6)	8 (3.5)
Hmax/ Mmax amp	0.68 (0.16)	0.68 (0.11)

CTG, Combine treatment group; PG, PNF group; PNF, Proprioceptive Neuromuscular facilitation; MAS, Modified Ashworth Scale; ROM, Range of motion

Interventions/ Test/ Factor being investigated Neuromuscular Electrical Stimulation (NMES) and stretching with Proprioceptive Neuromuscular facilitation (PNF) applied to the upper extremity after hot treatment with infrared, 5 days a week for 20 sessions.

Comparisons Stretching with Proprioceptive Neuromuscular facilitation (PNF) applied to the upper extremity after hot treatment with infrared, 5 days a week for 20 sessions

Length of Study/ Follow-up One month

Outcome measures studied Wrist spasticity (MAS); wrist extension ROM (degrees); Brunnstrom motor scale (upper); functional independence measure (FIM); Electrophysiological evaluation: Fmax/Mmax, Hmax/Mmax

Results Comparison of parameters after the treatment programme in both groups

	CTG Mean (SD) Median	PG Mean (SD) Median
Wrist spasticity (MAS)	1.8*	2*
Wrist extension (ROM) (degrees)	25 (6.2)	23.8 (5.6)
Brunnstrom motor scale (upper)	4.5*	4*
FIM total	109.8 (18.8)	102.7 (19.6)
Fmax/ Mmax (%)	3.6 (3)	3.5 (2.9)
Hmax/ Mmax amp	0.27 (0.15)	0.25 (0.19)

*Median; CTG, Combine treatment group; PG, PNF group; PNF, Proprioceptive Neuromuscular facilitation; MAS, Modified Ashworth Scale; ROM, Range of motion

Effect Size

Source of funding: Not reported

Does the study answer the question?/Further Comments

Authors concluded that Neuromuscular electrical stimulation given together with stretching of the wrist extensor muscles was more effective than stretching of the wrist extensor muscles alone in reducing spasticity

Shindo K;Fujiwara T;Hara J;Oba H;Hotta F;Tsuji T;Hase K;Liu M;

Effectiveness of hybrid assistive neuromuscular dynamic stimulation therapy in patients with subacute stroke: a randomized controlled pilot trial

Ref ID 16943

RID:

1079

2011 Nov

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Computer-generated randomisation but allocation concealment not specified; could bias in favour of intervention

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction = post-treatment only, no follow up

Overall Study Quality -Strengths and Weaknesses:

Computer-generated randomisation but allocation concealment not specified; could bias in favour of intervention; post-treatment only, no follow up; sample size not calculated "because standard mean of the population was not estimated"; small sample, underpowered

DETAILS

# of patients:	n=24; 12 in each group
Prevalence (Diagnostic):	
Patient Characteristics	Inclusion: first time unilateral supratentorial stroke; stroke onset within 60 days; age 20-80 years; muscle activities in the affected extensor digitorum communis (EDC) detectable with surface electrodes; could not fully extend paretic fingers and could not extend paretic fingers individually; passive range of motion >0° for the affected wrist extension and -10° for metacarpophalangeal joint extension; Mini-Mental State Examination score >23. Exclusion: severe cognitive defects such as unilateral spatial neglect or aphasia that preclude hybrid assistive neuromuscular dynamic stimulation (HANDS) therapy; severe proprioceptive deficits or pain in the paretic upper extremity; pacemaker or other implanted stimulator; seizure history; other serious medical conditions. Gender: HANDS: 7 male, 3 female; control: 8 male, 2 female. Mean (SD) age (years): HANDS: 58.2 (18.6) range 33-77; control: 57.9 (9.7) range 37-71. Time since stroke onset: HANDS: 34.4 (14.5) days range 17-60; control: 37.0 (14.6) range 14-58
Interventions/ Test/ Factor being investigated	HANDS: 3 weeks of HANDS therapy: neuromuscular electrical stimulation with integrated volitional electrical stimulator (IVES) plus wrist splint for 8 hours a day plus standard rehabilitation (1 hour physical therapy and 1 hour occupational therapy per day, 5 days a week plus speech therapy if indicated); instructed to use the affected hand as much as possible in activities of daily living
Comparisons	HANDS versus Control: wore the same wrist splint for 8 hours a day plus standard rehabilitation (1 hour physical therapy and 1 hour occupational therapy per day, 5 days a week plus speech therapy if indicated); instructed to use the affected hand as much as possible in activities of daily living
Length of Study/ Follow-up	Post-treatment (3 weeks); no follow up
Outcome measures studied	Fugl-Meyer Assessment (proximal and distal), Action Research Arm Test, Motor Activity Log amount of use [AOU] and quality of movement [QOM] scales, Modified Ashworth Scale
Results	Gain in Action Research Arm Test (ARAT) score: HANDS: 13.2 (7.6) n=10; control: 8.3 (8.1) n=10, p=0.218. Improvement ratio (post: pre score) in Action Research Arm Test (ARAT) score: HANDS: 1.99 (0.70) n=10; control: 1.51 (0.86) n=10, p=0.043. Gain in Motor Activity Log (MAL) AOU score: HANDS: 0.43 (0.38) n=10; control: 0.18 (0.20) n=10, p=0.089. Gain in Motor Activity Log (MAL) QOM score: HANDS: 0.51 (0.33) n=10; control: 0.26 (0.23) n=10, p=0.123
Effect Size	Gain in Fugl-Meyer Assessment (FMA) total score: HANDS: 12.2 (SD 5.3) n=10; control: 5.5 (6.0) n=10, p=0.023; FMA-d [distal]: HANDS: 5.8 (SD 2.1) n=10; control: 2.6 (3.3) n=10, p=0.009; proximal HANDS: 6.4 (SD 3.9) n=10; control: 2.9 (4.2) n=10, p=0.105
Source of funding:	Research Funds from Tokyo Metropolitan Rehabilitation Hospital and the Strategic Research Program for Brain Science (SRPBS) from the Ministry of Education
Does the study answer the question?/Further Comments	The authors concluded that HANDS in addition to conventional therapy may improve hand function in patients with moderate to severe hand impairment during early rehabilitation; however, trial was small and no follow-up beyond the end of the three-week intervention

Thrasher TA;Zivanovic V;McIlroy W;Popovic MR;

Rehabilitation of reaching and grasping function in severe hemiplegic patients using functional electrical stimulation therapy

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment adequate; small sample size; baseline characteristics only given for a few variables (e.g. no information on side of stroke, or gender by group); data only shown graphically and given as change scores but as a percentage of the maximum score not absolute values; post-intervention only no follow up.

DETAILS

of patients: 21 (10 FES + 11 control)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Hemiplegic patients hospitalised for recent stroke; score of 1 or 2 for combined arm and hand on Chedoke-McMaster Stages of Motor Recovery (CMSMR, i.e. spastic or flaccid paralysis of arm and hand with little or no voluntary movement); 2-7 weeks post stroke.

Exclusion: Oedema of affected upper limb; skin rash, allergy or wound where electrodes would be placed; loss of proprioception.

Baseline characteristics:

	FES	Control
Age (yr)	57 (14.7)	58 (19.7)

Days after stroke 29.8 (11.8) 28.5 (9.0)

Interventions/ Test/ Factor being investigated

FES: conventional OT and physio to shoulder, elbow, wrist and hand 5 days per week for 12-16 weeks (see below); each session combined with FES for 45 mins of the session; stimulator responded to push-button command by therapist when patient tried unsuccessfully to perform task; therapist guided arm to ensure a normal movement. In early stages, all movements performed with FES; in later treatments FES used less

Comparisons

Conventional OT and physio to shoulder, elbow, wrist and hand 5 days per week for 12-16 weeks; each session 45 mins (muscle facilitation, repetitive functional training, strengthening against resistance, ADL, caregiver training; included electrical stimulation for strengthening (not functional training)

Length of Study/ Follow-up

Post-intervention only, no follow up

Outcome measures studied

Rehabilitation Engineering Laboratory Hand Function Test

Results

Data only shown graphically and given as change scores but as a percentage of the maximum score not absolute values so not usable; FES reported to improve significantly more on RELHFT object manipulation, palmar grip torque, pinch grip pulling force ($p < 0.05$). There were no significant differences in RELHFT blocks score or eccentric load.

Effect Size

Source of funding:

Toronto Rehabilitation institute, Canadian Paraplegic Association Ontario

Does the study answer the question?/Further Comments

The authors report that FES improved hand function in patients with severe stroke. However, the sample size was small, baseline characteristics of the patients were not well described; data were only shown graphically and as percentages of maximum scores not absolute values, and there was no follow up.

Question: In people after stroke what is the clinical and cost effectiveness of constraint-induced therapy versus usual care on improving function and reducing disability?

Study Type	Randomised Controlled Trial
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Dahl AE;Askim T;Stock R;Langorgen E;Lydersen S;Indredavik B;

Short- and long-term outcome of constraint-induced movement therapy after stroke: a randomized controlled feasibility trial

Ref ID 389 **RID:** 225 2008

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =** Blinded assessors

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

no **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment adequate, blinded assessors, intention to treat analysis, no loss to follow up. But small sample size, no power calculation.

DETAILS

of patients: 18 allocated to CIMT and 12 to traditional rehabilitation. All completed intervention and all assessments

Prevalence (Diagnostic):

Patient Characteristics	<p>Patients characteristics: CIMT ; Control</p> <p>Mean age (years) 62 (8) ; 60 (12);</p> <p>Women n(%) 2 (11%) ; 5 (42%);</p> <p>living alone n(%) 5 (28%) ; 2 (17%);</p> <p>dominant side affected n(%) 14 (78%) ; 7 (58%);</p> <p>Months since stroke mean(SD): 21 (18) ; 26 (27);</p> <p>Median(range) 16 (1-64) ; 19 (1-92);</p> <p>Medical history:</p> <p>prior stroke n(%) 1 (6%) ; 2 (17%);</p> <p>TIA n(%) 0 (0%) ; 2 (17%);</p> <p>MI n(%) 3 (17%) ; 2 (17%);</p> <p>atrial fibrillation n(%) 2 (11%) ; 0 (0%);</p> <p>hypertension n(%) 8 (44%) ; 5 (42%);</p> <p>diabetes n(%) 4 (22%) ; 3 (25%);</p> <p>no differences significant.</p> <p>Range of movement requirement: more than 20 degrees active wrist extension and 10 degrees active finger extension</p>
Interventions/ Test/ Factor being investigated	<p>Constraint-induced movement therapy (CIMT); training 6 hours per day for 10 consecutive week days; in groups of 4 led by physical and occupational therapist, assisted by trained nurses; a mitten immobilised the non-paretic hand for target 90% of waking hours (actually 13 hours/day). Each participant formulated 5 realistic aims; exercises chosen from 150 in 10 fields (personal care, kitchen/household, games, handicrafts, gardening, office work, shopping, sports, strength, mobility), ranging from simple to complex tasks, individually adjusted for number of repetitions, tempo, resistance, range of movement, texture, weight, size and shape. Mini-breaks when shifted between fields of activity after half an hour.</p>
Comparisons	<p>CIMT (restraint 90% of waking hours)vs. traditional rehabilitation - community-based follow up according to patient's needs, involving both upper and lower limb training; could include inpatient rehab (physiotherapy + occupational therapy) then 2 outpatient sessions per week. Control group offered CIMT after 6 month follow up.</p>
Length of Study/ Follow-up	<p>Baseline; post-assessment after 2 weeks intervention; 6 month follow up</p>
Outcome measures studied	<p>Primary: Wolf Motor Function Test; mean of 15 timed tasks used. Secondary: 30-item Motor Activity Log, Functional Independence Measure, Stroke Impact Scale. Adverse symptoms.</p>
Results	<p style="text-align: center;">CIMT ; Control ; between-group p value</p> <p>WMFT Mean performance time:</p> <p>baseline : 2.17 (0.78) ; 2.27 (0.85)</p> <p>post-treatment : 1.56 (0.57)* ; 2.03 (0.82) ; p=0.030</p> <p>6 months: 1.82 (0.80) ; 1.77 (0.92); p=0.585.</p> <p>WFMT-functional ability (max=5)</p> <p>Baseline : 3.51±0.53 ; 3.31±0.51</p> <p>Post-treatment assessment: 3.85±0.50; 3.47±0.60; p=0.037</p> <p>6 month follow-up:3.95±0.61; 3.73±0.58;p=0.823</p> <p>FIM (max=126)</p> <p>Baseline: 106.17±8.54; 110.92±5.85</p> <p>Post-treatment: 107.33±8.80; 111.67±6.49;p=0.516</p> <p>6 month follow-up: 109.56±8.25; 112.92±6.75; p=0.571</p> <p>* p<0.001 vs. baseline</p> <p>Adverse symptoms: Four people in the CIMT group had muscle tenderness in their affected arm before starting the intervention. The symptoms either decreased or remained unchanged during the intervention. No injuries or side-effects were reported.</p>
Effect Size	

Source of funding: Norwegian Fund for Postgraduate Training in Physiotherapy and Clinical Services

Does the study answer the question?/Further Comments CIMT appears effective in the short term but no long-term effect found. No injuries or other side-effects were reported.

Dromerick AW;Edwards DF;Hahn M;

Does the application of constraint-induced movement therapy during acute rehabilitation reduce arm impairment after ischemic stroke?

Ref ID 1227 **RID:** 229 2000

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

N values for each group at the beginning of the study not stated.
Reasons people dropped out not stated.

DETAILS

# of patients:	CI = 11, Control=9 NB this is those who completed. 23 enrolled, not clear how many in each group																																																																
Prevalence (Diagnostic):																																																																	
Patient Characteristics	<p>Inpatients in acute stroke & brain injury rehabilitation service. Patients screened within 2 days of admission (usually within 7 days of stroke onset). Inclusion criteria: admission within 14 days of ischemic stroke, persistent hemiparesis leading to impaired UE function as indicated by a score of 1 or 2 on motor arm item of the National Institutes of Health Stroke Scale (NIHSS), evidence of preserved cognitive function, as indicated by 0 or 1 on consciousness communication and neglect items of NIHSS, presence of a protective response as indicated by scores of greater than or equal to 3 on the upper-arm item of the motor assessment scale and no UE injury or conditions that limited use before the stroke.</p> <p>Patients characteristics:</p> <table border="0"> <thead> <tr> <th></th> <th>CIMT</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Mean (SD) age (years)</td> <td>61.5+/-13.7yrs</td> <td>71.4+/-5.3yrs</td> </tr> <tr> <td>Gender female %</td> <td>25%</td> <td>63%</td> </tr> <tr> <td>Side affected right %</td> <td>75%</td> <td>63%</td> </tr> </tbody> </table> <p>No information on range of movement requirement</p>		CIMT	Control	Mean (SD) age (years)	61.5+/-13.7yrs	71.4+/-5.3yrs	Gender female %	25%	63%	Side affected right %	75%	63%																																																				
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Interventions/ Test/ Factor being investigated	<p>All subjects received routine interdisciplinary stroke rehabilitation , except for study treatment that occurred during the regularly scheduled occupational therapy sessions. Individualised circuit-training techniques were used in control and experimental groups. All received study treatment for 2 hours per day, 5 days per week for 2 consecutive weeks. Control group received standard occupational therapy treatment that included compensatory techniques for ADL, UE strength and range of motion and traditional positioning. Subjects also participated in a circuit training program allowing patients to perform bilateral self-range of motion and functional activities in a supervised setting. CI group received treatment that directed subject attention and effort toward the hemiparetic UE and minimised the use of the uninvolved UE during functional activities. Subjects wore a padded mitten for at least 6 hrs per day during the 14-day treatment period. Occupational therapy focussed on ADLs, UE training which used the affected UE as much as possible. CI circuit training encouraged the use of the hemiplegic arm with a variety of UE and functional tasks.</p>																																																																
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Effect Size																																																																	

Source of funding: American Heart Association and the James S McDonnell Foundation

Does the study answer the question?/Further Comments A clinical trial of CIM therapy during acute rehabilitation is feasible. CIM was associated with less arm impairment at the end of treatment. Long-term studies are needed to determine whether CIM early after stroke is superior to traditional therapies.

Hammer AM;Lindmark B;

Effects of forced use on arm function in the subacute phase after stroke: A randomized, clinical pilot study

Ref ID 2487 **RID:** 230 2009

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

high risk of bias **Direction =** Unblinded assessor so possible bias in favour of intervention

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment adequate; intention-to-treat analysis. But small sample size, no power calculation, non-blinded outcome assessor, 13% lost to follow up. It took almost 8 years to recruit 30 patients, i.e. patients highly selected and probably not representative of general population of patients with stroke. Lack of control over dose and content of treatment over time. Retrospective power calculation suggested study would have needed 58 patients per group (i.e. underpowered).

DETAILS

of patients: 15 assigned to treatment group + 15 to control group

Prevalence (Diagnostic):

Patient Characteristics

	CIMT;	Control
Mean age (years) and range	66.3 (10.3) range 51-83	60.4 (11.1) range 31-80
Gender male: female	14:1	9:6
Side affected dominant: non-dominant	12:3	7:8
mini mental state score	28.6 (1.3)	27.7 (2.5);
mean time since stroke (months)	2.6 (1.5)	2.3 (1.2);
From rehabilitation: geriatric depts	7:8	11:4
	no differences significant.	

Range of movement requirement: ability to move the shoulder and elbow voluntarily and extend 20 degrees in the wrist and 10 degrees in the fingers of the paretic arm and hand

Interventions/ Test/ Factor being investigated

All received standard interdisciplinary rehabilitation of daily training 5 days per week; intervention group (forced use) also wore a restraining sling on nonparetic arm with a target of 6 hours per day (actually achieved 3.7 hours/day). Physical and occupational therapy individualised; task-orientated approach; upper and lower limb training

Comparisons

CIMT: Forced use (restraint 6 hours/day) versus standard rehabilitation

Length of Study/ Follow-up

Pre-intervention; postintervention (2 weeks); 1 month follow up; 3 month follow up

Outcome measures studied

Fugl-Meyer test; Modified Ashworth Scale; Action Research Arm Test; Motor Assessment Scale; 16 hole peg test; isometric grip strength: Grippit ratio of paretic hand to non-paretic hand (none defined as primary outcome measure).

Results

Effect sizes*:	post-test;	1 month;	3 months:
Fugl-Meyer	0.50;	0.21;	0.11.
Modified Ashworth Scale:	0.13;	0.44;	0.00.
Action Research Arm Test	-0.13;	0.25;	0.56.
Motor Assessment Scale:	-0.22;	-0.46;	0.00.
16 hole peg test	0.57;	0.42;	0.28
Grippit ratio	0.31;	0.69;	0.23

*Analysis carried out on the basis of intention to treat analysis (ITT).

Effect Size

Source of funding:

Research Funds of Orebro County Council, Swedish Stroke Association

Does the study answer the question?/Further Comments

Study underpowered; no differences in changes between the groups on any measure at any time point; effect sizes were mainly small.

Lin K;Chang Y;Wu C;Chen Y;

Effects of constraint-induced therapy versus bilateral arm training on motor performance, daily functions, and quality of life in stroke survivors

Ref ID 2764

RID:

273

2009 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment adequate. But small trial;no power calculation; intention to treat not stated; sample represented small percentage of all stroke patients so may not be generalisable; post-treatment only, no follow up data

DETAILS

# of patients:	60 in total: 20 each to 3 interventions: 1) CIMT, 2) bilateral arm training and 3) control
Prevalence (Diagnostic):	
Patient Characteristics	<p>Patients characteristics:</p> <p>CIMT; bilateral arm training ; Control</p> <p>Mean age (years) 55.28 (9.34) 51.58 (8.67) 50.70 (13.93);</p> <p>Gender M:F 11M:9F ; 12M:8F; 11M:9F;</p> <p>Side affected R:L 8:12; 11:9; 12:8;</p> <p>Time since stroke mean(SD) months 21.25 (21.59) ; 18.50 (17.40) ; 21.90 (20.51);</p> <p>MMSE median (range) 28 (24-30) ; 29.5 (25-30) ; 28.5 (24-30);</p> <p>no significant differences between groups.</p> <p>Brunnstrom above stage III for proximal and distal part of upper limb; an amount of use score <2.5 on the motor Activity log of the upper limb; no serious cognitive defect; Modified Ashworth scale score ≤2 in any joint of the shoulder, elbow wrist, or fingers.</p>
Interventions/ Test/ Factor being investigated	1) CIMT: restriction of movement of unaffected hand by using a mitt 6 hours/day and intensive training of affected upper limb in functional tasks 2 hours/weekday for 3 weeks. 2) Bilateral arm training: simultaneous movement of affected and unaffected upper limbs in symmetrical or alternating patterns 2 hours/weekday for 3 weeks. 3) control: training in hand function, coordination, balance, movements of affected upper limb and practice on functional tasks with unaffected or both limbs, 2 hours/weekday for 3 weeks.
Comparisons	Analysis of covariance between the 3 groups; post hoc analyses compared the CIMT(restraint 6 hours/day) with control group, and bilateral arm training with control group, separately.
Length of Study/ Follow-up	Post-treatment only, no follow up
Outcome measures studied	Fugl-Meyer Assessment (FMA), Functional Independence Measure (FIM), Motor Activity Log (MAL), Stroke Impact Scale (SIS)
Results	<p>CIMT; BAT ; Control, p value</p> <p>Fugl Meyer Assessment (FMA):</p> <p>Pre-treatment: 46.05 (8.30) 45.50 (10.35) 49.75 (12.10);</p> <p>post-treatment: 52.30 (7.17) 52.25 (9.06) 51.25 (12.59),</p> <p>p<0.001**</p> <p>Functional Independence Measure (FIM):</p> <p>Pre-treatment: 119.4 (8.34) 116.7 (12.83) 114.3 (10.27);</p> <p>post-treatment: 122.05 (5.60) 119.15 (10.7) 116.65 (8.34), p=0.350***</p> <p>** effect size ES 0.51</p> <p>***effect size ES 0.19</p> <p>BAT=bilateral arm training</p>
Effect Size	
Source of funding:	National Science Council, National Health Institutes in Taiwan.
Does the study answer the question?/Further Comments	Significant effect of CIMT on function post-intervention but no follow up data.

Lin K;Wu C;Wei T;Lee C;Liu J;

Effects of modified constraint-induced movement therapy on reach-to-grasp movements and functional performance after chronic stroke: A randomized controlled study

Ref ID 2761

RID:

232

2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction = Only post-intervention no follow up data; likely to bias in favour of treatment group

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment adequate. But small sample size, no power calculation, intention to treat analysis not stated; only post-intervention outcomes not follow up data.

DETAILS

of patients:

34 randomised (17 to CIMT and 17 to traditional treatment, of whom 2 dropped out of traditional treatment group)

Prevalence (Diagnostic):

Patient Characteristics

	CIMT	Control
Mean age (years)	57.11 (18.30)	58.77 (15.15);
Gender Male: Female :	11: 6;	10:5;
Side affected: left: right	8:9 ;	6:9;
Time since stroke mean(SD) months	15.97 (3.46) ;	16.61 (2.89) ;
modified MMSE mean(SD)	84.70 (10.79);	86.50 (12.81);

	Motor Activity Log amount of use	0.64 (0.71);	0.69 (0.91);	
	no differences significant			
	Brunnstrom above stage III for proximal and distal part of arm; an amount of use score <2.5 on the motor Activity log of the affected arm; no serious cognitive defect; Modified Ashworth scale score = 2 in any joint of the shoulder, elbow wrist, or fingers			
Interventions/ Test/ Factor being investigated	Modified CIMT: restriction of movement of unaffected hand by a mitt for target 6 hours per day (actual 6.2 hours/day) plus intensive training of affected arm 2 hours per weekday for 3 weeks (typical activities picking up marbles, flipping cards, stacking blocks, combing hair, writing, daily life activities); level of challenge adapted to patient ability and improvement			
Comparisons	CIMT (restraint 6 hours/day) vs. Traditional rehabilitation: 5 days/week for 2 hours/day for 3 weeks involving strength, balance and fine motor dexterity training, functional task practice when possible, and stretching/weight bearing by the affected arm.			
Length of Study/ Follow-up	Post-intervention only			
Outcome measures studied	Kinematic analysis during functional grasping task; Motor Activity Log; Functional Independence Measure (FIM)			
Results		CIMT	Control	p value, effect size
	Functional Independence Measure (FIM)			
		pre-treatment 104.00 (13.60);	102.00 (17.8).	
		Post-treatment: 113.06 (10.55);	105.67 (15.85),	p=0.016, ES 0.43 (moderate)
Effect Size				
Source of funding:	National Health Research Institutes, National Science Council in Taiwan.			
Does the study answer the question?/Further Comments	Post-treatment scores on Functional Independence Measure improved more in CIMT group (p=0.016) among patients with chronic stroke with a moderate effect size (0.43). However, no follow up data were collected.			

Myint JM;Yuen GF;Yu TK;Kng CP;Wong AM;Chow KK;Li HC;Chun PW;

A study of constraint-induced movement therapy in subacute stroke patients in Hong Kong

Ref ID 4875

RID:

238

2008

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Small sample size; no power calculation; patients at high risk of falling excluded and fear of falling contributed to withdrawal, also some patients too impaired or recovered too fast for inclusion, so may not be generalisable to wider population; relatively short follow up (12 weeks).

DETAILS

of patients:

48 randomised (28 to CIMT intervention and 20 to control group); 5 did not receive intervention and 3 discontinued.

Prevalence (Diagnostic):

Patient Characteristics

	CIMT	Control
mean age (years)	63.4 (13.6)	63.9 (12.2);
Time since stroke mean (SD) days	38.2 (20.4) ;	44.9 (28.6) ;
Gender female: male	13:10	12:8;
affected hand dominant	11/23	14/20;
mini mental state examination	25.6 (4.2)	24.1 (5.5);
no differences significant.		
Minimal movement of ≥ 20 degrees wrist extension and 10 degrees extension of all digits		

Interventions/ Test/ Factor being investigated

10 days 4 hours/day 5 days/week for 2 weeks; upper limb training (items relevant to activities of daily living) with unaffected limb in a sling, with a target of 90% of waking hours during treatment days (all waking hours except when toileting, bathing or engaging in activities with potential risk of fall; actual 87.3% waking hours)

Comparisons	CIMT (restraint 90% of waking hours) vs. control: 4 hours conventional occupational and physical therapy/day 5 days/week for 2 weeks; neurodevelopmental techniques, bimanual tasks, compensatory techniques, strength, range of motion, positioning, mobility		
Length of Study/ Follow-up	Post-intervention and 12 weeks follow up		
Outcome measures studied	Primary outcome measures: Action Research Arm Test (ARAT) and Motor Activity Log (MAL); secondary outcomes Barthel Index (BI) and 9-hole peg test (9HPT)		
Results	CIMT ;	Control	p value
	ARAT:		
	baseline:	27.0 (13.4) ; 24.0 (13.2);	
	post-treatment:	47.1 (10.2) ; 33.6 (12.5);	
	12 weeks:	49.6 (9.9) ; 39.9 (14.1),	p=0.009.
	Barthel Index:		
	baseline:	86.7 (12.4) ; 79.5 (15.3);	
	post-treatment:	92.6 (8.5) ; 85.3 (13.6);	
	12 weeks:	97.6 (4.2) ; 93.4 (7.7),	p=0.305.
	Able to complete 9 Hole Peg Test:		
	baseline:	9 (34.8%) ; 6 (30%),	p=0.739;
	post-treatment:	16 (69.6%) ; 9 (45%),	p=0.022;
	12 weeks:	18 (78.3%) ; 10 (50%),	p=0.029.
Effect Size			
Source of funding:	not stated		
Does the study answer the question?/Further Comments	CIMT was better than control for subacute stroke patients with moderately impaired upper extremity function and effects were maintained at 12 weeks.		

Page SJ;Levine P;Leonard A;Szaflarski JP;Kissela BM;

Modified constraint-induced therapy in chronic stroke: Results of a single-blinded randomized controlled trial

Ref ID 2978 **RID:** 233 2008

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = 2 control conditions

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction = post-test only, no follow up

Overall Study Quality -Strengths and Weaknesses:

few details on baseline characteristics although stated to be no significant differences between groups; allocation concealment not stated; small sample size; no power calculation; post-test only, no follow up

DETAILS

of patients:

35 (13 in CIMT group; 12 in time-matched rehabilitation programme without arm restraint and 10 no treatment controls)

Prevalence (Diagnostic):

Patient Characteristics

"chronic stroke" i.e. >12 months post-stroke;
22 male + 13 female;
mean age 57.9 (8.4) years, range 47-76 years;
mean time since stroke 39.8 months (range 20-60 months);
23 right and 12 left hemiparesis
(distribution between intervention and control groups not reported).

Range of movement requirement: ability to selectively actively extend at least 10 degrees at the metacarpophalangeal and interphalangeal joints and 20 degrees at the wrist

Interventions/ Test/ Factor being investigated

CIMT: half-hour one-to-one sessions of therapy for more affected arm; 3 days per week for 10 weeks plus less affected arm restrained every weekday for 5 hours during a time of frequent arm use, using sling and hand in mesh polystyrene-filled mitt

Comparisons	CIMT (restraint 5 hours/day) vs. TR: time-matched rehabilitation group (half-hour one-to-one sessions of therapy for more affected arm; 3 days per week for 10 weeks focused on proprioceptive neuromuscular facilitation techniques, stretching, compensatory techniques); and no-treatment control group		
Length of Study/ Follow-up	Post-test only, no follow up		
Outcome measures studied	Primary: Action Research Arm Test (ARAT); secondary: Fugl-Meyer assessment of motor recovery after stroke (FM), Motor Activity Log (MAL)		
Results	CIMT ;	Timed matched Rehab ;	Control
	ARAT		
	Pretest 1: 29.69 (7.54);	25.83 (8.76);	23.30 (13.61).
	Pretest 2: 29.76 (7.27);	26.50 (9.28);	25.30 (16.08).
	Post-test: 40.54 (8.18);	29.17 (10.0);	25.20 (16.75).
	Mean improvement: 10.8 points; 3.0 points; 0.9 points		
	p<0.001 across 3 groups; CIMT significantly different from each other group.		
	Fugl Meyer:		
	Pretest 1: 41.38 (7.44);	37.00 (12.08);	30.60 (13.24)
	Pretest 2: 40.30 (7.38);	38.50 (11.05);	32.80 (14.34).
	Post-test: 48.23 (8.06);	42.42 (12.00);	34.50 (15.69).
	Mean improvement: 7.4 points; 4.6 points; 2.8 points		
	(p value not stated)		
Effect Size			
Source of funding:	Scientist Development Grant from American Heart Association		
Does the study answer the question?/Further Comments	CIMT improved function at post-test but no follow up.		

Ploughman M;Corbett D;

Can forced-use therapy be clinically applied after stroke? An exploratory randomized controlled trial

Ref ID 4874 **RID:** 237 2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = duration and sepcific techniques of therapy not standardised

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

high risk of detection bias

Direction = outcome assessors included principal investigator and were not blinded; could bias in favour of intervention

Overall Study Quality -Strengths and Weaknesses:

very small study; no power calculation; excluded patients over 75 years; method of randomisation and allocation concealment unclear; assessors not blinded; evaluation on discharge (unclear duration of treatment); duration and techniques of rehabilitation not standardised; duration of wear of constraint mitt not recorded daily; subgroup analyses presented on tiny numbers of patients (e.g. 5 females in treatment group versus 3 in control group)

DETAILS

of patients: 13 allocated to constraint group and 14 to control group

Prevalence (Diagnostic):

Patient Characteristics

Patient characteristics:

	Control	Treatment
Age mean (SD) years	61.62(5.68)	57.8(10.65)
Mean days post-stroke	38.8(23.4)	36(22.5)
Gender female: male	5:8	3:7
Side of hemiplegia left: right	9:4	4:6
MMSE score	29(1.29)	29.33(0.75)
admission Chedoke-McMaster Impairment Inventory arm score	2.77(0.93)	3(0.94)
Admission hand score	2.54(0.88)	3.1(0.88)
Baseline ARAT score	16 (13.64);	20.7 (15.49)
Motor control of the upper extremity of more than stage 2 but not more than stage 6 on the Chedoke-McMaster Impairment Inventory (CMII) of the arm and hand.		

Interventions/ Test/ Factor being investigated	wearing long thick knitted acrylic thumbless mitten to discourage use of uninvolved arm and hand; should have been worn 1 hour a day increasing to 6 hours by 2 weeks and 6 hours to end of treatment (but mean time worn only 2.7 hours a day)
Comparisons	CIMT (6 hours/day) vs. Conventional treatment i.e. facilitation of proximal motor control progressing to skilled task training, strength and endurance training, functional electrical stimulation, gait training, education
Length of Study/ Follow-up	Assessed at discharge but duration of therapy not standardised
Outcome measures studied	Outcome measures Action Research Arm Test (ARAT), Functional Independent Measure (FIM), Chedoke-McMaster Impairment Inventory (CMII), grip strength, not specified which was the primary outcome measure
Results	ARAT improved 85% with CIMT mitt (from baseline score of 20.7 (15.49)) vs. 74% without (from baseline 16.0 (13.64)), p=0.02. No significant difference in FIM or grip strength (data not presented). CMII arm function improved 53% with CIMT mitt (from baseline 3.0 (0.94)) and 33% without (from baseline 2.77 (0.93)), not significant. CMII postural control improved significantly more with mitt (p=0.04 but mean change scores only shown graphically). CMII hand control and shoulder pain changes not significantly different
Effect Size	
Source of funding:	General Hospital Health Foundation and Canadian Institute for Health Research
Does the study answer the question?/Further Comments	Sample too small, rehabilitation not standardised; wear time of mitt not recorded reliably and outcome assessment not blinded so cannot draw conclusions from this study. Insufficient data on our outcome measures to data extract.

Taub E;Uswatte G;King DK;Morris D;Crago JE;Chatterjee A;

A placebo-controlled trial of constraint-induced movement therapy for upper extremity after stroke

Ref ID 4877 **RID:** 239 2006

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Bias likely in favour of intervention group

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = All followed to 4 weeks; controls at 3 months and intervention group at 2 years

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Number of drop outs not reported - n values in results table and text do not agree (for WMFT table says n=20 in control, text says 18). No information presented on whether assessors were blinded to treatment group. Groups were allocated in blocks according to functional ability - not random; more women in CIMT than control group and women improved more than men on some outcomes.

DETAILS

of patients:

Constraint-Induced n=21, Control n=20

Prevalence (Diagnostic):

Patient Characteristics

	CIMT;	Control ;
Age (years)	54.6+/-12.1yrs,	50.7+/-19.2yrs,
Gender male: female	11:10	16:4
Side affected right:	11	9
Dominant side affected	11	9
Mean time since stroke (years)	3.6(4.5)	5.3(3.9),
Time since stroke 1-2years	14	5
Time since stroke 2-5yrs	4	8
Time since stroke 5-20yrs	3	7

Community based.

Range of movement inclusion requirement: ability to actively extend 10degrees or over at metacarpophalangeal and interphalangeal joints and 20 degrees at wrist

Interventions/ Test/ Factor being investigated

Constraint-Induced Movement therapy (paretic arm training and contralateral arm restraint) for 6 hours per day with additional hour of interpolated rest on each weekday of 2-week treatment period. Training consisted primarily of 'shaping' which involved: (1) quantifying and very frequent immediate feedback concerning

improvements in the speed and quality of movement (QOM) (2) selecting tasks that were tailored to address the motor deficits of the individual patient (3) modeling, prompting and cuing of task performance, and (4) systematically increasing the difficulty level of the task performed in small steps when 5 trials of improved performance occurred. The CI therapy participants also wore a resting hand splint/sling ensemble on their less affected upper extremity that prevented use of that arm for a target of 90% of waking hours for the entire 14day treatment period. Additional behavioural techniques such as behavioural contracts and problem solving were used to facilitate transfer of treatment gains from the therapeutic to the home setting. The control group received a general fitness program in which they performed strength, balance and stamina training exercises, played games that provided cognitive challenges, and practiced relaxation exercises for 6 hours per day for 10 consecutive week-days.

Comparisons Within groups (over time) and CI (restraint 90% of waking hours) vs control. Group x time interaction also assessed for CI efficacy

**Length of Study/
Follow-up** 2 years after end of treatment

Outcome measures studied Wolf motor function test (WMFT); Motor Activity Log (MAL) amount of use (AOU); primary or secondary outcome not stated

Results	CIMT;	Control ;
WMFT Performance time (s)		
Pre-treatment	5.3 (3.1),	4.1 (2.5),
Post-treatment	3.0 (1.1),	4.6 (4.4),
Change	-2.3 (2.3);	0.5 (3.6),
p value	p=0.005	
WMFT Functional ability (max=4)		
Pre-treatment	3.0 (0.4),	2.9 (0.4),
Post-treatment	3.2 (0.4),	2.9 (0.5),
Change	0.2 (3.0);	0.0 (0.4),
p value	p=0.1	
Motor Activity Log Amount Of Use:		
Pre-treatment	1.3 (0.6),	1.0 (0.5),
Post-treatment	3.1 (0.6),	1.1 (0.5),
Change	1.9 (0.6);	0.1 (0.3),
p value	p<0.0001	
4 week follow up: improvement in MAL score compared with baseline:	1.8 (0.8);	no change

Effect Size

Source of funding: National Institutes of Health and US Department of Veterans Affairs

Does the study answer the question?/Further Comments The results support the efficacy of CI therapy for rehabilitating upper extremity motor function in patients with chronic stroke.

van der Lee JH;Wagenaar RC;Lankhorst GJ;Vogelaar TW;Deville WL;Bouter LM;

Forced use of the upper extremity in chronic stroke patients: results from a single-blind randomized clinical trial

Ref ID 4889

RID:

254

1999 Nov

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = A third of patients swapped from randomised group to other group
invalidating randomisation method

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

No power calculation; a third of patients swapped from randomised group to the other group invalidating randomisation; groups differed on time since stroke and baseline Fugl-Meyer assessment.

DETAILS

of patients: 33 randomised to intervention and 33 to control

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: single stroke at least 1 yr before start of study ; hemiparesis on dominant side ; minimum of 20 degrees of active wrist extension and 10 degrees of finger extension ; ARA test score < 51 ; age 18 to 80 ; ability to walk indoors without a stick ; no severe aphasia.
Median age 61 years (range 22-80 years); median 3 years since stroke (inclusion criteria specified at least 1 year since stroke; range 1-20 years)

Interventions/ Test/ Factor being investigated

Forced use treatment: healthy arm immobilised using splint (worn at home during 12 days of treatment, except when travelling, sleeping, dressing or toileting) plus closed arm sling attached to the waist during treatment hours. Group activities in groups of 4 (housekeeping activities, handicrafts, games) 5 days a week, 6 hours a day

Comparisons	CIMT (restraint at least 6 hours/day) vs. control: NeuroDevelopmental Treatment (NDT): bimanual training. Group activities in groups of 4 (housekeeping activities, handicrafts, games) 5 days a week, 6 hours a day
Length of Study/ Follow-up	Follow up 3 weeks, 6 weeks, 6 months and 1 year after treatment
Outcome measures studied	Primary: Personal Care and Occupation domains of the Rehabilitation Activities Profile (RAP), Action Research Arm Test (ARAT). Secondary: Fugl-Meyer Assessment (FMA), Motor Activity Log (amount of use AOU) and quality of movement (QOM) scales)
Results	<p>ARAT: Forced use: 33.7 (12.2) baseline to 39.2 (13.1) at 3 weeks , 38 (13.1) at 6 weeks and 38.5 (13.6) at 1 year; Control: 27.3 (13.4) baseline; 30.0 (13.9) 3 weeks;30.8 (13.6) at 6 weeks and 30.7 (14.2) 1 year. Mean difference 3.0 points (95% CI 1.3 to 4.8 points), < MCID of 5.7 points.</p> <p>Fugl Meyer Assessment (FMA) : Forced use: 50.3 (9.0) baseline; 51.6 (8.0) at 3 weeks; 52.3 (8.3) at 6 weeks; 50.9 (9.9) at 1 year; Control: 44.1 (9.8) baseline; 45.0 (10.6) at 3 weeks; 46.7 (9.6) at 6 weeks; 45.5 (9.7) at 1 year; no treatment effect on this scale.</p> <p>Motor Activity Log (Amount Of Use): Forced use: 2.2 (1.1) baseline; 2.9 (1.0) at 3 weeks;2.8 (1.1) at 6 weeks; 2.5 (1.1) at 1 year; Control: 1.6 (1.1) baseline; 2.2 (1.2) at 3 weeks;2.1 (1.2) at 6 weeks; 1.8 (1.2) at 1 year. Mean difference in gain 0.52 points (95% CI 0.11 to 0.93 points) >MCID of 0.50 points, but the difference in favour of the forced use group were not maintained at 1 year.</p> <p>MAL QOM: improvement did not differ significantly between treatment conditions.</p>
Effect Size	
Source of funding:	Scientific Research Council for Medical and Health Research, Netherlands
Does the study answer the question?/Further Comments	Protocol violations involving the randomisation process. No significant effects using ITT analysis.

Wolf SL;Winstein CJ;Miller JP;Taub E;Uswatte G;Morris D;Giuliani C;Light KE;Nichols-Larsen D;EXCITE I;

Effect of constraint-induced movement therapy on upper extremity function 3 to 9 months after stroke: the EXCITE randomized clinical trial

Ref ID 637

RID:

228

2006

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Bias likely in favour of intervention group

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Large study (but 222 of target 240 participants randomised so still a little underpowered); 76.1% returned for 12 month assessment; blinded outcome assessment; 48.8% of control patients received clinical care during the study while 51.2% of intervention patients received additional therapies which could bias results in favour of intervention group

DETAILS

of patients: 106 randomised to interveniton group and 116 to "usual and customary care"

Prevalence (Diagnostic):

Patient Characteristics

Patients characteristics: CIMT ; Usual care
Age mean (SD) years 61(13.5) ; 63.3(12.6)
Female 37(34.9) ; 43(37.1)
Dominant side affected 50(47.2) ; 60(51.7)
Days since stroke mean (SD) 179.8(66.1); 187.7(70.8)
Active range of motion mean(SD) degrees:
Wrist extension 85(50) ; 80(48)
Finger extension 42(31) ; 44(30)
Lower functioning participants had at least 10 degrees of active wrist extension, at least 10 degrees of thumb abduction/extension, and at least 10 degrees of extension in at least 2 additional digits. These movements had to be repeated 3 times in 1 minute.

Interventions/ Test/ Factor being investigated

mitt on unaffected hand for a goal of 90% of waking hours for a total of 14 days (treatment days + weekends); on weekdays, adaptive task practice and standard task training of paretic limb 6 hours per day.

Comparisons	CIMT (restraint 90% waking hours) vs. "usual and customary care": ranged from no treatment to application of mechanical interventions (orthotics) or various occupational and physical therapy approaches at home or as a day patient or an outpatient																																																																																																				
Length of Study/ Follow-up	post-treatment; 4, and 12 months																																																																																																				
Outcome measures studied	Primary: Wolf Motor Function Test (WMFT); Motor Activity Log (MAL). Secondary: MAL for caregivers; number of MAL activities for which patients could score 3 or higher; tasks that could be completed on WMFT																																																																																																				
Results	<table border="0" style="width: 100%;"> <thead> <tr> <th></th> <th style="text-align: center;">CIMT ;</th> <th style="text-align: center;">Usual care;</th> <th style="text-align: center;">p value</th> </tr> </thead> <tbody> <tr> <td colspan="4">WMFT (no SDs given) log performance time:</td> </tr> <tr> <td>baseline:</td> <td style="text-align: center;">2.96;</td> <td style="text-align: center;">3.18</td> <td></td> </tr> <tr> <td>post-treatment:</td> <td style="text-align: center;">2.38;</td> <td style="text-align: center;">3.10,</td> <td style="text-align: center;">p<0.001;</td> </tr> <tr> <td>12 months:</td> <td style="text-align: center;">2.23;</td> <td style="text-align: center;">2.87,</td> <td style="text-align: center;">p<0.01.</td> </tr> <tr> <td colspan="4">ANOVA showed that difference between groups at 12 months was 0.42 (0.13 to 0.72), p<0.001.</td> </tr> <tr> <td colspan="4">WMFT Performance time (seconds):</td> </tr> <tr> <td>baseline:</td> <td style="text-align: center;">19.3;</td> <td style="text-align: center;">24.0</td> <td></td> </tr> <tr> <td>post-treatment:</td> <td style="text-align: center;">10.8;</td> <td style="text-align: center;">22.2,</td> <td style="text-align: center;">p<0.001;</td> </tr> <tr> <td>12 months:</td> <td colspan="3">9.3 (change from baseline 52%) vs. 17.7 control (change from baseline 26%).</td> </tr> <tr> <td colspan="4">WMFT Functional ability</td> </tr> <tr> <td>baseline:</td> <td style="text-align: center;">2.39;</td> <td style="text-align: center;">2.21</td> <td></td> </tr> <tr> <td>post-treatment:</td> <td style="text-align: center;">2.69;</td> <td style="text-align: center;">2.30,</td> <td style="text-align: center;">p<0.001;</td> </tr> <tr> <td>12 months:</td> <td colspan="3">2.75 CIMT vs. 2.47 control.</td> </tr> <tr> <td colspan="4">ANOVA showed mean difference 0.11 (-0.06 to +0.27), p<0.001</td> </tr> <tr> <td colspan="4">WMFT Weight</td> </tr> <tr> <td>baseline:</td> <td style="text-align: center;">4.45;</td> <td style="text-align: center;">3.53</td> <td></td> </tr> <tr> <td>post-treatment:</td> <td style="text-align: center;">6.04;</td> <td style="text-align: center;">4.10</td> <td></td> </tr> <tr> <td>12 months:</td> <td style="text-align: center;">7.32;</td> <td style="text-align: center;">5.72</td> <td></td> </tr> <tr> <td colspan="4">ANOVA showed mean difference 0.67 (-1.52 to +2.86), p=0.32</td> </tr> <tr> <td colspan="4">WMFT Grip</td> </tr> <tr> <td>baseline:</td> <td style="text-align: center;">7.53;</td> <td style="text-align: center;">7.23</td> <td></td> </tr> <tr> <td>post-treatment:</td> <td style="text-align: center;">9.51;</td> <td style="text-align: center;">7.91</td> <td></td> </tr> <tr> <td>12 months:</td> <td style="text-align: center;">12.13;</td> <td style="text-align: center;">14.47</td> <td></td> </tr> <tr> <td colspan="4">ANOVA showed mean difference -2.64 (-6.27 to +0.99), p=0.20</td> </tr> </tbody> </table>		CIMT ;	Usual care;	p value	WMFT (no SDs given) log performance time:				baseline:	2.96;	3.18		post-treatment:	2.38;	3.10,	p<0.001;	12 months:	2.23;	2.87,	p<0.01.	ANOVA showed that difference between groups at 12 months was 0.42 (0.13 to 0.72), p<0.001.				WMFT Performance time (seconds):				baseline:	19.3;	24.0		post-treatment:	10.8;	22.2,	p<0.001;	12 months:	9.3 (change from baseline 52%) vs. 17.7 control (change from baseline 26%).			WMFT Functional ability				baseline:	2.39;	2.21		post-treatment:	2.69;	2.30,	p<0.001;	12 months:	2.75 CIMT vs. 2.47 control.			ANOVA showed mean difference 0.11 (-0.06 to +0.27), p<0.001				WMFT Weight				baseline:	4.45;	3.53		post-treatment:	6.04;	4.10		12 months:	7.32;	5.72		ANOVA showed mean difference 0.67 (-1.52 to +2.86), p=0.32				WMFT Grip				baseline:	7.53;	7.23		post-treatment:	9.51;	7.91		12 months:	12.13;	14.47		ANOVA showed mean difference -2.64 (-6.27 to +0.99), p=0.20			
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Source of funding:	National Center for Med. Rehabilitation Research and National Institute of Neurological Diseases and Stroke																																																																																																				
Does the study answer the question?/Further Comments	Unlikely that intensity of treatment comparable between groups (could bias results in favour of intervention group) and no SDs for outcome measures to cannot extract data.																																																																																																				

Wu C;Chuang L;Lin K;Chen H;Tsay P;

Randomized trial of distributed constraint-induced therapy versus bilateral arm training for the rehabilitation of upper-limb motor control and function after stroke

Ref ID 477

RID:

798

2011

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

no

Direction =

Overall Study Quality -Strengths and Weaknesses:

Clear randomisation (computerised block randomisation), unclear allocation concealment, single-blinded trial, multicentred (4 hospitals); no follow up outcome measures. Not ITT analysis (1 missing outcome in each group). Clinical outcome measures were administered by certified and trained occupational therapists blinded to participant group.

DETAILS

of patients:

66 randomised (Distributed constraint-induced, n=22; bilateral arm training, n=22; control, n=22)

Prevalence (Diagnostic):

Patient Characteristics

	DistributedCIT(n=21)	Control(n=21)
Male,n	15	16
Female,n	7	6
Age, mean(SD)	51.91(11.93)	55.19 (2.50)
Months after stroke, mean (SD)	14.91(12.04)	17.77(12.45)
Brunnstrom stage of UE, median(range)		
Proximal	4.5(4.6)	5(3.6)
Distal	5(4.5)	5(3.6)

Brunnstrom above stage III for proximal part of upper extremity; an amount of use score <2.5 on the Motor Activity log.

Interventions/ Test/ Factor being investigated	Distributed CIT: using a mitt to restrict the unaffected hand for 6 hours/day and intensively train the affected UE in functional tasks, for 2 hours/day, 5 days/week for 3 weeks.																		
Comparisons	Control group: compensatory practice on functional tasks with the unaffected UE or both UEs.																		
Length of Study/ Follow-up	No follow up time.																		
Outcome measures studied	Wolf Motor Function Test: performance time and functional ability scores																		
Results																			
Effect Size	<p>Post treatment (3 weeks)</p> <table border="0"> <thead> <tr> <th></th> <th>Distributed CIT</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>WMFT</td> <td></td> <td></td> </tr> <tr> <td>Performance time</td> <td></td> <td></td> </tr> <tr> <td>mean(SD)</td> <td>4.02 (2.49)</td> <td>5.83 (4.65)</td> </tr> <tr> <td>Functional ability</td> <td></td> <td></td> </tr> <tr> <td>mean(SD)</td> <td>3.78(0.71)</td> <td>3.66(0.87)</td> </tr> </tbody> </table>		Distributed CIT	Control	WMFT			Performance time			mean(SD)	4.02 (2.49)	5.83 (4.65)	Functional ability			mean(SD)	3.78(0.71)	3.66(0.87)
	Distributed CIT	Control																	
WMFT																			
Performance time																			
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Functional ability																			
mean(SD)	3.78(0.71)	3.66(0.87)																	
Source of funding:	National Science Council and the National Health Research Institutes in Taiwan.																		
Does the study answer the question?/Further Comments	The distributed CIT patients had decreased WMFT performance time and higher functional ability scores (with overall improvements in motor functions of the affected upper extremities) than the control patients, at the end of the study intervention.																		

Wu CY;Chen CL;Tang SF;Lin KC;Huang YY;

Kinematic and clinical analyses of upper-extremity movements after constraint-induced movement therapy in patients with stroke: a randomized controlled trial

Ref ID 529 **RID:** 226 2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Random number table for randomisation - not ideal

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

no power calculation; random number table used for randomisation; allocation concealment not clear; baseline characteristics comparable; intensity of treatment similar between groups; post-treatment only, no follow up

DETAILS

# of patients:	24 in CIMT group and 23 in traditional intervention group																												
Prevalence (Diagnostic):																													
Patient Characteristics	<p>Inclusion criteria: Able to reach Brunnstrom stage III or above for the proximal part of the UP ; considerable non-use of the more affected UE (MAL AOU score <2.5)</p> <table border="0" style="width: 100%;"> <tr> <td></td> <td style="text-align: center;">CIMT;</td> <td style="text-align: center;">Traditional</td> </tr> <tr> <td>intervention</td> <td></td> <td></td> </tr> <tr> <td>Patients characteristics:</td> <td></td> <td></td> </tr> <tr> <td>Mean (SD) age (years)</td> <td style="text-align: center;">53.93(11.2) ;</td> <td style="text-align: center;">56.77(129)</td> </tr> <tr> <td>Gender male: female</td> <td style="text-align: center;">16:8</td> <td style="text-align: center;">17:7</td> </tr> <tr> <td>Side affected right: left</td> <td style="text-align: center;">11:13</td> <td style="text-align: center;">11:12</td> </tr> <tr> <td>Mean (SD) time since stroke (months)</td> <td style="text-align: center;">12.51(9.64) ;</td> <td style="text-align: center;">11.98(11.72)</td> </tr> <tr> <td>Brunnstrom stage proximal part of UE (median)</td> <td style="text-align: center;">4.5 ;</td> <td style="text-align: center;">4.5</td> </tr> </table>		CIMT;	Traditional	intervention			Patients characteristics:			Mean (SD) age (years)	53.93(11.2) ;	56.77(129)	Gender male: female	16:8	17:7	Side affected right: left	11:13	11:12	Mean (SD) time since stroke (months)	12.51(9.64) ;	11.98(11.72)	Brunnstrom stage proximal part of UE (median)	4.5 ;	4.5				
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Brunnstrom stage proximal part of UE (median)	4.5 ;	4.5																											
Interventions/ Test/ Factor being investigated	<p>CIMT: typical training activities involved use of more affected limb for daily tasks (e.g. reaching and moving a jar, picking up and drinking from cup, picking up hairbrush and combing hair, cleaning window); 2 hours/day, 5 days/week for 3 weeks; less affected hand in mitt 6 hours a day. Also interdisciplinary rehabilitation 1.5 hours/day, 5 days/week for 3 weeks</p>																												
Comparisons	<p>CIMT (restraint 6 hours/day) vs. Traditional intervention: neurodevelopmental therapy emphasising functional task practice, stretching and weight bearing with more affected arm and fine-motor dexterity; 2 hours/day, 5 days/week for 3 weeks. Also interdisciplinary rehabilitation 1.5 hours/day, 5 days/week for 3 weeks</p>																												
Length of Study/ Follow-up	Only post-test at end of 3 weeks training																												
Outcome measures studied	Kinematic analysis of a reaching task; Fugl-Meyer Assessment (FMA); Motor Activity Log (MAL): amount of use (AOU) and quality of movement (QOM) scores																												
Results	<table border="0" style="width: 100%;"> <tr> <td></td> <td style="text-align: center;">CIMT;</td> <td style="text-align: center;">Traditional intervention</td> <td style="text-align: center;">p value, effect size</td> </tr> <tr> <td>FMA</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Pre-treatment</td> <td style="text-align: center;">39.50 (13.45)</td> <td style="text-align: center;">41.74 (13.47),</td> <td style="text-align: center;">p=0.64;</td> </tr> <tr> <td>Post-treatment</td> <td style="text-align: center;">46.75 (11.58)</td> <td style="text-align: center;">44.78 (13.08)</td> <td style="text-align: center;">p=0.019, ES 0.35.</td> </tr> <tr> <td>MAL AOU</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Pre-treatment</td> <td style="text-align: center;">0.64 (0.86)</td> <td style="text-align: center;">0.60 (0.92)</td> <td style="text-align: center;">p=0.87;</td> </tr> <tr> <td>Post-treatment</td> <td style="text-align: center;">1.85 (1.24)</td> <td style="text-align: center;">0.81 (1.13)</td> <td style="text-align: center;">p<0.001, ES 0.66</td> </tr> </table>		CIMT;	Traditional intervention	p value, effect size	FMA				Pre-treatment	39.50 (13.45)	41.74 (13.47),	p=0.64;	Post-treatment	46.75 (11.58)	44.78 (13.08)	p=0.019, ES 0.35.	MAL AOU				Pre-treatment	0.64 (0.86)	0.60 (0.92)	p=0.87;	Post-treatment	1.85 (1.24)	0.81 (1.13)	p<0.001, ES 0.66
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MAL QOM
Pre-treatment 0.72 (1.01) 0.69 (1.17) p=0.94;
Post-treatment 1.85 (1.14) 0.84 (1.08) p<0.001, ES 0.65.

Effect Size

Source of funding: Medical Research Center at Chang Gung Memorial Hospital, National Science Council Taiwan

Does the study answer the question?/Further Comments Post-test scores only, no follow up so long term outcome of intervention unknown

Wu CY;Chen CL;Tsai WC;Lin KC;Chou SH;

A randomized controlled trial of modified constraint-induced movement therapy for elderly stroke survivors: changes in motor impairment, daily functioning, and quality of life

Ref ID 585 **RID:** 269 2007 Mar

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =** Bias likely in favour of intervention

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

table of random numbers used so inadequate concealment of allocation; some baseline characteristics not equivalent between groups which could bias in favour of intervention; post-test only, no follow up; no power calculation

DETAILS

of patients: 13 in CIMT and 13 in traditional rehabilitation group

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: Brunnstrom stage III for the proximal part of upper extremity or above ; no serious cognitive deficits ; considerable non-use of affected limb (AOU score <2.5 on the MAL) ; no excessive spasticity in any of the joints of the affected UP (MAS score =<2 in any joint)

Patient characteristics:

	mCIMT ;	traditional rehabilitation
Mean (SD) age	71.44(6.42) ;	71.94(6.79)
Gender male: female	8:5	7:6
Side affected right: left	6:7	7:6
Mean time since stroke (months)	6.7(8.99) ;	8.32(7.97)
Brunnstrom stage of proximal part of UE (median)	4.5 ;	4.5
AOU MAL	0.8(1.38) ;	1.37(1.71)
MAS	0.26(0.32) ;	0.32(0.34)

Interventions/ Test/ Factor being investigated

CIMT:individualised 2-hour therapy sessions 5 times a week for 3 weeks involving shaping and adaptive repetitive tasks focusing on daily activities (e.g. turning light switch on and off, reaching and moving a jar, picking up and drinking from cup, picking up brush and combing hair); 15 minutes of therapy on normalising muscle tone; unaffected hand in mitt every weekday for 6 hours at time of frequent arm use

Comparisons

CIMT (restraint 6 hours/day) vs. Traditional rehabilitation: 2 hour therapy session; 75% spent on neurodev elopmental techniques emphasising functional task practice, stretching, weight bearing, fine motor dexterity; 25% on compensatory techniques

Length of Study/ Follow-up

Post-test only at end of 3 week treatment period

Outcome measures studied

Fugl-Meyer Assessment (FMA); Functional Independence Measure (FIM); Motor Activity Log (MAL) amount of use (AOU) and quality of movement (QOM); Stroke Impact Scale (SIS)

Results

	CIMT;	Control ;	between-group p value, effect size
FMA			
Pre-treatment	41.85 (11.33)	47.08 (10.94)	
Post-treatment	49.54 (12.84)	49.38 (10.18)	p=0.008, ES 0.48
FIM			
Pre-treatment	95.08 (15.24)	98.31 (21.48)	
Post-treatment	104.85 (12.13)	100.85 (20.08)	p=0.018, ES 0.42
MAL AOU			
Pre-treatment	0.80 (1.38)	1.37 (1.71)	NS
Post-treatment	1.78 (1.28)	1.57 (1.76)	p=0.003, ES 0.55.
MAL QOM			
Pre-treatment	0.79 (1.29)	1.35 (1.64)	NS
Post-treatment	1.99 (1.31)	1.49 (1.58)	p<0.001, ES 0.63.

Effect Size

Source of funding: National Health Research Institutes, National Science Council

Does the study answer the question?/Further Comments post-test only, no follow up

Wu CY;Lin KC;Chen HC;Chen IH;Hong WH;

Effects of modified constraint-induced movement therapy on movement kinematics and daily function in patients with stroke: a kinematic study of motor control mechanisms

Ref ID 16012 **RID:** 800 2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Patients recruited from 2 medical centers (Chang Gung Memorial Hospital and National Taiwan University hospital); all patients were blind to the study hypotheses; demographic and clinical characteristics of the mCIMT group and the TR group were comparable; a certified occupational therapist blind to the study hypotheses and subject allocation was trained to administer the assessments; patients randomized with equal probability; unclear randomization; unclear allocation concealment

DETAILS

of patients:

30 patients randomized. 15 patients to the Traditional Rehabilitation (TR) and 15 patients to the modified Constraint-Induced Movement Therapy (mCIMT)

Prevalence (Diagnostic):

Patient Characteristics

Thirty patients post stroke (mean age, 54 years; range 45-47 years); right-handed dominant before stroke by self-report and were 12-36 months (mean, 18.07 months) post onset of a first-ever cerebrovascular accident. Inclusion criteria: able to actively extend at least 10 degrees at the metacarpophalangeal and interphalangeal joints and 20 degrees at the wrist; considerable non-use of the more affected UE (amount-of-use score <2.5 on the MAL); no serious cognitive deficits (score ≥70 on the modified Mini-Mental State Exam); no balance problems; no excessive spasticity in any joint of the affected UE (Modified Ashworth scale ≤2 in any point)

Characteristics of Study Participants

	mCIMT (n=15)	TR (n=15)
Gender (M/F)	8/7	9/6
Age (mean [SD])	54.66 (8.63)	53.31 (6.29)
Months after stroke		
Mean (SD)	18.53 (6.92)	17.61 (7.55)
Modified Mini-Mental Exam		
Mean (SD)	93.56 (8.21)	90.51 (8.53)
MAL (amount of use)		
Mean (SD)	.95 (.89)	1.11 (1.01)
Modified Ashworth Scale	.34 (.30)	.29 (.29)

mCIMT = modified Constraint-Induced Movement Therapy; TR = Traditional Rehabilitation; UE = Upper Extremity; MAL = Motor Activity Log.

Interventions/ Test/ Factor being investigated

modified Constraint-Induced Movement Therapy (mCIMT) training administered intensively 2 hours per day, 5 days per week, for 3 weeks. Training took place during scheduled occupational therapy sessions, and other routine interdisciplinary stroke rehabilitation proceeded as usual.

Comparisons

Traditional Rehabilitation group received training matched to the mCIMT in duration and intensity of occupational therapy activities

Length of Study/ Follow-up

3-week intervention period

Outcome measures studied

Functional Independence Measure (FIM)

Results

Means and Standard Deviations of Performance on the Clinical Measures from Pre-treatment to Post-treatment

Clinical Measure	Pre-treatment	
	mCIMT (n=15)	TR (n=15)
FIM	99.60 (20.56)	95.93 (17.00)
Clinical Measure	Post-treatment	
	mCIMT (n=15)	TR (n=15)
FIM	106.93 (15.16)	98.20 (15.69)

FIM = Functional Independence Measure

Effect Size

Source of funding:

In part by the National Health Research Institutes and the National Science Council in Taiwan

Does the study answer the question?/Further Comments

Relative to traditional rehabilitation, modified Constraint-Induced Movement Therapy (mCIMT) produced a greater improvement in functional performance and motor control. Improvement of motor control after mCIMT was based on improved spatial and temporal efficiency

Question: In people after stroke what is the clinical and cost-effectiveness of repetitive task training versus usual care on improving function and disability?

Study Type	Randomised Controlled Trial
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Blennerhassett J;Dite W;

Additional task-related practice improves mobility and upper limb function early after stroke: a randomised controlled trial

Ref ID 733

RID:

9

2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

strengths: randomised trial, adequate randomisation and allocation concealment method, low attrition

weaknesses: small sample size

DETAILS

of patients:

N=30 (n=15 upper limb, n=15 mobility)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: able to walk 10m and provide informed consent
Exclusion criteria: deteriorating medical condition, independent community ambulation

Patients characteristics counts or mean (SD)

	Mobility	Upper limb
Male	8	9
Female	7	6
Age(years)	53.9(19.8)	56.3(10.5)
Stroke type		
Infarct	11	11
Haemorrhage	4	4
Side affected		
Right	8	7
Left	7	9

Rehabilitation time frames and training session details

	Mobility	Upper Limb
Stroke onset to start group (days)	36(25.1)	; 50.1(49.2)
Admission to start group (days)	18.3(14.1)	; 23.7(31.8)
Start group to discharge (days)	40.7(28.1)	; 67.5(43.1)
Length of inpatient rehabilitation (days)	58.3(30.1)	; 91.3(53.6)
Number of additional practice sessions	16.4(1.9)	; 15.9(2.4)
Total interdisciplinary therapy time during 4 weeks (minutes)	1906(594)	1871(529)

Interventions/ Test/ Factor being investigated

Mobility intervention: circuit training: sit to stand, step ups, obstacle course, plus stretching/strengthening exercise, and some endurance training (stationary, bikes/treadmill)
Upper extremity intervention: reach and grasp, hand-eye coordination activities, stretching and strengthening exercise
Both groups were during inpatient rehabilitation and additional to usual care for 5 hours per week, based on Movement Science Approach.
Sessions were 60min 5 times a week for 4 weeks (20hours total)
Sessions were delivered by a physical therapist in groups of up to 4 participants
After 4 weeks of training participants ceased the additional practice and continued with their interdisciplinary rehabilitation program

Comparisons

usual care + mobility vs usual care + upper limb training

Length of Study/ Follow-up

6 months

Outcome measures studied

Upper limb functional outcome measures: MAS upper arm, MAS hand
Lower limb functional outcome measures: 6MWT
Timed Up and Go test (TUGT)

Results

Test	Group	Initial	4weeks	6 months
6MWT (metres)	Mobility	183(85)	404(101)	416(171)
	Upper limb	181(85)	288(124)	313(154)
MAS (upper arm)	Mobility	5(1-6)	6(4-6)	6(5-6)
	Upper Limb	5(2-5)	6(5-6)	5(4.5-6)
MAS(hand)	Mobility	6(2-6)	6(5-6)	6(3-6)
	Upper limb	6(0-5)	6(5-6)	6(4.2-6)
TUGT (sec)	Mobility	24.3 (7.0);	11.5 (3.8);	10.8 (4.5)
	Upper limb	25.3 (17);	19.1 (14.4);	21.3 (30.3)

6MWT: 6 minutes walk test ; MAS: Motor Assessment Scale

Effect Size

Source of funding:

not reported

Does the study answer the question?/Further Comments

Yes. Following 4 weeks training, the Mobility group had better locomotor ability than the Upper limb group (between group differences in the 6MWT of 116.4m 95%CI 31.4to 201.3m. The findings support the use of additional task related practice during inpatient stroke rehabilitation. The circuit class format was a practical and effective means to provide supervised additional practice that led to significant and meaningful functional gains

Higgins J;Salbach NM;Wood-Dauphinee S;Richards CL;Cote R;Mayo NE;

The effect of a task-oriented intervention on arm function in people with stroke: a randomized controlled trial

Ref ID 742 **RID:** 18 2006

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

strength: adequate randomisation, allocation concealment, full intention to treat analysis

DETAILS

# of patients:	N=91 (upper extremity intervention n=47 control group n=44)																					
Prevalence (Diagnostic):																						
Patient Characteristics	<p>Inclusion: clinical diagnosis of first or recurrent stroke ; residual walking deficit resulting from the most recent stroke ; mental competency evaluated using the telephone version of the Mini Mental State Examination ; ability to walk 10m independently using an aide or orthotic with or without supervision ; ability to comprehend the instructions for the testing procedures ; residence in the community ; discharge from physical rehabilitation ; time interval between the most recent stroke and time to recruitment of one year or less</p> <p>Exclusion: neurological deficit caused by metastatic disease ; recovery of walking ability defined as the achievement of age-and gender specific norms on the 6 minute walk test that were computed using a regression equation ; discharge to a permanent care facility or comorbidity precluding participation in either intervention</p> <p>Baseline characteristics:</p> <table border="0"> <tr> <td>Characteristics:</td> <td>walking group</td> <td>; Arm group</td> </tr> <tr> <td>Age (mean(SD))</td> <td>71(12)</td> <td>; 73(8)</td> </tr> <tr> <td>Gender no(%) men/women</td> <td>26(59)/18(41)</td> <td>; 30(64)/17(36)</td> </tr> <tr> <td>Side of hemiplegia no(%) left/right/bilateral</td> <td>17(39)/27(61)/0</td> <td>; 22(47)/24(51)/1(2)</td> </tr> <tr> <td>Type of stroke no(%) ischaemic/haemorrhagic</td> <td>40(91)/4(9)</td> <td>; 36(77)/11(23)</td> </tr> <tr> <td>No of strokes no(%) 1/2/4</td> <td>39(89)/5(11)/0</td> <td>; 41(87)/5 (11)/1(2)</td> </tr> <tr> <td>No of days post stroke at baseline mean(SD)</td> <td>239(83)</td> <td>; 217(73)</td> </tr> </table>	Characteristics:	walking group	; Arm group	Age (mean(SD))	71(12)	; 73(8)	Gender no(%) men/women	26(59)/18(41)	; 30(64)/17(36)	Side of hemiplegia no(%) left/right/bilateral	17(39)/27(61)/0	; 22(47)/24(51)/1(2)	Type of stroke no(%) ischaemic/haemorrhagic	40(91)/4(9)	; 36(77)/11(23)	No of strokes no(%) 1/2/4	39(89)/5(11)/0	; 41(87)/5 (11)/1(2)	No of days post stroke at baseline mean(SD)	239(83)	; 217(73)
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Gender no(%) men/women	26(59)/18(41)	; 30(64)/17(36)																				
Side of hemiplegia no(%) left/right/bilateral	17(39)/27(61)/0	; 22(47)/24(51)/1(2)																				
Type of stroke no(%) ischaemic/haemorrhagic	40(91)/4(9)	; 36(77)/11(23)																				
No of strokes no(%) 1/2/4	39(89)/5(11)/0	; 41(87)/5 (11)/1(2)																				
No of days post stroke at baseline mean(SD)	239(83)	; 217(73)																				
Interventions/ Test/ Factor being investigated	<p>Subjects in both groups participated in 18 sessions of task-oriented training given 3 times a week for 6 weeks in a rehabilitation or hospital setting.</p> <p>Arm group: each session lasted 90 minutes. At the start of intervention subjects were asked to identify daily activities that were difficult to perform and that they wanted to improve. Examples of such tasks included manipulating playing cards, clothes pins as well as writing exercises. When subjects had maximised their performance, tasks were changed or their level of difficulty heightened at the discretion of the therapist. All subjects were given a home programme to be done for a minimum of 15min per day for the period of the intervention.</p> <p>Walking group: 10 functional tasks designed to strengthen the lower extremities and enhance walking balance, speed as well as distance.</p>																					
Comparisons	task oriented arm intervention vs walking intervention																					
Length of Study/ Follow-up	6 weeks																					
Outcome measures studied	Nine-Hole-Peg Test																					
Results	<p>Measures Arm training ; walking training; group difference Mean(SD) ; mean(SD) ;</p> <table border="0"> <tr> <td>Nine-HolePeg Test /3</td> <td></td> <td></td> </tr> <tr> <td>Pre</td> <td>1(1) ; 1(1)</td> <td></td> </tr> <tr> <td>Post</td> <td>1(1) ; 1(1)</td> <td></td> </tr> <tr> <td>Change</td> <td>0(0) ; 0(0) ;</td> <td>P=0.6 (Wilcoxon rank sum test)</td> </tr> </table>	Nine-HolePeg Test /3			Pre	1(1) ; 1(1)		Post	1(1) ; 1(1)		Change	0(0) ; 0(0) ;	P=0.6 (Wilcoxon rank sum test)									
Nine-HolePeg Test /3																						
Pre	1(1) ; 1(1)																					
Post	1(1) ; 1(1)																					
Change	0(0) ; 0(0) ;	P=0.6 (Wilcoxon rank sum test)																				
Effect Size																						
Source of funding:	Heart and Stroke Foundation of Canada, Canadian Stroke Network																					
Does the study answer the question?/Further Comments	A task oriented intervention did not improve manual dexterity of the affected arm																					

Kwakkel G;Wagenaar RC;Twisk JW;Lankhorst GJ;Koetsier JC;

Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial

Ref ID 738

RID:

14

1999

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

strength

weaknesses: possibility of patients receiving treadmill training as part of intervention

DETAILS

of patients:

N=101(n=31 leg training gp ; n=33 arm training gp ; n=37 control gp)

Prevalence (Diagnostic):

Patient Characteristics

Setting The Netherlands

Inclusion: primary first ever stroke in the territory of middle cerebral artery confirmed by CT or MRI, age 30-80 years, impaired motor function of the arm and leg, inability to walk at first assessment

Exclusion: complicating medical history or severe deficits in communication, memory or understanding

Baseline characteristics:

	Control	; arm training	; leg training
M/F	14/23	; 16/17	; 13/18
Age mean(SD)	64.1(15)	; 69(9.8)	; 64.5(9.7)
Stroke characteristics:			
Left/right	13/24	; 16/17	; 13/18
TACI	25	; 19	; 17
PACI	9	; 11	; 13
LACI	3	; 3	; 1

Clinical characteristics:

Hemianopia 15(41%) ; 11(33%) ; 7(23%)

Outcome variables at baseline:

Frenchay activities index 26.8(6.8) ; 26.5(6.1) ; 27.1(7)

At baseline all patients had a Barthel index of 9 points or lower and could be classified as severely or very severely disabled. No patient was able to walk unaided

Interventions/ Test/ Factor being investigated

All groups received 15min per day leg rehabilitation, 15min per day arm rehabilitation and 1.5h per day ADL training by an occupational therapist. Leg and arm training groups received intervention individually applied by local physical and occupational therapists for 30 minutes on 5 days a week for 20 weeks after the stroke.

Leg training: key element of leg rehabilitation were sitting, standing and weight-bearing exercises during standing and walking, with an emphasis on achieving stability and improving gait velocity. Treadmill training was promoted if equipment was available.

Arm training: included functional exercises that facilitated forced arm and hand activity such as leaning, punching a ball, grasping, and moving objects.

Control group: Immobilisation of the paretic arm and leg by means of an inflatable pressure splint; the splint was applied with the patient supine for 30min on 5 days a week.

Comparisons

arm training vs leg training vs control (splinting)

Length of Study/ Follow-up

26 weeks (assessed at weeks 6, 12, 20 and 26)

Outcome measures studied

Action Research Arm test (ARAT), 10m timed walking test: comfortable and maximum walking speed.

Results

	Control group	; Arm training	; Leg training
Dexterity (ARAT)			
[Median (IQR) value]			

Wk 6	0(0-1)	; 1(0-14)	; 1(0-43)
Wk 12	0(0-1)	; 3(0-34)	; 2(0-53)
Wk 20	0(0-2)	; 9(0-39)	; 2(0-56)
Wk 26	0(0-2.25)	; 4(0-38)	; 3(0-56)

Comfortable walking speed (m/s)
[mean (SD)]

Wk 6	0.17 (0.37); 0.21 (0.39); 0.40(0.45)
Wk 12	0.31 (0.39); 0.46 (0.47); 0.58 (0.50)
Wk 20	0.37 (0.41); 0.55 (0.46); 0.65 (0.46)
Wk 26	0.44 (0.44); 0.55 (0.44); 0.63 (0.47)

Maximum walking speed (m/s)
[mean (SD)]

Wk 6	0.22 (0.50); 0.33 (0.60); 0.55 (0.65)
Wk 12	0.41(0.55); 0.55 (0.63); 0.79 (0.65)
Wk 20	0.52 (0.58); 0.76 (0.64); 0.88 (0.66)
Wk 26	0.57 (0.60); 0.73 (0.62); 0.85 (0.65)

Effect Size

Source of funding: supported by grant from the Netherlands Heart Foundation

Does the study answer the question?/Further Comments From week 12 onwards patients in both the leg and arm training groups showed significant improvement in dexterity compared to patients in the control group. Greater intensity of leg rehabilitation improves functional recovery and health related functional status, whereas greater intensity of arm rehabilitation results in small improvements in dexterity, providing further evidence that exercise therapy primarily induces treatment effects on the abilities at which training is specifically aimed

Salbach NM;Mayo NE;Wood-Dauphinee S;Hanley JA;Richards CL;Cote R;

A task-orientated intervention enhances walking distance and speed in the first year post stroke: a randomized controlled trial

Ref ID 744 **RID:** 20 2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear **Direction =**

Overall Study Quality -Strengths and Weaknesses:

strength: adequate randomisation and allocation concealment, full intention to treat analysis, adequate compliance

weaknesses: unblinding of outcome evaluator, subject withdrawal

DETAILS

of patients:

N=91 (n=44 mobility intervention ; n=47 upper extremity intervention) Quebec setting

Prevalence (Diagnostic):

Patient Characteristics

Setting Quebec

Inclusion: clinical diagnosis of first or recurrent stroke ; residual walking deficit resulting from the most recent stroke ; mental competency evaluated using the telephone version of the Mini Mental State Examination ; ability to walk 10m independently using an aide or orthotic with or without supervision ; ability to comprehend the instructions for the testing procedures ; residence in the community ; discharge from physical rehabilitation ; time interval between the most recent stroke and time to recruitment of one year or less

Exclusion: neurological deficit caused by metastatic disease ; recovery of walking ability defined as the achievement of age-and gender specific norms on the 6 minute walk test that were computed using a regression equation ; discharge to a permanent care facility or comorbidity precluding participation in either intervention

Baseline characteristics:

Characteristics:	mobility training	;	UE training
Age (mean(SD))	71(12)	;	73(8)
Gender no(%) men/women	26(59)/18(41)	;	30(64)/17(36)
Side of hemiplegia no(%) left/right/bilateral	17(39)/27(61)/0	;	22(47)/24(51)/1(2)
Type of stroke no(%) ischaemic/haemorrhagic	40(91)/4(9)	;	36(77)/11(23)
No of strokes no(%) 1/2/4	39(89)/5(11)/0	;	41(87)/5(11)/1(2)
No of days post stroke at baseline mean(SD)	239(83)	;	217(73)

Interventions/ Test/ Factor being investigated

Subjects in both groups participated in 18 sessions of task-oriented training given 3 times a week for 6 weeks in a rehabilitation or hospital setting.

Mobility training: standardised programme supervised by a physical or occupational therapist, of 10 walking related tasks designed to strengthen the lower extremities and enhance walking balance, speed and distance in a progressive manner. The study therapist recorded the duration and level of difficulty achieved by a subject in each task on individualised log sheets every session.

Upper Extremity training (UE): performed functional upper extremity tasks such as manipulating cards, using a keyboard and writing. Tasks were done while sitting to minimise the load on the lower extremities and subjects were recommended to practice these tasks at home.

Comparisons

mobility training vs upper extremity training

Length of Study/ Follow-up

Baseline, posttreatment (mean 4 days), 6 weeks

Outcome measures studied

Primary Outcome: 6 minute walk test (MWT), 5min walk, timed 'up and go' (sec)

Results

Results:

Outcome	mobility training	;	UE training	;	group difference (95%CI)
	Mean(SD)		mean(SD)		
6MWT (metres)					
Pre	209(126)	;	204(131)		
Post	249(136)	;	209(132)		
Change	40(72)	;	5(66)	;	35(4,64)
5min walk (comfortable speed) metres/second					
Pre	0.64(0.33)	;	0.61(0.37)		
Post	0.78(0.40)	;	0.64(0.37)		

Change 0.14(0.18) ; 0.03(0.2) ; 0.11(0.03,0.19)
5min walk(max speed) metres/second
Pre 0.79(0.45) ; 0.81(0.49)
Post 0.99(0.56) ; 0.8(0.49)
Change 0.2(0.26) ; -0.01(0.18) ; 0.21(0.12,0.3)
Timed up and go (sec)
Pre 24.4 (18.8); 25.5 (21.7)
Post 23.2 (20.6); 27.1 (27.1); -2.9 (-7.8, 2.0)

Effect Size

Source of funding: Quebec Reseau provincial de recherche en adaptation-readaptation, Canadian Stroke Network

Does the study answer the question?/Further Comments The study findings support the efficacy of a task-oriented intervention in enhancing walking distance and speed

Winstein CJ;Rose DK;Tan SM;Lewthwaite R;Chui HC;Azen SP;

A randomized controlled comparison of upper-extremity rehabilitation strategies in acute stroke: A pilot study of immediate and long-term outcomes

Ref ID 1173 **RID:** 153 2004 Apr

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

high risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Unclear randomisation, inadequate allocation concealment, no blinding. High rate of loss to follow-up at 9 months (7 in the functional task group , 7 in strength training and 5 in the standard care group).

DETAILS

of patients:

n=64 (n=21 standard care ; n=functional task practice; n=21 strength training)

Prevalence (Diagnostic):

Patient Characteristics

Overall, 33 (55%) of participants were men, and only 3 (5%) participants were younger than 5 or older than 75 years. The most prevalent type of stroke was ischemic (85%). The majority of strokes occurred on the left side and resulted in right hemiparesis (68%). The most prevalent location of lesion was subcortical (72%). The average time since onset±standard deviation (SD) was 16.1±7.7 days.

Inclusion criteria: first time stroke from infarction in the anterior circulation confirmed by magnetic resonance imaging or computed axial tomography scan, onset of stroke from 2 to 35 days before study entry and FIM instrument total score at admission of 40 to 80. Participants were excluded if they had peripheral nerve or orthopedic conditions that interfered with arm movement, had cardiac disease that limited function by exertional dyspnea, angina, or severe fatigue, or had subarchanoid haemorrhage without evidence of infarction, progressive hydrocephalus, previous history of brain injury, or severe aphasia, neglect, agitation or depression that could limit participation.

Interventions/ Test/ Factor being investigated

Task specific functional training (FT)- Focused on the systematic and repetitive practice of tasks that could be performed within the level of available voluntary motion. Tasks were progressively arranged and customised to account for any unique proximal-to distal recovery patterns of reaching and grasping actions. All tasks were designed to be standard, repeatable and to have some functional goal (e.g. pointing, grasping, stirring).
Strengthening and motor control training (ST) - used resistance to available arm motion to increase strength. Exercises were performed using either eccentric, isometric or concentric muscle contractions and concentric exercises were performed in a gravity-lessened position or against gravity, if possible. These exercises were progressed to repetitions against resistance using free weights. Progression of exercises used a protocol of high-intensity progressive resistance training of shoulder, elbow, wrist and hand motions.

Comparisons

Standard care (SC)- standard care for the upper extremity was delivered primarily by occupational therapist and could include muscle facilitation exercises emphasising the neurodevelopmental treatment approach, neuromuscular electric stimulation applied primarily for shoulder subluxation, stretching exercises, activities of daily living including self-care where the upper limb was used as an assist if appropriate and caregiver training.

Length of Study/ Follow-up

Post treatment and at 9 months

Outcome measures studied

Fugl-Meyer score - range of motion (ROM), pain, sensory, motor function and FIM- mobility, self-care.

Results

Post-treatment change from baseline:
Outcome: SC (n=20); FT (n=20) ; ST (n=20)
FIM (mean SD)
Mobility: 14.10 ±7.58; 15.00 ±6.22; 15.00 ±7.14

Self-care: 17.00 ±5.17; 15.85 ±5.21; 16.15 ±5.81
Upper extremity Fugl-Meyer (mean SD)
ROM: -0.60 ± 1.93; -1.90 ± 2.02; -0.75± 2.00
Pain: -0.60 ± 1.79; -1.60 ± 2.80; -0.70± 2.30
Sensory: 0.75 ± 1.33; 0.75 ± 2.99; 1.30± 2.23
Motor function: 9.05 ± 7.60; 16.50 ± 13.74; 18.20± 13.54

At 9 months follow-up:
Outcome: SC (n=15); FT (n=13) ;S (n=16)
FIM (mean SD)
Mobility:5.67 ±5.47; 4.54 ±5.78; 2.44 ±1.82
Self-care: 6.07 ±4.62; 6.38 ±5.59; 2.75 ±4.34
Upper extremity Fugl-Meyer (mean SD)
ROM: -0.33± 1.45;-0.46± 2.76 ; -2.13± 2.96
Pain: -1.00± 2.88;-1.23± 2.42; -1.19± 4.00
Sensory: 0.07± 1.03; 0.69± 2.36; 0.25± 0.68
Motor function: 8.33± 11.26;5.77± 4.49; 5.38± 9.11

Effect Size

Source of funding:

National Institute of Child health and human development; Health and the Foundation for Physical therapy

Does the study answer the question?/Further Comments

Yes. Post-treatment, those participants in the FT and ST had significantly greater increases in Fugl-Meyer motor scores compared to SC participants. At 9 months there was no significant difference between the treatment arms for any outcomes.

Winstein CJ;Rose DK;Tan SM;Lewthwaite R;Chui HC;Azen SP;

A randomized controlled comparison of upper-extremity rehabilitation strategies in acute stroke: A pilot study of immediate and long-term outcomes

Ref ID 1173 **RID:** 22 2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: randomised, adequate allocation concealment

Weaknesses: unblinded, loss to follow up

DETAILS

of patients:

N=64 N=21 to standard care ; N=22 to Functional-Task Practice ; N=21 to Strength training

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: 1st time stroke from infarction in the anterior circulation confirmed by MRI or computed axial tomography scan ; onset of stroke from 2 to 35 days before study entry ; FIM total score at admission of 40-80

Exclusions: peripheral nerve or orthopaedic conditions that interfered with arm movement ; cardiac disease that limited function by exertional dyspnea, angina or severe fatigue, subarachnoid hemorrhage without evidence of infarction, progressive hydrocephalus, previous history of brain injury, severe aphasia, neglect agitation or depression that could limit participation.

Baseline characteristics:

Parameter standard care ; functional training ; strength training

Gender

Men 12(60) ; 9(45) ; 12(60)
Women 8(40) ; 11(55) ; 8(40)

Age group

<35 2(10); 0(0) ; 0(0)
35-75 18(90) ; 19(95) ; 20(100)
>=75 0(0) ; 1(5) ; 0(0)

Type of stroke

Ischemic 16(84) ; 16(84) ; 19(100)
Intracerebral hemorrhage 3(16) ; 3(16) ; 0(0)
Subarachnoid hemorrhage 0(0) ; 0(0) ; 0(0)

Time since onset (d) 15.4(5.5) ; 15.5(6) ; 17.3(10.6)

Orpington Prognostic Scale

Less severe (1.6-4.1) 14(70) ; 12(60) ; 14(70)
More severe (4.2-6.8) 6(30) ; 8(40) ; 6(80)

Upper extremity Fugl-Meyer

ROM 23.25(1.21) ; 23.6(0.82) ; 22.55(2.39)
Pain 22.4(2.5) ; 22.4(2.09) ; 21.65(3.33)
Sensory 9.95(3.65) ; 8.6(4.1) ; 9.6(3.72)
Motor function 23.55(22.31) ; 18.7(16.4) ; 19.85(49.56)

Interventions/ Test/ Factor being investigated

Standard care: delivered primarily by an occupational therapist and could include muscle facilitation exercises emphasising the neurodevelopmental treatment approach, neuromuscular electric stimulation applied primarily for shoulder subluxation, stretching exercises, activities of daily living including self-care where

the upper limb was used as an assist if appropriate, and caregiver training. Task-specific functional training focused on the systematic and repetitive practice of tasks that could be performed within the level of available voluntary motion. Tasks were progressively arranged and customised to account for any unique proximal-to-distal recovery patterns of reaching and grasping actions. All tasks were designed to be standard, repeatable and to have some functional goal. The principle of motor learning were applied as the physical therapists systematically provided knowledge of results and progressed task difficulty to keep the participants challenged, motivated and engaged. Doable tasks were ordered randomly during practice to facilitate learning and to mini real-world activities. A 3rd group included strengthening and motor control training using resistance to available arm motion to increase strength. This program was implemented on alternate days for 3 days a week

Comparisons

functional task practice vs standard care

**Length of Study/
Follow-up**

posttreatment (4-6weeks post randomisation) and 9 months post randomisation

Outcome measures studied

Fugl-Meyer score

Results

Results

Posttreatment change from baseline scores: All evaluable patients

Characteristics ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.6 ±1.93 ; -1.9±2.02 ; 0.16

Pain -0.6±1.79 ; -1.6±2.8 ; 0.36

Sensory 0.75±1.33 ; 0.75±2.99 ; 1

Motor Function^ 9.05±7.6 ; 16.5±13.74 ; 0.04

Posttreatment change from baseline scores: less severe OPS score

Characterisitcs ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.29±1.33 ; -1.42±1.44 ; 0.2

Pain -0.36±1.86 ; -1.17±1.7 ; 0.46

Sensory 0.43±1.09 ; 0.83±2.17 ; 0.35

Motor function^ 9.36±8.05 ; 21.75±13.57 ; 0.005

^normalising log-transformations

Long term change from posttreatment scores: all evaluable patients

Characterisitcs ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.33±1.45 ; -0.46±2.76 ; 0.14

Pain -1±2.88 ; -1.23±2.42 ; 0.54

Sensory 0.07±1.03 ; 0.69±2.36 ; 0.41

Motor function 8.33±11.26 ; 5.77±4.49 ; 0.24

Long term change from posttreatment scores: less severe OPS scores

Characterisitcs ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.64±1.29 ; 0.11±1.97 ; 0.5

Pain -1±2.86 ; -0.44±1.88 ; 0.86

Sensory -0.18±0.75 ; 0.00±1 ; 0.27

Motor function 4.82±6.93 ; 6.44±4.56 ; 0.44

* pvalue assessing differences in combined treatment (FT plus strength training) versus standard care

Effect Size

Source of funding:

National institute of Child Health and Human Development, Foundation for Physical Therapy

Does the study answer the question?/Further Comments

Compared with standard care participants, those in the functional task practice and strength training groups had significantly greater increases in Fugl-Meyer motor scores ($p=0.04$) posttreatment. Treatment benefit was primarily in the less severe participants, where improvement in FT and ST group Fugle-Meyer motor scores more than doubled that of the SC group. The authors concluded that task specificity and stroke severity are important factors for rehabilitation of arm use in stroke. An additional 20 hours of therapy specific to the upper extremity and distributed over 4 to 6 weeks positively influenced both immediate and long term outcomes only for the less severe cohort. The immediate benefits of a functional task approach were similar to those of a resistance-strength approach, however the former was more beneficial in the long term.

Winstein CJ;Rose DK;Tan SM;Lewthwaite R;Chui HC;Azen SP;

A randomized controlled comparison of upper-extremity rehabilitation strategies in acute stroke: A pilot study of immediate and long-term outcomes

Ref ID 746

RID:

281

2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: randomised, adequate allocation concealment

Weaknesses: unblinded, loss to follow up

DETAILS

of patients:

N=64 N=21 to standard care ; N=22 to Functional-Task Practice ; N=21 to Strength training

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: 1st time stroke from infarction in the anterior circulation confirmed by MRI or computed axial tomography scan ; onset of stroke from 2 to 35 days before study entry ; FIM total score at admission of 40-80

Exclusions: peripheral nerve or orthopaedic conditions that interfered with arm movement ; cardiac disease that limited function by exertional dyspnea, angina or severe fatigue, subarachnoid hemorrhage without evidence of infarction, progressive hydrocephalus, previous history of brain injury, severe aphasia, neglect agitation or depression that could limit participation.

Baseline characteristics:

Parameter standard care ; functional training ; strength training

Gender

Men 12(60) ; 9(45) ; 12(60)

Women 8(40) ; 11(55) ; 8(40)

Age group

<35 2(10); 0(0) ; 0(0)

35-75 18(90) ; 19(95) ; 20(100)

>=75 0(0) ; 1(5) ; 0(0)

Type of stroke

Ischemic 16(84) ; 16(84) ; 19(100)

Intracerebral hemorrhage 3(16) ; 3(16) ; 0(0)

Subarachnoid hemorrhage 0(0) ; 0(0) ; 0(0)

Time since onset (d) 15.4±5.5 ; 15.5±6 ; 17.3±10.6

Orpington Prognostic Scale

Less severe (1.6-4.1) 14±70 ; 12±60 ; 14±70

More severe (4.2-6.8) 6±30 ; 8±40 ; 6±80

Upper extremity Fugl-Meyer

ROM 23.25±1.21 ; 23.6±0.82 ; 22.55±2.39

Pain 22.4±2.5 ; 22.4±2.09 ; 21.65±3.33

Sensory 9.95±3.65 ; 8.6±4.1 ; 9.6±3.72

Motor function 23.55±22.31 ; 18.7±16.4 ; 19.85±49.56

Interventions/ Test/ Factor being investigated

Standard care: delivered primarily by an occupational therapist and could include muscle facilitation exercises emphasising the neurodevelopmental treatment approach, neuromuscular electric stimulation applied primarily for shoulder subluxation, stretching exercises, activities of daily living including self-care where the upper limb was used as an assist if appropriate, and caregiver training.

Task-specific functional training focused on the systematic and repetitive practice of tasks that could be performed within the level of available voluntary motion.

Tasks were progressively arranged and customised to account for any unique proximal-to-distal recovery patterns of reaching and grasping actions. All tasks were designed to be standard, repeatable and to have some functional goal. The principle of motor learning were applied as the physical therapists systematically provided knowledge of results and progressed task difficulty to keep the participants challenged, motivated and engaged. Doable tasks were ordered randomly during practice to facilitate learning and to mini real-world activities.

A 3rd group included strengthening and motor control training using resistance to available arm motion to increase strength. This program was implemented on alternate days for 3 days a week

Comparisons

functional task practice vs standard care

Length of Study/ Follow-up

posttreatment (4-6weeks post randomisation) and 9 months post randomisation

Outcome measures studied

Fugl-Meyer score

Results

Results

Posttreatment change from baseline scores: All evaluable patients

Characteristics ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.6 ±1.93 ; -1.9±2.02 ; 0.16

Pain -0.6±1.79 ; -1.6±2.8 ; 0.36

Sensory 0.75±1.33 ; 0.75±2.99 ; 1

Motor Function^ 9.05±7.6 ; 16.5±13.74 ; 0.04

Posttreatment change from baseline scores: less severe OPS score

Characterisitcs ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.29±1.33 ; -1.42±1.44 ; 0.2

Pain -0.36±1.86 ; -1.17±1.7 ; 0.46

Sensory 0.43±1.09 ; 0.83±2.17 ; 0.35

Motor function^ 9.36±8.05 ; 21.75±13.57 ; 0.005

^normalising log-transformations

Long term change from posttreatment scores: all evaluable patients

Characterisitcs ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.33±1.45 ; -0.46±2.76 ; 0.14

Pain -1±2.88 ; -1.23±2.42 ; 0.54

Sensory 0.07±1.03 ; 0.69±2.36 ; 0.41

Motor function 8.33±11.26 ; 5.77±4.49 ; 0.24

Long term change from posttreatment scores: less severe OPS scores

Characterisitcs ; SC ; FT ; pvalue*

Upper extremity Fugl-Meyer

ROM -0.64±1.29 ; 0.11±1.97 ; 0.5

Pain -1±2.86 ; -0.44±1.88 ; 0.86

Sensory -0.18±0.75 ; 0.00±1 ; 0.27

Motor function 4.82±6.93 ; 6.44±4.56 ; 0.44

* pvalue assessing differences in combined treatment (FT plus strength training) versus standard care

Effect Size

Source of funding:

National institute of Child Health and Human Development, Foundation for Physical Therapy

Does the study answer the question?/Further Comments

Compared with standard care participants, those in the functional task practice and strength training groups had significantly greater increases in Fugl-Meyer motor scores (p=0.04) posttreatment. Treatment benefit was primarily in the less severe participants, where improvement in FT and ST group Fugle-Meyer motor scores more than doubled that of the SC group. The authors concluded that task specificity and stroke severity are important factors for rehabilitation of arm use in stroke. An additional 20 hours of therapy specific to the upper extremity and distributed over 4 to 6 weeks positively influenced both immediate and long term outcomes only for the less evere cohort. The immediate benefits of a functional task approach were similar to those of a resistance-strength approach, however the former was more beneficial in the long term.

Question: In people after stroke who can walk, what is the clinical and cost effectiveness of treadmill plus body support versus treadmill only on improving walking?

Study Type	Randomised Controlled Trial
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Barbeau H;Visintin M;

Optimal outcomes obtained with body-weight support combined with treadmill training in stroke subjects

Ref ID 1033 **RID:** 175 2003

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Block randomisation. No details of allocation concealment reported. Double blind. Of the 100 patients, 79 completed the study [43 (86% were in the BWS group and 36 (72%) in the no-BWS group. ITT not reported.

DETAILS

of patients: N=100 (n=50 locomotor training with BWS , n =50 locomotor training with no BWS)

Prevalence (Diagnostic):

Patient Characteristics	<p>Characteristic: BWS group (n=50); no-BWS group (n=50) Age (yrs): 66.5±12.8 ; 66.7±10.1 Side of lesion: R/L: 20/30 ; 29/21 Delay onset of stroke to study (d): 68.1±26.5; 78.430</p> <p>The subjects were stratified according to their initial over ground walking speed, endurance, initial treadmill speed and endurance , functional balance, motor recovery, side of the lesion and age.</p>
Interventions/ Test/ Factor being investigated	<p>Locomotor training with body weight support (BWS) The experimental group trained on a treadmill while a percentage of their body weight was supported by an overhead harness. Both the experimental and control groups trained 4 times a week for 6 weeks under the supervision of a physical therapist. During each session, patients walked a maximum of 3 trials for no more than 20 minutes.</p>
Comparisons	<p>The control group trained on a treadmill but without BWS. Subjects in this group wore the harness for security and to endure similar experimental conditions, but no BWS was provided. In addition to gait training, all subjects- regardless of their group allocation received regular, weekday physical therapy.</p>
Length of Study/ Follow-up	<p>At completion of the 6 week programme.</p>
Outcome measures studied	<p>over ground walking speed (m/s), Treadmill walking speed (m/s), over ground walking endurance (m), treadmill walking endurance (m).</p>
Results	<p>Statistical analysis using ANCOVA on clinical outcomes</p> <p>Variable: BWS/no BWS (n); BWS/no BWS Over ground walking speed (m/s): 0-0.2: 25/23 ;0.08 (p<0.01) >0.2: 17/13; 0.210</p> <p>Treadmill walking speed (m/s): 0-0.5: 19/25; 0.617 >0.5: 24/10; 0.337</p> <p>Overground walking endurance (m): 0-20: 17/17; 0.016 (p<0.02) >20: 24/19; 0.700</p> <p>Treadmill walking endurance (m): 0-6:26/15; 0.017 >6:17/20:0.238</p>
Effect Size	
Source of funding:	<p>Heart and Stroke Foundation of Canada, The National Health Research and Development Program</p>
Does the study answer the question?/Further Comments	<p>Yes. After 6 weeks of locomotor training, the BWS group scored significantly higher in all clinical outcomes.</p>

Duncan PW;Sullivan KJ;Behrman AL;Azen SP;Wu SS;Nadeau SE;Dobkin BH;Rose DK;Tilson JK;Cen S;Hayden SK;

Body-weight-supported treadmill rehabilitation after stroke

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomised, single blind. Intervention not completed by 13% of participants in the early locomotor training (Early LT) group, and 3% of those in the home exercise (he) group. ITT used.

DETAILS

of patients:

N= 265 (n=139 early LT , n=126 in HE)

Prevalence (Diagnostic):

Patient Characteristics

The mean age of participants was 62.0±12.7 years; 54.9% were men, and 22.1% were black. At randomisation, the average number of days since the stroke was 63.8±8.5. A total of 71.1% of participants had had ischemic strokes, 99.5% had modified Rankin scores between 2 and 4 (1 indicating no significant disability, 2 slight disability, 3 moderate disability, 4 moderately severe disability and 5 severe disability).

Inclusion criteria: age of 18 years or older, a stroke within 45 days before study entry and the ability to undergo randomisation within 2 months after the stroke, residual paresis in the leg affected by stroke, the ability to walk 3m with assistance from no more than one person and the ability to follow a three-step command, a

self selected speed for walking 10 m of less than 0.8m per second and residence in the community by the time of randomisation. Exclusion criteria were: dependency on assistance of daily living before the stroke, contraindications to exercise, pre-existing neurologic disorders, and inability to travel to the treatment site.

After completion of baseline assessments 2 months after the stroke participants were randomly assigned to early locomotor training, late locomotor training or home exercise.

Interventions/ Test/ Factor being investigated

Early locomotor training (Early LT). Locomotor training included stepping on a treadmill with partial body weight support and manual assistance as needed for 20 to 30 minutes at 3.2 km per hour, followed by a progressive programme of walking over ground for 15 minutes. The body weight system provided dynamic, pneumatic control of the patients weight throughout the gait cycle and provided ergonomic seating for trainers assisting with patients leg movements. The treadmill speeds ranged from 0 to 1.6 km per hour increasing by increments of 0.16 km per hour

Comparisons

The home exercise (HE) programme was designed as an active control, not as a high intensity task specific walking programme. Progression through the programme was managed by a physical therapist in the home, with the goals of enhancing flexibility, range of motion in joints, strength of arms and legs, coordination and static and dynamic balance.

Length of Study/ Follow-up

6 months and 12 months

Outcome measures studied

mean comfortable or usual walking speed-m/sec and mean distance walked in 6 min- metres

Results

Mean comfortable or usual walking speed- m/sec: Early LT; HE
Change from baseline-
6 months: 0.25±0.21; 0.23±0.20
12 months: 0.23±0.20; 0.25±0.22

Mean distance walked in 6 min- metres: Early LT; HE
Change from baseline:
6 months: 81.8±62.8; 75.9±69.3
12 months:73.2±69.4; 85.2±72.9

Effect Size

Source of funding:

none reported.

Does the study answer the question?/Further Comments

Yes. At 1 year there was no significant difference between early locomotor training and home exercise for walking speed or distance walked.

Eich HJ;Mach H;Werner C;Hesse S;

Aerobic treadmill plus Bobath walking training improves walking in subacute stroke: a randomized controlled trial

Ref ID 1112

RID:

128

2004 Sep

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study. Unclear risk

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strength: clear randomisation and allocation concealment, only 1 missing data but ITT used, adequate sample size, clearly reported

weaknesses: content of therapy in control group unclear

DETAILS

of patients:

Intervention: 25 subjects, Control: 25 subjects

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: age 50-75 years, first time supratentorial stroke, stroke interval < 6weeks before study onset, able to walk a minimum distance of 12 m with either intermittent help or stand-by while walking, moderately affected with a Barthel index between 50-80, participation in a 12 week comprehensive rehabilitation programme, cardiovascular stable, according to 12-lead ECG, bicycle ergometry reaching at least 50W and examination by cardiologist, no other neurologic or orthopaedic disease impairing walking, able to understand the purpose and content of the study.

Baseline characteristics

Treadmill group

Affected side 14left 11right

Time of stroke to enrollment SD(mean) weeks = 6.1(2.2)

Age SD(mean) years = 62.4(4.8)

Sex female/male =8/17

Barthel index mean(SD) = 67.8(13.6)

Control group:

Affected side 14left 11right
Time of stroke to enrollment SD(mean) weeks = 6.32(2.53)
Age SD(mean) years = 62.4(4.8)

Sex female/male =9/16
Barthel index mean(SD) = 65.6(14.1)

Interventions/ Test/ Factor being investigated

Treadmill training for 30 minutes and other individual physiotherapy for 30minutes. During treadmill training patients wore a modified parachute harness to prevent falls. The body weight was either not supported or supported to a maximum of 15% according to individual needs. If necessary 1 or 2 therapists provided help with setting the paretic limb or assisting weight sifting and hip extension. The aerobic treadmill training programme consisted of 30 sessions of 30minutes of graded treadmill walking at a defined training heart rate.
Bobath walking: patients in this group received 60 minutes of individual physiotherapy.
The individual physiotherapy in both groups was Bobath oriented: it exclusively concentrated on walking rehabilitation. Included tone-inhibiting and gait preparatory manoeuvres and walking practice on the floor and on the stairs. Necessary orthoses and walking aids were provided at the beginning of the study.

Comparisons

60 minutes of individual physiotherapy.
The individual physiotherapy in both groups was Bobath oriented: it exclusively concentrated on walking rehabilitation. Included tone-inhibiting and gait preparatory manoeuvres and walking practice on the floor and on the stairs. Necessary orthoses and walking aids were provided at the beginning of the study. All patients received 60 minutes of individual therapy time on each of 30 consecutive working days.

Length of Study/ Follow-up

End of study: 12 weeks

Outcome measures studied

Primary outcomes: 10 metre timed walk, 6 minute walk test
Secondary outcome: walking ability Rivermead Motor Assessment Score

Results

Outcome Experimental group ; control group
10 metre timed walk (m/s)
Wk0 0.4(0.17) ; 0.44(0.22)
Wk6 0.71(0.3) ; 0.6(0.22)
Wk18 0.77(0.35) ; 0.58(0.22)
6 minute walk test (m)
Wk0 108.1(50.8) ; 108.9(60.1)
Wk6 198.8(81.1) ; 164.4(69.3)
Wk18 224.8(90) ; 163(70.2)
Rivermead Gross function (0-13)*
Wk0 9(7-10) ; 9(6-10)
Wk6 11(11) ; 11(10-11)
Wk18 11(11) ; 11(10-11)

*median (IQR)
Between group differences:
Max walking speed: p<0.01 for wk0 to wk 6 and for wk6 to wk 18
Walking capacity: =<0.01 for wk0 to wk6 and for wk6 to wk18
Rivermead not significantly different between groups

Effect Size

Source of funding:

Not reported

Does the study answer the question?/Further Comments

Yes. Aerobic treadmill plus Bobath walking training in moderately affected stroke patients was better than Bobath walking training alone with respect to the outcomes of 6 minute walk test and 10 metre timed walk

Eich HJ;Mach H;Werner C;Hesse S;

Aerobic treadmill plus Bobath walking training improves walking in subacute stroke: a randomized controlled trial

Ref ID 946

RID:

127

2004 Sep

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Direction =

Overall Study Quality -Strengths and Weaknesses:

DETAILS

of patients:

Prevalence (Diagnostic):

Patient Characteristics

Interventions/ Test/ Factor being investigated

Comparisons

**Length of Study/
Follow-up**

Outcome measures studied

Results

Effect Size

Source of funding:

Does the study answer the question?/Further Comments

Franceschini M;Carda S;Agosti M;Antenucci R;Malgrati D;Cisari C;Gruppo Italiano Studio Allevio Carico Ictus;

Walking after stroke: what does treadmill training with body weight support add to overground gait training in patients early after stroke?: a single-blind, randomized, controlled trial

Ref ID 144

RID:

203

2009 Sep

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Limited description of concealment of allocation. Unclear direction.

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study. Unclear effect.

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction = Single blind study, not stated if assessors were blinded to allocation.
Unclear direction

Overall Study Quality -Strengths and Weaknesses:

Strengths: appropriate randomisation, study powered to detect outcome.
Weaknesses: single blind, not stated if assessors were blinded to allocation

DETAILS

of patients:

52 patients in intervention of body weight supported treadmill, 50 in control overground gait training

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: recruited within 45 days of the onset of hemiparesis caused by right or left ischemic or hemorrhagic stroke, able to control the sitting position on a rigid plane surface with the legs hanging freely and without the help of the arms for at least 30 seconds, able to control the trunk in the upright position even with the help of the upper extremities gripping a fixed support or other aid (cane, tripod), without lower limb plasticity (Ashworth scale more than or equal to 1).

Exclusion: significant disability before stroke (modified Rankin scale more than or equal to 2), significant prestroke gait disability (Walking Handicap scale more than or equal to 2), and mild gait impairment at time of enrollment (ability to walk without aids for at least 3 m, or to walk for more than 6 m with the aid of a cane or tripod).

Intervention

Age mean(SD) years = 65.5(12.2), gender female/male = 24/28, time to stroke to inclusion in study mean (SD) days = 28.9(12.0).

Intervention

Age mean(SD) years = 70.9 (12.2), gender female/male = 23/22, time to stroke to inclusion in study mean(SD) days = 26.1(10.9).

Interventions/ Test/ Factor being investigated

Patients in the intervention group did 20 minutes of gait training on a treadmill with body weight support followed by 40 minutes of conventional training. Training was administered 5 times a week for an overall number of 20 sessions, which should have been completed within 5 weeks of inclusion in the study. The quantity of body weight support was tailored to the patient's capability and was limited to 40% of body weight. Body weight support was applied by means of a climbing harness and was gradually reduced during the session depending on the patient's compliance and progress.

Gait training with body weight support was performed with the help of 2 trained physical therapists for each patient to control the paretic lower extremity and pelvis. Treadmill velocity was adjusted to enable gait training at increasing speeds, starting from 0.1 m/s and aiming at 1.2 m/s according to the patient's compliance and progress.

Comparisons

Patients in the control group underwent 20 sessions of conventional treatment (consisting of overground gait training) of 60 minutes each. Treatment was administered 5 times per week for an overall number of 20 sessions, which should have been completed within 5 weeks of inclusion in the study.

For both groups no specific indications were given to the rehabilitation team, and the treatment was tailored to the patient's needs, and the rehabilitation team, and the rehabilitation team's goals. Skilled therapists performed treatment according to the person's needs.

**Length of Study/
Follow-up**

End of study after 20 sessions, 2 weeks after study and at 6 month follow-up.

Outcome measures studied

10 metre timed walk test, 6 minute walk test, Barthel Index

Results

Body weight support group

At start of study

10 metre timed walk test (m/s) median(IQR) = not applicable, 6 minute walk test (m) median(IQR) = not applicable, Barthel Index median(IQR) = 6(3 to 9).

At end of study

10 metre timed walk test (m/s) median(IQR) = 0.5(0.3 to 0.9), 6 minute walk test (m) median(IQR) = 160(118 to 291.3), Barthel Index median(IQR) = 13(9.5 to 17).

2 weeks after study

10 metre timed walk test (m/s) median(IQR) = 0.6(0.4 to 0.9), 6 minute walk test (m) median(IQR) = 180.5(118 .5 to 291.3), Barthel Index median(IQR) = 15(11.8 to 18).

6 month follow-up

10 metre timed walk test (m/s) median(IQR) = 0.7(0.3 to 1.0), 6 minute walk test (m) median(IQR) = 217(108 .5 to 332.5), Barthel Index median(IQR) = 17(14.5 to 18.5).

Overground gait training control group

At start of study

10 metre timed walk test (m/s) median(IQR) = not applicable, 6 minute walk test (m) median(IQR) = not applicable, Barthel Index median(IQR) = 5(3 to 7).

At end of study

10 metre timed walk test(m/s) median(IQR) = 0.6(0.3 to 0.9), 6 minute walk test (m) median(IQR) = 170(90.5 to 250), Barthel Index median(IQR) = 12(8.5 to 16).

2 weeks after study

10 metre timed walk test (m/s) median(IQR) = 0.7(0.3 to 0.9), 6 minute walk test (m) median(IQR) = 193(105 to 286), Barthel Index median(IQR) = 15(11 to 18).

6 month follow-up

10 metre timed walk test (m/s) median(IQR) = 0.8(0.5 to 1.1), 6 minute walk test (m) median(IQR) = 210(140 to 335), Barthel Index median(IQR) = 17.5(14 to 19).

Effect Size

Source of funding:

Not stated

Does the study answer the question?/Further Comments

Yes. Treadmill with body weight support was comparable with conventional gait training with respect to the following outcomes; 10 metre timed walk test, 6 minute walk test, Barthel Index.

Chronic stroke survivors benefit from high-intensity aerobic treadmill exercise: a randomized control trial

Ref ID 186

RID:

1021

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = computer-based random number generator by study-independent staff

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction = blinding of outcome assessment not stated; could bias in favour of intervention

Overall Study Quality -Strengths and Weaknesses:

computer-based random number generator by study-independent staff;blinding of outcome assessment not stated; could bias in favour of intervention; sample size calculation: 15 subjects per group required to detect a significant difference in VO2peak (2.4mL/kg/min) with a power of 0.8 at p<0.05

DETAILS

of patients:

n=38 randomised, TAEX 20, control 18

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Chronic (>6 months) stroke survivors aged >60 years with residual hemiparetic gait (at least 1 clinical sign for paresis, spasticity or circumduction of affected leg while walking; ability to walk on treadmill at ≥0.3km/hr for 3 minutes with handrail support.Exclusion: Unstable angina pectoris, heart failure NYHA >II°, haemodynamically significant valvular dysfunction, peripheral arterial occlusive disease, dementia (Mini-Mental State Examination <20), aphasia (unable to follow 2 commands) major depression (CES-D >16) and other medical conditions

	precluding participation in aerobic exercise; patients already performing aerobic exercise for >20 min/day and >1 day/week. Gender: 29 male, 7 female. Mean (SD) age (years): 68.7 (6.3) range 60-84 years. Time since stroke onset: 65.1 (57.3) months
Interventions/ Test/ Factor being investigated	High-intensity aerobic treadmill exercise (TAEX) for 3 months (39 sessions) starting with 10-20 minutes at 40-50% heart rate reserve (HRR) building up to 30-50 minutes at 60-80% HRR
Comparisons	TAEX versus Conventional Care Physiotherapy (1-3 sessions of 1 hour each/week) including passive muscle tone-regulating exercises for upper and lower extremity, balance training
Length of Study/ Follow-up	Crossover trial but only results for first period extracted (at end of 3 months intervention) as intervention changed for second period
Outcome measures studied	Pry: Body-mass adjusted peak VO ₂ ; sustained walking ability (6 minute walk). 2ry: 10m timed walk at comfortable and maximal speeds; 5 chair rise test; Berg balance scale; Rivermead Index; SF-12
Results	Maximum walking speed in 10 minute walk increased in TAEX by 0.12 (0.12)m/s and decreased non-significantly in controls -0.02 (0.02)m/s, p<0.001. Comfortable walking speed increased in TAEX by 0.07 (0.02) m/s and remained unchanged in controls (0.0 (0.2)m/s, NS. Berg Balance Scale improved 1.7 (3) points in TAEX and decreased in controls -0.9 (3.2) p<0.05. 5 chair rise test (leg strength) improved in TAEX by 2.4 (0.9) s and in controls 0.1 (0.9) s NS. RMI improved in TAEX 13.2 (1.7) to 13.3 (1.7) and declined in controls (12.1 (2.5) to 11.3 (2.5), p=0.02. Mental score of SF-12: improved in TAEX by 2.2 (1.2) points more than controls -1.8 (1.5), p=0.006. Other subscores of SF-12 did not differ
Effect Size	Body-mass adjusted peak VO ₂ improved by 5.5 (1.0)mL/kg/min in TAEX and non-significantly deteriorated in control -0.8 [0.8]ml/kg/min; ITT p<0.001. Distance walked in 6 minutes: increased in TAEX by 57.7 (44.6) m and in controls by 4.7 (5.9) m p<0.001
Source of funding:	grant of the "Forschungskolleg Geriatrie" of the Robert Bosch Foundation
Does the study answer the question?/Further Comments	TAEX effectively improves cardiovascular fitness and gait in people with chronic stroke

Hoyer E;Jahnsen R;Stanghelle JK;Strand LI;

Body weight supported treadmill training versus traditional training in patients dependent on walking assistance after stroke: a randomized controlled trial

Ref ID 937

RID:

921

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

A blocked randomisation procedure was applied to secure even numbers in the two treatment groups, and numbers concealed in envelopes were prepared by an external statistician. Assignment to treatment groups was conducted after the baseline evaluation test to secure that the participants' functional level was within the inclusion criteria. Time for daily training was the same in the two intervention groups

DETAILS

of patients:

60 patients were included in this study. 30 randomised to the treadmill group and 30 randomised to the traditional group

Prevalence (Diagnostic):

Patient Characteristics

Patients mainly <6 months after onset of stroke, use of wheel-chair, dependence on assistance for walking with or without walking aids, medically stable, no neurological or orthopaedic contraindications for walking. The patients' need for assistance should not be beyond one person for shorter transfer and for taking some steps over ground.

Baseline characteristics of the study groups.

Variables	Traditional group N=30	Treadmill group N=30
Age, yrs; mean (SD), min-max	52 (13.1), 18-69	52.3 (10.4), 24-68
Gender, men/women; n	20/10	18/12
Diagnosis,		
haemorrhagia/infarctus, n	13/17	15/15
Hemiplegia, left/right; n	17/13	17/13
Days since stroke: mean (SD),		

	min-max	99 (39.4), 38-215	96 (42), 31-211
Interventions/ Test/ Factor being investigated		Treadmill training with body weight support (TTBWS), plus conventional gait training and functional training for a period of minimum 10 weeks. TTBWS was daily for the 1st 4 weeks (20 sessions), and then 1-2 times a week (10 sessions) for the remaining 6 weeks	
Comparisons		Intensive gait training (30 min) and functional training (30 min) daily for minimum 10 weeks	
Length of Study/ Follow-up		11 weeks	
Outcome measures studied		Functional independence measure (FIM), 10 m walk test (m/s), 6-min walk test (m)	

Results

Effect of traditional training and treadmill training on walking and transfers after 5 and 11 weeks

	Traditional group n = 30	Treadmill group, n = 30
Physical tests	Mean (SD)	Mean (SD)
10m walk test (m/s)		
Baseline	0.20 (0.13)	0.22 (0.14)
5 weeks	0.32 (0.22)	0.33 (0.24)
11 weeks	0.36 (0.24)	0.40 (0.27)
6-min walk test (m)		
Baseline	58.98 (40.48)	70.32 (47.75)
5 weeks	98.03 (61.90)	108.39 (76.84)
11 weeks	115.28 (83.45)	137.51 (94.60)
FIM 9, shorter transfer (sec)		
Baseline	51.65 (29.55)	52.14 (33.01)
5 weeks	45.67 (28.61)	40.32 (28.98)
11 weeks	39.85 (31.89)	33.02 (25.07)
FIM 13, stairs nine steps up – down (sec)		
Baseline	118.42 (90.30)	82.38 (46.37)
5 weeks	80.79 (61.55)	61.31 (43.04)
11 weeks	67.03 (51.70)	48.40 (31.82)

Effect Size

Source of funding: Funded by the South-Eastern Norway Regional Health Authority.

Does the study answer the question?/Further Comments Authors concluded that study showed no significant difference between patients in need of walking assistance after stroke, who practiced TTBWS and over ground training versus those who conducted traditional gait training alone, although most outcome measures showed a small tendency in favour of the treadmill group.

Kang HK;Kim Y;Chung Y;Hwang S;

Effects of treadmill training with optic flow on balance and gait in individuals following stroke: randomized controlled trials

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = "divided randomly...by an independent person who picked one of the sealed envelopes": unclear randomisation

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction = assessment at end of intervention only, no follow up

Overall Study Quality -Strengths and Weaknesses:

"divided randomly...by an independent person who picked one of the sealed envelopes"; unclear randomisation; could bias in favour of intervention; assessment at end of intervention only, no follow up; no sample size calculation; small sample size

DETAILS

of patients:

n=30; 10 in treadmill group; 10 in control group; 10 in "optic flow" group (not extracted)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Patients with hemiparetic stroke 6 months after diagnosis; could walk unaided for >15 minutes; without visual disability or hemianopia; Mini-Mental State Examination score 21 or higher; Brunnstrum stage >4. Exclusion: Cardiovascular problems, orthopaedic and other neurological diseases except for stroke influencing gait. Gender: treadmill 4 male, 6 female, control 6 male, 4 female. Mean (SD) age (years): treadmill 56.3 (7.6), control 56.1 (7.8). Time since stroke onset: treadmill 13.5 (4.0), control 15.1 (7.4)

Interventions/ Test/ Factor being investigated

Treadmill training 3 times a week for 4 weeks, 30 minutes each day – speed increased by 0.1km/hr each time patients could walk stably for 20 seconds; 2 x 15 minutes with 5 minute break

Comparisons	Treadmill versus Control: general stretching adding range of motion to both sides of trunk, arms and legs. All patients received conventional physiotherapy 5 times a week for 4 weeks
Length of Study/ Follow-up	assessment at end of 4 week intervention, no follow up
Outcome measures studied	Timed up and go, functional reach, 10m walk test, 6 minute walk test
Results	Gait velocity 0.03 (0.02) treadmill vs. 0.01 (0.02) NS. 6 minute walk test 4.65 (3.25) vs. control 1.79 (3.08)
Effect Size	Timed up and go: 1.50 (0.93) treadmill vs. 0.40 (0.84) control NS. Functional reach test: 2.38 (1.59) treadmill vs. 0.20 (0.16) control (p<0.05).
Source of funding:	Sahmyook University
Does the study answer the question?/Further Comments	Main focus of study was on "treadmill with optic flow" rather than standard treadmill training; small sample precludes definitive conclusion

Kosak MC;Reding MJ;

Comparison of partial body weight-supported treadmill gait training versus aggressive bracing assisted walking post stroke

Ref ID 5088 **RID:** 698 2000

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation method and allocation concealment unclear; unblinded due to nature of intervention ;control group not usual care; single-centre trial; did not specify whether trial was analysed based on intention-to-treat approach (1 patient in the PBWSTT group chose to discontinue treatment); a timed 10 metre walk test is often used to measure walking speed but was inappropriate for this patient population as they were initially unable to walk 10 metres and would not been testable.

DETAILS

of patients:

56 patients (22 in partial body weight supported treadmill group; 34 in aggressive bracing assisted walking group)

Prevalence (Diagnostic):

Patient Characteristics

	PBWSTT (n=22)	ABAW (n=34)
Age, mean (SEM)	74 (2)	70 (2)
Male/female, n	13/19	18/16
Days post stroke at study entry, mean (SEM)	39 (3)	40 (4)

Interventions/ Test/ Factor being investigated

Partial body weight supported treadmill training (PBWSTT) was provided (each session up to 45 minutes as tolerated) by a commercially available overhead motorized lift system attached to a parachute-type body harness + 45 minutes of traditional physical therapy with/without bracing, 5 days per week. A physical therapist and a physical therapy aide provided assistance with weight shifting, leg advancement, and foot placement as needed throughout the gait cycle. Treadmill speed was increased as tolerated from 0.8 to 3.2km/h

Comparisons

Aggressive bracing assisted walking (ABAW) for up to 45 minutes as tolerated + 45 minutes of traditional physical therapy with/without bracing, 5 days per week. A hemi-bar and a knee-ankle-foot orthosis were used if necessary. Patients were usually able to begin using a hemi-walker or quadraped cane once able to walk 3.7 to 7.6 metres at the hemi-bar.

Length of Study/ Follow-up

No follow up time. Mean number of treatment sessions = 12.5

Outcome measures studied

1.Overground walking endurance (distance walked until the patient indicated fatigue or fatigue-related deterioration in gait quality noted by therapist) 2. walking speed (over a 2-minute test period)

Results

	PBWSTT	ABAW
Post treatment		
Walking endurance(m), mean (SEM)	74 (15)	72 (11)
Walking speed (2 min test)(m/min),mean(SEM)	11(2)	11
(1)	Subgroup analysis of severely affected patients, those with hemisphaeresis-hemisensory-hemianopic visual deficits, showed significantly greater walking endurance and speed scores for the PBWSTT group and speed, compared with the ABAW group.	

Effect Size

Source of funding: The Burke Rehabilitation Hospital

Does the study answer the question?/Further Comments Authors concluded that partial body weight-supported treadmill training and aggressive bracing assisted walking (ABAW) are equally effective gait training techniques except for a subset of patients with major hemispheric stroke who are difficult to mobilize using ABAW alone.

Kuys SS;Brauer SG;Ada L;

Higher-intensity treadmill walking during rehabilitation after stroke in feasible and not detrimental to walking pattern or quality: a pilot randomized trial

Ref ID 15960

RID:

764

2011 Apr

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Methods of randomisation and allocation concealment reported.
Blind outcome assessment. N=6 (3 in experimental group and n=3 control group) lost to follow-up. ITT used.

DETAILS

of patients:

N=30 (n=15 experimental group; n=15 control group)

Prevalence (Diagnostic):

Patient Characteristics

All participants with first stroke.

Baseline characteristic: experimental group; control group

Age (yr) mean (SD): 63 (14); 72 (17)

Males, n (%): 7 (50); 5 (33)

Left side hemiplegia, n(%): 5 (36); 9 (60)

Time since stroke(days), mean (SD):52 (32); 49 (30)

Inclusion and exclusion criteria: Participants were included in the study if they have had a diagnosis of first stroke confirmed by CT scan, were referred for physiotherapy rehabilitation and scored 2 or more walking item of the Motor Assessment Scale (i.e. were able to walk with stand-by help), were medically stable, were able to understand simple instructions and a mini-mental state exam score of at least 24. Participants were excluded if their walking speed was considered normal (>1.2 m/s), they had any cardiovascular problems that limited their participation in rehabilitation or had other neurological or musculoskeletal conditions affecting their walking.

Interventions/ Test/ Factor being investigated

The experimental group walked on the treadmill for 30 mins (excluding rests), three times a week for 6 weeks, at an intensity of 40-60% heart rate reserve or a Borg Rating of Perceived Exertion of 11-14; the minimum required for training cardio respiratory fitness. The experimental group also received usual physiotherapy intervention, comprising approximately one hour per day of comprehensive therapy using a task oriented approach targeting impairments and activity limitations specific to each participant.

Comparisons

The control group received usual physiotherapy intervention only.

Length of Study/ Follow-up

Baseline , 6 weeks, 18 weeks.

Outcome measures studied

Detriment to walking measured by walking quality and walking pattern. Benefit to walking was measured by walking capacity, comfortable walking speed, fast walking speed.

Results

Walking pattern [Mean (SD)] : experimental; control

Week 6

Linear kinematics

Cadence (steps/min): 85 (26); 84 (29)

P step length (m):0.49 (0.15); 0.45 (0.15)

NP step length (m):0.46 (0.20); 0.47 (0.12)

Angular kinematics

Knee extension at heel strike: -15 (6); -18 (8)

Hip extension at mid-stance:-7(7); -10 (5)

Knee extension at mid stance: -11 (6); -14 (9)

Hip extension at heel-off: 4 (11); 3 (12)

Knee flexion at toe-off: -37 (11); -36 (16)

Hip flexion at mid swing: -20 (6); -24 (7)

Ankle dorsiflexion at mid swing: 28 (8); 25 (10)

Week 18

Linear kinematics

Cadence (steps/min): 85 (29); 83 (29)

P step length (m): 0.49 (0.15); 0.45 (0.15)

NP step length (m):0.47 (0.12); 0.45 (0.15)
Angular kinematics
Knee extension at heel strike: -17 (9);-17 (8)
Hip extension at mid-stance:-9 (6); -6 (6)
Knee extension at mid stance: -12 (8); -11 (7)
Hip extension at heel-off: 5 (9); 4 (11)
Knee flexion at toe-off: -31 (13); -35 (15)
Hip flexion at mid swing: -13 (9); -20(8)
Ankle dorsiflexion at mid swing: 29 (13); 28 (12)

Week 6

Walking quality: experimental; control
Visual analogue scale (0 to 100 mm): 76 (16);79 (19)

Week 18

Visual analogue scale (0 to 100 mm): 78 (26); 79 (16)

Week 6

Walking capacity (m):284 (139); 279 (163)
Comfortable walking speed (m/s): 0.63 (0.30); 0.68 (0.37)
Fast walking speed (m/s): 0.86 (0.43); 0.86 (0.47)

Week 18

Walking capacity (m):279 (163); 291 (157)
Comfortable walking speed (m/s): 0.68 (0.37); 0.72 (0.35)
Fast walking speed (m/s): 0.86 (0.47); 0.91 (0.46)

No adverse events occurred during the higher intensity treadmill walking. Six participants missed treadmill walking sessions; three experiencing musculoskeletal pain. Two experimental group participants fell during the intervention period. The falls did not occur during treadmill walking nor did they occur on days when treadmill walking was undertaken. One participant missed one session and continued with the study. The second had only one session left when she fell during a weekend pass and suffered a subdural haemorrhage which required emergency surgery.

Effect Size

Source of funding:

None reported

Does the study answer the question?/Further Comments

Yes. There was no between group differences in walking pattern and quality. By week 6, the experimental group improved walking capacity by 2 m (95% CI 10 to 14), comfortable walking speed by 0.18m/s (95% CI 0.07 to 0.29) and fast walking speed by 0.18m/s (95% CI 0.03 to 0.35) more than the control group. By week 18, the experimental group was still walking 0.26 m/s (95% CI 0.12 to 0.41) faster than the control group. There were no adverse events reported.

Langhammer B;Stanghelle JK;

Exercise on a treadmill or walking outdoors? A randomized controlled trial comparing effectiveness of two walking exercise programmes late after stroke

Ref ID 4342

RID:

214

2010 Jan

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Envelopes used, limited description of how envelopes were selected. Direction unclear

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study. Unclear direction

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths: assessor blinded to allocation
Weakness: unclear if randomisation method was appropriate

DETAILS

# of patients:	Treadmill intervention group: 21 patients, Walking outdoor: 18 patients
Prevalence (Diagnostic):	N/A
Patient Characteristics	<p>Inclusion criteria Neurological impairment, aged > 50 years.</p> <p>Exclusion criteria Barriers to physical exercise, insufficient language, unstable cardiac status, neurosurgery, premorbid history of orthopaedic problems.</p> <p>Intervention Age mean(SD) years = 74(13.3), gender female/male = 11/21 first time ever stroke 17 out of 21 subjects, length of stay in private rehabilitation facility days mean(SD) = 15.9(5.3).</p> <p>Control Age mean(SD) years = 74(10.4), gender female/male = 12/18 first time ever stroke 16 out of 18 subjects, length of stay in private rehabilitation facility days mean(SD) = 16.9(5.4).</p>

Interventions/ Test/ Factor being investigated	<p>Treadmill group The treadmill had hand railings to hold on to, otherwise there were no safety precautions or body support. The participants walked on the treadmill, and the exercises were carried out with the treadmill in a flat position. The speed was started on the lowest level and was increased within the first minutes to the working level. The working load was increased in cooperation with the participants to a level they felt comfortable with and they felt no insecurity in balance or discomfort otherwise. The group were supposed to do walking exercises for up to 30 minutes five days a week while they attended the private rehabilitation centre.</p>
Comparisons	<p>Outdoor walking group Exercised five days a week at a comfortable speed and with the use of ordinary assistive devices when necessary. The walk was performed regardless of weather conditions. The length of the walk was dependent on time rather than distance, and the intention was a 30-minute continuous walk.</p> <p>The other activities in the physiotherapy department were the same in the two groups. Each patients had a programme consisting of 30 minutes with individual therapy, with the main focus on balance, strength and coordination, 60 minutes of circle training, with the main focus on endurance, strength, flexibility and balance, and 20 minutes of group exercise training in a sitting position with a therapist.</p> <p>All participants were encouraged to do 30 minutes of exercise on their own every afternoon with an individually tailored programme. In addition, a relaxation group of 20 minutes was offered twice a week. The total amount of physiotherapy during a day was 3 hours with an additional 20 minutes relaxation and 30 minutes of education, giving a total of approximately 21 hours of therapy per week.</p>
Length of Study/ Follow-up	End of study: mean 2.5 weeks
Outcome measures studied	6 minute walk test, 10 metre timed walk test
Results	<p>Treadmill training group: Start of study 10 metre timed walk test (m/s) mean(SD) = 0.8(0.5) 6 minute walk test (m) mean(SD) = 277.7(139.9)</p> <p>End of study 10 metre timed walk test (m/s) mean(SD) = 1.0(0.4) 6 minute walk test (m) mean(SD) = 320.6(153.8)</p> <p>Control group Start of study 10 metre timed walk test (m/s) mean(SD) = 0.8(0.4) 6 minute walk test (m) mean(SD) = 299.4(159.3)</p> <p>End of study 10 metre timed walk test (m/s) mean(SD) = 0.9(0.4) 6 minute walk test (m) mean(SD) = 310.1(164.4)</p>
Effect Size	
Source of funding:	None stated
Does the study answer the question?/Further Comments	Yes, at mean end of stay study endpoint here were significant differences in favour of the treadmill group compared with walking outdoors group for the following outcomes; 6 minute walk test and 10 metre timed walk test.

Laufer Y;Dickstein R;Chefez Y;Marcovitz E;

The effect of treadmill training on the ambulation of stroke survivors in the early stages of rehabilitation: a randomized study

Ref ID 1209

RID:

219

2001 Jan

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Unclear direction

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study. Unclear direction

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Unclear direction

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction = Unclear

Overall Study Quality -Strengths and Weaknesses:

Strength: blinding of therapist giving the therapy common to both groups

Weaknesses:

1) very poor randomisation and allocation concealment (patients were alternately assigned to a group by order of admittance to study). 2) Small sample size
3) Numbers of patients invovled in the study unclear as the authors mention N=25 but in the results mention that 29 patients admitted to the study but 4 did not complete the protocol (3 discharged before completion and 1 readmitted to acute hospital). No information on those patients data.

DETAILS

# of patients:	N=25 (n=13 treadmill ; n=12 floor walking)												
Prevalence (Diagnostic):													
Patient Characteristics	<p>Inclusion: 1) 1st supratentorial strokes in anterior brain circulation as evidenced by CT, 2)no additional neurological and/or orthopaedic deficiencies impairing ambulation, 3)no cardiac respiratory or medical condition that could interfere with protocol, 4) no severe cognitive or communication impairment that could hamper the understanding of simple instructions, 5) onset of stroke no more than 90 days prior to beginning of study, and 6) ability to walk on treadmill at a speed of at least 0.2km/hr with minimal to moderate assistance for 2 minutes without rest.</p> <p>Baseline characteristics</p> <table border="0"> <tr> <td>Parameter</td> <td>Treadmill ; floor walking</td> </tr> <tr> <td>Gender M/F</td> <td>7/6 ; 7/5</td> </tr> <tr> <td>Age mean(SD)</td> <td>66.6(7.2) ; 69.3(8.1)</td> </tr> <tr> <td>Days post stroke mean(SD)</td> <td>32.6(21.2) ; 35.8(17.3)</td> </tr> <tr> <td>Side of paresis R/L</td> <td>8/5 ; 7/5</td> </tr> <tr> <td>Etiology hemorrhage/infarct</td> <td>4/9 ; 2/10</td> </tr> </table>	Parameter	Treadmill ; floor walking	Gender M/F	7/6 ; 7/5	Age mean(SD)	66.6(7.2) ; 69.3(8.1)	Days post stroke mean(SD)	32.6(21.2) ; 35.8(17.3)	Side of paresis R/L	8/5 ; 7/5	Etiology hemorrhage/infarct	4/9 ; 2/10
Parameter	Treadmill ; floor walking												
Gender M/F	7/6 ; 7/5												
Age mean(SD)	66.6(7.2) ; 69.3(8.1)												
Days post stroke mean(SD)	32.6(21.2) ; 35.8(17.3)												
Side of paresis R/L	8/5 ; 7/5												
Etiology hemorrhage/infarct	4/9 ; 2/10												
Interventions/ Test/ Factor being investigated	<p>Gait training of the control group consisted of ambulating on floor surface at a comfortable speed using walking aids, assistance, and resting periods as needed. Gait training of the experimental group consisted of ambulating on a motor-driven treadmill which was adjusted to the subject's comfortable walking speed. Generally during the treadmill training the subjects held onto a horizontal bar at their front or side, and a therapist standing on the floor beside them provided assistance with hip flexion and foot placement as needed. With the more limited or apprehensive subjects, treadmill training began with the treating therapist standing behind the subject on the treadmill, guarding the subject and providing manual assistance with his flexion as needed. In most cases, after 2 or 3 such training sessions the subjects were willing to stand alone on the treadmill and receive assistance from the therapist alongside the subject.</p>												
Comparisons	<p>Conventional walking. Actual walking time during training sessions was identical in both groups: 4 min per day the first week, 6 min per day in 2nd week and 8min per day in 3rd week. Total intervention periods (including rest periods) generally ranged between 8-20 minutes. In addition to the routine treatment, all patients received 5 gait-training sessions a week (total of 15 sessions).</p>												
Length of Study/ Follow-up	<p>. Both groups received routine treatment during the study, namely 5 daily physical therapy treatments per week. The treatments were based on the Bobath approach and were provided by staff who were blinded to treatment allocation.</p>												
Outcome measures studied	10 metre timed walk test												
Results	<p>Control group ; Treadmill group 10 metre timed walk test Pre test 0.18(0.16) ; 0.2(0.12) Post test 0.33(0.24)* ; 0.47(0.4)* *statistically significant improvement (p <0.05)</p>												
Effect Size													
Source of funding:	Ministry of Health, Chief Scientific Office, Jerusalem, Israel												
Does the study answer the question?/Further Comments	Yes. Treadmill training versus overground walking were comparable with respect to the outcome of 10 metre timed walk test.												

Luft AR;Macko RF;Forrester LW;Villagra F;Ivey F;Sorkin JD;Whitall J;McCombe-Waller S;Katzel L;Goldberg AP;Hanley DF;

Treadmill exercise activates subcortical neural networks and improves walking after stroke: a randomized controlled trial

Ref ID 297

RID:

197

2008 Dec

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Unclear Direction

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study. Unclear direction.

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Uncertain

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Strengths:well described randomisation
Weaknesses: high drop out, unclear reporting of statistical effect size

DETAILS

of patients:

Intervention: 57 subjects, Control: 56 subjects

Prevalence (Diagnostic):

N/A

Patient Characteristics	<p>Intervention Age mean(SD) years = 63.6(10), gender female/male = 20/14, time to stroke to inclusion in study mean (range) months = 44.6(18.8 to 70.5).</p> <p>Control Age mean(SD) years = 63,2 (8.7), gender female/male = 18/19, time to stroke to inclusion in study mean(range) months = 62.5(36.0 to 88.9).</p> <p>Inclusion: walking at 3 mins at 0.9 m/s without signs myocardial ischaemia Exclusions: heart failure, PAD, unstable angina, aphasia, major depression</p>
Interventions/ Test/ Factor being investigated	<p>Treadmill exercise training group (T-EX)</p> <p>The T-EX training goal was three 40-minute exercise sessions per week at an aerobic intensity of 60% of heart rate reserve. Duration and intensity started low (10 to 20 minutes, 40-50% heart rate reserve) and increased approximately 5 minutes and 5% heart rate reserve every 2 weeks as tolerated. To reach intensity targets treadmill velocity and incline were increased by 0.05m/s and 1% increments respectively.</p> <p>The study duration was 6 months</p>
Comparisons	<p>Control group Performed 13 supervised traditional stretching movements on a raised mat table with a therapist's assistance as previously described. Each movement was performed actively if possible or passively with a therapist's assistance. Movements included quadriceps, calf, hip, and hamstring stretch, low back rotation and stretch, chest stretch, bridging, shoulder shrug, abduction, and flexion, heel slides and short arc of quadriceps. The duration of each control session and the number of sessions were equal to the T-EX sessions.</p>
Length of Study/ Follow-up	<p>At 3 month during study and at the end of the 6 month study</p>
Outcome measures studied	<p>10 metre timed walk test (m/s)</p>
Results	<p>10 metre timed walk test (m/s) increased (baseline to 3 months to 6 months) with T-EX (0.72, 0.59, 0.85 m/s compared to 0.82, 0.69, 0.95 m/s) 2-fold more than in control (0.66, 0.54 to 0.79 m/s compared to 0.71, 0.58 to 0.84 m/s), 14% versus 7%, but the difference did not reach significance (group x time effect: P=0.28)</p>
Effect Size	
Source of funding:	<p>National Institute of Health, University of Maryland</p>
Does the study answer the question?/Further Comments	<p>Unclear as effect size was not reported in paper.</p>

Nilsson L;Carlsson J;Danielsson A;Fugl-Meyer A;Hellstrom K;Kristensen L;Sjolund B;Sunnerhagen KS;Grimby G;

Walking training of patients with hemiparesis at an early stage after stroke: a comparison of walking training on a treadmill with body weight support and walking training on the ground

Ref ID 783

RID:

218

2001 Oct

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Poor description of envelope use for randomisation, unclear direction

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study, unclear direction

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction = Uncertain

Overall Study Quality -Strengths and Weaknesses:

Strengths:
Weaknesses: inadequate randomisation method, single blind

DETAILS

of patients:

Body weight support treadmill: 36 subjects, Control 37 subjects

Prevalence (Diagnostic):

N/A

Patient Characteristics

Body weight support treadmill group:
Age median(range) years = 54(24 to 67), gender female/male = 16/20, time of stroke to inclusion in study median(range) days = 22(10 to 56) , time in rehabilitation department median(range) days = 68(21 to 137).

Control group:
Age median(range) years = 56(24 to 66), gender female/male = 17/20, time of stroke to inclusion in study median(range) days = 17(8 to 53) , time in rehabilitation department median(range) days = 66(25 to 137).

Inclusion: less than 70 years, first stroke, within 8 weeks onset stroke, subjects needing more than 14 seconds to walk 10 m.

Exclusion: comorbidity such as CAD, psychiatric illness.

Interventions/ Test/ Factor being investigated	<p>Body weight support treadmill: the treatment group received 30 minutes of walking training five days a week on a treadmill with body weight support. The body weight support was gradually reduced as fast as possible as the goal was to attain walking on the treadmill with full weight-bearing. The body weight support level and walking velocity were individually chosen and were adjusted to the improvement in the patient's walking ability.</p> <p>The two groups spent an equal amount of time on walking training during the rehabilitation period. During another 30 minutes five days a week, both the treatment and the control group had other types of physical therapy training to improve motor control and to strengthen functionally weak muscles, such as transfers and range of motion exercises as well as techniques to improve motor function in the paretic side.</p> <p>The treatment time for the two groups varied between 3 and 19 weeks, median 68 days in the treatment group and 66 days in the control group.</p>
Comparisons	<p>Control: the control group received individually walking training by a physiotherapist for 30 minutes five days a week. The physiotherapy approach used was according to a Motor Relearning Programme for Stroke by Carr and Shepherd. The training consisted of walking on the ground and did not include training on a treadmill. For the patients who could not walk, exercises in standing were designed to allow weight-bearing on the hemiparetic leg and training to maintain appropriate segmental alignment for balance.</p>
Length of Study/ Follow-up	10 months follow-up
Outcome measures studied	FIM, 10 metre timed walk test (m/s)
Results	<p>Body weight support treadmill</p> <p>Start of study 10 metre timed walk test (m/s) (m/s) mean(SD) = 0.4(0.2) FIM motor items mean(SD) = 53.7(17.7)</p> <p>Follow-up 10 metre timed walk test (m/s) mean(SD) = 0.7(0.3) FIM motor items mean(SD) = 81.9(9.6)</p> <p>Control</p> <p>Start of study 10 metre timed walk test (m/s) mean(SD) = 0.4(0.2) FIM motor items mean(SD) = 56.1(56.1)</p> <p>Follow-up: 10 metre timed walk test (m/s) mean(SD) = 0.8(0.4) FIM motor items mean(SD) = 80.3(15.9)</p> <p>In within-group comparisons, both the treatment group and the control group had improved between admission and discharge with respect to FIM motor items, and 10 metre timed walk test. No difference observed between 2 groups.</p>
Effect Size	
Source of funding:	National Swedish Board Health & Welfare, Swedish Stroke Association,
Does the study answer the question?/Further Comments	Yes. No difference observed in treadmill versus control group for the outcomes of 10 metre timed walk test (m/s) and FIM motor items score.

Olawale O;Jaja S;Anigbogu C;Appiah-Kubi K;Jones-Okai D;

Exercise training improves walking function in an African group of stroke survivors: a randomized controlled trial

Ref ID 16002

RID:

794

2011

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomised. No details of randomisation and allocation concealment reported. N=60 (n=20 in each group) completed 12 weeks of treatment/training. No blinding. No ITT used.

DETAILS

of patients:

N=67 (n= 22 in group A, n=22 group B, n=23 group C)

Prevalence (Diagnostic):

Patient Characteristics

Patients were a African group of stroke survivors

Characteristics: group A; group B; group C

Age (Yrs): 56.8±6.4; 56.8±8.3; 57.2±5.9
Mean duration of stroke (months): 10.2±6.9; 10.7±6.8; 10.3±5.9

Inclusion: All patients whose stroke occurred not less than 3 months and not more than 24 months before entering the study . Subjects were included if they were able to walk 10 metres independently with or without a walking aid.

Interventions/ Test/ Factor being investigated

Subjects in group A had 12 weeks of conventional physiotherapy treatment and treadmill walking exercise training (TWET) while those in group B had 12 weeks of conventional physiotherapy treatment and over ground walking exercise training (OWET). Subjects in group A went through a one-hour session of conventional physiotherapy including 25 minutes of treadmill walking exercise training; those in group B went through a one-hour session of conventional therapy including 25 minutes of over ground walking exercise training. Three treatment/training sessions were conducted each week.

Comparisons

Subjects in group C had one hours session of conventional physiotherapy treatment only for 12 weeks .

Length of Study/ Follow-up

4 weeks, 8 weeks, 12 weeks.

Outcome measures studied

10 metre walk time (10 MWT) , Six minute walk distance (6 MWD)

Results

Changes in walk time function with exercise training
10 metre walk time (s)

Groups: week 4; week 8; week 12
Group A : 8.4 ± 1.2; 17.7 ± 1.5; 22.6 ± 1.5
Group B: 10.4 ± 1.4; 17.4 ± 1.5; 26.8 ± 1.3
Group C: 1.9 ± 0.4; 2.9 ± 0.3; 2.2 ± 0.7

Changes in walk distance function with exercise training
6 minute walk distance (m)

Groups : week 4; week 8; week 12
Group A: 9.4 ± 2.7; 23.1 ± 4.9; 31.0 ± 4.3
Group B: 14.0 ± 2.1; 13.6 ± 5.7; 45.2 ± 4.6
Group C: 1.0 ± 0.3; 1.3 ± 0.6; 2.9 ± 0.8

Effect Size

Source of funding:

None reported.

Does the study answer the question?/Further Comments

Yes. The study indicated that treadmill and over ground walking exercise training programme, combined with conventional rehabilitation improved walking function in an African group of stroke survivors

Pohl M;Mehrholz J;Ritschel C;Ruckriem S;

Speed-dependent treadmill training in ambulatory hemiparetic stroke patients: a randomized controlled trial.[see comment]

Ref ID 1397

RID:

130

2002 Feb

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Unclear direction

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study. Unclear direction

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear Risk

Direction = Unclear

Overall Study Quality -Strengths and Weaknesses:

Strengths: appropriate randomisation method
Weaknesses: single blind, unclear if assessors were aware of treatment allocation

DETAILS

of patients: Structured speed-dependent treadmill training (STT) group: 20 subjects. Limited progressive treadmill training group (LTT) group: 20 subjects. Control group: 20

Prevalence (Diagnostic): N/A

Patient Characteristics
Structured speed-dependent treadmill training (STT) group:
Age mean(SD) years = 58.2(10.5), gender female/male = 4/16, time of stroke to inclusion in study mean (SD) weeks = 16.2(16.4).

Limited progressive treadmill training group (LTT) group
Age mean(SD) years = 57.1(13.9), gender female/male = 6/14, time of stroke to inclusion in study mean (SD) weeks = 16.8(20.5).

Control
Age mean(SD) years = 61.6(10.6), gender female/male = 7/13, time of stroke to inclusion in study mean (SD) weeks = 16.1(18.5).

Inclusion: at least 4 weeks post stroke, no or slight spasticity.
Exclusion: CAD, previous treadmill training, cognitive deficits, movement disorders, arthrosis.

Interventions/ Test/ Factor being investigated	<p>Structured speed-dependent treadmill training (STT) group:</p> <p>12 x 30 min of STT, 8 x 45 min conventional physiotherapy (gait training allowed). Total 12 hours of treatment.</p> <p>During a period of 1-2 minutes, the belt speed was increased, in communication with the patient, to the highest speed at which the patient's pulse was allowed to return to its resting level. If the patient maintained the speed and felt safe during the 10 seconds at Vt1, the speed would then be increased by 10% during the next attempt.</p> <p>Each time the patient successfully completed 10 seconds of walking at the set speed, the speed was increased during the next phase by 10%. Over the course of each training session, the speed was increased at least by a factor of 3 and at most by a factor of 5 (Vt1 to Vt5). The total walking distance varied from session to session. At the next training session, the treadmill would be set (after a short warm-up) to the last-achieved maximum speed from the previous session. The treadmills were run at 0% incline.</p> <p>Limited progressive treadmill training group (LTT) group:</p> <p>12 x 30 min of LTT, 8 x 45 min conventional physiotherapy (gait training allowed). Total 12 hours of treatment.</p> <p>For the LTT group, the training speed was increased by no more than 5% of the maximum initial walking speed each week (20% over 4 weeks). The total walking distance was also allowed to vary in this group. During training, the therapist directly assisted the patients in executing the walking cycle. The treadmills were run at 0% incline.</p>
Comparisons	<p>Control group:</p> <p>12 x 45 min of conventional gait training, 8 x 45 min conventional physiotherapy (gait training allowed). Total 15 hours of treatment. Conventional gait training: physiotherapeutic gait therapy based on the latest description of the principles of the proprioceptive neuromuscular facilitation (PNF) and Bobath concepts was performed by experienced and skilled therapists with additional qualification in the PNF and Bobath techniques.</p>
Length of Study/ Follow-up	<p>Study end: 4 weeks</p>
Outcome measures studied	<p>10 metre timed walk test</p>
Results	<p>Structured speed-dependent treadmill training (STT) group:</p> <p>Start of study: 10 metre timed walk test (m/s) mean(SD) = 0.61(0.32) End of study: 10 metre timed walk test (m/s) mean(SD) = 1.63(0.80)</p> <p>Limited progressive treadmill training (LTT) group:</p> <p>Start of study: 10 metre timed walk test (m/s) mean(SD) = 0.66(0.39) End of study: 10 metre timed walk test (m/s) mean(SD) = 1.22(0.74)</p> <p>Control</p> <p>Start of study: 10 metre timed walk test (m/s) mean(SD) = 0.66(0.42) End of study: 10 metre timed walk test (m/s) mean(SD) = 0.97(0.64)</p>
Effect Size	
Source of funding:	<p>None stated.</p>

Does the study answer the question?/Further Comments

Yes. Structured speed-dependent treadmill training group improved for the outcome of 10 metre timed walk test compared with limited progressive treadmill training group and control group. Limited progressive treadmill training group improved for the outcome of 10 metre timed walk test compared with control group.

Visintin M;Barbeau H;Korner-Bitensky N;Mayo NE;

A new approach to retrain gait in stroke patients through body weight support and treadmill stimulation

Ref ID 1314

RID:

129

1998 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Unclear direction.

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Single blind study, unclear direction of effect

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = No details given on patient characteristics in the 2 arms at end of study or at 3 month follow-up

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

No

Direction = Low risk of detection bias as evaluations done by blind assessor not aware of group assignment

Overall Study Quality -Strengths and Weaknesses:

Strengths: evaluations at end of study and follow-up done by blind assessor not aware of group assignment
Weaknesses: no description of randomisation concealment, 21% drop out at end of study and 52% drop out at 3 months, possible attrition bias as no details were given on patient characteristics compariaions between the 2 arms at end of study, and at 3 months follow up.

DETAILS

# of patients:	50 patients in body weight support treadmill group and 50 patients in treadmill group
Prevalence (Diagnostic):	N/A
Patient Characteristics	<p>Body weight support treadmill group: mean age(SD) = 66.5(12.8) years, female/male = 19/31, delay onset treatment(SD) days = 68.1(26.5), overground endurance 10 m walkway(SD) (range 0 to 320) (m) = 44.6(67.4) (2 to 320), overground walking speed(SD) (range 0.0 to 1.3) (m/s) = 0.19 (0.17) (0.01 to 0.87).</p> <p>Treadmill group: mean age(SD) = 66.7(10.1) years, female/male = 22/28, delay onset treatment(SD) days = 74.8(30.0), overground endurance 10 m walkway(SD) (range 0 to 320) (m) = 46.2(72.2) (0 to 320), overground walking speed(SD) (range 0.0 to 1.3) (m/s) = 0.16(0.17) (0.06 to 0.62).</p>
Interventions/ Test/ Factor being investigated	Body weight support treadmill. The experimental group received gait training on a treadmill while an overhead harness supported a percentage of their body weight. Individuals in the body weight support group were provided up to 40% body weight support at the beginning of training, and the percentage of body weight support was progressively decreased as the subject's gait pattern and ability to walk improved.
Comparisons	Treadmill. The control group received gait training on a treadmill with no body weight support, i.e. while bearing full weight on their lower extremities. Both groups received gait training for 6 weeks at a frequency of four times per week. Gait training was performed by the subject's treating therapist in the physiotherapy department. During each session the patients were allowed to walk for a maximum of three trials and for a total duration not exceeding 20 minutes. In addition to gait training, all subjects included in the trial, regardless of group allocation, received regular weekday physiotherapy aimed at maximising function. Subjects in both groups were trained with the assistance of one or two therapists, as needed.
Length of Study/ Follow-up	At end of study after six weeks training and at 3 months follow up
Outcome measures studied	10 metre timed walk (m/s)
Results	<p>At end of study: six week training There was a significant difference between the body weight support group and no- body weight support group (mean(SD) score) for overground walking speed (0.34(0.04) versus 0.25(0.04) m/s; P=0.029).</p> <p>3 month follow up The 79 subjects who completed the training protocol were contacted for a follow-up evaluation at 3 months after training. Of these, 52 (66%) were available to participate in the follow-up evaluation. Twenty-seven subjects were lost for reasons including a medical event or a repeated stroke, lack of willingness to participate or a move out of the province. Of the 52 subjects re-evaluated, 29 were in the body weight support group and 23 were in the no- body weight support group.</p> <p>There was a significant difference between the body weight support and no- body weight support groups (mean(SD) score) overground walking speed (10 metre timed walk) (0.52(0.06) versus 0.30(0.06) m/s; P=0.006).</p>
Effect Size	
Source of funding:	Heart and Stroke Foundation of Canada, National Health Research and Development Program

Does the study answer the question?/Further Comments

Yes. Body weight supported treadmill improved overground walking speed at end six week training period and at 3 month follow-up,

Question: In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?

Study Type	Randomised Controlled Trial
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Dias D;Lains J;Pereira A;Nunes R;Caldas J;Amaral C;Pires S;Costa A;Alves P;Moreira M;Garrido N;Loureiro L;

Can we improve gait skills in chronic hemiplegics? A randomised control trial with gait trainer

Ref ID 4873

RID:

236

2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Results not complete and only given as paired differences. Assessors were blinded to treatment allocation

DETAILS

of patients:

n=40 control 20 (14M, 6F) Treated 20 (16M, 4F)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion/exclusion: First ever stroke, chronic stage with more than 12 months evolution, motor stabilisation, lower limb motor deficit (motricity index <100;>0), age 18-80yrs, cognitive status on mini mental state >19, communication skills to

understand treatment, absence of cardiac, psychological and orthopaedic conditions that might interfere with results, no rehabilitation management in last 6 months.

	Intervention ; control
Age	70.35(7.36) ; 68(10.69)
Time after stroke(months)	47.10(63.83) ; 48.45(29.51)

Interventions/ Test/ Factor being investigated

Both groups followed interventions 5x/week for 5 weeks, 40mins duration each. Control = classical Bobath method, rehabilitation management inc. initial 20min session for joint mobilisation and muscle strengthening plus 20min balance & gait training. Treated group used a gait trainer (REHA-STIM). 2 footplates on 2 bars, 2 rockers and 2 cranks to provide propulsion. Also had a 20 min session of joint mobilisation and muscle strengthening. In following 20 mins, patients were managed in the gait trainer with max 30% body weight relief during first sessions. The weight support was progressively decreased during treatment. Each patient supervised by a physio who corrected knee motion manually when needed.

Comparisons

Change within group and interaction effect (change in outcome measure over time)

Length of Study/ Follow-up

End of study (5 weeks) and 3 month follow up

Outcome measures studied

Rivermead Mobility Index, Barthel Index, 10m walk (m/sec), 6 minute walk (m).

Results

	Exercise group changes	Control group changes:
Pre- to post-treatment:		
RMI Mean difference (SD):		
	-0.35 (0.75); p=0.049	-1.26 (1.82) ; p=0.007
BI-mobility items:		
	0.50 (7.93); NS	
10 meters walking test speed		
	-0.11 (0.17); 0.011	
6 minute walking distance test(m)		
	-18.92 (26.33); 0.005	-23.28 (2.16) ; 0.001
Post-treatment to follow-up:		
RMI - Mean difference (SD)		
	1.35 (3.38); NS	-0.16(0.90) ; NS
BI-mobility items		
	-3.50 (6.51); 0.027	
10 meters walking test speed		
	0.13 (0.36); NS	
6 minute walking distance test(m)		
	9.88(34.80); NS	-0.56(22.65) ; NS

RMI:Rivermead Mobility Index ; BI: Barthel index

Effect Size

Source of funding:

Not stated

Does the study answer the question?/Further Comments

Both groups of chronic hemiplegic patients improved after either PBWS with gait trainer or Bobath treatment. Only subjects undergoing PBWS with gait trainer maintained functional gain after 3 months.

Multicenter randomized clinical trial evaluating the effectiveness of the Lokomat in subacute stroke

Ref ID 4872

RID:

259

2009 Jan

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Could bias against gait training

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

randomisation table used so randomisation/allocation concealment inadequate; 72 participants enrolled and 9 withdrew or were removed for poor attendance or decline in health (unclear from which groups); not intention-to-treat analysis; no power calculation; patients in gait training group older (59.9 vs. 54.6 year, $p=0.05$), could bias against gait training; shorter time since stroke (110.9 vs. 138.9 days, $p=0.08$) but analyses adjusted for this; lack of blinding in assessment of outcomes

DETAILS

of patients:

72 enrolled; 33 completed in gait training group and 30 in control group (unclear how many initially allocated to each group)

Prevalence (Diagnostic):

Patient Characteristics

Protocol specified self-selected walking speed 0.1 to 0.6m/s (severe gait impairment = 0.1 to 0.4m/s over 5m; moderate = 0.4 to 0.6m/s); patients in gait training group older (59.9 vs. 54.6 year, $p=0.05$); shorter time since stroke in gait training group (110.9 vs. 138.9 days, $p=0.08$) -

	protocol specified <6 months since stroke;	
	Gait training;	control
male: female	21:12	18:12
right: left	11:22	17:13 (p=0.06);
ischaemic: haemorrhagic	26:7	21:9;
baseline Center for Epidemiological Studies Depression Scale:	8.2	7.4
baseline Folstein mini mental state examination	26.7	26.8.

Interventions/ Test/ Factor being investigated

Lokomat gait training: device initiated stepping patterns after which participant instructed to follow; initial walking speeds 0.42m/s; training intensity increased by changing speed, level of body-weight support and duration of continuous walking; goal of walking with no body support for 45 minutes at 0.83m/s (top speed of device); computer monitor provided biofeedback based on previous step for hip and knee joints. Trained 3 days per week for 8-10 weeks (maximum total 24 sessions); each session 1.5 hours total including setup, training, rest breaks (45 minutes for intervention)

Comparisons

Lokomat gait training versus conventional gait training (control) using static and dynamic postural tasks, trunk positioning, improving lower and upper limb range of motion, overground walking, then higher level balance and gait activities including stairs; could include up to 15 minutes per session on treadmill.

Length of Study/ Follow-up

pre-test; after 12 and 24 (total; post-test) sessions; 3 month follow up.

Outcome measures studied

1ry: self-selected walking velocity over 5 metres; walking distance during 6 minute timed walk. 2ry: Berg Balance Test, Functional Ambulatory Category, NIH Stroke Scale, Motor Assessment Scale, Rivermead Mobility Index, Frenchay Activities Index, SF-36.

Results

Change scores from baseline:

		Lokomat ;	control ;	p
Walking speed (m/s):	Post-training:	0.12 (0.03) ;	0.25 (0.03) ;	p=0.002;
	3 months:	0.15 (0.04) ;	0.30 (0.03) ;	
		p=0.006.		
6 minute walk test (m):	Post-training:	50.2 (9.9) ;	83.5 (10.8) ;	p=0.03;
	3 months:	62.2 (14.9) ;	102.0 (15.2) ;	
		p=0.07.		
Rivermead Mobility Index:	Post-training:	2.0 (0.30) ;	1.6 (0.3) ;	p=0.36;
	3 months:	2.6 (0.4) ;	2.2 (0.5) ;	p=0.53.

Effect Size

Source of funding:

National Institute on Disability and Rehabilitation Research and Christopher Reeve Paralysis Foundation

Does the study answer the question?/Further Comments

The study found that conventional gait training was better than the Lokomat device for stroke patients with moderate to severe gait impairments; they explain this by the limitations on trunk and pelvis movement, and swinging the arms while walking, that are caused by the device, and the alterations in lower extremity muscle and joint movements caused by the device. Also, the top speed of the Lokomat was only 0.83m/s; the maximum walking speed of some patients might exceed this, limiting the ability of the device to improve walking speeds. To deliver a consistent protocol across time, the investigators did not use some newer features of the device. Biofeedback was based on the previous step not the current step in real time. Participants in the Lokomat group did not receive conventional gait training (multidisciplinary, including therapist-assisted treadmill training). Not necessarily generalisable to other periods after stroke, impairment levels, lesion locations etc.

Hornby TG;Campbell DD;Kahn JH;Demott T;Moore JL;Roth HR;

Enhanced gait-related improvements after therapist- versus robotic-assisted locomotor training in subjects with chronic stroke: A randomized controlled study

Ref ID 2544

RID:

231

2008

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Method of randomisation not clear, assessors not blinded to treatment group. Length of treatment period only given in number of sessions (12) not duration, or information on how many sessions per week.

DETAILS

of patients:

48 total (24 in each group 15/9 M/F in each)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: hemiparesis of >6months duration after unilateral, supratentorial, ischemic or hemorrhagic stroke. No evidence of bilateral or brain stem lesions. All subjects required to walk >10m without physical assistance at speeds of at least 0.8m/s at self-selected velocity using assistive devices and bracing below the knee as needed.
Exclusion criteria: significant cardiorespiratory/metabolic disease, other

neurological or orthopaedic injury that may limit exercise participation or impair locomotion, size limitations for the harness/counterweight system or robotic orthosis, no botulinum toxin therapy in lower limbs <6months prior to enrollment, scores <23 on mini mental state examination, no concurrent physical therapy.
Patients characteristics:

	Treated	control
Mean age	57+/-10yrs	57+/-11yrs
Gender male: female	15:9	15:9
Race white: other	12:12	12:12
Side affected right: left	16:8	16:8
Ischaemic: : haemorrhagic	12:12	10:14
Mean months post-stroke	50+/-51month	73+/-87months
Number with ankle foot orthoses	18	12
Number with assistive device	13	12

Interventions/ Test/ Factor being investigated

Locomotor training protocol in both groups consisted of 12 sessions (30mins/session) with therapist(control) or robotic assistance(treated). In both groups subjects wore harness attached to a counterweight system to provide body weight support. Approx 30-40% body weight supported in first session and decreased approx 10% increments per session as tolerated without substantial knee buckling or toe drag. Training started at 2kmph during first session, increased by 0.5kmph every 10mins as tolerated to 3kmph where it remained for subsequent visits. BP & heart rate maintained below 220/110mmHg and 85% of age-predicted max (respectively). Rest breaks if necessary. Treated group had continuous symmetrical stepping assistance using the Lokomat. Subjects encouraged to generate max effort throughout training, particularly in paretic limb. Visuale feedback from a full-length mirror and verbal encouragement from therapists were also provided. Control group had therapist assisted training, at similar weight support and speeds to robotic assisted group. A therapist provided manual facilitation at the paretic limb to facilitate stepping. Assistance provided only as necessary to ensure continuous walking as opposed to approximating normal kinematics. Visual feedback from a mirror and verbal encouragement also provided. Lower extremity orthoses were removed if stepping could proceed with minimal risk of orthopaedica injury.

Comparisons

Robotic assisted treated vs control therapist assisted (and severity of impairment moderate vs severe)

Length of Study/ Follow-up

Before and after 12 treatment sessions and 6 months follow-up

Outcome measures studied

Primary: walking speed, at normal speed (self-selected velocity SSV) and as fast as possible (fast velocity FV). Secondary: 6 min walk test at self selected velocity (SSV).

Results

	Treated	control
Walking speed (self selected; mean (SD); m/s):		
Pre-treatment	0.45 (0.19)	0.43 (0.22)
Post-treatment	0.52 (0.21)	0.56 (0.28)
Follow-up	0.5 (0.21)	0.52 (0.25)
p value treated vs. control	p=0.03	
p value moderate vs. severely impaired	p=0.03	
Walking speed (fast; m/s)		
Pre-treatment	0.59 (0.3)	0.6 (0.33)
Post-treatment	0.65 (0.32)	0.73 (0.39)
Follow-up	0.66 (0.34)	0.72 (0.38)
p value treated vs. control	p=0.02	
p value moderate vs. severely impaired	p=0.04	
6 min walk (m)		
Pre-treatment	170(86)	170(86)
Post-treatment	186(88)	204(96)
Follow-up	193(94)	203(104)
p value treated vs. control	p=0.14	
p value moderate vs. severely impaired	p=0.13	

Effect Size

Source of funding: National Institute of Disability and rehabilitation research, Department of Education

Does the study answer the question?/Further Comments Therapist-assisted LT facilitates greater improvements in walking ability in ambulatory stroke survivors as compared to a similar dosage of robotic-assisted LT.

Husemann B;Muller F;Krewer C;Heller S;Koenig E;

Effects of locomotion training with assistance of a robot-driven gait orthosis in hemiparetic patients after stroke: a randomized controlled pilot study

Ref ID 600 **RID:** 227 2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear or unknown **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Results for Barthel index given as median +/- interquartile range. For walking speed SE is reported rather than SD. Assessors were kept blind to treatment allocation, although patients and investigators administering treatment weren't (but impossible to do in this study).

DETAILS

of patients:

Control:14 (10M, 4F) Treated:16 (11M, 5F)

Prevalence (Diagnostic):

Patient Characteristics

Hospital based Inpatient rehabilitation. No prior stroke, no other neurological or orthopaedic disorder, independent ambulation before the stroke, no severe medical illnesses. Hemiparesis severe with lower extremity strength graded 3 or less on MRC scale in > 2 muscle groups. Must score 1 or less on functional ambulation classification. Interval between stroke and start of treatment 28 - 200 days.

Patient characteristics:

	Treated	control
Mean age	60+/-13 years	57+/-11 years
Gender male: female	11:5	10:4
Infarct: haemorrhage	12:4	10:4
Side affected right: left	12:4	11:3
Mean days post-stroke	79+/-56 days	89 +/- 61 days

Interventions/ Test/ Factor being investigated

Both groups received 20 treatment sessions plus an additional 20 sessions of conventional physiotherapy. Final assessments performed after 40 sessions of therapy which was after 4 weeks for most patients, 5 weeks max. Treated group: Patients walked on a treadmill (woodway treadmill) with the help of a robotic-driven gait orthosis (Lokomat). At the beginning of the treatment period, 30% of body weight of each subject was supported. Walking sessions were kept at a demanding level; the velocity of the treadmill set to max speed tolerated by the patients, force of the drives regulated and body weight support was reduced as soon as patients could tolerate it. Therapists motivated patients to actively move their legs. All patients in treated group scheduled for one 60min session per workday = 30 mins real walking time (when mounting, dismounting and adjustments accounted for). Control group - received 30 mins of conventional physiotherapy per workday. Focus was on gait rehabilitation, exercising trunk stability and symmetry, step initiation and weight support on the paretic leg. In every session, patient walked some steps with the help of therapists. Treadmill training was provided if possible with the help of one or two therapists.

Comparisons

Before and after therapy and treatment vs control

Length of Study/ Follow-up

Final assessment after 40 treatment session (between 4-5 weeks). No further follow up.

Outcome measures studied

Primary: 10m timed walking test (speed in m/s). Secondary: German version of Barthel Index

Results

	Walking speed (mean±SE) m/s:	
	Treatment	Control
Baseline	0.14 (0.02)	0.12 (0.03)
4 weeks	0.20 (0.03)	0.20 (0.05)
p value	p=0.125	p=0.006
Barthel index (median± IQR):		
Baseline	35(41.25)	35(18)
4 weeks	50(25)	50(10)
p value	p=0.001	p=0.005

Effect Size

Source of funding:

Not stated.

Does the study answer the question?/Further Comments

This pilot study indicates that Lokomat therapy is a promising intervention for gait rehabilitation. Although there was no difference between groups in gain of functional scores, the Lokomat group showed an advantage of robotic training over conventional physiotherapy in improvement of gait abnormality and body tissue composition.

Morone G;Iosa M;Bragoni M;De AD;Venturiero V;Coiro P;Riso R;Pratesi L;Paolucci S;

Who may have durable benefit from robotic gait training?: A 2-year follow-up randomized controlled trial in patients with subacute stroke

Ref ID 16925

RID:

999

2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = randomisation and allocation concealment not stated

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction = impossible to blind intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

randomisation and allocation concealment not stated;Outcome evaluation blinded; No sample size calculation; ITT analysis; Baseline characteristics similar

DETAILS

# of patients:	n=48, stratified into low motricity index (LM) and high motricity index (HM) groups and randomised (12 LM intervention, 12 LM control, 12 HM intervention, 12 HM control)
Prevalence (Diagnostic):	
Patient Characteristics	Inclusion: non-ambulant patients with motor and gait dysfunction due to subacute stroke. Exclusion: none stated. Gender: not stated. Mean (SD) age (years): 55.58 (13.35) LM intervention, 60.17 (9.59) LM control, 68.33 (9.11) HM intervention, 62.92 (17.43) HM control. Time since stroke onset: mean 20 days
Interventions/ Test/ Factor being investigated	Robot-assisted gait training group: 2 therapy sessions per day 5 days per week for 3 months; Gait Trainer for first 4 weeks
Comparisons	Robot-assisted gait training versus Control group: conventional gait training
Length of Study/ Follow-up	at discharge and Follow up 2 years after discharge
Outcome measures studied	Primary outcome measure: Functional ambulation category. Secondary outcome measures: Barthel Index, Rivermead Mobility Index
Results	Barthel Index: discharge 69.6 (15.1) LM intervention, 52.1 (14.1) LM control, p=0.005; 64.2 (21.2) HM intervention, 74.2 (20.3) HM control NS. Follow up: 76.9 (11.5) vs. 64.7 (14.0) p=0.024; 74.3 (18.7) vs. 77.6 (20.4) NS. RMI: discharge 9.4 (2.7) LM intervention, 4.9 (2.0) LM control, p=0.001; 7.4 (4.1) HM intervention, 10.1 (4.0) HM control NS. Follow up: 11.8 (3.5) vs. 7.0 (3.6) p=0.010; 10.4 (3.8) vs. 10.6 (3.9) NS
Effect Size	Functional ambulation category: discharge 4.0 (0.9) LM intervention, 2.1 (1.2) LM control, p<0.001; 3.8 (1.1) HM intervention, 3.7 (1.0) HM control NS. Follow up: 4.7 (0.5) vs. 3.1 (1.3), p<0.002; 4.3 (0.9) vs. 4.0 (1.0) NS
Source of funding:	Italian Ministry of Health and Santa Lucia Foundation
Does the study answer the question?/Further Comments	the higher efficacy of the combination of robotic therapy and conventional therapy versus conventional therapy alone that was observed at discharge only in patients with greater motor impairments was sustained after 2 years.

Peurala SH;Airaksinen O;Huuskonen P;Jakala P;Juhakoski M;Sandell K;Tarkka IM;Sivenius J;

Effects of intensive therapy using gait trainer or floor walking exercises early after stroke

Ref ID 4945

RID:

380

2009 Feb

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomised, inadequate details of allocation concealment. Drop-outs, n=9 [n=5 in gait trainer (GT); n=1 walking (WALK); n=3 conventional treatment (CT)]. ITT not reported.

DETAILS

# of patients:	N=56 (n=22 gait trainer (GT); n=21 walking (WALK); n=13 conventional treatment (CT))
Prevalence (Diagnostic):	
Patient Characteristics	<p>Characteristics: GT ;WALK; CT</p> <p>Age yrs (mean SD): 65.7 ; 65.3; 69.5 (11.0)</p> <p>Post stroke, days (mean SD): 8.6(2.3); 7.8 (3.0); 9.5 (1.9)</p> <p>Infarction/haemorrhage (n): 11/6; 16/4; 8/2</p> <p>Left/right hemiparesis (n): 9/8; 12/8;6/4</p>
Interventions/ Test/ Factor being investigated	<p>Inclusion criteria: First time stroke patients (within 10 days of stroke onset).</p> <p>Gait trainer. The patient was supported with a harness and his or her feet were placed on motor-driven foot-plates. The amount of body weight support (BWS) provided by harness was chosen according to the patients individual needs.</p>
Comparisons	<p>Control group 1 (Walking): Patients practiced walking over ground with 1 or 2 physiotherapists, using walking needs. Control group 2:conventional treatment: One or 2 physiotherapy sessions daily, but not at the same intensity as gait training and walking.</p>

Length of Study/ Follow-up	At the end of 3 weeks of rehabilitation
Outcome measures studied	10 metre walk test (MWT), 6 minutes walk test (MWT), Rivermead Mobility Index (RMI).
Results	<p>At 3 weeks: Outcome: GT (n=9) ; WALK (n=14) [mean (95% CI)] 10MWT time, sec : 13.2 (7.0 to 19.4) ;14.6 (9.6 to 19.5) , group difference p-value p=0.452</p> <p>Outcome: GT (n=9) ; WALK (n=12) [mean (95% CI)] 6 MWT, distance ,m: 321.2 (218.1 to 424.3); 370.8 (280.5 to 459.1), group difference p-value p=0.547</p> <p>Outcome: GT (n=16) ; WALK (n=20); CT (n=10) [mean (95% CI)] RMI: 9.8 (7.7 to 11.9); 9.8 (7.9 to 11.6); 8(5.2 to 10.8), group difference p-value p=0.703</p>
Effect Size	
Source of funding:	Supported by the Social Insurance Institution of Finland, the Brain Research and Rehabilitation Centre Neuron, Finland and the Department of Neurology
Does the study answer the question?/Further Comments	Yes. At the end of 3 weeks, mean walking velocity (10 MWT) and walking distance (6MWT) were not different between the gait trainer exercise and walking groups (10 MWT, p=0.452; 6 MWT ,=0.547). The Rivermead Mobility Index improved in all groups but p-value for group difference was not statistically significant (p=0.703)

Peurala SH;Tarkka IM;Pitkanen K;Sivenius J;

The effectiveness of body weight-supported gait training and floor walking in patients with chronic stroke

Ref ID 15999 **RID:** 787 2005 Aug

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Unclear randomisation and inadequate allocation concealment No blinding reported.

DETAILS

# of patients:	N=45 (n=15 gait trainer (GT) exercise with FES (functional electric stimulation) , n =15 GT exercise without FES) ;n=over ground exercise WALK)
Prevalence (Diagnostic):	
Patient Characteristics	<p>Characteristics: GT with FES ; GT without FES; WALK Age (yrs): 53.3±8.9; 51.2±7.9; 52.3±6.8 Post stroke (yrs): 2.6±2.4; 2.4±2.6; 4.0±5.8</p> <p>Twenty two patients had left-sided and 23 had right sided hemiparesis. The cause was a supratentorial infarction in 25 cases and an intracerebral haemorrhage in 20 cases. Seventeen patients had aphasia, and 5 had neglect based on assessment by a neuropsychologist or speech therapist. The mean time since the onset of stroke± SD was 2.9±3.8 yrs.</p> <p>Inclusion: Chronic stroke patients (> 6 months), under 65 years of age.</p>
Interventions/ Test/ Factor being investigated	Gait trainer (GT) with FES and Gait trainer (GT) without FES. Each session 20 mins, for a total of 3 weeks. In the gait trainer (GT) a patient is supported with a harness and his/her feet are placed on motor driven footplates. The speed of the gait trainer can be selected from 0 to 2 km/h which determines the number of steps during each session. The training progression was carried out by increasing the speed and aiming to support less than 20% of the body weight.
Comparisons	The WALK group practiced walking over ground or over uneven terrain with their individual walking aids In the WALK group, the training progression was carried out by increasing the speed with the aim of decreasing reliance on walking aids or different surfaces for walking. The duration of walking exercise was 20 mins
Length of Study/ Follow-up	at the end of 3 weeks of rehabilitation.
Outcome measures studied	10 metre walk test (MWT), 6 minutes walk test (MWT), Total Functional Independence measure (FIM).
Results	<p>At the end of 3 weeks Outcome: GT with FES; GT without FES; WALK 10 MWT time (s): 35.9±29.9; 30.3±23.6; 32.1 ±15.9 6 MWT distance (m): 151.7 ±97.4; 177.5±111.5 ; 135.1±67.9 FIM score (points): 100.9±12.3; 106.8±10.2; 102.3±10.9</p>

Effect Size

Source of funding: Supported by the Social Insurance Institution of Finland, the Brain Research and Rehabilitation Centre Neuron, Kuopio, Finland and the Department of Neurology

Does the study answer the question?/Further Comments Yes. In 3 weeks of gait oriented rehabilitation, 10 MWT time decreased by 18% to 24% and 6 MWT distance increased by 14% to 17% ($p < 0.001$).

Pohl M;Werner C;Holzgraefe M;Kroczeck G;Mehrholtz J;Wingendorf I;Hoolig G;Koch R;Hesse S;

Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (DEutsche GAngtrainerStudie, DEGAS)

Ref ID 1758

RID:

280

2007 Jan

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Adequate randomisation and allocation concealment; baseline comparability between groups; sample size calculation and adequate power; blinded assessment of primary (but not secondary) outcome measures; intention-to-treat analysis absolute treatment duration of physiotherapy comparable between groups; inclusion of only 5% of all stroke patients limits generalisability

DETAILS

of patients: 77 gait training (GT) + 78 control

Prevalence (Diagnostic):

Patient Characteristics

	Gait training ;	Control
Mean age	62.3 (12.0; range 26-79);	64.0 (11.6; 37-79);
female: male	27:50;	24:54;
time since stroke(wk)	4.2 (1.8);	4.5 (1.9);
Barthel Index (BI) mean(SD)	37.9 (12.9);	36.8 (12.7);
Functional Ambulation Category (FAC):		
	0.99 (0.89);	1.19 (1.12);
gait velocity (m/s)	0.13 (0.17);	0.14 (0.19);
maximum walking distance (m)		
	32.3 (49.3);	32.9 (49.9);
Rivermead Mobility Index (RMI)		
	3.5 (1.8);	3.4 (2.2);
Motricity Index	32.3 (22.6);	33.4 (24.0);
Stroke: ischaemic: haemorrhagic		
	61:16;	63:15;
Side: left: right	41:36;	45:33.

Interventions/ Test/ Factor being investigated

Group A (gait training) received 20 minutes of repetitive locomotor therapy on the gait trainer, immediately followed by 25 minutes of one-to-one physiotherapy everyweek day for 4 weeks; group B (control) received 45-minute physiotherapy in the same period; physiotherapy in both groups concentrated on restoration of stance and gait; the remaining comprehensive rehabilitation programme, including group but no additional individual physiotherapy sessions, was the same for both groups and included occupational therapy for upper limb rehabilitation

Comparisons

Gait training versus control

Length of Study/ Follow-up

Post-test after 4 week training period and 6 month follow up

Outcome measures studied

1ry: Functional Ambulation Category (0=cannot walk/needs 2 therapists; 5= independent inc. stairs) from videos; Barthel Index. 2ry: walking velocity (10m walking time), walking endurance (6min walking test), Rivermead Mobility Index, Motricity Index

Results

	Intervention ;	Control	
BI (≥75)(mean SD): post-test:	72.3 (21)	58.7 (21.6)	p<0.0001;
6 months:	77.5 (23.1)	65.1(28)	p=0.025.
Gait velocity (m/s): baseline means (SD):	0.13 (0.17);	0.14 (0.19);	
post-test means (SD):	0.44 (0.47);	0.32 (0.36);	
change scores:	0.31 (0.40);	0.18 (0.28),	p<0.0001;
6 months mean (SD):	0.53 (0.31);	0.36 (0.42),	
change from post-test	0.09 (0.15);	0.04 (0.17)NS.	
Gait endurance (m) baseline mean (SD):	32.3 (49.3);	32.9 (49.9);	
post-test:	134.4 (125.5);	92.5 (104.9);	
change scores:	102.2 (97.1);	59.6 (72.9),p<0.0001;	
6 months mean (SD):	165.5 (152.5);	112.1 (127.7),	
change from post-test	31.1 (55.7);	19.6 (52.6),	NS.
Rivermead Mobility Index: baseline mean (SD):	3.5 (1.8);	3.4 (2.2);	
post-test:	8.5 (3.9);	6.3 (3.7);	
change scores:	5.0 (2.9);	2.9 (2.6),	p<0.0001;
6 months mean (SD):	10.0 (4.1);	7.8 (4.8);	
change from post-test:	1.5 (2.2);	1.5 (3.1),	NS.

Effect Size

Source of funding: Bundesministerium fur Bildung und Forschung and Reha-Stim company (which holds the national patent for the gait trainer device)

Does the study answer the question?/Further Comments This was a large high quality study, with blinded assessment of the primary outcome measures, which demonstrated that gait training increased the likelihood of patients with subacute stroke being able to walk independently post-treatment and have a Barthel Index over 75/100.

Schwartz I;Sajin A;Fisher I;Neeb M;Shochina M;Katz-Leurer M;Meiner Z;

The effectiveness of locomotor therapy using robotic-assisted gait training in subacute stroke patients: a randomized controlled trial

Ref ID 4879 **RID:** 284 2009 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

At baseline there was a difference between groups in stroke type: more patients in the GT group experienced a hemorrhagic event as compared with the control group (37.9% vs 13.4% P=0.02). At study entry, all patients except 2 in the control group had FAC score of 3 - these 2 patients were excluded from the final FAC statistical analysis (Not one of our outcome measurers however).

DETAILS

of patients: n=67 Gait training=37, control=30

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Stroke patients admitted to dept. of physical medicine & rehabilitation. Independent ambulation before stroke and cognitive and cooperative ability to follow simple instructions. Neurological condition severity between 6 and 20 according to National Institutes of Health Stroke Scale, interval between stroke and start of treatment was no longer than 3 months.
Exclusion criteria=previous stroke, haemodynamic instability or other active medical illnesses, or pressure sores in the lower limbs.

	Gait training	Control	
Mean (SD) age	62(8.5),	65(7.5);	
%Male:	56.7%	66.7%	
%Married:	81%	76.6%	
%Israeli born:	32.4%	33.3%	
Education >12yr %:	64.8%	70%	
Mean days post-stroke	21.6(8.7)	23.6(10.1)	
NIHSS at entry:	10.5(2.6)	10.4(2.8);	
R hemisphere stroke %:	54%	73.3%	
Ischemic stroke %:	62.1%	86.6%	(P=0.02)

Interventions/ Test/ Factor being investigated

Study group treated with robotic driven gait orthosis, the Lokomat. Overall time of Lokomat treatment, inc. getting in and out=1hr, net training was 30min. Speed of treadmill set to max tolerated by the patients. At the beginning of the treatment, patients required intensive support of their body weight to stand on the treadmill without knees buckling. Approx 50% of body weight supported by harness, during the following sessions the support was reduced in approx 10% increments per session as tolerated without substantial knee buckling or toe drag. All patients in both groups received regular physio for 30mins each work day 5 times a week for 6weeks. Patients in GT group were scheduled for 30mins of one robotic training per work-day, 3 times a week for 6 weeks, whereas the control patients were treated with additional regular physiotherapy for gait training for 30mins (overall 60mins of regular physiotherapy) 3 times a week. Focus on this training was gait rehabilitation, ie, on the patients' exercised trunk stability and symmetry, step initiation, and weight support on the paretic leg. In every session the patient walked some steps with the help of therapists. Both groups received an equal amount of net physiotherapy of 4 hours per week of gait training. All patients received an additional half hour of training per day of upper limb strengthening, static balance training in sitting position, range of motion, and stretching exercises.

Comparisons

GT vs control, within subjects over time.

Length of Study/ Follow-up

No follow up, assessed end of 6 weeks treatment

Outcome measures studied

Daily living functions evaluated with FIM, Gait assessed by 10m walk test (velocity - walking at fastest possible speed). 2min walk test used for exercise tolerance.

Results

	Gait training	Control	
Motor FIM:			
Pre-treatment	44.1(13.1)	42.8(11),	
Post-treatment	66.9 (15.6)	60.3(14.8)	
p value over time			p<0.01
p value time x group			p<0.05

Cognitive FIM:		
Pre-treatment	21.8(19.3)	30.7(15.9)
Post-treatment	27.5(20.6)	34.7(27.1)
p value over time		p<0.04
p value time x group		p=0.73
Intervention pre, post		

Effect Size

Source of funding: Israeli Ministry of Health

Does the study answer the question?/Further Comments This controlled study showed, at the end of a 6-week trial, that locomotor therapy with regular physiotherapy produced promising effects on functional and motor outcomes in patients after a subacute stroke as compared with regular physiotherapy alone.

Tong RK;Ng MF;Li LS;

Effectiveness of gait training using an electromechanical gait trainer, with and without functional electric stimulation, in subacute stroke: a randomized controlled trial

Ref ID 647

RID:

270

2006 Oct

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Could bias in favour of intervention

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk

Direction = Post-test only (4 weeks), no follow up; assessment not blinded, could bias in favour of intervention

Overall Study Quality -Strengths and Weaknesses:

Randomized, but non-blinded. Most outcome measures recorded by an un-blinded assessor (the physio) with the exception of FIM and Barthel recorded by a nurse blinded to intervention group. FIM & Barthel reported as median & interquartile range
Control group older than both experimental groups

DETAILS

of patients:

N=50 : CCT=20, EGT=15, EGT-FES=15

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: People with a first stroke admitted to inpatient unit of rehab hospital in Hong Kong. Diagnosis of ischemic brain injury or intracerebral haemorrhage shown by MRI or CT less than 6 weeks after onset of stroke; Sufficient cognition to follow simple instructions and understand content and purpose of study (Mini-Mental state score >21); Ability to stand upright, supported or unsupported for 1 min; Significant gait deficit (FAC score <3); and no skin allergy to electric stimulation.

Exclusion: Recurrent stroke or other neurological deficit that would affect ambulation ability; Any additional medical or psychological condition that would affect ability to comply with protocol e.g. significant orthopaedic or chronic pain condition, major post-stroke depression, history or potentially fatal cardiac arrhythmias, implanted cardiac pacemaker, Parkinson's disease, or clinical signs of a newly developed thrombosis of the thigh; Aphasia with an inability to follow 2 consecutive step commands or a cognitive deficit; or severe hip, knee or ankle contracture that would preclude passive range of motion of the leg.

Patients characteristics:	Gait training	Control
Mean age (years)	66.1+/-9.9	71.4+/-14
Gender male: female	9:6	12:8
Ischaemic: : haemorrhagic	11:4	17:3
Side affected right: left	7:8	7:13
Mean weeks post-stroke	2.7+/-1.3	2.7+/-1.2

Interventions/ Test/ Factor being investigated

Gait training using electromechanical gait trainer with and without functional electric stimulation (FES). All patients had regular weekday 40min physio sessions and 1.5hour multi-disciplinary treatments consisting of occupational therapy, speech therapy and psychology throughout 4 week study period. Study consisted of 1 training session per weekday during the 4 weeks. FES was not allowed during regular physio sessions. Each participant of experimental groups had gait training with body weight support by the electromechanical gait trainer.

Control gait training (CGT): 30min upper-limb and trunk mobility training + 20min overground gait training + 10min lower limb training + 1.5hrs multidisc treatment. Training based on principles of proprioceptive neuromuscular facilitation and Bobath concepts. Conducted by each subject's own hospital physical therapist. Participants could undergo overground walking training with or without a walking aid or orthoses and with or without manual assistance depending on their abilities. Rehab was tailored to each patient's needs focussing on his/her impairments and disabilities. Each session was documented with type of activity and duration recorded.

Electromechanical Gait Training (EGT): 30min upper-limb and trunk mobility training + 20min EGT walking + 10min lower limb training + 1.5hrs multi-disc treatment. Each gait training session lasted 20mins with optional rest break of 1-3min after first 10min. EGT simulated normal gait cycle in a symmetric manner with ratio of 60:40 in stance and swing phases. Gait trainer supported body weight via a harness according to the participant's ability to lift his/her foot during the walking phase. Step length and walking speed could be adjusted from 34-48cm and 0-0.7m/s respectively. Target training velocity slow (0.2-0.6m/s) to avoid over-exertion of participants. Physical therapist would give assistance during gait training to help with knee extension and give verbal cueing to facilitate head and trunk extension and midline awareness. Those who achieved adequate balance on trainer were encouraged not to use horizontal bar for support.

Blood pressure was monitored continuously during each session to safeguard participants health. Intervention was ceased if a participant reported having a headache, confusion or onset of angina and if an excessive change in blood pressure was detected. Rest break given if participant was fatigued. A log of gait speed generated was kept, percentage of body-weight support, total walking distance and number of rest breaks. If more than 3 scheduled sessions were missed the participant was withdrawn from the study.

Comparisons

Control vs. EGT vs. EGT + FES. Difference scores from post-treatment minus pretreatment. Within group and between 3 group comparisons done.

**Length of Study/
Follow-up**

End of 4 weeks treatment only

Outcome measures studied

Walking speed by timed 5m walk (m/s) walking as fast as possible; FIM and Barthel (assessor blinded). Also Elderly Mobility Scale, Berg Balance Scale, Functional Ambulatory Category, Motricity Index leg subscale.

Results

	Gait training	Control
5min walking speed (m/s, mean(SD)):		
Pre-treatment	0.00(0.00)	0.00(0.00)
Post-treatment	0.47(0.21)	0.24(0.3)
5min walking speed (m/s, mean(SD)):		
Pre-treatment	0.00(0.00)	0.00(0.00)
Post-treatment	0.47(0.21)	0.24(0.3)
Barthel (median (IQR)) :		
Pre-treatment	54(18)	42.5(28)
Post-treatment	84(19)	73(32.5)
p value	p=0.084 (NS)	
FIM (median (IQR)):		
Pre-treatment	56(20)	66.5(18)
Post-treatment	91(17)	89.5(26.5)
Adverse effects did not occur.		

Effect Size

Source of funding:

Research Grant Committee, Hong Kong Polytechnic University & Institutional Review Board, University of Hong Kong / Hospital Authority Hong Kong West

Does the study answer the question?/Further Comments

In this sample with subacute stroke, participants who trained on the electromechanical gait trainer with body-weight support, with or without FES, had a faster gait, better mobility and improvement in functional ambulation than participants who underwent conventional gait training. Future studies with assessor blinding and larger sample sizes are warranted.

Werner C;von Frankenberg S;Treig T;Konrad M;Hesse S;

Treadmill training with partial body weight support and an electromechanical gait trainer for restoration of gait in subacute stroke patients: a randomized crossover study

Ref ID 15998

RID:

786

2002 Dec

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Details of randomisation and allocation concealment reported, cross-over study. Blind outcome assessment. No. of drop-outs not reported.

DETAILS

of patients:

N=30 (n=15 in therapy on the gait trainer and n=15 in therapy on the treadmill)

Prevalence (Diagnostic):

Patient Characteristics

The participants were 17 men and 13 women, mean age 60.0 (± 10.3)years, mean post-stroke interval of 6.7 (± 3.1) weeks. Fourteen patients survived a left-sided stroke and 16 patients a right-sided stroke; cause of stroke was supratentorial ischemia (21 cases) or intracerebral haemorrhage (9 cases).

Inclusion criteria: first time supratentorial stroke; age < 75 years; stroke interval between 4 and 12 weeks before study onset; at least firm continuous or intermittent support from 1 person to walk, corresponding to a functional ambulation category (FAC) level of 2 or less; ability to sit unsupported at the edge of the bed and to stand for at least 10s with help; hip or knee extension deficit of <20°; and passive dorsiflexion of the affected ankle to a neutral position.

Interventions/ Test/ Factor being investigated

Therapy on the gait trainer. The harness-secured patients were positioned on 2 footplates, whose movements simulated stance and swing phases with a ratio of 60% to 40% between the 2 phases. A servo controlled motor assisted the gait movement, with the rotation speed of the gear system being kept constant, and the vertical and horizontal movements of the centre of mass were controlled in a phase-dependent manner by ropes attached to the harness and connected to the

gear system. Treatment duration/session was 15 to 20 minutes with an optional break after 10 mins.

Comparisons

Therapy on the treadmill. Treadmill training consisted of a motor driven treadmill whose speed could be varied from 0 to 5 km/hr. The patients wore a modified parachute harness and a simple pulley released part of the body weight as on the gait trainer .

**Length of Study/
Follow-up**

6 weeks

Outcome measures studied

10 m walking velocity.

Results

Effect Size

Baseline to 6 weeks
outcome : gait trainer ; treadmill
10 m walking velocity (m/s): 0.18±0.07 (0.42±0.21); 0.17±0.06 (0.37±0.23)

Source of funding:

Grant of the Bundesministerium fuer Bildung Forschung, Biofuture BE011.

**Does the study answer the
question?/Further Comments**

Yes. Gait velocity improved significantly over time in both groups, but there was no group difference.

Question: In people after stroke what is the clinical and cost-effectiveness of ankle/foot orthoses of all types to improve walking function versus usual care?

Study Type	Randomised Controlled Trial
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Beckerman H;

Walking ability of stroke patients: efficacy of tibial nerve blocking and a polypropylene ankle-foot orthosis

Ref ID 5004 **RID:** 497 1996

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/Unknown risk **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Randomization carried out with sealed envelopes, using random permuted blocks; 4 months had to have elapsed between the cerebrovascular accident and participation to prevent confounding of the study results by initial recovery; not possible to blind participants with orthosis due to nature of intervention; results from sub-group analysis; median values reported for the results; three patients withdrew from the trial, 2 cases from PTH/AFO and one from PTH/PAFO

DETAILS

of patients: 30 patients included. 16 in the Placebo Thermocoagulation/Ankle Foot Orthosis (PTH/AFO); 14 in the Placebo Thermocoagulation/Placebo Ankle Foot Orthosis

Prevalence (Diagnostic):

Patient Characteristics

Characteristic	Baseline Characteristics of the participants	
	PTH/AFO	PTH/PAFO
Gender		
Female	3	4
Male	13	10
Age (yr)		
Median	55.5	60.5
Range	33-69	41-72
Months Post Stroke		
Median	39.5	24.5
Range	5-143	9-185
Hemiplegic side		
Left	7	8
Right	9	6
Type of Stroke		
Hemorrhagic	4	2
Ischemic	12	12

PTH, Placebo Thermocoagulation; AFO, Ankle Foot Orthosis; PAFO, Placebo Ankle Foot Orthosis

Interventions/ Test/ Factor being investigated

Placebo Thermocoagulation/Ankle Foot Orthosis (PTH/AFO); AFO: Polypropylene AFO was custom made for each patient. AFO in 5° dorsiflexion, corrected for shoe heel height, designed to prevent an equinus or equinovarus position of the foot during walking and inhibit the synergistic extension pattern.

Comparisons

Placebo Thermocoagulation/Placebo Ankle Foot Orthosis (PTH/PAFO); PTH: needle placed into the tibial nerve, localized and anesthetized with no radiofrequency output; PAFO: Polypropylene AFO that allows normal range of motion of dorsiflexion and plantar flexion.

Length of Study/ Follow-up

3 months

Outcome measures studied

Walking ability measured with the Sickness Impact Profile (SIP), validated for the Dutch language; 2ry outcome: walking speed, walked on an 11-m walkway while wearing shoes, orthosis, and walking devices

Results

Characteristic	Baseline Values of main Outcome Measures	
	PTH/AFO (n=16)	PTH/PAFO (n=14)
Sickness Impact Profile (%)		
Ambulation		
Median	43.3	50.4
Range	29.8-67.2	27.9-63.2
Physical dimension		
Median	26.5	39.9
Range	7.6-45.4	18.3-62.8
Total Score		
Median	23.1	35.0
Range	8.2-47.5	11.7-53.3
Walking speed (m/sec)		
Comfortable with shoes		
Median	.44	.32
Range	.19-.85	.17-1.09
Maximal safe with shoes		
Median	.55	.40
Range	.33-1.13	.17-1.48

Median Improvement on Main Outcome Measures at 12-Week Follow-Up

Outcome Measures	N	Median	Range
Improvement SIP ambulation (%)			
PTH/AFO	14	3.23	-12.8/13.2
PTH/PAFO	13	.00	9.0/15.8
Improvement SIP physical Dimension (%)			

PTH/AFO	14	3.05	-1.5/10.0
PTH/PAFO	13	.84	11.2/8.6
Improvement SIP total score (%)			
PTH/AFO	14	2.52	-1.9/10.2
PTH/PAFO	13	1.02	-9.9/8.1
Walking speed (m/sec)			
Comfortable with shoes			
PTH/AFO	14	.05	-.15/.17
PTH/PAFO	13	-.01	-.07/.19
Maximal safe with shoes			
PTH/AFO	13	.04	-.33/.18
PTH/PAFO	13	.02	-.21/.87

Positive signs indicate improvement from the baseline; negative signs indicate a decline from the baseline scores.

Adjusted Treatment Effects With 95% Confidence Intervals for the Main Outcome Measures at 12-Week Follow-Up

Outcome Measure	Adjusted Difference (Effect)	95% Confidence Interval
Improvement SIP ambulation (%)		
Effect AFO/PTH	2.26	-3.36/7.89
Improvement SIP physical dimension (%)		
Effect AFO/PTH	.80	-3.30/4.91
Improvement SIP total score (%)		
Effect AFO/PTH	2.27	-1.85/6.39
Walking speed (m/sec) Comfortable with shoes		
Effect AFO/PTH	.01	-.06/.07
Maximal safe, with shoes		
Effect AFO/PTH	.06	-.02/.15

Effects adjusted for baseline differences with respect to age, period poststroke, and quadriceps strength. Positive signs indicate improvement from the baseline; negative signs indicate a decline from the baseline scores.

Effect Size

Source of funding:

Not mentioned.

Does the study answer the question?/Further Comments

Authors concluded that AFO was 2.72% (95% CI -.94% to 6.38%) more effective than the placebo AFO but not statistically significant.

de Wit DC;Buurke JH;Nijlant JM;Ijzerman MJ;Hermens HJ;

The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial

Ref ID 141

RID:

468

2004 Aug

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomized cross-over trial; randomization not clear; well written and reported; blinding of outcome assessment not mentioned; small sample size; not possible to blind participants due to the nature of intervention

DETAILS

of patients:

20 patients were registered and randomized. Group 1 (walking with plastic, nonarticulated AFO first) N = 10; Group 2 (walking without AFO first) N = 10

Prevalence (Diagnostic):

Patient Characteristics

	Group 1	Group 2 (AFO – without AFO)	(Without AFO – AFO)
Age years (range)		61.1 (51-73)	61.2 (41-70)
Time since stroke, months (range)		26.9 (8-42)	24.2 (8-48)
Time wearing AFO, months (range)		20.8 (6-39)	20.9 (6-44)
Median Motricity Index, affected leg (IQR)		59.5 (26)	53.0 (28.3)
Median FAC score (IQR)		4.5 (1)	4.5 (1)

IQR, interquartile range.

Eighteen patients had an ischaemic stroke and two a haemorrhagic stroke; 11 patients had a left hemiplegia and nine a right hemiplegia. Patients had to be able to walk independently with shoes with and without orthosis (walking aids were permitted)

Interventions/ Test/ Factor being investigated	Walking with plastic, nonarticulated Ankle Foot Orthosis (AFO)																																																																																				
Comparisons	Walking without AFO																																																																																				
Length of Study/ Follow-up	Not applicable																																																																																				
Outcome measures studied	Motricity Index of the affected leg and the Functional Ambulation Category (FAC) score. Walking ability was assessed with 1) Comfortable walking speed, 2) Timed Up and Go (TUG) test and, 3) Stairs test																																																																																				
Results	<p>Descriptive statistics and results of paired t-test (p-values)</p> <p>Velocity (cm/s)</p> <table border="0"> <thead> <tr> <th></th> <th>With AFO</th> <th>Without AFO</th> <th>Difference</th> </tr> </thead> <tbody> <tr> <td>Mean (SD)</td> <td>49.6 (24.3)</td> <td>44.9 (24.0)</td> <td>4.8 (8.4)</td> </tr> <tr> <td>Median</td> <td>44.2</td> <td>34.3</td> <td>4.2</td> </tr> <tr> <td>Minimum</td> <td>18.0</td> <td>18.0</td> <td>-17.0</td> </tr> <tr> <td>Maximum</td> <td>93.0</td> <td>93.0</td> <td>24.0</td> </tr> <tr> <td>IQR</td> <td>37.6</td> <td>43.9</td> <td>0.1</td> </tr> <tr> <td>p-value</td> <td></td> <td></td> <td>0.020</td> </tr> </tbody> </table> <p>Comfortable walking speed was measured in the gait laboratory on a 10m walkway. Walking speed was automatically measured with two infra-red beams over a distance of 7.5m. patients walked the 10-m walkway three times.</p> <p>Timed Up and Go {TUG} (seconds)</p> <table border="0"> <thead> <tr> <th></th> <th>With AFO</th> <th>Without AFO</th> <th>Difference</th> </tr> </thead> <tbody> <tr> <td>Mean (SD)</td> <td>25.6 (11.7)</td> <td>29.2 (12.9)</td> <td>3.6 (2.5)</td> </tr> <tr> <td>Median</td> <td>23.3</td> <td>29.3</td> <td>3.2</td> </tr> <tr> <td>Minimum</td> <td>10.3</td> <td>10.5</td> <td>0.2</td> </tr> <tr> <td>Maximum</td> <td>49.7</td> <td>56.7</td> <td>8.1</td> </tr> <tr> <td>IQR</td> <td>19.6</td> <td>23.8</td> <td>4.9</td> </tr> <tr> <td>p-value</td> <td></td> <td></td> <td>0.0001</td> </tr> </tbody> </table> <p>TUG: the patient is timed while he or she rises from a chair, walks 3 m, turns, walks back and sits down again. Patients were permitted to use a walking aid, but no physical help. Same standard chair with seat height 47cm and arm height 67cm was used for all patients. This test is a reliable and valid test for quantifying functional walking ability in elderly people with different kind of medical history, including strokes.</p> <p>Stairs (seconds)</p> <table border="0"> <thead> <tr> <th></th> <th>With AFO</th> <th>Without AFO</th> <th>Difference</th> </tr> </thead> <tbody> <tr> <td>Mean (SD)</td> <td>73.0 (37.8)</td> <td>81.6 (44.4)</td> <td>8.6 (11.8)</td> </tr> <tr> <td>Median</td> <td>68.6</td> <td>74.5</td> <td>3.4</td> </tr> <tr> <td>Minimum</td> <td>27.4</td> <td>27.8</td> <td>-3.3</td> </tr> <tr> <td>Maximum</td> <td>157.9</td> <td>181.8</td> <td>34.1</td> </tr> <tr> <td>IQR</td> <td>59.2</td> <td>68.1</td> <td>15.9</td> </tr> <tr> <td>p-value</td> <td></td> <td></td> <td>0.004</td> </tr> </tbody> </table> <p>The stairs test is an extended version of the TUG, including the same tasks from the TUG, with the addition of stairs ascent and descent. They were allowed the use of a walking aid and the rail of the stairs, if necessary.</p> <p>Effect on subjective impressions Sixty-five percent (13/20) experienced less difficulties (p=0.001) and 70% (14/20) felt more self-confident (p=0.005) while wearing the AFO (≥ 1 point change on the scales). In both difficulty and self-confidence 25% (5/20) of the patients scored no effect of the AFO. These differences were judged by the authors as clinically significant.</p>		With AFO	Without AFO	Difference	Mean (SD)	49.6 (24.3)	44.9 (24.0)	4.8 (8.4)	Median	44.2	34.3	4.2	Minimum	18.0	18.0	-17.0	Maximum	93.0	93.0	24.0	IQR	37.6	43.9	0.1	p-value			0.020		With AFO	Without AFO	Difference	Mean (SD)	25.6 (11.7)	29.2 (12.9)	3.6 (2.5)	Median	23.3	29.3	3.2	Minimum	10.3	10.5	0.2	Maximum	49.7	56.7	8.1	IQR	19.6	23.8	4.9	p-value			0.0001		With AFO	Without AFO	Difference	Mean (SD)	73.0 (37.8)	81.6 (44.4)	8.6 (11.8)	Median	68.6	74.5	3.4	Minimum	27.4	27.8	-3.3	Maximum	157.9	181.8	34.1	IQR	59.2	68.1	15.9	p-value			0.004
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Median	44.2	34.3	4.2																																																																																		
Minimum	18.0	18.0	-17.0																																																																																		
Maximum	93.0	93.0	24.0																																																																																		
IQR	37.6	43.9	0.1																																																																																		
p-value			0.020																																																																																		
	With AFO	Without AFO	Difference																																																																																		
Mean (SD)	25.6 (11.7)	29.2 (12.9)	3.6 (2.5)																																																																																		
Median	23.3	29.3	3.2																																																																																		
Minimum	10.3	10.5	0.2																																																																																		
Maximum	49.7	56.7	8.1																																																																																		
IQR	19.6	23.8	4.9																																																																																		
p-value			0.0001																																																																																		
	With AFO	Without AFO	Difference																																																																																		
Mean (SD)	73.0 (37.8)	81.6 (44.4)	8.6 (11.8)																																																																																		
Median	68.6	74.5	3.4																																																																																		
Minimum	27.4	27.8	-3.3																																																																																		
Maximum	157.9	181.8	34.1																																																																																		
IQR	59.2	68.1	15.9																																																																																		
p-value			0.004																																																																																		
Effect Size																																																																																					
Source of funding:	Not mentioned																																																																																				

Does the study answer the question?/Further Comments

The effect of an AFO on walking ability is statistically significant, but the mean differences (Comfortable walking speed, TUG and Stair test) too small to be clinically relevant.
Results show that the effect of an AFO on walking ability and subjective impressions are statistically significant.

Erel S;Uygur F;Engin S;Yakut Y;

The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial

Ref ID 16004

RID:

796

2011

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Subjects underwent block randomization; participants assigned to interventions by concealed block randomization carried out by a colleague unaware of the nature of the study; study and control groups were assessed by means of the same tests initially with tennis shoes only at the time of randomization; not possible to blind the patients or therapist to the treatment because of the nature of the intervention; 12.5% loss to follow up; study was adequately

powered

DETAILS

of patients: 32 participants randomized; 16 to intervention (DAFO+tennis shoes); 16 to the control group (tennis shoes only)

Prevalence (Diagnostic):

Patient Characteristics

Patients included if they:
were post-stroke patients of at least 6 months duration (chronic hemiparetic patients); at a cognitive level to understand the aim of the study, to give informed consent; were at level 3-5 according to Functional Ambulation Classification; were not wearing ankle-foot orthosis; had a maximum spasticity level of 3 according to the Modified Ashworth Scale; had a range of passive dorsiflexion up to at least 90 degrees; were above 18 years old.

Characteristics	Study group (n = 14)	Control group (n =14)
Age (year) mean (SD)	42.50 (14.89)	50.64 (9.22)
Sex, n (%) men/women	11 (78.6)/3 (21.4)	7 (50)/7 (50)
Side of hemiplegia n (%) right/left	5 (35.7)/9 (64.3)	4 (28.6)/8 (57.1)
Duration of stroke (month) mean (SD)	30.21 (13.84)	25.36 (13.44)
Use of cane during walking n (%), use/not use	3 (21.6)/11 (78.4)	6 (42.9)/8 (57.1)
FAC, n (%)		
3	2 (14.3)	2 (14.3)
4	8 (57.1)	11 (78.6)
5	4 (28.6)	1 (7.1)
Type of stroke, n (%)		
Ischaemic	3 (21.6)	1 (7.1)
Haemorrhagic	11 (78.4)	13 (92.9)

Interventions/ Test/ Factor being investigated Dynamic Ankle Foot Orthoses (DAFO) fabricated at the University's orthotics department by a physiotherapist. Fabrication time was 2-3 days on average. DAFO were worn inside tennis shoe.

Comparisons

Control group wore only tennis shoes.

Length of Study/ Follow-up

After 3 months the study group was assessed while wearing DAFO in tennis shoes and the control group with tennis shoes only

Outcome measures studied

Timed Up and Go Test; Timed Up Stairs; Timed Down Stairs; Gait Velocity; Functional Reach; Physiological Cost Index

Results

Comparison of the groups initially and at the third month for Functional Reach (FR), Timed Up and Go (TUG), Timed Up Stairs (TUS), Timed Down Stairs (TDS), Gait Velocity (GV) and Physiological Cost Index (PCI)

Initial assessment

	Study group (n = 14) S Mean (SD)	Control group (n =14) S Mean (SD)
FR (cm)	28.50 (8.48)	27.11 (5.41)
TUG (secs)	16.57 (10.01)	22.50 (13.53)
TDS (secs)	15.29 (12.72)	18.00 (10.38)
TUS (sec)	13.64 (12.59)	18.93 (15.99)
GV (m/s)	0.84 (0.40)	0.65 (0.19)
PCI (beats/min)	0.19 (0.10)	0.31 (0.23)

Third month assessment

	Study group (n = 14) DAFO+S Mean (SD)	Control group (n =14) Mean (SD)
FR (cm)	33.43 (9.59)	28.46 (4.40)

TUG (secs)	14.79 (10.36)	19.07 (8.19)
TDS (secs)	13.29 (11.21)	15.36 (8.37)
TUS (sec)	12.00 (10.21)	15.00 (7.29)
GV (m/s)	0.99 (0.45)	0.72 (0.20)
PCI (beats/min)	0.12 (0.06)	0.28 (0.13)

S, tennis shoes; DAFO, dynamic ankle foot orthosis

Effect Size

Source of funding: Not reported

Does the study answer the question?/Further Comments Authors concluded that in chronic hemiparetic patients, wearing Dynamic Ankle Foot Orthoses (DAFO) may lead to improvements in gait velocity and Physiological Cost Index but their effect on functional ambulation activities is inconclusive

Tyson SF;Rogerson L;

Assistive walking devices in nonambulant patients undergoing rehabilitation after stroke: the effects on functional mobility, walking impairments, and patients' opinion

Ref ID 5016

RID:

509

2009 Mar

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/Unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomized cross over trial; no dropouts; allocation was concealed, neither the tester nor patient could be blind to the testing order because it is obvious if someone is using an assistive device; to negate the effects of rehabilitation or spontaneous recovery, all testing was performed in a single day; small sample size; result is limited to the immediate effects on walking activity.

DETAILS

of patients: 20 patients included. Cross over trial.

Prevalence (Diagnostic):

Patient Characteristics

Age (years)	
Mean (SD)	65.6 (10.4)
Time since stroke (weeks)	
Mean (SD)	6.5 (5.7)
Type of stroke	
Right hemiparesis	7
Left hemiparesis	13
Motricity Index Score	
Mean (SD)	48/100 (17.5)
RASPS*	
Mean (SD)	6.7/18 (0.7)
BBAS**	
Mean (SD)	6.4/12 (1.1)

None were using assistive devices as part of their rehabilitation; they were severely impaired group
In their daily physiotherapy sessions, the treating physiotherapist categorized their walking activity as follows: 10 (50%) were unable to walk without assistive devices, 8 (40%) needed constant support, and 2 (10%) were able to walk with intermittent support.
Median Functional Ambulation Categories (FAC) was 1 (walking with constant support; interquartile range, 1, 1).

* Rivermead Assessment of Somatosensory Perception Score; **Brunel Balance Assessment Score

Interventions/ Test/ Factor being investigated Ankle Foot Orthosis (AFO)

Comparisons No device: Walking without the orthosis

Length of Study/ Follow-up Not applicable

Outcome measures studied Functional mobility measured using the Functional Ambulation Categories (FAC), a reliable, valid 6-point ordinal scale of the independence of walking; walking speed and step length of the weak leg, measured using a five-meter walk test.

Results The median (IQR) Values for the Functional Ambulation Categories (FAC) and the P Values, effect sizes and Numbers Needed to Treat (NNT) for Comparison with Walking With No Device

	Comparison with walking		
	Median (IQR)	with no aid (p value)	Effect size (% Change) NNT (95% CI)
No device (control)	1 (1-1)		
AFO	2 (1-2)	.0001	1.04 (44) 3 (1.7-3.7)

The Mean (SD) Values for Walking Impairments Under each Experimental Condition

	Speed (m/s)	Weak Step Length (m)
No device (control)	0.3 (0.14)	0.53 (0.16)
AFO	0.30 (0.12)	0.53 (0.15)

Participants' Responding Yes to Questions About the AFO

	AFO % (n/N)
Was the device comfortable? (p<.165)	85 (17/20)
Was the appearance off-putting? (p<.529)	15 (3/20)
If yes, would it stop you using it?	10% of whole group (2/4)

The five-meter walk test was repeated twice for each condition and mean values calculated.

Effect Size

Source of funding: Not mentioned.

Does the study answer the question?/Further Comments Results of this study show that using AFO can produce an immediate improvement in functional mobility in nonambulant people with stroke but does not affect walking impairments.

Tyson SF;Thornton HA;

The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions

Ref ID 539

RID:

482

2001

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Order of testing was randomized; data was collected by a physiotherapist not involved in the patients' treatment, all data was collected in one day to avoid any changes due to recovery; randomization not clear; small sample size (25 patients), intention to treat analysis not done, allocation concealment not mentioned

DETAILS

of patients:

Twenty- five patients were recruited with a mean age of 49.9 (SD 1) years. Gait was assessed as they walked with and without the hinged Ankle Foot Orthosis

Prevalence (Diagnostic):

Patient Characteristics

There were 16 (64%) men and nine women, 16 (64%) had a right hemiplegia and nine had a left hemiplegia. The mean duration of hemiplegia was 8.3 months (SD 5.5).

Patients

- were all over 18 years, had a hemiplegia following stroke
- were able to weight bear and step with the weak leg (but may not have a functional gait pattern
- had sufficient range to obtain plantargrade in both heels

Interventions/ Test/ Factor being investigated

Hinged AFO made for each patient by an orthotist using 4mm polypropylene with a metal ankle joint and adjustable plantar flexion stop which was set to prevent plantar flexion but allowed full dorsiflexion. A 7m length of paper is divided into a 5m walkway with a metre at each end for the start and finish line. Small stickers (orthopaedic felt with an adhesive backing and soaked in ink) were attached to the subjects' shoes at the apex of the heel. The subject walked along the walkway leaving a trail of inky foot-prints.

Comparisons No orthosis

**Length of Study/
Follow-up**

Outcome measures studied Functional Ambulation Categories (FAC) used to assess the effect on functional mobility; Paper walk ways used to assess gait impairments - step and stride length of the weak and sound leg, symmetry of step length, velocity and cadence (step frequency)

Results

Functional Ambulation Categories (FAC) with and without AFO		
Level	Without AFO	With AFO
Continuous support	7 (28%)	1 (4%)
Intermittent support	8 (32%)	0 (0%)
Supervision	7 (28%)	3 (12%)
Independent on level ground	3 (12%)	19 (76%)
Independent anywhere	0 (0%)	2 (8%)

Function improved when using the hinged AFO. Without the hinged AFO the median FAC score was 2 (needs continuous support, range 1-4), with the hinged AFO the median score was 4 (able to walk independently on even ground, range 1-5). This difference was highly significant (p = 0.0045)

Mean values (SD) for each gait parameter, with P-values for comparison

	Without AFO	With AFO	P-values
Weak stride length* (cm)	39.4 (14.3)	44.3 (14.1)	0.005
Sound stride length* (cm)	39.3 (13.7)	43.8 (14)	0.014
Weak step length (cm)	21.7 (9.5)	23.7 (11.7)	0.303
Sound step length (cm)	19.4 (9.9)	20.8 (9.6)	0.334
Step symmetry	2.6 (4.9)	3 (7.8)	0.653
Cadence* (steps/min)	53.1 (16.8)	62.5 (17.2)	0.002
Velocity* (m/s)	0.18 (0.1)	0.25 (0.1)	0.00045

* Indicates a significant difference; Stride length for the left and right legs was measured as the distance between successive ipsilateral ink marks; step length was measured as the distance between contralateral ink marks; Symmetry was calculated by dividing the values for the sound step length by the weak step length.

Effect Size

Source of funding: Not mentioned

Does the study answer the question?/Further Comments The result of the study show that a hinged AFO can significantly improve functional mobility, and some gait impairments - velocity, cadence and stride length showed significant improvements but not step length or symmetry. Authors concluded that, the hinged AFO could reduce length of stay and level of support, and therefore the cost of rehabilitation and aftercare.

Question: In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing / others) versus usual care?

Study Type	Randomised Controlled Trial
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Chiu CWY;Man DWK;

The effect of training older adults with stroke to use home-based assistive devices

Ref ID 655

RID:

343

2004 Jul

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Could bias in favour of intervention

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction = Control group had fewer visits - could bias in favour of intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

high risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Method of randomisation not stated; allocation not concealed; OTs involved in delivering intervention involved in random assignment (although stated to be blind to study's purpose); control group had fewer visits; assessment during follow up home visit (not blinded); assessment at 3 months (authors state this may not have been long enough). Generalizability of the results limited by the period of the follow-up services.

DETAILS

of patients:

53 total (30 intervention + 23 control)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: 55 years or older; primary diagnosis of stroke; able to follow instructions; able to communicate using speech; living at home with family support; assessed by occupational therapists in hospital as needing a bathing device. Study carried out in one centre in Hong Kong.
Exclusion: acute or terminal disease.

	Intervention	Control
Mean age	72.1 (6.36)	72.2 (9.53)
Male: female	17:13	18:5
First:recurrent stroke	21:9	19:4
Infarction:haemorrhage	24:6	20:3

Interventions/ Test/ Factor being investigated

An additional home-based training programme on bathing devices. Group received additional home visits after discharge (mean 2.74 visits) for training (visit 1: explanation of device and safety; visit 2: opportunity to discuss problems using devices and devices checked for fit and safety; visit 3: optional, depending on patient's proficiency using device).

Comparisons

Both groups trained in use of devices in hospital. Comparison group had pre-discharge home visit (mean 1.39 visits) but no treatment post-discharge.

Length of Study/ Follow-up

3 months

Outcome measures studied

Functional Independence Measure (FIM) used to calculate sample size (presumably primary outcome but not stated); FIM and Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)

Results

FIM scores (higher = better)

	Intervention			Control	
	Pre-test	Post-test	Difference	Pre-test	Post-test
Difference					
FIM motor	67.7 (7.0)	78.6 (7.4)	10.8 (3.8)	66.5 (10.8)	73.5 (10.9)
7.0 (3.7)					
FIM cognitive	29.8 (5.6)	30.7 (5.3)	0.47 (2.0)	30.7 (5.6)	31.4 (5.3)
0.13 (0.63)					
Total	97.6 (10.7)	108.9 (11.6)	11.4 (4.2)	97.7 (11.8)	104.9 (12.0)
7.0 (3.7)					

3 month follow up

	Intervention	Control
FIM motor	78.6 (7.42) n=30	73.5 (10.9) n=23

QUEST (higher = better)

	Intervention	Control
Devices	4.59 (0.4)	3.58 (0.78)
Services	4.63 (0.39)	3.73 (0.35)
Total	4.62 (0.36)	3.72 (0.28)

	Intervention	Control
Rate of bathing device use	96.7%	56.5%
Able to bathe independently at 3 month	25/30	9/23

Effect Size

Source of funding:

not stated

Does the study answer the question?/Further Comments

The group receiving an OT home training programme in using bathing devices had higher use of devices and satisfaction with devices and services than controls not receiving home based training. However, this may have been confounded by the fact that the OTs were involved in randomization; allocation was not concealed; the study was not blinded; assessors carried out assessments in the patients' homes and this was not blinded; the intervention group received more visits overall than the control group; and the follow up of 3 months may be inadequate.

Corr S;Bayer A;

Occupational therapy for stroke patients after hospital discharge - a randomized controlled trial

Ref ID 393

RID:

341

1995

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Imbalance of gender distribution (more females in intervention group, p=0.03). Randomisation and allocation concealment adequate; self-report questionnaires for follow up at 1 year; vital status from GP.

DETAILS

of patients:

110 recruited (55 intervention group; 55 control group)

Prevalence (Diagnostic):

Patient Characteristics

Mean age of 75.5 years. All patients assessed by the medical and occupational therapy staff, using the Barthel Activities of Daily Living (ADL) index, the Wakefield Depression Scale, the Mini-Mental State Examination and Albert's Perception Test before randomisation

	Intervention	Control
Age (years) mean (range)	75.1 (41-96)	75.8 (54-94)
Male: female	15:40	26:29
Prior stroke	12 (23%)	9 (17%)
Days on stroke unit median (range)	50 (5-229)	50 (7-169)
Barthel ADL score median	15 (2-20)	14 (0-20)
Interventions/ Test/ Factor being investigated	After discharge, intervention group contacted and offered further rehabilitation at home by an OT; all accepted and were reviewed at 2, 8, 16 and 24 weeks after discharge. Intervention included teaching new skills, facilitating independence in ADL, facilitating return of function, enabling patients to use equipment, giving information to patient/carer; referring to or liaising with other agencies.	
Comparisons	No special intervention or follow up (usual care).	
Length of Study/ Follow-up	1 year	
Outcome measures studied	Barthel ADL Index; Nottingham Extended ADL Index.	
Results	Intervention	Control
Died	9 (16%)	11 (20%)
Lost to follow up	0	1
Barthel median (IQR)	13 (10-15)	12 (6-15)
Barthel no. (%) ≤ 12	22 (48%)	22 (51%)
Barthel no. (%) > 12	24 (52%)	21 (49%)
Nottingham Extended ADL Scale score:		
Total score median (range)	3 (0-20)	2 (0-21)
More patients in the intervention group than in the control group being independent in feeding themselves (35 (76%) versus 24 (56%)), and using the telephone (30 (65%) versus 14 (33%))		
Aids provided:		
Bath aids	11 (24%)	10 (24%)
Toilet aids	10 (22%)	3 (7%)
Stair rail	13 (28%)	5 (12%)
Walking aids	17 (37%)	8 (19%)
Kitchen aids	1 (2%)	1 (2%)
Other	7 (15%)	6 (14%)
Total	59	33
Readmissions	4 (9%)	11 (26%)
Effect Size		
Source of funding:	Stroke Association	
Does the study answer the question?/Further Comments	An intervention group (reviewed regularly by OT at home after discharge from stroke unit) had received more aids (particularly toilet aids and stair rails) and services (particularly district nurses) than a control group (receiving usual care) at 1 year post-discharge. They also had fewer re-admissions to hospital (p=0.03). However, there were few differences on measures of activities of daily living, mood and perceived quality of life.	

Domiciliary occupational therapy for patients with stroke discharged from hospital: randomised controlled trial

Ref ID 264

RID:

339

2000 Mar 4

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation and allocation concealment adequate; imbalance between groups at baseline adjusted for in analyses; blinded assessment of outcome

DETAILS

of patients:

138 randomised (67 intervention group; 71 control group)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Patients with a clinical diagnosis of stroke, admitted to a Glasgow Royal Infirmary NHS Trust, referred to OT department and discharge date set.

	Intervention	Control
Age (years) median (IQR)	71 (28-89)	71 (31-89)
Male	29 (43%)	31 (44%)
Rankin score before stroke: 0-2	62 (93%)	66 (93%)

Days from stroke onset median (IQR)	31 (17-57)	23 (13-66)
Barthel ADL score median (IQR)	17 (15-18)	18 (16-19)
Referral to medical day hospital	16 (24%)	21 (30%)

Interventions/ Test/ Factor being investigated Domiciliary OT: 6 week programme (around 10 sessions lasting 30-45 minutes) tailored to recovery goals set by patient (e.g. regaining self-care or domestic or leisure activities).

Comparisons Usual care (inpatient multidisciplinary rehabilitation, pre-discharge home visit [some pts], support services and equipment, regular review in multidisciplinary stroke clinic, referral to day hospital [some pts])

Length of Study/ Follow-up Post-intervention at 8 weeks and follow up at 6 months

Outcome measures studied 1ry: Nottingham Extended ADL Scale and "global" outcome of deterioration according to Barthel ADL Index or death. 2ry: Barthel, satisfaction with output services; resource use (staff time, readmission, provision of equipment/services), subjective health

	Intervention	Control	Difference
Results			
8 weeks			
Death	2	1	
no. unable to complete all assessments	1	1	
Nottingham Extended ADL score:			
Total median (IQR)	27 (19-43)	23 (11-35)	4 (-0.5 to +10.0)
Barthel ADL Index median (IQR)	18 (16-20)	17 (14-19)	1 (0.0 to 2.3)
Global outcome:			
No. (%) with improved ADL	38 (57%)	25 (35%)	
No. (%) no change	13 (19%)	16 (24%)	
No. (%) worse ADL or died	16 (24%)	30 (42%)	
6 months			
Death	6	5	
No. unable to complete all assessments	1	3	
Nottingham Extended ADL score:			
Total median (IQR)	28 (15-38)	21 (14-38)	7 (-3.6 to +7.8)
Barthel ADL Index median (IQR)	17 (15-19)	17 (13-18)	0 (-0.6 to +2.4)
Global outcome:			
No. (%) with improved ADL	27 (42%)	15	
(22%)			
No. (%) no change	6 (9%)	11 (16%)	
No. (%) worse ADL or died	32 (49%)	42	
(62%)			
Patient satisfaction:			
patients in the intervention group were more likely to report satisfaction across all 12 questions (summary odds ratio for agreement with statements 1.8 (1.4 to 2.4)).			
Groups were evenly matched at 6 months for place of residence, readmission to hospital, additional services and equipment provided and costs incurred by patients and carers (no data provided).			

Effect Size

Source of funding: Chest Heart and Stroke Scotland; Glasgow Royal Infirmary NHS Trust; Chief Scientists Office, Scottish Office

Does the study answer the question?/Further Comments

The functional outcome and satisfaction of patients with stroke is improved by an OT programme in the short term, but benefits may not be sustained by 6 months.

Logan PA;Ahern J;Gladman JR;Lincoln NB;

A randomized controlled trial of enhanced Social Service occupational therapy for stroke patients

Ref ID 4929

RID:

345

1997 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

Could bias in favour of intervention group

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation unclear; allocation concealment adequate; participants and those administering care not blinded, but outcome assessor was blinded; over 20% loss of outcome data in usual service group at each time point; less than 20% in enhanced service group (p<0.05), which could lead to bias in favour of intervention group.

DETAILS

of patients: 111 randomised (53 enhanced service and 58 usual care)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: first time stroke patients discharged from hospital and referred to OT department.
Exclusion: none stated

	Usual Service	Enhanced Service
Age (years)	74 (11.5)	71 (10.2)
Male	33 (57%)	23 (43%)
Living alone before stroke	29 (50%)	19 (36%)
Dysphasia	9 (15%)	14 (26%)
Left hemisphere affected	26 (45%)	24 (45%)
Days in hospital median (range)	45 (4-238)	39 (6-252)

Interventions/ Test/ Factor being investigated

Enhanced OT service: patients seen and treated by a single research OT (sooner than possible with routine service); equal access to aids and budgets for adaptations; able to check that equipment was appropriate.

Comparisons

Routine service

Length of Study/ Follow-up

Assessments at 3 and 6 months

Outcome measures studied

3 months: Extended Activities of Daily Living Scale (EADL) by post. 6 months: EADL by post and assessed at home using Barthel Index, General Health Questionnaire (GHQ); aids and adaptations received; carer GHQ

Results

	Usual Service	Enhanced
3 months:		
Dead	6	4
Nursing home	0	1
Alive at home but no consent	3	1
Did not return questionnaire	5	3
In hospital	0	0
Completed questionnaire	44	44
EADL total score median (range)	3 (0-18)	8 (0-19)
Mobility median (range)	0 (0-6)	2 (0-6)
6 months:		
Dead	7	5
Nursing home	6	1
Alive at home but no consent	6	2
Did not return questionnaire	NA	NA
In hospital	1	0
Completed questionnaire	38	45
EADL total score median (range)	6 (0-18)	8 (0-21)
Mobility median (range)	1 (0-6)	2 (0-6)
Barthel Index median (range)	16 (2-20)	16 (1-20)
GHQ (patient) total score median (range)	3.5 (0-18)	2 (0-17)
GHQ (carer) total score median (range)	4.5 (0-27)	26 1 (0-13) 29

Effect Size

Source of funding:

Stroke Association

Does the study answer the question?/Further Comments

Enhanced OT service enabled patients to be seen more quickly and more frequently, and they received more therapy and more equipment (especially stair rails) than those in the routine service group. At 3 months, the intervention group scored higher (better) on the EADL (more independent), but by 6 months there were no significant differences except in the mobility subscale. The Barthel Index and GHQ also showed no differences between the groups at 6 months, although the carers of intervention patients scored lower (better) on the GHQ. There was a higher drop out in the usual care group by 6 months (likely to be the most disabled patients). There was no baseline measure of disability in this study.

Parker CJ;Gladman JR;Drummond AE;Dewey ME;Lincoln NB;Barer D;Logan PA;Radford KA;

A multicentre randomized controlled trial of leisure therapy and conventional occupational therapy after stroke. TOTAL Study Group. Trial of Occupational Therapy and Leisure

Ref ID 243 **RID:** 338 2001 Feb

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = Around 20% loss at 6 months and
30% at 12 months in all groups

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

randomisation unclear; allocation concealment adequate; OTs not blinded; unclear if patients blinded; number of patients dropping out low (leisure 7/153, ADL 5/156, control 4/157) but no outcome data available around 20% in each group at 6 months (leisure 26/153 [17%], ADL 35/156 [22%] and control 31 [20%]) and 30% in each group at 12 months (40/153 [26%] leisure; 50/156 [32%] ADL and 45/157 [29%] control).

DETAILS

of patients: 466 randomised (153 leisure, 156 ADL and 157 control)

Prevalence (Diagnostic):

Patient Characteristics

	Leisure	ADL	Control
Age (years) median (IQR)	72 (65-79)	71 (66-78)	72 (65-78)
Barthel score median (IQR)	18 (15-19)	18 (16-20)	18 (16-19)
Male	88 (58%)	97 (62%)	84 (54%)
Pre-stroke Oxford Handicap Score:			
0	79 (52%)	85 (54%)	77 (49%)
1-2	61 (40%)	62 (40%)	64 (41%)
3-4	13 (8%)	9 (6%)	14 (9%)
Not known	0	0	2 (1%)
Living alone	44 (29%)	55 (35%)	49 (31%)

Interventions/ Test/ Factor being investigated

Leisure therapy or ADL therapy: Each aimed towards 10 therapy sessions of 30-60 minutes: leisure group to be treated with leisure activities (done for pleasure) to achieve leisure goals and ADL group with ADL activities for ADL goals. •ADL group: occupational therapy for improving independence in self care task (such as preparing a meal or walking)
•Leisure group: practicing leisure tasks as well as any ADL task necessary to achieve the leisure objectives.
•Protocol specified a minimum of 10 sessions lasting not less than 30 minutes each.

Comparisons

Multiple linear regression analysis ADL vs. Leisure Vs. Control

Length of Study/ Follow-up

6 months (end of treatment period) and 12 months (follow up)

Outcome measures studied

1ry: 6 months General Health Questionnaire (GHQ), Nottingham Leisure Questionnaire, Nottingham Extended ADL Scale. 2ry: International Stroke Trial outcome questions, Oxford Handicap Scale, Barthel, London Handicap Scale, carer GHQ.

Results

6 months Mean (SD) and 95% CI vs. control:

	Range (worst-best)	Leisure	ADL	Control
Mood (GHQ)	36-0	16.0 (6.9)	17.3 (7.1)	17.3 (6.9)
Leisure (NLQ)	0-60	15.9 (6.9)	15.0 (8.0)	15.2 (7.7)
Notts ADL	0-66	33.3 (18.4)	34.7 (18.4)	33.1 (18.9)
London handicap	0-100	64.5 (14.7)	62.7 (17.7)	63.5 (17.9)
Carer mood (GHQ)	36-0	13.4 (5.7)	14.2 (5.9)	14.2 (5.8)

	Leisure	ADL	Control
Barthel score; Median (IQR):			
6 months	17 (14-19)	18 (15-20)	17 (15-20)
12 months	17 (14-18)	17 (14-19)	17 (14-20)

Oxford Handicap Score 6 months			
0-1 (best)	34 (27%)	27 (23%)	28 (23%)
2	25 (20%)	28 (24%)	24 (19%)
3	44 (35%)	40 (34%)	39 (31%)
4-5 (worst)	21 (17%)	24 (20%)	33 (27%)

Oxford Handicap Score 12 months			
0-1 (best)	27 (25%)	30 (29%)	31 (30%)
2	20 (18%)	22 (21%)	19 (18%)
3	37 (34%)	31 (30%)	31 (30%)
4-5 (worst)	25 (23%)	21 (20%)	24 (23%)

No significant differences on any outcomes.

Effect Size

Source of funding: NHS Research and Development Programme (Cardiovascular disease and stroke: Health technology assessment), Lothian Health

Does the study answer the question?/Further Comments TOTAL trial (same patients as Logan 2003 ID 199). Two groups received similar amounts of intervention, one group supposed to be targeted at ADL and the other at leisure activities and a third group received no OT treatment (control). There were no differences between groups on any outcomes (mood, leisure activity, ADL) at 6 months (end of treatment period) or 12 months (follow up). The interventions were not standardised and there was around a 20% drop out by the end of the intervention period and 30% loss to follow up by 12 months.

Sackley C;Wade DT;Mant D;Atkinson JC;Yudkin P;Cardoso K;Levin S;Lee VB;Reel K;

Cluster randomized pilot controlled trial of an occupational therapy intervention for residents with stroke in UK care homes

Ref ID 101

RID:

353

2006 Sep

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = 36% of patients in control group died vs. 16% in intervention group; not discussed in paper

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation (at level of residential home) and allocation concealment adequate; pilot study so no formal power calculation; 36% of patients in control group died vs. 16% in intervention group; not discussed in paper but possibility of attrition bias

DETAILS

of patients:

12 residential care homes randomised (total of 118 pts consented to participate; 55 residents in homes allocated to standard care and 63 to OT)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Purposive sampling of residential homes in Oxfordshire to reflect variability of population (e.g. location, size, funding). 12 homes participated. Staff screened all residents with Barthel Index (score range 0-20; 20 more independent) and residents with scores 4-15 inclusive eligible (representing moderate to severe stroke-related disability).
Exclusion: acute illness; admitted for end-of-life care.

	Intervention	Control
Care home factors:		
Number of homes	6	6
Nursing or dual registered	4	4
Residential home	2	2
Beds per home mean (SD)	30.5 (8.5)	32.0 (11.5)
Residents with stroke per home mean (SD)	10.5 (3.5)	9.2 (5.2)
Individual factors:		
Age; yrs mean (SD) range	88.6 (6.5) 62-102	86.3 (8.8) 44-99
Female	52 (83%)	45 (82%)
Barthel Index score mean (SD) range	10.1 (5.7) 0-20	9.5 (5.2) 0-19

Interventions/ Test/ Factor being investigated

OT assessment, goal setting and intervention targeted at improving independence in ADL (including practising resident's performance of task; physical environment/provision of aids and adaptations and reducing complexity of task or changing tools; specific impairments e.g. tissue shortening in hand addressed by stretching, splinting); frequency and duration dependent on resident and therapist's agreed goals (over 3 months). Also education of staff and carers e.g. how to continue therapy when OT not there; referral/discussion with GP or other agencies. Median visits per resident per month 2.7 (range 1-25); time spent with therapist per resident per month 4.5 hours (range 1-10); most sessions lasted around 30 minutes.

Comparisons

Patients in control homes receiving usual care (OT not used routinely in any homes).

Length of Study/ Follow-up

3 months (end of intervention) and 6 months (follow up)

Outcome measures studied

1ry: Barthel Index. 2ry "poor global outcome" i.e. deterioration in Barthel Index or death. Also Rivermead Mobility Index (score 0-15, 15 more mobile); short Orientation-Memory-Concentration test

Results

	Intervention	Control	Difference*
Barthel Index mean (SD) N			
All participants Baseline	10.1 (5.7) 63	9.5 (5.2) 55	

All patients with 3 month data (end of intervention):

Baseline	10.2 (5.7) 59	9.2 (5.3) 46	
3 months	10.8 (5.5) 59	8.2 (5.2) 46	
Change (3 months-baseline)	0.6 (3.9) 59	-0.9 (2.2) 46	1.5 (-0.5 to +3.5)

All patients with 6 month data (follow up):

Baseline	10.5 (5.7) 53	10.2 (4.9) 35	
3 months	11.3 (5.3) 53	9.3 (4.7) 35	
6 months	10.2 (5.9) 53	8.1 (4.5) 35	
Change (6 months-baseline)	-0.3 (4.2) 53	-2.1 (3.7) 35	1.9 (-0.7 to +4.4)

Global poor outcome:

3 months	20 (32%)	31 (56%)	-25 (-51 to +1)
6 months	32 (51%)	42 (76%)	-26 (-48 to -3)

* Adjusted for cluster design

	Intervention	Control	Difference*
Rivermead Mobility Index			
All participants Baseline	4.9 (3.6) 63	4.0 (3.4) 55	

All patients with 3 month data (end of intervention):

Baseline	4.8 (3.6) 59	3.9 (3.5) 46	
3 months	5.2 (3.7) 59	3.5 (3.1) 46	
Change (3 mths-baseline)	0.4 (3.0) 59	-0.4 (1.9) 46	0.8 (-0.6 to +2.2)

All patients with 6 month data (follow up):

Baseline	5.0 (3.7) 53	4.5 (3.3) 35	
3 months	5.5 (3.7) 53	4.0 (2.9) 35	
6 months	4.5 (3.5) 53	3.4 (2.7) 35	
Change (6mths-baseline)	-0.5 (3.5) 53	-1.1 (3.7) 35	0.6 (-1.2 to +2.4) 0.30

Effect Size

Source of funding:

Stroke Association, Health Foundation, Department of Health, Research Capacity Development Program

Does the study answer the question?/Further Comments

The proportion of residents with a poor global outcome (worsening Barthel Index or died) was lower in the intervention than the control group ($p=0.03$ at 6 months). Changes in Barthel Index and Rivermead Mobility Index were not significant in this pilot study.

Walker MF;Gladman JR;Lincoln NB;Siemonsma P;Whiteley T;

Occupational therapy for stroke patients not admitted to hospital: a randomised controlled trial

Ref ID 267

RID:

340

1999 Jul 24

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation using random number tables; sealed opaque envelopes so allocation concealment adequate; participants and therapists not blinded but outcome assessment blinded; unclear how many patients completed intervention - analysis only on 163 patients who completed assessments at 6 months; no outcome data for 10/94 in intervention group and 12/91 controls (died or withdrew); follow up (at 6 months from study start) was only 1 month after treatment completion (intervention up to 5 months).

DETAILS

of patients:

185 randomised (94 to OT intervention and 91 to no therapy control group) but only 163 analysed (completed assessments at 6 months)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: Patients from community stroke register with a recent (<1 month) clinically diagnosed stroke and not admitted to hospital.
Exclusion: Identified later than 1 month after stroke; history of dementia; living in nursing or residential home; could not speak or understand English before stroke.

	Intervention	Control
Age (years) mean (SD)	73.6 (8.1)	75.1 (8.6)
Median (IQR) scores:		
Barthel Index	18 (15-20)	18 (15-20)
EADL (higher better)	10 (4-15)	11 (3-16)
Rivermead Motor Assessment (higher better)	8 (6-11)	8 (6-11)
Carer strain index (higher = greater strain)	4 (1-7)	4 (1-7)
General Health Questionnaire 28 (higher = worse)	26 (18-35)	27 (19-32)

Interventions/ Test/ Factor being investigated	Visits (mean 5.8 SD 3.3, range 1-15; mean duration 52 SD 11.8, range 24-90 minutes) from research OT for up to 5 months; frequency agreed between therapist, patient and, if appropriate, carer. Aim was independence in personal (e.g. bathing, feeding, dressing, stair mobility) and instrumental (e.g. outdoor mobility, driving, travelling by public transport, household chores) ADL; patients also encouraged to take part in leisure pursuits. Focus on intervention not assessment or liaison. Homework tasks set when possible.
Comparisons	Intervention vs. control (no additional input from research OT; usual care only).
Length of Study/ Follow-up	6 months after randomisation
Outcome measures studied	1ry: EADL scale. 2ry: Barthel, Rivermead motor assessment gross function section, London handicap scale (range 0-100, lower=greater handicap), GHQ 28 (patient and carer), carer strain index.

Results

	Intervention	Control	Mean diff. (95% CI)
6 mths median (IQR) scores:			
Barthel Index	20 (18-20)	18 (16-20)	1 (0 to 1)
EADL	16 (11-18.5)	12 (6-17)	3 (1 to 4)
Rivermead Motor Assessment:			
6 or less	10 (12%)	22 (28%)	
7-11	51 (61%)	46	
(58%)			
>11	23 (27%)	12 (15%)	
Carer strain index	1 (1-4)	3 (1-6)	1 (0-2)
GHQ 28 patient	20 (14-30)	23 (15-3)	-2 (-6 to +2)
GHQ 28 carer	18 (11-24)	18 (13-27)	0 (-4 to +3)

Effect Size

Source of funding: Stroke Association

Does the study answer the question?/Further Comments Patients with stroke who had not been admitted to hospital benefitted from the intervention in the short term (3 points on ADL scale likely to be clinically significant) but follow up was only for 1 month after intervention. However, study excluded a substantial number of patients in institutional care. Also, intervention reduced carer strain (but again only short follow up so no information on durability of effect).

Question: In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?

Study Type	Randomised Controlled Trial
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Trexler LE;Trexler LC;Malec JF;Klyce D;Parrott D;

Prospective randomized controlled trial of resource facilitation on community participation and vocational outcome following brain injury

Ref ID 1789

RID:

629

2010 Nov

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

No details on randomisation method and unclear allocation concealment; no blinding; small sample size - low statistical power; 27.3% of all patients had stroke

DETAILS

of patients:

23 patients randomised, 12 in resource facilitation group and 11 in control group

Prevalence (Diagnostic):

Patient Characteristics		Resource facilitation (n=12)	Control (n=11)
	Age, mean(SD)	43.18 (11.97)	42.64 (12.79)
	Male, n	6	8
	Female, n	5	3
	Education, mean (SD)	13.27 (2.10)	13.36 (3.14)
	Number of stroke patients	3	3
	Time since injury, mean day (SD)	64.5 (46.93)	124.18 (107.38)
Interventions/ Test/ Factor being investigated	Resource facilitation services with standard follow up care - assisted the participants in returning to work by providing employer education, titrating return-to-work schedules and functions, supports through occupational therapy, arranging transportations, promoting access to mental health services, promoting family education, and assisting with access to a variety of state agency resources. Services were provided in various settings according to the individual needs of the participants (e.g. home, community, place of work, outpatient neurorehabilitation clinic). Participants were assigned to 1 or 2 resource facilitators and contacted every 2 weeks; mean no. of hours of intervention = 10.6.		
Comparisons	Standard care. All participants received follow up services recommended by their healthcare providers to which they had access, no additional attempt to facilitate access or receipt of services. Some members of the control group may have received outpatient rehabilitation therapies, neuropsychological services or medical follow up.		
Length of Study/ Follow-up	Patients were followed-up for 6-months.		
Outcome measures studied	Full-time and part-time employment (employment item of the M2PI - the Mayo-Portland Adaptability Inventory questionnaire).		
Results	At 6 months	Resource facilitation (n=12)	Control (n=11)
	Full-time employment, n (%)	4 (33.3%)	3 (27.3%)
	Part-time employment, n(%)	3 (25%)	1 (9.1%)
Effect Size			
Source of funding:	US Dep of Health and Human Services, Health Resources and Services Administration, Traumatic Brain Injury Planning and Implementation Partnership		
Does the study answer the question?/Further Comments	Authors concluded that resource facilitation services that have a clear focus on return to work may have a substantial impact on return to work and on participation in the community and at home after brain injury. There were significant limitations to the study quality (small sample size, not blinded and the study employed diagnostically heterogeneous individuals - 27.3% of all patients had stroke). Other limitations include possible differences in terms of other postacute services received in the two groups - more resource facilitation participants received services from specialised outpatient brain injury rehab and vocational rehab compared to the control group, which may account for better outcomes. Although the group differences were not significant, it may be attributable to the small sample size.		

Question: What is the clinical and cost-effectiveness of supported information provision versus unsupported information provision on mood and depression in people with stroke?

Study Type	Randomised Controlled Trial
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Ellis G;Rodger J;McAlpine C;Langhorne P;

The impact of stroke nurse specialist input on risk factor modification: a randomised controlled trial

Ref ID 259 **RID:** 709 2005

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Randomisation was by using a computer-generated random sequence concealed in sequentially numbered opaque sealed envelopes; Stroke Nurse Specialist (SNS) did not attempt to contact the patient's General Practitioner (GP) or hospital specialist in order to influence prescribing; outcomes recorded by an independent blinded assessor; Study achieved powered claculations; analysis was by an intention-to-treat basis

DETAILS

of patients: 205 patients were recruited at their concluding visit to the stroke clinic or geriatric medical day hospital. Intervention = 100; Control = 105

Prevalence (Diagnostic):

Patient Characteristics

Patients eligible if they had a clinical diagnosis of stroke, or Transient Ischemic Attack (TIA) in the previous 3 months. They had to have one or more of the following risk factors: high blood pressure, a history of current smoking, high cholesterol and/or diabetes with no severe cognitive impairments.

	Intervention n=100 (%)	Control n=105 (%)	P value
Age	63.3 (62.4-66.1)	65.8 (64.0-67.5)	0.25
Sex (male)	54 (54%)	52 (50%)	0.68
Diagnosis			
TIA	29 (29%)	27 (26%)	0.18
Stroke	61 (61%)	68 (65%)	0.18

Data presented as the mean (95% CI) or number (%).

Interventions/ Test/ Factor being investigated

Additional input from the Stroke Nurse Specialist, who reviewed them at monthly intervals for approximately 3 months. Patients were interviewed and given individual advice on lifestyle changes, the importance of medication compliance and its relevance to secondary prevention. Lifestyle issues were discussed in depth and tailored to the patient's circumstances and functional abilities.

Comparisons

Usual care, which included generic risk factor advice from medical staff as well as the Stroke Nurse Specialist (SNS), given within the outpatient context. Following enrolment, control group had no further input from the SNS.

Length of Study/ Follow-up

Outcomes recorded at 5 months.

Outcome measures studied

Geriatric Depression Score

Results

Outcome	Intervention n=94	Control n=98
Geriatric Depression Score*	4.3 (3.6-4.9)	5.1 (4.4-5.7)

Data presented as the mean (95% confidence intervals) or number (%); *Positive scores indicate worse outcome

Effect Size

Source of funding:

Study was funded by a grant from the Chief Scientists Office Scotland

Does the study answer the question?/Further Comments

There was no significant difference between the groups with the Geriatric Depression Score. Patients in the intervention group were more likely to express satisfaction and knew who to contact if they needed to.

Hoffmann T;McKenna K;Worrall L;Read SJ;

Randomised trial of a computer-generated tailored written education package for patients following stroke

Ref ID 407

RID:

710

2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Computer generated randomisation in sequence thus ensuring concealed allocation; Outcome assessor was blind to patients' group allocation, conducted baseline and follow-up interviews; study was powered and achieved minimum recruitment of 130 patients; Data were analysed on an intention-to-treat basis; Of the 138 patients randomised, 133 (96.4%) completed the study; Baseline characteristics of the two groups were similar.

DETAILS

of patients:

138 patients randomised; 69 allocated to intervention group; 69 allocated to control group

Prevalence (Diagnostic):

Patient Characteristics

Patients with diagnosed stroke or transient ischaemic attack; had a reported English-proficiency level; corrected hearing and vision; no reported or observable dementia and was medically stable.

	Intervention group	Control group
Characterristic		
Mean (SD) age (yrs)	67.2 (15.3)	69.1 (14.8)
Male	42 (63.6)	31 (46.3)
Mean (SD, range) yrs of formal education	10.5 (3.7, 4-19)	10.1 (3.0, 5-20)
Mean (SD, range) duration (days) between stroke and hospital interview	8.3 (5.9, 1-38)	8.4 (4.8, 3-21)
First stroke	45 (68.2)	45 (67.2)
Aphasia	13 (19.7)	9 (13.4)
Stroke-related visual perceptual impairment	8 (12.1)	10 (14.9)
Stroke-related vision impairment	18 (27.3)	17 (25.4)

Interventions/ Test/ Factor being investigated	Computer-generated tailored written information ('What you need to know about stroke') designed so that the health professional providing the intervention (in this trial, the research nurse) communicates and collaborates with the patient to establish his or her informational needs. The system contains three tailored features. Patients identify which topics they would like to receive information about, the amount of information that they would like about each topic, and the font size that they would like the information to be printed in.
Comparisons	Generic written information: Research nurse provided patients in the control group with a series of three stroke fact sheets produced by the Stroke Association of Queensland which covered topics such as how stroke occurs, risk factors, and physical, cognitive and emotional changes following a stroke
Length of Study/ Follow-up	3 Months
Outcome measures studied	Self-efficacy; Hospital Anxiety Depression

Results

Outcome	Mean (SD) baseline scores		Change scores (0-3 months)			
	Intervention group (n=66)	Control group (n=67)	Intervention Grp (n=66)	Control Grp (n=67)	95%CI	P value
Self-efficacy						
Section 1 (to get information about the disease)	8.1 (2.3)	7.9 (2.5)	0.2	0.7	-1.5 to 0.4	0.27
Section 2 (to obtain help from family, community and friends)	7.9 (1.8)	8.1 (1.5)	0.0	0.2	-0.8 to 0.3	0.32
Section 3 (to communicate with the doctor)	8.6 (1.8)	9.1 (1.7)	0.3	-0.1	-0.2 to 1.1	0.20
Section 4 (to control/manage depression)	7.7 (2.0)	7.8 (1.8)	0.0	0.3	-0.8 to 0.2	0.27
Section 5 (to manage the disease in general)	7.8 (1.8)	8.0 (1.9)	0.4	0.3	-0.3 to 0.7	0.49
Section 6 (to manage symptoms)	7.3 (2.0)	7.7 (1.8)	0.0	-0.2	-0.5 to 0.9	0.64
HAD anxiety	6.4 (4.2)	6.9 (4.3)	-0.1	-1.5	0.2 to 2.8	0.03
HAD depression	5.0 (3.9)	4.7 (3.3)	0.4	0.3	-1.2 to 1.2	0.99

Six sections of the Self-Efficacy to Perform Self-Management Behaviours Scale were used to measure self-efficacy. The items in each section are scored on a 10-point Likert scale and a mean score is calculated for each section, with higher scores indicating greater self-efficacy.

The Hospital Anxiety and Depression (HAD) Scale consists of separate subscales for anxiety and depression with the scores for each subscale ranging from 0 to 21, with lower scores indicating lower levels of the emotion being measured.

Effect Size

Source of funding:	Trial was funded by the Medical Benefits Fund (MBF) of Australia. Sponsors played no role in the trial's design, data collection, analysis, or interpretation.
Does the study answer the question?/Further Comments	Authors reported no significant differences between patients in the intervention and control groups for change in knowledge about stroke, self-efficacy, depression, or perceived health status from baseline to follow-up. Anxiety change scores improved slightly more in favour of the control.

Lowe D;Sharma A;Leathley M;

The CareFile project: a feasibility study to examine the effects of an individualised information booklet on patients after stroke

Ref ID 5059 **RID:** 762 2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Could bias towards intervention

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Randomised pilot study; Randomisation not clear; Single blinded study; Outcome assessor blinded; Allocation concealment using sealed opaque envelopes; Intention-to-treat analysis not mentioned; Data for mood scores not given; unclear how authors analysed data for mood scores; researcher was involved in randomisation

DETAILS

# of patients:	100 patients randomised; 50 allocated to intervention; 50 allocated to control																					
Prevalence (Diagnostic):																						
Patient Characteristics	<p>Patients with a confirmed primary diagnosis of acute stroke, without severe cognitive or communication problems, not in an institutional care and able to complete a questionnaire.</p> <table border="0"> <thead> <tr> <th colspan="3">Characteristics of Study Participants</th> </tr> <tr> <th></th> <th>Intervention</th> <th>Control group</th> </tr> </thead> <tbody> <tr> <td>Patients, n</td> <td>50</td> <td>50</td> </tr> <tr> <td>Median age, y (range)</td> <td>68 (62-74)</td> <td>73 (65-80)</td> </tr> <tr> <td>Female, n (%)</td> <td>21 (42)</td> <td>19 (38)</td> </tr> <tr> <td>Ischaemic stroke, n (%)</td> <td>44 (96%)</td> <td>41 (94)</td> </tr> <tr> <td>Median Barthel ADL Index at 7 days (range)</td> <td>12 (8-16)</td> <td>12 (7-19)</td> </tr> </tbody> </table>	Characteristics of Study Participants				Intervention	Control group	Patients, n	50	50	Median age, y (range)	68 (62-74)	73 (65-80)	Female, n (%)	21 (42)	19 (38)	Ischaemic stroke, n (%)	44 (96%)	41 (94)	Median Barthel ADL Index at 7 days (range)	12 (8-16)	12 (7-19)
Characteristics of Study Participants																						
	Intervention	Control group																				
Patients, n	50	50																				
Median age, y (range)	68 (62-74)	73 (65-80)																				
Female, n (%)	21 (42)	19 (38)																				
Ischaemic stroke, n (%)	44 (96%)	41 (94)																				
Median Barthel ADL Index at 7 days (range)	12 (8-16)	12 (7-19)																				
Interventions/ Test/ Factor being investigated	CareFile in addition to usual care. The CareFile content includes telephone numbers for stroke-related services and local support agencies, general information about stroke and information personal to the patient.																					
Comparisons	Usual care, including Stroke Association information leaflets and follow-up in Stroke Review Clinic																					
Length of Study/ Follow-up	6 months																					
Outcome measures studied	Primary: Knowledge of stroke. Secondary: satisfaction with information given, utilisation of CareFile, blood pressure, participation and mood (Yale single question).																					
Results	<p>Results:</p> <p>At baseline, 23 (48%) and 25 (52%) patients in the intervention and control groups, respectively, answered 'yes' to the Yale scale for screening depression. While the proportions answering 'yes' were greater at three and then six months (Intervention: 31 [70%]; Control: 26 [59%]), no significant difference were evident.</p> <p>The control group and the intervention group had similar knowledge of stroke scores at baseline ($p=0.91$). At three months post-stroke, patients in the intervention group had a higher knowledge score than patients in the control group ($P<0.05$) and this higher knowledge was still evident six months post-stroke ($p<0.005$).</p>																					
Effect Size																						
Source of funding:	Study was supported by a £5000 research grant from Bristol Myers Squibb.																					
Does the study answer the question?/Further Comments	<p>The proportion of patients answering 'yes' to the Yale single question scale for screening depression increased during the study (more with the intervention group) but no significant difference were evident.</p> <p>Authors stated that a simple education package, in the form of an individualized information booklet, resulted in a significant improvement in knowledge and recognition of risk factors for stroke.</p>																					

Randomized controlled trial of a comprehensive stroke education program for patients and caregivers

Ref ID 5098

RID:

730

1999

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Stroke patients and their informal carer were randomised through a central telephone service to receive either an invitation to attend the multidisciplinary Stroke Education Program (SEP); Patients and carer randomised as a pair (data analysed seperately); randomisation was computerised, stratified and in blocks of 8; low initial response led to a change in the randomisation process in the 7th month of the study (ratio of 2 SEP to 1 conventional care); Outcome assessor blinded, Data analysed on an intention-to-treat basis; Low SEP attendance; Low response rate by SEP non-attenders; Total (cumulative) sample size lower than the estimated size needed to detect an effect; >50% loss to follow-up

DETAILS

of patients:

SEP - Patients = 121, Carers = 107; Control group - Patients = 83, Carers = 69

Prevalence (Diagnostic):

Patient Characteristics

Patients were approached between 5 and 9 days after stroke. Patients excluded if they were discharged within 24 hours, lived outside of the study area, or were admitted from a residential or nursing home.

Characteristics of Study Participants

	SEP	Control group
Patients, n	121	83
Age, y (range)	74 (36-94)	76 (36-95)
Female, n (%)	62 (51)	45 (54)
Previous stroke/TIA, n (%)	48 (40)	29 (35)
Pre-stroke NEADL, n (range)	16 (2-21)	16 (1-22)
Barthel ADL Index at 7 days (range)	11 (0-20)	9 (0-20)
Age at which full-time education ended, n (%)		
12-14	77 (64)	51 (62)
15-18	33 (27)	25 (30)
19-23	5 (4)	2 (2)
Not known	6 (5)	5 (6)

Values are medians unless otherwise indicated; TIA, Transient Ischemic Attack; Patients who attended the SEP had a higher level of activity before stroke (median NEADL, 17 versus 16; P=0.05);

Interventions/ Test/ Factor being investigated

Multidisciplinary Stroke Education Program (SEP) consisting of a rolling program of one 1-hour small group educational sessions for inpatients and their informal carer followed by six 1-hour educational sessions after discharge from hospital. SEP included input from nursing, physiotherapy, occupational therapy, speech and language therapy, clinical psychology, social work, district nursing, the local carers centre, and the stroke club.

Comparisons

Information leaflet (on a number of topics) and routine communication with nurses, doctors and therapy staff members throughout their inpatient stay.

Length of Study/ Follow-up

6 months

Outcome measures studied

Hospital Anxiety Depression Scale; Nottingham Extended ADL; Knowledge about stroke

Results

Patient Emotional and Functional Outcomes at 6 months After Stroke

	SEP	Control group	P
Patients, n	90	64	
HAD scale, n (%)	66	51	
Anxiety cases (+11)	36 (55)	29 (61)	
Depression cases (+11)	30 (46)	23 (46)	
Nottingham EADL Scale, median n (range)			
Mobility	1 (0-6)	1.5(0-6)	0.395
Kitchen	3 (0-5)	4 (0-5)	0.469
Domestic	0 (0-5)	1 (0-5)	0.581
Leisure	2 (0-6)	2 (0-6)	0.983
Total	7 (0-22)	8 (0-21)	0.689

Values are medians unless otherwise indicated; Low SEP attendance: 51 stroke patients and 20 informal carers attended ≥3 outpatient sessions, of whom 55 (77%) returned the evaluation questionnaire. Low response rate by SEP non-attenders: 18 patients and 33 carers who did not attend returned questionnaires, which gave a response rate of 33%

Effect Size

Source of funding:

Northern and Yorkshire Regional Health Authority National Health Service Research and Development Directorate

Does the study answer the question?/Further Comments

Authors concluded that the SEP improved patient knowledge about stroke and increased some aspects of satisfaction with services, this was not associated with an improvement in their perceived health status and psychological outcomes

Smith J;Forster A;Young J;

A randomized trial to evaluate an education programme for patients and carers after stroke

Ref ID 908

RID:

719

2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear/Unknown risk

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomisation was by using random length restricted permuted blocks; Allocation concealment achieved using sealed, numbered, opaque envelopes kept in a locked separate location; All patients received usual practice care from the date of admission until randomisation; Outcome assessors blinded; Data analysed on an intention-to-treat basis; Study achieved estimated sample size to detect a difference in the 2ry outcome; 21% loss to follow-up (intervention=15; control=22)

DETAILS

of patients: Randomised 170; Intervention = 84; Control = 86

Prevalence (Diagnostic):

Patient Characteristics

Patients with a diagnosis of acute stroke; no receptive aphasia; no cognitive impairment and understood English

Characteristics of Study Participants

	Intervention	Control
Patients, n	84	86
Median age, yrs (range)	75 (31-91)	74 (50-92)
Female, n (%)	39 (46)	45 (52)
Living alone (%)	30 (36)	31 (36)
Previous stroke, n (%)	14 (17)	14 (16)
Pre-stroke Barthel ADL Index	20 (12-20)	20 (5-20)
Median length of stay, days (range)	36 (3-108)	33 (4-149)
Median age left education, years (range)	14 (10-18)	14 (14-19)

Interventions/ Test/ Factor being investigated

Specifically designed stroke information (Stroke Recovery Programme) manual and were invited to attend education meetings every two weeks with members of their multidisciplinary team (doctors, nurse, physiotherapist and occupational therapist). Aim of the manual was to facilitate patients and carers adjustment to stroke. The intention of the meeting was to provide background information about stroke, discuss patient's progress, answer specific questions and develop shared rehabilitation goals. Patients and carers unable to attend a meeting due to early discharge were invited to meet with the consultant in the outpatients clinic.

Comparisons

Usual practice. Members of the stroke unit multidisciplinary team were free to discuss aspects of treatment and respond to any specific queries.

Length of Study/ Follow-up

Patients and carers were followed-up by home visits at 3 and 6 months

Outcome measures studied

Primary outcome: Knowledge of stroke; secondary outcome: Frenchay Activities Index, Hospital Anxiety Depression Scale.

Results

Summary of secondary outcomes at baseline, three and six months.

	Baseline	3 Months	6 Months
Hospital Anxiety and Depression Scale			
Intervention (n=84):	(n=51)	(n=49)	(n=50)
Anxiety (21→0)			
Median (range)	8 (1-21)	7 (0-15)	7 (0-15)
'Cases' (score≥11)	35%	10%	16%
Median change from baseline (range)	-	-1.5 (-14 to 16)	-3 (-11 to 16)
Control group (n=86):	(n=57)	(n=45)	(n=43)
Anxiety (21→0)			
Median (range)	7 (0-16)	7 (0-21)	7 (0-19)
'Cases' (score≥11)	25%	24%	33%
Median change from baseline (range)	-	0 (-13 to 10)	-1 (-12 to 13)
Hospital Anxiety and Depression Scale			
Intervention (n=84):	(n=51)	(n=49)	(n=50)
Depression (21→0)			
Median (range)	7 (0-21)	6 (0-15)	6 (0-20)
'Cases' (score≥11)	22%	10%	10%
Median change from baseline (range)	-	-1 (-12 to 11)	0 (-11 to 13)
Control group (n=86):	(n=57)	(n=45)	(n=43)
Depression (21→0)			
Median (range)	7 (1-20)	6 (0-19)	7 (1-21)

'Cases' (score≥11)	21%	20%	26%
Median change from baseline (range)	-	-1 (-11 to 14)	0 (-10 to 11)
Frenchay Activities Index			
Intervention (n=84) :	-	(n=72)	(n=68)
Score range (0→45)			
Median (range)	-	1 (0-30)	5 (0-32)
Control group (n=86):	-	(n=69)	(n=64)
Depression (21→0)			
Median (range)	-	0 (0-23)	3 (0-33)

→ Denotes worst score to best score

Effect Size

Source of funding:

Does the study answer the question?/Further Comments

Question: In people after stroke what is the clinical and cost-effectiveness of psychological therapies provided to the family (including patients)?

Study Type	Randomised Controlled Trial
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Smith GC;Egbert N;Dellman-Jenkins M;Nanna K;Palmieri PA;

Reducing depression in stroke survivors and their informal caregivers: A randomized clinical trial of a web-based intervention

Ref ID 16938 **RID:** 1010 2012

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** More dyads in the intervention condition included PWS with language or cognitive impairment reported negative

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =** Likely to overestimate the effect

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Strength – This study provided a lot of detail about the intervention and carried out a good analysis adjusting for baseline values. It was also good that they provided outcome scores both for the individual who has had a stroke and the caregiver. The intervention was designed according to a recognised psychological treatment model.
Weakness – It is a bit unclear why so many dyads that were screened were in the end ineligible. Also why did the caregiver always have to be a woman and the person with stroke the husband was a bit unclear.

DETAILS

of patients: Intervention N=30 (15 dyads of persons with a stroke and their spousal caregivers) N=34 (17 dyads of persons with a stroke and their spousal caregivers)

Prevalence (Diagnostic):

Patient Characteristics

Inclusion criteria: The caregiver was a female who provides care at home to a husband after stroke. Either the person who has had a stroke (PWS) or the caregiver (CG) scored five or more on the Personal Health Questionnaire (PHQ-9: at least mild depression)

Exclusion: Neither PWS nor CG were medically unstable or terminally and both were cognitively able to participate.

Of 161 dyads screened 40 were eligible. The authors state that strict eligibility criteria, along with national recruitment approach yielded many ineligible prospective participants. They go on to give examples, such as 'not a wife caring for her husband' or because neither member of the dyad screened positively for depressive symptoms.

	CG		PWS
	Intervention	Control	
Intervention	Control		
Age (8)	55 (7) 59 (14)	55 (13)	60
PHQ Score N (%)			
0-4 Minimal (13.3)	3 (20) 1 (5.9)	4 (23.5)	2
5-9 Mild (40)	6 (40) 4 (23.5)	7 (41.2)	6
10-14 Moderate (13.3)	2 (13.3) 8 (47.0)	4 (23.5)	2
15-19 Moderately severe (33.3)	3 (20.0) 2 (11.8)	1 (5.9)	5
≥20 Severe (0)	1 (6.6) 2(11.8)	1 (5.9)	0
Fist Stroke N (%) (93.3)	14 (82.4)		14
PWS had Language/Cognitive Impairment N (%) (35.3)	2 (13.3)		6
PWS had other medical Problems N (%) (61.5)	12 (75.0)		8
Baseline scores on RCT outcomes			
Depression M (SD) (12.9)	21.7 (13.2) 19.3 (13.4)	17.7 (11.7)	21.3
Mastery M (SD) (23.5 (4.1)	23.0 (3.3) 23.5 (4.1)	23.9 (4.0)	22.5 (3.2)
Self-Esteem M (SD) (28.8 (6.6)	28.8 (6.0) 28.8 (6.6)	32.6 (5.0)	27.8 (6.1)
Social Support M (SD) (5.6)	35.9 (6.4) 40.9 (8.4)	31.9 (8.3)	39.1

Interventions/ Test/ Factor being investigated

The intervention was based on the Stress Proces Model (SPM; Pearlin, Aneshensel, Mullan & Whitlach, 1995) which is based on the principle that the effect of stressors on psychological stress is mediated by the key psychosocial resources of mastery, self-esteem and social support. It consisted of an online support program of five components designed to provide the caregivers with knowledge resources and skills to help them both reduce their personal distress and to provide optimal emotional care to the PWS. It states that attempts were repeatedly made to acknowledge the positive and negative feelings of both members of the CG-PWS dyad, as well as to illustrate how they were intertwined and CGs were encouraged to interact with PWS in ways to enhance their mutual well-being (a comprehensive description of the intervention is provided in a Table, details not included here for brevity).

Comparisons

The dyads in the control condition had access to the same online resource room that the intervention group had. But had no exposure to the key intervention components

Length of Study/ Follow-up

Post-test (after 11 wks) and a one month follow-up

Outcome measures studied

Primary outcome: Centre for Epidemiological Studies Depression scale (CESD), Secondary outcomes: Mastery Scale, Self-Esteem scale, Medical Outcomes Study Social Support survey.

Results

Scores were analysed using ANCOVA group by time with baseline values as the covariate. X is the baseline adjusted mean. ESa refers to standardised effect size for mean difference between intervention and control (univariate). ESb is the effect size for multivariate F test reported as partial eta-squared. Only ITT analysis reported here. **p<0.01

	T2				T3	
	Control	Intervention	Control	Intervention	Control	Intervention
	X (SE)	X (SE)	ESa	X (SE)	ESa	ESb
CG only						
Depression	13.9 (2.0)	19.7 (1.8)	-.79	13.4 (1.6)	16.6	
(1.5)	-.52	6.13**	.17			
Mastery	24.2 (0.7)	23.6 (0.6)	.23	24.1 (0.5)	24.4	
(0.5)	-.15	0.09	.00			
Self-Esteem	31.6 (0.6)	31.9 (0.6)	-.12	31.1 (0.7)	32.6	
(0.7)	-.53	1.41	.05			
Social Support	37.0 (1.7)	37.0 (1.6)	.00	33.8 (1.6)	36.3	
(1.5)	-.40	0.31	.01			
PWS only						
Depression	19.5 (2.2)	20.4 (2.1)	-.10	14.0 (2.1)	17.9	
(1.9)	-.49	1.15	.04			
Mastery	21.6 (1.2)	22.8 (1.2)	-.25	24.6 (1.1)	24.4	
(1.1)	.05	0.11	.00			
Self-Esteem	26.7 (1.0)	27.7 (0.9)	-.26	28.5 (1.2)	27.2	
(1.2)	.27	0.02	.00			
Social Support	41.5 (1.7)	41.0 (1.6)	.08	43.2 (1.2)	44.0	
(1.2)	-.17	0.01	.00			

Effect Size

Please see above

Source of funding:

A grant number was reported but it was unclear where it came from.

Does the study answer the question?/Further Comments

Yes. It was concluded that caregivers benefitted from the web-based program.

Question: In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?

Study Type	Randomised Controlled Trial
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Anderson C;Rubenach S;Mhurchu CN;Clark M;Spencer C;Winsor A;

Home or hospital for stroke rehabilitation? results of a randomized controlled trial : I: health outcomes at 6 months

Ref ID 4959 **RID:** 414 2000

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Randomization was computer generated and maintained in sealed opaque envelopes. No stratification was performed. Blinding of assessors, data analyzed on the basis of intention to treat.

DETAILS

of patients: 86 patients randomized from 2 affiliated teaching hospitals. 42 allocated to Early hospital discharge and home-based rehabilitation; 44 allocated to conventional

Prevalence (Diagnostic):

Patient Characteristics	Home-Based Scheme			
	Conventional Care	Home-Based Scheme		
Variable	(n=42)	(n=44)		
Age, y				
Mean (SD)	72 (11)	71 (11)		
Median (interquartile range)	75 (66-78)	74 (66-78)		
Male	26 (62)	22 (50)		
Previous stroke	9 (21)	8 (18)		
Modified Barthel Index*				
Median (interquartile range)	85 (80-97)	86 (77-95)		
*Scale 0-100 (low score=low level of physical function)				
Interventions/ Test/ Factor being investigated	Early hospital discharge and individually tailored home-based/community rehabilitation (median duration, 5 weeks). A team was formed that comprised a full time program coordinator (an occupational therapist); a consultant in rehabilitation; and physiotherapists, occupational therapists, social workers, speech therapists, and rehabilitation nurses. Efforts were made so that discharge from hospital could occur within 48 hours of randomization.			
Comparisons	Conventional care and rehabilitation in hospital, either on an acute-care medical geriatric ward or in a multidisciplinary stroke rehabilitation unit run by specialists in rehabilitation or geriatric medicine.			
Length of Study/ Follow-up	All patients (and their caregivers) were followed up at 1, 3, 6, and 12 months after randomization.			
Outcome measures studied	Health related quality of life as assessed by SF-36, adverse events (death and falls), modified barthel index, caregiver strain index.			
Results	Home-Based Scheme (n=46)	Conventional Care (n=51)	Mean or Median Difference	95% CI for Difference
Variable				
SF-36*, mean (SD)				
Physical functioning	41.3 (29.1)	42.5 (28.1)	-1.2	(-13.8,
Social functioning	74.7 (31.3)	82.8 (23.8)	-8.1	(-20.4, 4.2)
Modified BI**, Median (interquartile range)	96 (88.3-100)	98 (85.5-100)	0	(-2.0, 2.0)
Adverse events (%)				
Dead at 6 months	2 (5)	0(0)		(-1.7, 11.2)
Falls	5 (12)	7(16)		(-18.6,
10.6)				
Caregiver Strain	(n=24)	(n=25)		
Mean (SD)	0.2 (0.4)	0.2 (0.4)	0.01	(-0.3, 0.3)
Not assessed	0	4		
Length of stay, d	15 (8-22)	30 (17.3-48.5)	-13	(-22, -6.0)
*Scale 0-100 (low score=low level of health-related quality of life)				
**Scale 0-100 (low score=low level of physical function)				
Effect Size				
Source of funding:	Grant from the Federal Government.			
Does the study answer the question?/Further Comments	Clinical outcomes for patients did not differ significantly between the groups at 6 months after randomization, but the total duration of hospital stay in the experimental group was significantly reduced (15 versus 30 days; p<0.001). Caregivers among the home-based rehabilitation group had significantly lower mental health SF-36 scores (mean difference, 7 points). Authors concluded that EHD and home-based rehabilitation for patients with stroke can reduce the use of hospital rehabilitation beds without compromising clinical patient outcomes. There is a potential risk of poorer mental health on the part of caregivers. Choice of management strategy and cost may depend on convenience and costs but also on further evaluations of the impact of stroke on caregivers.			

Askim T;Rohweder G;Lydersen S;Indredavik B;

Evaluation of an extended stroke unit service with early supported discharge for patients living in a rural community. A randomized controlled trial

Ref ID 676

RID:

394

2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization in blocks of four, six or eight. The order of the blocks was randomly chosen. Sealed opaque envelopes used for randomization and procedure was carried out by an external office, independent and blinded assessor. Low statistical power, small sample size might increase risk of uneven distribution of confounders.

DETAILS

of patients:

Prevalence (Diagnostic):

Patient Characteristics	ESUS (n=31)	OSUS (n=31)	
Age, mean/median	76.9/77.0	76.3/76.0	
Sex, number (%) male	16 (51.6)	17 (54.8)	
Living alone, number (%)	11 (35.5)	15 (48.4)	
Barthel Index, mean/median	57.7/55.0	54.0/55.0	
Interventions/ Test/ Factor being investigated	Extended service consisting of stroke unit treatment combined with a home based programme of follow-up care co-ordinated by a mobile stroke team that offers early supported discharge and works in close co-operation with the primary health care system during the first four weeks after discharge. The mobile team consisted of a nurse, a physiotherapist, an occupational therapist and the consulting physician.		
Comparisons	Ordinary service defined as the stroke unit treatment of choice according to evidence-based recommendations.		
Length of Study/ Follow-up	All patients were followed up at 6, 26 and 52 weeks after onset of stroke.		
Outcome measures studied	Barthel Index and Caregiver Strain Index (CSI) at 6, 26 and 52 weeks. Mortality and length of stay were registered during the 52 weeks.		
Results	ESUS	OSUS	95% CI
6 weeks post stroke			
BI, Mean (SD)	(n=29) 75.2 (30.6)	(n=29) 74.0 (31.2)	-15.1 to 17.5
Caregiver Strain Index	(n=29)	(n=29)	
Mean (SD)	1.5 (2.3)	2.2 (2.4)	
26 weeks post stroke			
BI, Mean (SD)	(n=23) 75.0 (32.9)	(n=28) 77.7(27.6)	-20.0 to 14.7
Caregiver Strain Index	(n=22)	(n=23)	
Mean (SD)	1.8 (2.5)	1.0 (1.6)	
52 weeks post stroke			
BI, Mean (SD)	(n=23) 71.7 (34.7)	(n=25) 79.0(28.7)	-25.9 to 11.4
Caregiver Strain Index	(n=23)	(n=22)	
Mean (SD)	1.7 (2.7)	1.2 (1.9)	
Mortality, number (%)	(n=31) 8 (25.8)	(n=31) 5 (16.1)	-0.11 to 0.31
Length of stay	(n=31)	(n=31)	
Inpatient care (days)			
Stroke unit, mean (SD)	12.9 (10.3)	13.6 (15.0)	-3.0 to 4.0
Stroke unit and rehabilitation clinics, mean (SD) ^a	23.5 (30.5)	30.5 (44.8)	-5.0 to 7.0
ESUS, extended stroke unit service; OSUS, ordinary stroke unit service; CI, confidence interval; BI, Barthel Index. ^a Within 52 weeks			
Effect Size			
Source of funding:	Not mentioned. Study conducted in Norway.		
Does the study answer the question?/Further Comments	Authors concluded that an extended stroke unit service with early supported discharge seems to have no positive effect on functional outcome for patients living in rural communities, but might give a trend toward better quality of life. No significant difference in length of stay.		

Early supported discharge of patients with acute stroke: a randomized controlled trial

Ref ID 821

RID:

395

2002

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Block randomization by computer-generated random numbers, treatment allocation kept in sealed envelopes which were subsequently opened once a new subject was included.

DETAILS

of patients:

82 patients randomized; 40 allocated to Conventional Hospital Rehabilitation (CRS) and 42 to Early Supported Discharge (ESD).

Prevalence (Diagnostic):

Patient Characteristics

	ESD (n=42) Median (IQR)	CRS (n=40) Median (IQR)
Age in years	79.5 (69-84)	78.0 (74-82)
Gender: female	21 (50%)	24 (60%)
Premorbid (NEADL)	35 (28-44)	30 (14-46)
Barthel ADL index score at day 7	16.5 (12-19)	14 (11-18)

IQR, Interquartile range; NEADL, Nottingham Extended Activities of Daily Living Scale

Interventions/ Test/ Factor being investigated	After a short stay (3 – 12 days), the patients in both groups were, according to clinical condition and needs, either discharged or transferred to the stroke rehabilitation unit. Early supported discharge with a multidisciplinary team for each stroke patient were offered support and supervision from the project team whenever needed. Four weeks after discharge, the patients in the ESD group were seen at the outpatient clinic																				
Comparisons	Conventional procedures for discharge and continued rehabilitation, which were anticipated to be less well organized.																				
Length of Study/ Follow-up	Follow-up was 3 months and six months after stroke.																				
Outcome measures studied	Primary outcome: Nottingham Extended Activities of Daily Living Scale (NEADL); Secondary outcome: The General Health Questionnaire, mortality																				
Results	<p>Median length of stay was reduced from 31 days in the conventional hospital rehabilitation group to 22 days in the early supported discharge group (p=0.09); No difference was found regarding primary outcome;</p> <p>The General Health Questionnaire score showed a significant difference in favour of the early supported discharge group at three months (19.5/24, p=0.02), but not at six;</p> <p>At six months, the proportion of patients being dead or in an institution showed a trend of being higher in the conventional rehabilitation group (OR 3.8, 95% CI 0.8-23)</p> <table border="0" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th colspan="3" style="text-align: center;">6 months post stroke</th> </tr> <tr> <th></th> <th colspan="3" style="text-align: center;">Median (IQR)*</th> </tr> <tr> <th></th> <th style="text-align: center;">ESD (n=34)</th> <th style="text-align: center;">CRS (n=31)</th> <th style="text-align: center;">p-value</th> </tr> </thead> <tbody> <tr> <td>NEADL</td> <td></td> <td></td> <td></td> </tr> <tr> <td> Total</td> <td style="text-align: center;">40 (29-45)</td> <td style="text-align: center;">37 (20-46)</td> <td style="text-align: center;">0.93</td> </tr> </tbody> </table> <p>*IQR: Inter quartile range NEADL: Nottingham Extended Activities of Daily Living</p>		6 months post stroke				Median (IQR)*				ESD (n=34)	CRS (n=31)	p-value	NEADL				Total	40 (29-45)	37 (20-46)	0.93
	6 months post stroke																				
	Median (IQR)*																				
	ESD (n=34)	CRS (n=31)	p-value																		
NEADL																					
Total	40 (29-45)	37 (20-46)	0.93																		
Effect Size																					
Source of funding:	Not Mentioned																				
Does the study answer the question?/Further Comments	the authors concluded that early supported discharge after stroke is feasible and it is possible that it has benefits compared with conventional rehabilitation																				

Donnelly M;Power M;Russell M;Fullerton K;

Randomized controlled trial of an early discharge rehabilitation service: the Belfast community stroke trial

Ref ID 308

RID:

413

2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization was computer generated, allocation concealment done, blinding, intention to treat

DETAILS

of patients:

113 patients randomized. 59 allocated to early hospital discharge and Community-based multidisciplinary Stroke Team (CST), and 54 to the usual care

Prevalence (Diagnostic):

Patient Characteristics

Assessment*	Baseline Assessments of Key Outcomes		95% CI
	Hospital Rehab. (n=54)	Community Rehab. (n=59)	
Barthel ADL			-1.62 to 1.13
Mean (SD)	13.89 (3.93)	14.14 (3.38)	
Nottingham ADL			-2.38 to 4.02
Mean (SD)	5.77 (4.79)	4.95 (5.39)	
Missing	32	39	
SF-36 Phyc. Func.			-2.55 to 3.17
Mean (SD)	35.35 (7.20)	35.04 (7.72)	
Missing	3	3	
SF-36 Mental Health			-2.23 to 5.74
Mean (SD)	47.52 (10.59)	45.76 (10.15)	
Quality of life			-2.89 to 0.62
Mean (SD)	16.53 (3.65)	17.67 (4.14)	
Missing	18	17	
Carer Strain	n=25	n=27	-0.70 to 3.24
Mean (SD)	6.55 (3.67)	5.07 (3.10)	

*Higher scores indicate better outcomes except for carer strain.
Demographic data not stated.

Interventions/ Test/ Factor being investigated	Earlier hospital discharge combined with Community-based multidisciplinary Stroke team rehabilitation comprising 0.33 coordinator, 1 occupational therapist, 1.5 physiotherapists, 1 speech and language therapist, and 2 rehabilitation assistants. On average the number of home visits over a 3-month period was 2.5 per week each lasting 45 minutes. Patients in the CST group were to be discharged as soon as their home was assessed.
Comparisons	Usual hospital rehabilitation comprising inpatient rehabilitation in a stroke unit and follow-up rehabilitation in a day hospital
Length of Study/ Follow-up	12 months
Outcome measures studied	Barthel ADL, Nottingham ADL, SF-36 (Physical Functioning and Mental Health), Quality of Life, and Carer Strain.

Results

12 months Assessment of Key Outcomes

Assessment*	Hospital Rehab. (n=46)	Community Rehab. (n=51)	95% CI
Barthel ADL			-2.24 to 0.58
Mean (SD)	17.15 (3.81)	17.98 (3.10)	
Nottingham ADL			-4.04 to 0.91
Mean (SD)	10.43 (5.92)	12.00 (6.34)	
SF-36 Physc. Func.			-13.70 to 11.88
Mean (SD)	34.67 (32.01)	35.59 (31.32)	
SF-36 Mental Health			-9.95 to 5.58
Mean (SD)	67.30 (20.07)	69.49 (18.26)	
Carer Strain	n=25	n=27	-2.14 to 2.30
Mean (SD)	6.00 (4.23)	5.92 (2.86)	
EuroQol			
Mean (SD)	68.21 (20.31)	66.36 (18.45)	

*Higher scores indicate better outcomes except for carer strain
**5 patients died, 9 missing, and 2 did not participate in 12-month assessment. There was an 8 day difference in mean inpatient stay (p=0.304), although the median difference was 0.5 days (p=0.823). Overall, the ESD group spent 202 fewer inpatient days than the hospital rehab.

Effect Size

Source of funding: South and East Belfast Health and Social Services Trust and the Northern Ireland Chest Heart and Stroke Association

Does the study answer the question?/Further Comments There were no statistically significant differences in hospital duration, costs, or outcome measures at baseline and 12 months except for higher satisfaction reported by CST patients. Authors concluded that a mixed model of hospital-based and community-based rehabilitation services is likely to lead to increased patient choice and satisfaction and a potential reduction in bed pressures for less severe stroke patients

Fjaeartoft H;Indredavik B;Johnsen R;Lydersen S;

Acute stroke unit care combined with early supported discharge. Long-term effects on quality of life. A randomized controlled trial

Ref ID 1651

RID:

402

2004

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

Overall Study Quality -Strengths and Weaknesses:

Outcome assessors were blinded; randomization unclear. Follow-up study of Indredavik et al, 2000 focussing on long term quality of life. Both groups received identical stroke unit care during the acute phase with focus on early mobilization/rehabilitation combined with a standadized medical programme.

DETAILS

of patients: 320 patients randomized; 160 allocated to the ESUS group and 160 to the OSUS group.

Prevalence (Diagnostic):

Patient Characteristics

Characteristics	ESUS (n=160)	OSUS (n=160)
Age, mean/median, y	74.0/74.5	73.8/74.0
Sex, % male	54	44
SSS, mean*	43.6	43.2
Barthel Index, mean**	60.4	58.5

*Assessed at inclusion before randomization; **Assessed within 24 hours after randomization; SSS, Scandinavian Stroke Scale.

Interventions/ Test/ Factor being investigated Extended Stroke Unit Service (ESUS) defined as stroke unit treatment similar to OSUS combined with service from a mobile team that offers early supported discharge and coordinates further rehabilitation and follow-up in close cooperation with the primary healthcare system. The team consisted of a nurse, a physiotherapist, an occupational therapist, and a physician.

Comparisons	Ordinary Stroke Unit Service (OSUS) consisting of treatment in a combined acute and rehabilitation stroke clinic and/or the primary healthcare system. Also defined as stroke unit treatment according to evidence-based recommendations.		
Length of Study/ Follow-up	one year follow-up		
Outcome measures studied	Caregivers Strain Index; Global Nottingham Health Profile 1&2		
Results		ESUS	OSUS
	Caregivers Strain Index	(n=133)	(n=125)
	Mean (SD)	15.7 (2.7)	16.4 (3.1)
	Median (range)	15.0 (13-24)	16.0 (13-25)
	The ESUS group had significantly better QoL (mean score 78.9) assessed by global NHP after one year than the OSUS group (mean score 75.2) (p=0.048). More strain on the Caregiver in the ESUS group (p=0.089)		
Effect Size			
Source of funding:	Study was supported by the Norwegian Department of Health and the Stroke Units Fund of Stroke Research, University Hospital of Trondheim, Norway		
Does the study answer the question?/Further Comments	More strain on the Caregiver with the ESUS group with p<0.089. Stroke unit treatment combined with early supported discharge in addition to reducing the length of hospital stay can improve long-term QoL. However, similar trials are necessary to confirm the benefit of this type of service.		

Indredavik B;Fjaertoft H;Ekeberg G;Loge AD;Morch B;

Benefit of an extended stroke unit service with early supported discharge: A randomized, controlled trial

Ref ID 907 **RID:** 396 2000 Dec

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Outcome assessors were blinded; randomization unclear, allocation concealment unclear

DETAILS

of patients:

320 patients randomized; 160 allocated to the ESUS group and 160 to the OSUS group. Both groups received identical stroke unit care during the acute phase with

Prevalence (Diagnostic):

Patient Characteristics

Characteristics	ESUS (n=160)	OSUS (n=160)
Age, mean/median, y	74.0/74.5	73.8/74.0
Sex, % male	54	44
SSS, mean*	43.6	43.2
Barthel Index, mean**	60.4	58.5

*Assessed at inclusion before randomization; **Assessed within 24 hours after randomization; SSS, Scandinavian Stroke Scale.

Interventions/ Test/ Factor being investigated

Extended Stroke Unit Service (ESUS) defined as stroke unit treatment similar to OSUS combined with service from a mobile team that offers early supported discharge and coordinates further rehabilitation and follow-up in close cooperation with the primary healthcare system. The team consisted of a nurse, a physiotherapist, an occupational therapist, and a physician.

Comparisons

Ordinary Stroke Unit Service (OSUS) consisting of treatment in a combined acute and rehabilitation stroke clinic and/or the primary healthcare system. Also defined as stroke unit treatment according to evidence-based recommendations.

Length of Study/ Follow-up

Patients assessed at 6, and 26 weeks

Outcome measures studied

Primary outcome: Barthel Index score at 26 weeks after onset of stroke.
Secondary outcomes: Barthel Index score at 6 Weeks.

Results

Time	ESUS (n=121)		OSUS (n=122)		P
	No.	%	No.	%	
6 Weeks					
Barthel Index ≥ 95	56	46.3	42	34.4	0.060
26 Weeks					
Barthel Index ≥ 95	63	52.1	47	38.5	0.034

Number and Proportion of Patients Deceased After 6 and 26 Weeks from Onset of Stroke in ESUS and OSUS

ESUS (n=160)	OSUS (n=160)
-----------------	-----------------

Time	No.	%	No.	%	P
6 Weeks					
Dead	4	2.5	7	4.4	0.357
26 Weeks					
Dead	13	8.1	15	9.4	0.692

The average stay in the hospital (stroke unit plus rehabilitation clinics) was 18.6 days in the ESUS group versus 31.1 days in the OSUS group (p=0.0324). However the average length of stay in the stroke unit was similar in the 2 groups. The mortality in the ESUS group at 6 weeks was 2.5% versus 4.4% in the OSUS group, but this difference was not significant (p=0.3573). The proportion of patients independent in ADL after 26 weeks, defined as BI≥95, was 60% in ESUS versus 49.4% in OSUS (p=0.056).

Effect Size

Source of funding:

Study was supported by the Norwegian Department of Health and the Stroke Units Fund of Stroke Research, University Hospital of Trondheim, Norway

Does the study answer the question?/Further Comments

The authors concluded that an ESUS with early supported discharge seems to improve functional outcome and to reduce the length of stay in institutions compared with traditional stroke unit care.

Mayo NE;Wood-Dauphinee S;Cote R;Gayton D;Carlton J;Buttery J;Tamblyn R;

There's no place like home : an evaluation of early supported discharge for stroke

Ref ID 4958

RID:

410

2000 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization was stratified by site and balanced within block sizes that varied from 4 to 8, allocation concealment done, blinding not mentioned. A total of 11 (19.6%) people in the usual care group missed 1 or both follow-up assessments. 7 (12%) people in the home group (intervention) were lost by the time of the three-month assessment.

DETAILS

of patients:

114 patients; 58 allocated to the intervention group and 56 allocated to the control group.

Prevalence (Diagnostic):

Patient Characteristics

Construct and instrument	Home group (n=58)	Usual group (n=56)
Men, n (%)	37 (63.8)	40 (71.4)
Women, n (%)	21 (36.2)	16 (28.6)
Age, y	70.3±12.7	69.6±12.7
BADL: Barthel, 0-100 (n)	84.6±14.4	82.7±13.9

Values are mean±SD

*No significant differences between groups on any baseline variables

Interventions/ Test/ Factor being investigated

Rehabilitation at home after prompt discharge from hospital with the immediate provision of follow-up services by a multidisciplinary team offering nursing, physical therapy (PT), occupational therapy (OT), speech therapy (ST), and dietary consultation. Duration of intervention was 4 weeks for all participants.

Comparisons

usual care practices for discharge planning and referral for follow-up services. These included physiotherapy, occupational therapy and speech therapy, as requested by the patient's care provider and offered through extended acute-care hospital stay; inpatient or outpatient rehabilitation; or home care via local community health clinics

Length of Study/ Follow-up

3 months

Outcome measures studied

Main outcome: Physical Component Summary of the Medical Outcomes Study Short Form-36 (SF-36): Measuring Health Related Quality of Life (HRQL). Secondary outcomes: Barthel Index (BI) for Basic Activities of Daily Living (BADL) - This assessed disability.

Results

Effects	Home	Usual	Significant
	Mean±SD (n)*	Mean±SD (n)*	
Physical health**	39.5±9.6 (56)	37.2±8.4 (47)	Group
	42.9±10.1 (51)	37.9±10.6 (44)	GroupXtime
Mental health	45.8±12.7 (56)	45.7±12.3 (47)	
	46.5±11.7 (51)	46.7±10.8 (44)	
BADL: BARTHEL, 0-100	97.1±6.9 (48)	95.1±10.6 (43)	
GroupXtime			

Physical health (Physical Component Summary) and mental health (Mental Component Summary) have been standardized to have a mean of 50 and SD of 10.

*Not all subjects were able to complete the SF-36, and it was not administered until after discharge.

**Significant effect of group: $F_{1,101}=3.99$; $p=0.048$; significant effect of groupXtime: $F_{2,94}=4.17$; $p=0.018$.
 BI, significant effect of groupXtime: $F_{2,194}=34.14$; $p<0.0001$. The total length of stay for the home group was, on average, 10 days, 6 days shorter than that for the usual care group. The duration of stay in acute care was significantly shorter by 3 days for the home group (mean 9.8 days, SD 5.3 days) compared with the control group (12.4 days, SD 7.4 days).

Effect Size

Source of funding: Project was funded by National Health Research Development Program (grant 6605-1714-104). Study was conducted in Canada

Does the study answer the question?/Further Comments Prompt and supported discharge led to better physical health. In addition, a favourable reintegration to community living was noticed

Rodgers H;Soutter J;Kaiser W;Pearson P;Dobson R;Skilbeck C;Bond J;

Early supported hospital discharge following acute stroke: pilot study results

Ref ID 4960

RID:

415

1997 Nov

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization from three acute hospitals in Newcastle upon Tyne was computer generated, allocation concealment not done, blinding not mentioned, intention to treat analysis not done. Study was a pilot RCT. The median Barthel ADL Index at 7 days post stroke of patients randomized to ESD was 15 and 13 for those randomized to conventional care (non-significant).

DETAILS

of patients:

92 patients randomized ; 46 allocated to Conventional Care (CC) and 46 allocated to Early Supported Discharge (ESD).

Prevalence (Diagnostic):

Patient Characteristics

Demography	ESD (n=46)	CC (n=46)
Age, years: median (range)	73 (47-93)	73 (44-91)
Female	20 (43%)	22 (48%)
Living alone	22 (48%)	21 (46%)
Barthel ADL Index: median (range) 7 days post stroke	15 (2-20)	13 (2-20)

Patients were from three local acute hospitals in Newcastle upon Tyne
ADL, Activities of Daily Living

Interventions/ Test/ Factor being investigated

Early Supported Discharge with home care from the Stroke Discharge Team that was community based. The team consisted of an occupational therapist, physiotherapist, speech and language therapist, social worker and occupational therapy technician. The stroke discharge rehabilitation service was available five days per week but the home care component of the service was available 24h per day and seven days per week if required. The stroke discharge service was withdrawn gradually and a contact name and number was provided to patients in case of subsequent queries or problems

Comparisons

Inpatient and outpatient care was provided for the control group by conventional hospital and community services. Discharge planning and services post discharge for patients randomized to conventional care were arranged and provided according to the usual practice of each participating ward or unit.

**Length of Study/
Follow-up**

3 months

Outcome measures studied

length of stay, mortality, Nottingham Extended Activities of Daily Living (NEADL), quality of life

Results

Outcomes at three months post stroke	ESD (n=45)	CC (n=42)
Nottingham EADL: median (range)	10 (0-18)	7 (0-21)
Overall health: median (range)	3 (1-5)	3 (2-5)
Quality of Life: median (range)	2 (1-5)	3 (1-5)
Mortality	1 (2%)	4 (10%)
Length of stay Including readmissions (days) Median (interquartile ranges)	14 (8-31)	23 (11-58)
Number of patients Readmitted	5/46 (11%)	5/46 (12%)

Effect Size

Source of funding:

Research funding was provided by National CVD and Stroke R & D Programme, and by Newcastle Health Authority Primary Care Development Fund

Does the study answer the question?/Further Comments

Median length of stay for patients randomized to early supported discharge was 13 days compared to 22 days in the conventional care group (p=0.02). At three months post stroke the median Nottingham EADL score of patients randomized to early supported discharge was 10 compared to 7 for those who received conventional care (Not Significant). No statistical significant difference in global health status of patients or carer stress. Authors concluded that an early supported discharge service following acute stroke with individualized rehabilitation in the community is feasible and can be evaluated by a randomized controlled trial but a larger multicentre trial is needed before such a service is widely adopted.

Rudd AG;Wolfe CD;Tilling K;Beech R;

Randomised controlled trial to evaluate early discharge scheme for patients with stroke.[Erratum appears in BMJ 1998 Feb 7;316(7129):435]

Ref ID 1085

RID:

400

1997 Oct 25

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization in restricted permuted blocks of 10 with random number tables provided in blank sealed opaque envelopes. Blinding unclear

DETAILS

of patients: 331 patients from two teaching hospitals in London. 167 allocated to early discharge with community therapy and 164 allocated to conventional care.

Prevalence (Diagnostic):

Patient Characteristics

Variable	Community therapy (n=167)	Conventional (n=164)
Male (%)	92 (55)	93 (57)
Female (%)	75 (45)	71 (43)
Age (years)		
Mean (SD)	70 (11)	72 (12)
Length of stay ^a (days)		
Mean (SD)	22 (25)	25 (30)
Not known	1	0
Barthel score ^b		
0-14	70 (42)	65 (40)
15-19	78 (47)	78 (48)
20	17 (10)	20 (12)
Not known	2	1

^a Length of stay to randomisation; ^b Barthel score at randomization

Interventions/ Test/ Factor being investigated

Early discharge with a planned course of domiciliary physiotherapy, occupational therapy, and speech therapy, with visits as frequently as considered appropriate (maximum one day visit from each therapist) for up to 3 months after randomization

Comparisons

Usual care with no augmentation of social services resources.

Length of Study/ Follow-up

Patients were assessed at discharge and at 2, 4, 6, and 12 months

Outcome measures studied

Main outcome: Barthel score at 12 months; Secondary outcomes: Hospital Anxiety and Depression Scale (HADS), CareGiver strain index

Results

Outcome assessment 1 year after stroke according to place of rehabilitation

Detail	Community therapy (n=136)	Conventional (n=126)	p-value
BADL			
Mean (SD)	16 (4)	16 (4)	0.30
Not assessed	1	0	
CareGiver strain			
Mean (SD)	5 (4)	4 (3)	0.14
Not assessed	61	67	
HADS			
No (%) with anxiety:			
Normal	79 (69)	79 (81)	0.06
Borderline	16 (14)	12 (12)	
Abnormal	20 (17)	7 (7)	
Not assessed	21	28	
No (%) with depression:			
Normal	70 (61)	59 (60)	0.9
Borderline	20 (18)	19 (19)	
Abnormal	24 (21)	21 (21)	
Not assessed	22	27	

Numbers (percentages) of patients with stroke who were eligible and followed up, according to place of rehabilitation.

Detail	Community therapy (n=167)	Conventional (n=164)	p-value (x2 test)
Dead by 12mths	26 (16)	34 (21)	0.22

Followed at 12mths alive	136 (81)	126 (77)	0.83
Lost to follow up	5 (3)	4 (2)	0.83
Stroke recurrence	10 (6)	5 (3)	0.20
Readmitted	44 (26)	42 (26)	0.20
Length of stay from randomization			
Mean (SD)	12 (19)	18 (24)	0.0001
Not known	2	1	
Total No of bed days (from randomization)	1956	2854	

Effect Size

Source of funding:

Funding by The Stroke Association, Lambeth, Southwark and Lewisham Health Authority, the Special Trustees of St Thomas's Hospital, the Nuffield Provincial

Does the study answer the question?/Further Comments

Authors concluded that early discharge with specialist community rehabilitation after stroke is feasible, as clinically effective as conventional care, and acceptable to patients. Considerable reductions in use of hospital beds are achievable.

von Koch,L;Widen HL;Kostulas V;Almazan J;de Pedro-Cuesta J;

A randomized controlled trial of rehabilitation at home after stroke in Southwest Stockholm: outcome at six months

Ref ID 947

RID:

397

2000 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Computerized randomization and sealed numbered envelopes, blinding of assessors, intention to treat analysis not mentioned. 6-month follow-up study of Widen et al, 1998. 6 months after onset of stroke, 78 patients, 40 in the HRG and 38 in the RRG, were evaluated.

DETAILS

of patients:

A total of 83 patients was recruited to the trial, 42 in the Home Rehabilitation Group (HRG) and 41 in the Routine Rehabilitation Group (RRG).

Prevalence (Diagnostic):

Patient Characteristics

Variable (range)	HRG, n=40 (%)	RRG, n=38 (%)
Age, years	72, 49-84*	73, 49-89*
Men/women	22/18	21/17
Associated diseases before stroke	35 (88)	25 (66)
Localization of lesion right/left	15/23	22/13

*Median, range.
HRG = home rehabilitation group; RRG = routine rehabilitation group

Interventions/ Test/ Factor being investigated

Early supported discharge and continued rehabilitation at home by a specialized team. The rehabilitation programme was tailor-made for each patient, continued in their homes for 3 to 4 months. In all, HRG patients received a mean of 12 visits (range 3-31) by a home rehabilitation team therapist.

Comparisons

Routine rehabilitation

Length of Study/ Follow-up

6 month follow-up

Outcome measures studied

Activities of daily living index; reported falls, Readmission, Length of stay

Results

Variable (range)	HRG, n=40 (%)	RRG, n=38 (%)	p-value
Presence of aphasia	11 (27.5)	5 (13.2)	0.1979
Barthel ADL, independent	31 (78)	23 (61)	0.1434
Frenchay Activities Index (0-45)	24, 20-28.5*	21.5, 16-27*	0.2535

*Median, interquartile range.

The mean number of days of initial hospitalization was 14 in the home rehabilitation group (range 5-33) and 29 in the routine rehabilitation group (range 5-136), a difference that was statistically significant (p=0.002). The number of patients with recurrent hospitalization in the first six months after stroke was 10 in both groups, and the mean length of stay was 6 days for both the HRG AND RRG. Patients reporting falls: HRG = 26 (66%); RRG = 25 (66%)

Effect Size

Source of funding:

Study was supported by the Swedish Medical Research Council and by grants from The Swedish Stroke Association of Neurologically Disabled (NHR). The

Does the study answer the question?/Further Comments

The authors concluded that early supported discharge with continued rehabilitation at home proved no less beneficial as a rehabilitation service.

Question: In people after stroke what is the clinical and cost effectiveness of intensive rehabilitation versus standard rehabilitation?

Study Type	Randomised Controlled Trial
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Ozdemir F;Birtane M;Tabatabaei R;Kokino S;Ekuklu G;

Comparing stroke rehabilitation outcomes between acute inpatient and nonintense home settings

Ref ID 3272 **RID:** 370 2001

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk of bias **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Randomization by selecting patients consecutively, one by one, according to when they enrolled in the study (unclear), blinding not done, allocation concealment, intention to treat not mentioned.

DETAILS

of patients: sixty patients randomized into 2 equal groups. 30 patients in the intensive rehabilitation group and 30 patients in the less intensive rehabilitation group.

Prevalence (Diagnostic):

Patient Characteristics

	Intensive Rehab. (n=30)	Less Rehab. (n=30)	p
Mean age ±SD (R) (yr)	59.1 ±5.9 (49-79)	61.8 ±9.2 (43-84)	>.05*
Gender (n)	21 M, 9 F	19 M, 11 F	>.05**

Prior stroke (%)	6.7	10	>.05***
Side of involvement	13 right, 17 left	14 right, 16 left	>.05**
FIM score \pm SD	41.21 \pm 19.45	39.20 \pm 23.57	>.05*

M, male; F, female.
* Independent samples t test.
** Chi-square test.
*** Fisher's exact test.

Interventions/ Test/ Factor being investigated

Therapeutic and neuromuscular exercises with occupational therapy with professional supervision for 2 hours a day, 5 days a week (intense multidisciplinary inpatient rehabilitation service).

Comparisons

Conventional exercises with family caregiver and limited professional supervision given at home for 2 hours once a week.

Length of Study/ Follow-up

Mean follow-up: 60 days

Outcome measures studied

Functional status assessed with the changes in Functional Independence Measure (FIM) instrument.

Results

	Outcome changes		
	Intensive Rehab.	Less Rehab.	P
FIM score \pm SD	59.63 \pm 14.19	12.30 \pm 13.38	.001*

* Independent samples t test.

Effect Size

Source of funding:

Not mentioned

Does the study answer the question?/Further Comments

Authors concluded that intense inpatient rehabilitation services for stroke survivors provide significantly more favourable functional and cognitive outcomes with relatively low complications than did nonintense rehabilitation efforts in home settings.

Ryan T;Enderby P;Rigby AS;

A randomized controlled trial to evaluate intensity of community-based rehabilitation provision following stroke or hip fracture in old age

Ref ID 299

RID:

357

2006 Feb

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization carried out using a random number table(blocks of 10) and sealed opaque envelopes, blinding of assessors. The study set out to achieve a ratio of 2:1 (intensive/non-intensive), this was not achieved. Suitable patients did not consent to participate. 25% stroke patient loss to follow up.

DETAILS

of patients:

Intensive group = 45; Non-intensive group = 44

Prevalence (Diagnostic):

Patient Characteristics

	Stroke (n=89)	
	Less intensive	Intensive
Age, yrs; mean (SD)	77.3 (6.4)	76.4 (6.1)
Length of time since stroke (mean days and SD)	45.8 (31.2)	45 (47.3)
Barthel Score (median and IQR)	16 (12-18)	16 (14-18)
Frenchay Activities Index (median and IQR)	25 (18-31)	24 (16.5-30)
EQ-5D (median and IQR)	0.52 (0.26-0.75)	0.56 (0.28-0.72)
EQ VAS (median and IQR)	0.70 (0.50-0.80)	0.6 (0.48-0.66)

Interventions/ Test/ Factor being investigated

Domiciliary provided intensive rehabilitation: six or more face-to-face contacts per week from members of a multidisciplinary rehabilitation team

Comparisons

Non-intensive rehabilitation: three or less face-to-face contacts per week from members of a multidisciplinary rehabilitation team

Length of Study/ Follow-up	Patients followed up for the length of treatment = 12 weeks (duration of study)		
Outcome measures studied	Barthel Index; Frenchay Activities Index (FAI); Hospital Anxiety and Depression Scale; Euroqol 5D (EQ-5D) and Euroqol Visual Analogue Scale (EQ-VAS)		
Results	Outcome [mean (SD)]	Stroke (n=67)	
		Less intensive	Intensive
	Barthel	2.65 (2.1)	2.75 (2.1)
	Frenchay Activities Index	8.08 (7.7)	8.87 (7)
	EQ-5D	0 (0.25)	0.14 (0.25)
	EQ VAS	0.01 (0.1)	0.09 (0.2)
Effect Size			
Source of funding:	Funding source: NHS Executive Trent, UK		
Does the study answer the question?/Further Comments	Following stroke, people who received a more intensive community-based multidisciplinary rehabilitation service may experience short-term benefit in relation to social participation and some aspects of health related quality of life.		

Smith DS;Goldenberg E;Ashburn A;Kinsella G;Sheikh K;Brennan PJ;Meade TW;Zutshi DW;Perry JD;Reeback JS;

Remedial therapy after stroke: a randomised controlled trial

Ref ID 4987

RID:

461

1981 Feb 14

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

No ITT used.

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization not clear; allocation concealment not mentioned, intention to treat analysis not mentioned; no blinding; death or the onset of serious illness resulting in non-attendance accounted for missing ADL scores at three months for five patients in group 1, three in group 2 and two in group 3 and at 12 months for 10 in group 1, seven in group 2, and nine in group 3.

DETAILS

of patients:

A total of 133. They were each allocated at random to one of the three regimen used. Group 1 (intensive rehabilitation)= 46; Group 2 (conventional rehabilitation)=

Prevalence (Diagnostic):

Patient Characteristics

Characteristics of trial patients

	Group		
	1 (n=46)	2 (n=43)	3 (n=44)
Men (%)	67	73	59
Mean age (years)	63	66	65
Interval from stroke to trial entry (days)	35	41	37
mean total ADL score at entry:			
Men	21.2	21.2	21.5
Women	24.0	23.1	20.5
All patients	22.0	21.5	21.1

Mean hours of treatment given in groups 1 and 2

	Group 1	Group 2
Physiotherapy:		
Individual	48.3	22.3
Group	31.3	16.3
Total	79.6	38.6
Occupational therapy	44.5	27.4

Interventions/ Test/ Factor being investigated

Intensive group (grp 1): received physiotherapy and occupational therapy in groups and individually for up to six months (except for four patients who made a full recovery earlier) and time spent in therapy was recorded. Attendance in the rehabilitation department four whole days a week.

Comparisons

Conventional group (grp 2): received physiotherapy and occupational therapy in groups and individually for up to six months (except for five patients who made a full recovery earlier) and time spent in therapy was recorded, attendance three half days a week. The 'no routine' rehab group (grp 3) were regularly visited at home by a health visitor, who paid an average of seven visits (range 3-13) to each patient. These visits usually lasted one to two hours and took place during the six months after discharge from hospital.

Length of Study/ Follow-up

12 months

Outcome measures studied

Activities of Daily Living (ADL) index: seventeen items on mobility, self-care, and simple household tasks were rated on a three-point scale. The lesser the score the better the ADL.

Results

Decrease in total ADL scores between entry to trial and 3-month and 12-month follow-up. Figures in parentheses are in numbers of patients

	Group 1	Group 2	Group 3
Between entry and 3-month review:			
Men	2.96 (27)	2.80 (30)	1.88 (26)
Women	4.64 (14)	3.10 (10)	0.88 (16)
Total	3.54 (41)	2.87 (40)	1.50 (42)
Between entry and 12-month review:			
Men	2.68 (25)	2.42 (26)	0.36 (22)
Women	5.36 (11)	4.10 (10)	1.00 (13)
Total	3.50 (36)	2.89 (36)	0.60 (35)

For all patients (both sexes): at three months: 1 vs 3, $p < 0.01$; 1 and 2 vs 3, $p < 0.01$; at 12 months: 1 vs 3, $p < 0.05$

Numbers of patients who deteriorated between entry to trial and 3-months and 12-month follow-up. Figures in parentheses are mean increases in ADL scores for those who deteriorated.

	Group 1	Group 2	Group 3
Between entry and 3-month review*:			
Deteriorated	1 (1)	4 (1)	10 (1.9)
Total	41	40	42
Between entry and 12-month review**:			
Deteriorated	2 (2.5)	4 (2.5)	8 (7.6)
Total	36	36	35

Test for trend: * $p < 0.01$, ** $p < 0.05$.

Effect Size

Source of funding:

Not mentioned

Does the study answer the question?/Further Comments

Authors concluded that outpatient rehabilitation after stroke is effective. The actively treated groups (1 and 2) fared significantly better than the 'no routine' rehab. group, although patients in this group improved slightly. Patients in the intensive group tended to progress better than those in the conventional group, suggesting also that an intensive regimen is more effective than a conventional one.

Werner RA;Kessler S;

Effectiveness of an intensive outpatient rehabilitation program for postacute stroke patients

Ref ID 638

RID:

362

1996 Mar

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

High risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization by three-digit number table used to place individuals in either the treatment or the control group based on whether the number was greater or less than 667, single blind (assessor blinded), intention to treat analysis not done.

DETAILS

of patients:

Forty patients randomised. 28 to the treated arm (intensive rehabilitation) and 12 to the control arm (no treatment). Five patients in the treated arm loss to follow-up

Prevalence (Diagnostic):

Patient Characteristics

	Intensive Rehab. (n=28)	No treatment (n=12)
Age	59 ± 9	66 ±
13		
Gender (%female)	50	55
Initial FIM-MM	75 ± 14	70 ± 19
Years postacute stroke	2.9 ± 1.8	3.3 ± 1.9
FIMM-MM: Functional Independence Measure- Motor Measure		

Interventions/ Test/ Factor being investigated

Intensive 12-wk outpatient rehabilitation program consisting of an hour each of physical and occupational therapy, four times per week, for 12 weeks; therapy focused on neuromuscular facilitation and functional tasks.

Comparisons

No treatment supplied.

Length of Study/ Follow-up

Followed up for the duration of treatment - 9 months.

Outcome measures studied Change in Functional Independence Measure Motor measure (FIM-MM)

Results	Comparing changes in FIM-MM		
	Intensive Rehab. (n=28) ^a	No treatment (n=12)	P value
Total FIM-MM change from time 0 to 3 mths	6.6	1.5	0.03
Total FIM-MM change from time 3 to 9 mths	0.7	-1.0	0.36

^a For comparisons made at 9 mths, n=23.
FIMM-MM: Functional Independence Measure- Motor Measure, a higher FIMM-MM score means greater functional independence. The change in FIMM-MM score was different in the two groups at a p = 0.03 level using an unpaired t test

Effect Size

Source of funding: Not mentioned

Does the study answer the question?/Further Comments The study suggests that significant functional gains that are clinically relevant can still be attained in the postacute stroke survivor, despite prior inpatient rehabilitation services.

Question: In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?

Study Type	Randomised Controlled Trial
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Bakheit AM;Shaw S;Barrett L;Wood J;Carrington S;Griffiths S;Searle K;Koutsi F;

A prospective, randomized, parallel group, controlled study of the effect of intensity of speech and language therapy on early recovery from poststroke aphasia

Ref ID 4914 **RID:** 317 2007

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = table of random numbers used rather than computer generated list - unclear risk of bias

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = could bias in favour of intervention

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = could bias in favour of intensive therapy

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Table of random numbers used rather than computer generated list; 16/51 (31%) in intensive group and 8/46 (17%) in standard group did not complete treatment; further loss to follow up over 24 weeks so final numbers 31/51 intensive group and 35/46 control. Intention-to-treat analysis.

DETAILS

of patients: 51 intensive and 46 control

Prevalence (Diagnostic):

Patient Characteristics	<p>Inclusion: 1st stroke; <93.8 on Western Aphasia Battery; English speaker; medically stable. Exclusion: depression, Parkinson's disease, moribund, severe dysarthria, living >15 miles away.</p> <table border="0"> <thead> <tr> <th></th> <th>Control</th> <th>Intensive</th> </tr> </thead> <tbody> <tr> <td>Mean age</td> <td>69.7 (SD 15.0, range 17-91)</td> <td>71.2 (SD 14.9, range 26-92)</td> </tr> <tr> <td>Male</td> <td>46%</td> <td>51% male;</td> </tr> <tr> <td>Right hand dominant</td> <td>93%</td> <td>90%</td> </tr> </tbody> </table> <p>Mean (SD) days post stroke 28.1 (14.9) 34.2 (19.1)</p>		Control	Intensive	Mean age	69.7 (SD 15.0, range 17-91)	71.2 (SD 14.9, range 26-92)	Male	46%	51% male;	Right hand dominant	93%	90%
	Control	Intensive											
Mean age	69.7 (SD 15.0, range 17-91)	71.2 (SD 14.9, range 26-92)											
Male	46%	51% male;											
Right hand dominant	93%	90%											
Interventions/ Test/ Factor being investigated	<p>Five 1-hourly sessions a week for 12 weeks, targeted at improving understanding and expression of spoken and written language, including picture/object selection, naming objects, describing and recognising associations between items, facilitating expression of feelings and opinions, improving communication skills, using gestures and non-verbal communication, using communication aids and equipment. Part of multidisciplinary rehabilitation. (Mean amount 4.3 (SD 1.0) hours per week achieved.)</p>												
Comparisons	<p>Standard therapy (i.e. the same but only for two 1-hour sessions per week; actual amount achieved 1.6 (0.5) hours per week).</p>												
Length of Study/ Follow-up	<p>Baseline through 12 weeks of treatment plus further 12 weeks of follow up (week 24 in all)</p>												
Outcome measures studied	<p>Western Aphasia Battery conducted at weeks 4, 8, 12 and 24 (primary outcome not stated).</p>												
Results	<p style="text-align: center;">Intervention vs. Control</p> <p>Baseline: 44.2 (30.2), n=51 vs. 37.9 (27.2), n=46; Week 4: 56.2 (30.4), n=42 vs. 54.6 (28.1), n=44; Week 8: 64.4 (28.8), n=36 vs. 62.0 (26.4), n=39, Week 12: 70.3 (26.9), n=35 vs. 66.2 (26.2), n=38, Week 24: 69.9 (25.2), n=31 vs. 68.0 (26.3), n=35</p>												
Effect Size													
Source of funding:	<p>Tavistock Trust for Aphasia</p>												
Does the study answer the question?/Further Comments	<p>No difference between the groups on the outcome measure at any time point. Many patients prescribed the intensive therapy either declined or were too ill to tolerate the prescribed treatment, especially in the first 4 weeks.</p>												

Denes G;Perazzolo C;Piani A;Piccione F;

Intensive versus regular speech therapy in global aphasia: A controlled study

Ref ID 1882

RID:

292

1996 May

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction = No information on randomisation/allocation concealment

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unknown

Direction = could bias in favour of intervention

Overall Study Quality -Strengths and Weaknesses:

very small sample size (8-9 per group); unclear randomisation/allocation concealment/blinding

DETAILS

of patients:

8 in intensive treatment group and 9 in standard treatment group

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: global aphasia with lesion restricted to left hemisphere; exclusion not stated.
Intensive treatment: 3 female + 5 male; mean age 58.1 years (SD 11.8); mean 3.2 (1.8) months post-stroke
Standard treatment: 6 female + 3 male; mean age 62.1 years (SD 8.7); mean 3.0 (1.6) months post-stroke

Interventions/ Test/ Factor being investigated

Intensive treatment: mean 130 (range 94-160) individual speech therapy sessions of 45-60 minutes each over a mean of 6 months (range 5.2-7 months); conversational setting, using speaking, gesturing, facial expression.

Comparisons

Intensive vs. standard therapy: Standard treatment: mean 60 (range 56-70) individual speech therapy sessions of 45-60 minutes each over a mean of 6 months (range 5.2-7 months); conversational setting, using speaking, gesturing, facial expression.

Length of Study/ Follow-up

6 months

Outcome measures studied Aachener Aphasia Test T score (difference baseline-end score, minus a mean T score difference from untreated patients to allow for spontaneous recovery) in the Token Test (error score), Repetition Test, Written Language, Comprehension and Profile Level

Results Mean improvement at 6 months

	Intensive	vs.	Standard
Token Test:	11.4 (11.6)	vs.	5.2 (7.8), NS
Repetition:	8.9 (7.7)	vs.	6.1 (6.1), NS
Written language:	11.0 (9.8)	vs.	2.1 (3.1), p<0.05
Naming:	10.2 (9.9)	vs.	4.5 (4.2), NS
Comprehension:	12.6 (15.2)	vs.	2.3 (3.8), NS
Profile level:	10.0 (8.6)	vs.	4.3 (3.8), NS

Effect Size

Source of funding: Grant of Regione Veneto

Does the study answer the question?/Further Comments Authors concluded that the number of patients achieving significant improvement was greater in the intensive group but sample size inadequate and no information on no-treatment controls or their scores (indicating spontaneous recovery) used to calculate T scores for the patients in this study.

Doesborgh SJC;van de Sandt-Koenderman MWME;Dippel DWJ;van HF;Koudstaal PJ;Visch-Brink EG;

Cues on request: The efficacy of multicue, a computer program for wordfinding therapy

Ref ID 1042 **RID:** 304 2004 Mar

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

Allocation sequence was computer generated and concealed in sequentially numbered opaque sealed envelopes until randomisation; The assessment and rating of the primary outcome variables was not blinded; Limited generalizability; Intention-to-treat analysis not mentioned.

DETAILS

of patients: 19 persons with aphasia entered the study.
10 to no treatment and 9 to Multicue.

Prevalence (Diagnostic):

Patient Characteristics

	Multicue (n = 8)	No treatment (n =10)
Age {mean (sd)}	62 (9)	65 (12)
Sex (Male)	4	5
Time post onset inclusion {mean (range)} mths	13 (11-16) mths	13 (11-17)
Site of stroke		
left hemisphere	8	10
Handedness		
right-handed	7	10
left-handed	1	
BNT (max = 180) {mean (sd)}	63 (37)	74 (35)
ANELT-A (max = 50) {mean (sd)}	34 (9)	29 (12)

Interventions/ Test/ Factor being investigated

The experimental group received 10 - 11 hours of treatment with Multicue in sessions of 30 - 45 minutes with a frequency of two to three times a week in a period of approximately 2 months.

Comparisons

The comparison group received no treatment for 6 - 8 weeks.

Length of Study/ Follow-up

Patients followed up for length of study: 6 - 8 weeks.

Outcome measures studied

Boston Naming Test (BNT)
•Each response is scored on a 4-point rating scale.
Verbal communicative ability was measured with the Amsterdam Nijmegen Everyday Language Test, scale A (ANELT-A).
•Verbal responses are scored on a 5-point scale.

Results

	Mean (sd)	Mean (sd)	t (df)	p (2-tailed)
BNT score pre-treatment (max = 180)	63.1 (36.9)	74.0 (34.9)	0.64 (16)	0.53
BNT score post-treatment (max = 180)	75.6 (38.7)	75.7 (36.7)	0.00 (16)	1.0
BNT mean improvement	12.5 (11.8)	1.7 (17.4)	-1.50 (16)	0.15
ANELT-A score pre-treatment (max=50)	33.9 (9.2)	28.6(12.2)	-1.00 (16)	0.33
ANELT-A score post-treatment (max=50)	34.3 (8.4)	25.5(10.3)	-1.95 (16)	0.07
ANELT-A mean				

Improvement 0.4 (4.0) -3.1 (7.0) -1.25 (16) 0.23

Effect Size

Source of funding: Netherlands Organisation for Scientific Research.

Does the study answer the question?/Further Comments Multicue therapy in the chronic phase phase of aphasia, following impairment-oriented treatment may have beneficial effect on word finding in the picture naming, but not on verbal communication.

Hartman J;Landau WM;

Comparison of formal language therapy with supportive counseling for aphasia due to acute vascular accident

Ref ID 871 **RID:** 907 1987 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias **Direction =**

Overall Study Quality -Strengths and Weaknesses:

Inadequate randomisation and allocation concealment; 50/60 randomised dropped out (16.67%); blinded assessment of outcome.

DETAILS

# of patients:	60 randomised (30 to speech therapy and 30 to counselling).
Prevalence (Diagnostic):	
Patient Characteristics	Inclusion: 1st stroke affecting left hemisphere; native speakers of American English; functionally normal hearing and vision; right-handed. Exclusion: multiple vascular lesions; other serious pathology; inadequate current history; left-handed; too ill to participate. Age range: speech therapy: 30-86 years (mean 65.8 years); counselling group: 32-91 years (mean 63.7 years). Speech therapy: 18 men and 12 women; counselling: 10 men and 20 women.
Interventions/ Test/ Factor being investigated	Conventional speech therapy: language drills; home practice; auditory stimulation at single-word and phrase level; follow spoken commands; reading; repetition, sentence completion, cueing strategies, twice weekly for 6 months.
Comparisons	Conventional speech therapy vs. unstructured conversation-based counselling/support focused on problems of everyday life; encouraging independent problem-solving by patient/family, twice weekly for 6 months.
Length of Study/ Follow-up	post-treatment and 3 months`
Outcome measures studied	Primary: Porch Index of Communicative Ability (PICA) change 1 month (baseline) to month 7 (post-treatment) and month 10 (3-month follow up) analysis of covariance with month 1 as covariate
Results	Pre-treatment: speech therapy: 8.79 (3.36), n=30; counselling 8.85 (3.72), n=30. Post-treatment: speech therapy: 10.52 (3.24), n=30; counselling 10.65 (3.78), n=30. 3-month follow up: speech therapy: 11.22 (2.88), n=24; counselling 10.86 (4.02), n=26. All differences non-significant.
Effect Size	
Source of funding:	not stated
Does the study answer the question?/Further Comments	This was a small study with a high drop-out rate comparing standard speech therapy with counselling (each twice weekly for 6 months) and showing no difference between the groups at post-treatment or at 3-month follow-up.

Katz RC;Wertz RT;

The efficacy of computer-provided reading treatment for chronic aphasic adults

Ref ID 688

RID:

293

1997 Jun

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

Low risk of bias Direction =

Overall Study Quality -Strengths and Weaknesses:

Randomization; the assessment of the outcome variables was blinded (single blind); method of randomization not clear; limited generalizability; intention-to-treat analysis not mentioned; allocation concealment not clear

DETAILS

of patients: 36 patients included.
21 in the Computer Reading Treatment group (experimental arm) and 15 in the

Prevalence (Diagnostic):

Patient Characteristics

	Computer Reading treatment (n=21)			No treatment (n=15)		
	M	SD	Range	M	SD	Range
Range						
Age (yrs)	61.6	10.0	48-83	62.8	5.1	53-70
Education (yrs)	14.4	3.3	8-23	13.6	2.2	10-18
Time Postonset (yrs)	6.2	5.2	1.0-19.0	8.5	5.4	1.8-22.0
Language treatment (yrs)	3.0	4.2	0.3-18.8	2.4	2.0	1.0-7.0

M: Mean, SD: Standard deviation.

Interventions/ Test/ Factor being investigated	Computer-provided reading treatment for chronic aphasic adults administered to all subjects at entry, after 3 months (13 weeks), and 6 months (26 weeks) postentry.					
Comparisons	Versus no treatment					
Length of Study/ Follow-up	26 weeks					
Outcome measures studied	The Porch Index of Communicative Ability (PICA) and the Western aphasia Battery (WAB) Aphasia Quotient (AQ) section. The two tests contained a total of 13 language measures.					
Results	Language measures	Computer Reading			No-Treatment	
		Entry	26Wks	Change	Entry	26Wks
	Change PICA (percentiles) overall*	57.3 (17.9)	66.4 (19.4)	9.1*	59.5 (16.2)	61.3 (17.4)
	WAB Aphasia Quotient*	68.9 (24.3)	73.6 (22.6)	4.7*	72.2 (24.8)	72.2 (23.7)
	Means (with standard deviations) and change scores on outcome measures in each group during the 26-week treatment trial. Results of univariate ANOVA and subsequent independent t tests are indicated by asterisks. *p<.01					
Effect Size						
Source of funding:	Study was supported by the Department of veterans Affairs Rehabilitation Research and Development Service, Department of Medicine and Surgery					
Does the study answer the question?/Further Comments	The computer reading treatment group displayed significantly more improvement on the PICA percentiles and on the WAB Aphasia Quotient than the No-Treatment group. The result suggest that the computerized reading treatment provided to chronic aphasic patients was efficacious.					

Lincoln NB;McGuirk E;Mulley GP;Lendrem W;Jones AC;Mitchell JR;

Effectiveness of speech therapy for aphasic stroke patients. A randomised controlled trial

Ref ID 901 **RID:** 299 1984 Jun 2

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias

Direction =

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk

Direction =

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

unclear

Direction =

Overall Study Quality -Strengths and Weaknesses:

randomisation and allocation concealment unclear; only 27/104 allocated to treatment achieved 3/4 of the sessions or more; no follow up (post-treatment only)

DETAILS

# of patients:	At 6 weeks post stroke, 163 randomised to treatment and 164 to control; by week 10 (baseline),104 in treatment group and 87 in no treatment group.
Prevalence (Diagnostic):	
Patient Characteristics	Inclusion: acute stroke (1st or later). Exclusion: unable to perform language assessment; very mild aphasia; severe dysarthria. 109 men and 82 women; mean age 68.2 years (range 38-92 years).
Interventions/ Test/ Factor being investigated	Two 1-hour speech therapy sessions per week (no specific type of therapy; therapists organised their own form of treatment) from week 10 post-stroke to week 34.
Comparisons	Standard speech therapy (2 hours/week) versus no treatment (controls offered treatment at week 34).
Length of Study/ Follow-up	week 34 post-stroke i.e. post treatment; no follow up.
Outcome measures studied	Porch Index of Communicative Ability (PICA); Functional Communication Profile (FPA)

Results No differences between the groups on PICA or FPA at baseline (week 10), mid-point of treatment (week 22) or post-treatment (week 34); results only shown graphically.

Effect Size

Source of funding: Research Committee of the Trent Regional Health Authority

Does the study answer the question?/Further Comments Only 27 patients of the 163 initially randomised to speech therapy actually received 3/4 or more of the scheduled sessions and there were no differences between the speech therapy and no-treatment control groups on the outcome measures post-treatment; there was no follow up. The large attrition rate means that no assessment can be made of the value of the speech therapy. This was not an intensive intervention but standard therapy only.
High drop out rate due to death, health status (unfit) and refusal to participate

Wertz RT;Weiss DG;Aten JL;Brookshire RH;Garcia-Bunuel L;Holland AL;Kurtzke JF;LaPointe LL;Milianti FJ;Brannegan R;

Comparison of clinic, home, and deferred language treatment for aphasia. A Veterans Administration Cooperative Study

Ref ID 880 **RID:** 286 1986 Jul

QUALITY

A. Selection bias (systematic differences between the comparison groups)

A4 Based on your answers t, in your opinion was selection bias present? If so, what is the likely direction of its effect?:

Unclear/unknown risk **Direction =**

B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)

B4 Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)

C4 Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?:

Low risk of bias **Direction =**

D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)

D6 Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?:

low risk of bias

Direction =

Overall Study Quality -Strengths and Weaknesses:

randomisation and allocation concealment unclear; 23% of patients dropped out but no difference between the groups; blinded assessment of outcomes; no follow up; no standard deviations reported.

DETAILS

of patients:

38 in speech therapy group; 43 in home therapy group; 40 in deferred treatment group

Prevalence (Diagnostic):

Patient Characteristics

Inclusion: male veteran 75 years or under; 2-24 weeks post 1st stroke; left hemisphere lesion; sensory/motor ability enough to gesture/write; able to read/write English; 10th-80th percentile on PICA; home therapist available. Exclusion: major medical/psychological disorder; vision worse than 20/100; hearing worse than 40-dB speech reception threshold; >2 weeks language therapy; living in institution.
Mean age group 1: 59.2 (6.7); group 2: 60.2 (6.7); group 3: 57.2 (6.6).
Mean weeks post-onset: group 1: 6.6 (4.8); group 2: 7.1 (5.8); group 3: 7.8 (6.6).
PICA percentile: group 1: 46.59 (16.05); group 2: 49.97 (22.77); group 3: 49.18 (19.46).

Interventions/ Test/ Factor being investigated

Group 1: speech therapist administered 8-10 hours/week for 12 weeks, then 12 weeks no treatment. Group 2: home treatment group: trained family member or friend administered 8-10 hours/week for 12 weeks, then 12 weeks no treatment. Group 3: deferred treatment: 12 weeks no treatment then speech therapist administered 8-10 hours/week for 12 week

Comparisons

Repeated measures analysis of covariance (covariates: baseline score, language severity and weeks post-onset) between the 3 groups

Length of Study/ Follow-up

24 weeks (end of 2nd treatment period); no follow up

Outcome measures studied

Primary: Porch Index of Communicative Ability (PICA) percentiles for overall scores, gestural, verbal and graphic scores. Mean change in scores baseline to week 12 (groups 1 and 2 treated, group 3 untreated) and week 12 to week 24 (group 3 treated)

Results

0-12 weeks: PICA overall: group 1: 18.16 (p<0.05 vs. group 3); group 2: 16.86; group 3: 12.23
Gestural: group 1: 17.50; group 2: 13.99; group 3: 12.96
Verbal: group 1: 13.85; group 2: 13.10; group 3: 9.85
Graphic: group 1: 17.03; group 2: 16.11; group 3: 10.20
12-24 weeks: PICA overall: group 1: 3.00; group 2: 1.03; group 3: 6.86
Gestural: group 1: 3.55; group 2: 2.78; group 3: 9.45
Verbal: group 1: 2.55; group 2: 1.92; group 3: 5.62
Graphic: group 1: 3.14; group 2: 0.61; group 3: 5.83

Effect Size

Source of funding:

Veterans Administration Cooperative Studies Program, Medical Research Service

Does the study answer the question?/Further Comments

In the 1st 12 weeks, the speech therapist-treated group improved more than deferred treatment (controls), while the home-treated group did not differ significantly from either the speech therapy group or the control group. At 24 weeks when the control group had received treatment, there was no difference between the 3 groups.

Evidence tables for included primary (qualitative) studies

Question: Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?

Study	Hale LA 2010 Country: Dunedin, New Zealand
Aim	To explore the feasibility and acceptability of using Goal Attainment Scaling (GAS) in home-based stroke rehabilitation (HBSR)
Design	Interpretative description: multiple semi-structured in-depth interviews
Population	Four physiotherapist and seven patients (3 men, 4 women) participated in this qualitative study. The physiotherapy participants were all female, with between 6 and 39 years of clinical experience working in community physiotherapy, and were aged between 29 and 60 years. None of the therapists had prior knowledge of GAS
Method	<p>A variety of data sources were used in this study; multiple semi-structured in-depth interviews with the physiotherapy participants, the physiotherapists' detailed clinical case notes, researcher field notes, and where possible the researcher observed, as a non-participant, the physiotherapists' interactions with these patients.</p> <p>Most interviews were done telephonically. Anonymity was assured by the use of pseudonyms for both the physiotherapists and the patients.</p> <p>Following an initial baseline GAS session with each patient, each physiotherapist was interviewed by telephone by the researcher in order to justify the scaled goals set.</p> <p>At the end of the study, physiotherapist from each of the two participating clinical sites were interviewed in pairs to discuss their perceptions using GAS</p>
Data analysis	<p>All interviews were audio-taped and fully transcribed word for word.</p> <p>Data from all sources (the interviews, treatment observation notes, the clinical notes and researcher field notes) were read multiple times and compared with each other to construct a story for each patient.</p> <p>Discrepancies in data from the various sources were explicitly looked for but were not found; rather data from the various sources complemented each other.</p> <p>The constructed stories were sent to the physiotherapist concerned for verification and modification if required.</p>
Findings	<p>Enthusiastically cautious: the physiotherapy participants were undecided about the use of GAS in their practice. Whilst they could see the benefits of using it, they did not think it appropriate for all patients with stroke that they saw.</p> <p>The therapists were concerned with the reliability of GAS in that different therapists could set different indicators for the same patient.</p> <p>Another useful tool in the box of interventions: one therapist found GAS useful in guiding treatment and that it was a good tool to assist therapists to set patient-centred goals. Another therapist used the set goals as a means of encouraging, motivating and prompting a patient.</p> <p>Time consuming: setting goals and indicators could be time consuming. Some patients had cognitive issues, which made it difficult. GAS did take time at first, with experience it got faster and easier to set the goals and levels</p> <p>Not easy to set goals: for many patients it was not easy to set the goals and identify the indicator levels, especially if a patient made rapid progress or for patients who presented with cognitive or communication issues</p>
Conclusion	Authors concluded that GAS may be a useful means of quantifying outcome in HBSR. Focusing on patient-centred goals may enhance patient motivation and

thereby improve patient satisfaction with services; however, the setting of goals and indicators was found to be time-consuming and difficult to achieve with some patients. Physiotherapy participants questioned the reliability of the process, especially as it pertains to measuring outcome, highlighting the need for further research to enhance the robustness of the process.

Comments

A combination of face to face and telephone interviews was used in this study. Using only face-to-face in-depth interviews may have yielded richer data than the combination of face-to-face and telephone interviews. Telephone interviews lack the personal contact made in face-to-face interviews and lose verbal cues. A further limitation to the study is that only one researcher interviewed and analysed the data. Methods well described.

Study	Worrall L 2011 Country: Brisbane, Australia
Aim	To describe the goals of people with aphasia and to code the goals according to the International Classification of Functioning (ICF)
Design	Qualitative descriptive study: involved semi-structured, in-depth interviews
Population	<p>50 participants (24 males, 26 females; mean age 63.9 ± 10.8 years) with aphasia post stroke (mean duration 54.9± 43.6 months were recruited through an aphasia registry, in addition to community contacts in three Australian cities. Participants had a mean Western Aphasia Battery Aphasia Quotient of 69.6 (± 24.2)</p> <p>Maximum variation sampling was used in order to obtain major variations in the participants' experiences of rehabilitation services.</p> <p>Variation within the sample was sought for the characteristics of gender, age, time, time post-onset (<12mpo; >12 mpo), and aphasia severity (Western Aphasia Battery Quotient).</p> <p>Individuals with other severe communication impairments (e.g., speech disorders such as dysarthria, cognitive impairments, hearing, or visual impairment) were excluded from the study and all participants had to be able to participate in an in-depth interview in English using speech, gesture, writing, pictures, and/or drawings.</p> <p>First 15 consecutive participants recruited at one site (i.e., 30% of the total sample) constitute the sub-sample whose goals were coded according to the ICF</p>
Method of gaining views	<p>All interviews were video recorded and conducted in the participants' homes by experienced speech pathologists trained in in-depth interviewing techniques with people with aphasia.</p> <p>Supported conversation techniques were used to facilitate the interaction.</p> <p>Family members were interviewed separately, but, at the request of the participant with aphasia, were often present at the interview</p> <p>Interview scheduled for the participants with aphasia included the following topics:</p> <p>Their experience of aphasia (e.g., tell me about when you first had aphasia);</p> <p>Their rehabilitation goals and needs (e.g., when you first had your stroke, what was important to you? What were your concerns? What did you want to work on in speech therapy? What were your goals?);</p> <p>Their aphasia rehabilitation and service experiences (e.g., did you work on these areas in speech therapy? If yes, how did you work on them? If no, what did you want to work on? Did speech therapy help?);</p> <p>Aphasia services they would have wanted (e.g., what other services or things</p>

did you want at that time related to your aphasia?)

These topics were repeated for specified times after their stroke (e.g., when they first went home, when they had outpatient speech therapy, and at the time of the interview).

Data analysis

Video recorded interviews were transcribed verbatim

Qualitative content analysis was conducted to identify codes for the participants' goals and those codes with similar content were then merged into super ordinate goal categories

NVivo qualitative data analysis software and MS Word software programs were used to manage the data during analysis

The goals of the subsample were classified according to the ICF

In addition, 6 guidelines were established to ease the process of linking items to the ICF, as well as to improve consistency between researchers prior to reliability study taking place.

To determine coding reliability, 30% of the sample was re-coded 2-4 weeks after the original coding.

While intra-rater reliability met or exceeded the minimum acceptable level of 80%, the inter-rater reliability fell below this level.

Findings

Nine broad themes were derived from the data.

To provide a flavour of whether themes were prominent or not, terms like "most" participants or "some" participants were inserted to provide some context for categories.

Return to pre-stroke life: Most participants expressed their desire to be normal again and to escape their current situation and return home to the security of their old life. Their main priority was to be rid of the consequences of the stroke.

Communication: all participants with aphasia naturally spoke of the importance of recovering their communicative function. They described intense feelings of frustration, hopelessness, isolation, and depression at not being able to talk. Many stressed that the aphasia was often of higher priority to them than their physical impairments which contrasted with health care systems' focus on physical recovery. They spoke in a general sense about their desire for communicative function, as well as more specifically. They spoke about the range of their communication needs (e.g., communication for basic needs as well as communication to express their opinions). They spoke about the need for communication rehabilitation to be connected to real life. Participants often mentioned specific words or names they wanted to say in real life. They also spoke about how communication gave them confidence.

Information: one of the most commonly reported goals was that of obtaining information. Several people reported that they were not told by their therapist, particularly in the early weeks or months, of the term used to describe their communication difficulty, and if the word "aphasia" was mentioned, it was rarely explained clearly. Participants wanted information about aphasia and stroke for themselves and their family. They also wanted information about their prognosis and what to expect at different stages of rehabilitation. On a practical level they needed information about aphasia and stroke to access services and explain their difficulties to friends or people in the community. In addition, having information allowed people to start taking control and to participate in decisions about their own therapy and their own rehabilitation. Some participants also wanted more information about their therapy.

Speech therapy and other health services: Most participants wanted speech therapy that met their needs at different stages of recovery, was relevant to their life, more frequent and continued for longer. They wanted positive relationships and interactions with their speech therapists and other health

service providers

Control and independence: Goals in this category included wanting to get out of an institution to their home, or wanting to do things by or for themselves. Some expressed frustration at not being a part of the decision making in their care, seeking information from sources other than health professionals

Dignity and respect: Many people reported a feeling of being disempowered by their aphasia. They wanted respect, stating that they were competent people, despite their communication difficulties.

Social, leisure, and work: It was very common for people to have social goals, including being able to converse with family, chat with friends, read a night time story to the grandchildren, and to feel comfortable in a crowd. Social goals were characteristics of later stages of recovery, but were also featured throughout their rehabilitation. People with aphasia were upset by boredom and isolation. Younger people with aphasia were particularly aware of the loss of work and career and often held deep, strong desires to return to some employment.

Altruism and contribution to society: A few people spoke of goals related to improving the lives of others, including other people with aphasia. Some participants devoted time to helping speech pathology students by being available for clinical placements, some volunteered in groups, and some wanted to increase people's awareness of aphasia.

Physical function and health: Physical recovery and general health goals were closely woven into the success of other kinds of goals. Many knew it was their physical improvements that would determine whether or not they could manage at home, and this often dominated rehabilitation. Once home, people's goals often included physical health, going for walks, keeping fit, going to the gym, and managing their weight, diabetes, or epilepsy.

ICF coding of goals

This study also aimed to determine how the goals were coded across the levels of the ICF. Goals were linked to the full bio psychosocial spectrum, although activity and participation goals figured most prominently. Participants spoke broadly about general non-specific physical health or general health goals; because the ICF covers this entire domain, these goals were coded as "non-definable goals of physical health". Some goals required the combination of two codes in order to accurately reflect their meaning.

Conclusion

People with aphasia in this study were able to articulate a wide range of goals post-stroke that encompassed all of the ICF components but had a particular focus on the activity and participation components

Comments

Inter-coder reliability did not reach an acceptable level, suggesting that different clinicians are likely to code goals in different ways. Methods well described.

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I.1 Economic evidence tables

I.1.1 Anderson C, Mhurchu CN, Rubenach S, et al. Home or hospital for stroke rehabilitation? Results of a randomized controlled trial - II: cost minimization analysis at 6 months. Stroke 2000;31:1032-7.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA</p> <p>Study design: Within-RCT analysis</p> <p>Approach to analysis: Analysis of individual level resource use where possible, with unit costs applied.</p> <p>Perspective: Australian health care system (carers time was also included in analysis but has been excluded from results reported here).</p> <p>Time horizon: 6 months</p> <p>Treatment effect duration: n/a</p> <p>Discounting: Costs:</p>	<p>Population: Patients with acute stroke requiring rehabilitation</p> <p>N = 86</p> <p>M = 56%</p> <p>Mean age = 71</p> <p>Country = Australia</p> <p>Intervention 1: Hospital-based rehabilitation (in an acute-care medical geriatric ward or in a multidisciplinary stroke rehabilitation)</p> <p>N = 44</p> <p>Mean age = 71</p>	<p>Total healthcare costs† (mean per patient):</p> <p>Intvn 1: £4640</p> <p>Intvn 2: £3423</p> <p>Incremental (2-1):- £1217 (CI -£2306,-£127) ; p=NR)</p> <p>Hospital costs (mean per patient):</p> <p>Intvn 1: £3877</p> <p>Intvn 2: £1558</p> <p>Incremental (2-1):- £2319 (CI -£3311, -£1327; p=NR)</p> <p>Home-based rehabilitation costs (mean per patient):</p> <p>Intvn 1: £39</p> <p>Intvn 2: £1480</p> <p>Incremental (2-1): £1441 (CI £1184, £1697; p=NR)</p> <p>Community services costs (mean per patient):</p> <p>Intvn 1: £724</p>	<p>From clinical review – Anderson 2000⁵</p> <p>SF36 (MD): physical functioning -1.2 (-13.3, 10.9); social functioning -8,1 (-19.89, 3.69)</p> <p>Barthel (MD): 0 (-2.0, 2.0)</p> <p>Falls (RR): 0.75 (0.26, 2.17)</p> <p>Caregiver strain (MD): 0.00 (-0.23, 0.23)</p>	<p>Primary ICER (Intvn 2 versus Intvn 1):</p> <p>ICER: n/a</p> <p>CI: n/a</p> <p>Probability cost-effective: n/a</p> <p>Other: n/a</p> <p>Subgroup analyses: n/a</p> <p>Analysis of uncertainty: One way sensitivity analysis over initial hospital costs (varied to 50% and 75% of baseline value) and home-based rehabilitation costs (increased by 25%, 50% and 75% from the baseline value). Sensitivity analysis shows that results were generally robust to changes in hospital and community-based costs. Hospital-based care became less costly than ESD when hospital costs were reduced by 50%.</p>

I.1.1 Anderson C, Mhurchu CN, Rubenach S, et al. Home or hospital for stroke rehabilitation? Results of a randomized controlled trial - II: cost minimization analysis at 6 months. Stroke 2000;31:1032-7.

<p>n/a; Outcomes: n/a</p>	<p>M = 50% Drop-outs = 4 Intervention 2: Early-supported discharge (hospital at home) N = 42 Mean age = 72 M = 62% Drop-outs: 0</p>	<p>Intvn 2: £386 Incremental (2-1):- £338 (CI -£769, £93; p=NR)</p> <p>Currency & cost year: Costs reported as Australian dollars (presented here as 1998 UK pounds£). Cost year unclear; unit cost sources varied between 1994 and 1999.</p> <p>Cost components incorporated: Hospital costs (initial length of stay, readmissions, outpatient visits). Home based rehabilitation team. Community services (GP visits, therapy in the home, district nursing, meals on wheels, respite care, day centre visits, alternative therapies, permanent admission to residential care). Caregiver time was also costed but has been excluded from results presented here in line with NICE reference case.</p>		
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Data sources

Health outcomes: Within-RCT analysis (reported separately in Anderson 2000⁵; study included in clinical review). Quality-of-life weights: n/a. Cost sources: Resources use: hospital department records, patient questionnaires, contact time as tracked by staff, staff records and rehabilitation service records. Unit costs: hospital records and national data sources.

I.1.1 Anderson C, Mhurchu CN, Rubenach S, et al. Home or hospital for stroke rehabilitation? Results of a randomized controlled trial - II: cost minimization analysis at 6 months. Stroke 2000;31:1032-7.

Comments

Source of funding: South Australian Health Commission via grant from federal government. Limitations: Not a full economic evaluation since QALYs were not calculated. QALYs not used. Some uncertainty about the applicability of Australian resource use and unit costs from over 10 years ago. RCT-based analysis so from one study by definition therefore not reflecting all evidence in area. Some uncertainty about whether time horizon is sufficient. Limited sensitivity analysis. Other: n/a.

Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; RCT = randomised clinical trial

† Total healthcare costs, difference and CI calculated by NCGC as paper total includes productivity costs. ‡ Converted using 1998 Purchasing Power Parities²⁵

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations

I.1.2 Beech R, Rudd AG, Tilling K, et al. Economic consequences of early inpatient discharge to community-based rehabilitation for stroke in an inner-London teaching hospital. Stroke 1999;30:729-35.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA</p> <p>Study design: Within-RCT analysis</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied.</p> <p>Perspective: UK NHS and PSS</p> <p>Time horizon: 12 months</p> <p>Treatment effect duration:</p>	<p>Population: Patients admitted to hospital following a stroke</p> <p>N = 331</p> <p>M = 185 (56%)</p> <p>Mean age = 71</p> <p>Country = UK</p> <p>Intervention 1: Conventional rehabilitation</p> <p>Mean age:72</p>	<p>Total costs (mean per patient):</p> <p>Intvn 1: £7,432</p> <p>Intvn 2: £6,800</p> <p>Incremental (2-1): -£632 (CI NR; p=NR)</p> <p>Inpatient costs (mean per patient):</p> <p>Intvn 1: £6343</p> <p>Intvn 2: £4862</p> <p>Incremental (2-1): -£1481 (CI NR; p=NR)</p>	<p>From clinical review – Rudd 1997²⁷</p> <p>Mortality (RR): 0.75 (0.47, 1.19)</p> <p>Barthel (SMD): 0.0 (-0.24, 0.24)</p> <p>HADS (RR): 2.65 (1.16, 6.05)</p> <p>Caregiver</p>	<p>Primary ICER (Intvn 2 versus Intvn 1): ICER: n/a</p> <p>CI: n/a</p> <p>Probability cost-effective: n/a</p> <p>Other: n/a</p> <p>Subgroup analyses: n/a</p> <p>Analysis of uncertainty: Various one-way sensitivity analyses were performed around resource use and costs – ESD continued to result in a cost saving in plausible sensitivity analyses. The cost saving disappeared under the following</p>

I.1.2 Beech R, Rudd AG, Tilling K, et al. Economic consequences of early inpatient discharge to community-based rehabilitation for stroke in an inner-London teaching hospital. Stroke 1999;30:729-35.

n/a Discounting: Costs: n/a; Outcomes: n/a	M = 57% Drop outs: 4 Intervention 2: Early supported discharge (ESD) Mean age = 70 M = 55% Drop-outs: 5	Non-inpatient costs (mean per patient): Intvn 1: £1089 Intvn 2: £1938 Incremental (2-1): £849 (CI NR; p=NR) Currency & cost year: 1997 UK pounds. Cost components incorporated: Inpatient costs (general staff, diagnostic tests, rehabilitation). Non-inpatient rehabilitation costs Community services (GP visits; meals on wheels, home help, district nurse, lunch club)	strain 1.00(-0.19, 2.19)	scenarios: When the difference in overall stay between groups is reduced to 3 days (6 days in basecase). When the overhead rate was reduced to 5%(69% in base case).
Data sources				
Health outcomes: Within-RCT analysis (reported separately in Rudd 1997 ²⁷ study included in clinical review). Quality-of-life weights: n/a. Cost sources: Hospital financial records; PSSRU 1997.				
Comments				
Source of funding: Stroke Association; Lambeth, Southwark and Lewisham Health Authority; the Special Trustees of St Thomas's Hospital; the Nuffield Provincial Hospitals Trust; Wandsworth Health Gain Fund. Limitations: QALYs not used. Some uncertainty about the applicability of resource use and unit costs from over 10 years ago. RCT-				

I.1.2 Beech R, Rudd AG, Tilling K, et al. Economic consequences of early inpatient discharge to community-based rehabilitation for stroke in an inner-London teaching hospital. *Stroke* 1999;30:729-35.

based analysis so from one study by definition therefore not reflecting all evidence in area. Some local costs used; some uncertainty as to whether these will reflect national costs. Some uncertainty about whether time horizon is sufficient. Doesn't report if residential care has been considered in analysis. Other: n/a.

Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; RCT = randomised clinical trial

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious Limitations / Very serious limitations

I.1.3 Bowen, A. Hesketh, E. Patchick, A. Young, L. Davies, A. Vail, A. Long, C. Watkins, M. Wilkinson, G. Pearl, Ralph M. Lambon, and P. Tyrrell. Clinical effectiveness, cost-effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke: a randomised controlled trial (the ACT NoW Study). *Health Technol Assess* 16 (26):1-160, 2012.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: Cost-utility analysis</p> <p>Study design: Within-study analysis</p> <p>Perspective: NHS, providers/funders of non-hospital care facilities and of patients and families.</p>	<p>Population: Adults with aphasia or dysarthria admitted to hospital with stroke. N = 170 Mean age = 70 M = 56%</p> <p>Country = United Kingdom</p> <p>Intervention 1: Speech and language therapy delivered by NHS speech and language therapists.</p>	<p>Incremental cost‡: includes multiple imputation values and adjusted for baseline covariates Intvn 1 – Intvn 2 = £110 95% CI = -£640, £861</p> <p>Currency & cost year: 2008-2009 UK pounds (quoted in the paper)</p> <p>Cost components incorporated:</p>	<p>Primary outcome measure Mean utility scores obtained at the end of follow-up(SD) Intvn 1= 0.51(0.42) Intvn 2=0.47(0.38)</p> <p>Incremental utility score‡: includes multiple imputation values and adjusted for baseline covariates Intvn 1 – Intvn 2 = 0.01</p>	<p>ICER‡ (Intvn 1 versus Intvn 2): £22,000 per QALY gained (over six months)</p> <p>In the deterministic analysis, speech and language therapy is dominated by attention control when the incremental costs and utilities are adjusted for baseline covariates.</p> <p>Analysis of uncertainty: Sensitivity analysis was run by conducting 10,000 simulations on the estimates of incremental costs and outcomes. The probability that SL therapy is cost-effective is 48% at a willingness to pay threshold of £20,000.</p>

I.1.3 Bowen, A. Hesketh, E. Patchick, A. Young, L. Davies, A. Vail, A. Long, C. Watkins, M. Wilkinson, G. Pearl, Ralph M. Lambon, and P. Tyrrell. Clinical effectiveness, cost-effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke: a randomised controlled trial (the ACT NoW Study). Health Technol Assess 16 (26):1-160, 2012.

<p>Time horizon: 6 months</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p>	<p>22 patient contacts (mean), for 18 hours (mean), delivered over 13 weeks N =85</p> <p>Intervention 2: Attention control absent of any intuitive form of communication therapy or strategy, delivered by employed visitors with no professional experience of stroke or SL therapy 19 patient contacts (mean), for 15 hours (mean), delivered over 13 weeks N =85</p>	<p>Length of stay in inpatient care (costing included the use of invasive procedures, tests, assessments and therapy services).</p> <p>Length of stay in community-based rehabilitation and care facilities</p> <p>Cost of SL therapists and personnel delivering AC (this included training costs in the AC arm)</p> <p>Use of hospital-based outpatient and day patient clinics and services.</p>	<p>95% CI = -0.03, 0.04</p> <p>Incremental QALYs (at 6 months): Intvn 1 – Intvn 2 = 0.005 95% CI = -0.015, 0.02</p>	<p>The impact of certain variables on the results was explored in sensitivity analyses.</p> <p>Attention control was more cost-effective at any WTPT less than £25,000 when the following variables were analysed</p> <ul style="list-style-type: none"> using trial specific costs rather than national costs (which was likely to include start-up costs of implementing the interventions) using available case data rather than imputed missing data using alternative outcome measures rather than the EQ-5D scores <p>SL therapy was more cost-effective at any WTPT when the following variables were analysed</p> <ul style="list-style-type: none"> using an alternative regression model to estimate incremental costs and outcomes using the TOM measure of communication outcomes measure using the Communication Outcomes After Stroke scale (COAST) in combination with the Discrete Choice Experiment weights rather than EQ-5D scores.
<p>Data sources</p>				
<p>Health outcomes: Within-study analysis (study included in clinical review).</p>				
<p>Quality-of-life weights: EQ5D data was collected from study participants at the end of follow-up</p>				

I.1.3 Bowen, A. Hesketh, E. Patchick, A. Young, L. Davies, A. Vail, A. Long, C. Watkins, M. Wilkinson, G. Pearl, Ralph M. Lambon, and P. Tyrrell. Clinical effectiveness, cost-effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke: a randomised controlled trial (the ACT NoW Study). Health Technol Assess 16 (26):1-160, 2012.

Cost sources: NHS reference costs 2008-2009, PSSRU 2009, Chartered Institute of Public Finance and Accountancy 2005

Comments:

Source of funding: NIHR HTA programme, NHS trusts, The Stroke Association

Limitations: Utility scores were obtained at follow-up but not at baseline as the authors felt it was not feasible to do so. There was a difference in stroke severity at baseline between the two groups meaning that it cannot be assumed that the two groups would have similar utility scores. QALYs could not be calculated and the health outcome is just the difference in utility at the end of follow-up. The scores don't show how health status has changed over time as the value is from one time point (at the end of follow-up). There was a lot of missing observations for the resource use and health outcomes in both groups. This meant that using available case data could bias the results. The authors used multiple imputation to impute missing values for participants who completed scheduled follow-up for at least one of the outcome measures. This was done to reduce the impact of missing observations.

Overall applicability*: Directly applicable Overall quality**: Potentially serious limitations

Abbreviations: n/a = not applicable; CI = confidence interval; ICER=incremental cost-effectiveness ratio

[‡]Probabilistic results calculated by conducting 10,000 simulations on the estimates of incremental costs and outcomes.

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations.

I.1.4 L. Claesson, G. Gosman-Hedstrom, M. Johannesson, B. Fagerberg, and C. Blomstrand. Resource utilization and costs of stroke unit care integrated in a care continuum: A 1-year controlled, prospective, randomized study in elderly patients. The Goteborg 70+ stroke study. Stroke 31:2569-2577:2569-2577, 2000.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: Cost-consequence analysis (various health outcomes) Study design: Within-trial analysis	Population: Patients with acute stroke within seven days Mean age = 80.1(stroke unit) 79.7 (general ward) M = NR	Total costs‡(mean per patient) Intvn 1: £11,554 Intvn 2: £10,709 Incremental (2-1): -£845	Primary outcome measure Study reports that at 3 months, a beneficial effect of stroke unit care on mortality and the need for institutional care was found.	Primary ICER (Intvn 2 vs. Intvn 1): ICER: N/A CI: N/A Probability cost-effective: N/A Other: Over a 1 year period, there are

I.1.4 L. Claesson, G. Gosman-Hedstrom, M. Johannesson, B. Fagerberg, and C. Blomstrand. Resource utilization and costs of stroke unit care integrated in a care continuum: A 1-year controlled, prospective, randomized study in elderly patients. The Goteborg 70+ stroke study. Stroke 31:2569-2577:2569-2577, 2000.

<p>(RCT - Fagerberg 2000¹³)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied.</p> <p>Perspective: Swedish health care system†</p> <p>Time horizon: 1 year</p> <p>Treatment effect duration: n/a</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p>	<p>Country = Sweden</p> <p>Intervention 1: General medical ward.</p> <p>Patients received conventional acute medical care, physiotherapy and occupational therapy but these were not based on a structured stroke unit care process.</p> <p>Intervention 2: Acute stroke unit linked to a care continuum (defined as continued care in geriatric stroke units when a long rehabilitation period is needed). The stroke unit consisted of two wards, one in a general medical ward and one in a neurology ward.</p>	<p>Currency & cost year: Costs reported as 1996 Swedish Crowns (presented here as 1996 UK pounds*)</p> <p>Cost components incorporated: Acute hospitalisation costs - based on 'hotel cost' per hospital day and included staff costs, rent costs, food, cleaning and transportation.</p> <p>Institutionalized living - nursing home costs, assisted living costs, home for the elderly costs.</p> <p>Outpatient care costs- physician, outpatient rehabilitation, nurse, occupational therapy, physiotherapy and speech therapy visits</p> <p>Different kinds of support - assistance devices, safety alarm, taxi service</p> <p>Informal care provided by relatives was also costed but has been excluded from</p>	<p>However, there was no significant difference between the interventions in terms of mortality, functional ability and proportion of patients living at home at 1 year.</p>	<p>minimal differences in health outcomes between stroke units and general medical wards. However, costs attributed to care originating from stroke units are slightly lower which would make them a more cost-effective option.</p> <p>Subgroup analyses: N/A</p> <p>Analysis of uncertainty: NR</p>
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I.1.4 L. Claesson, G. Gosman-Hedstrom, M. Johannesson, B. Fagerberg, and C. Blomstrand. Resource utilization and costs of stroke unit care integrated in a care continuum: A 1-year controlled, prospective, randomized study in elderly patients. The Goteborg 70+ stroke study. Stroke 31:2569-2577:2569-2577, 2000.

results presented here in line with NICE reference case.

Data sources

Health outcomes: Within-trial analysis (reported separately in Fagerberg 2000¹³; study included in clinical review.

Quality-of-life weights: n/a

Cost sources: The cost per hospital day on different wards was obtained from Sahlgrenska University Hospital. Prescription costs were based on official Swedish retail prices. All other estimates of unit costs were obtained from the Civic administration of the city of Goteborg.

Comments

Source of funding: Swedish Stroke Association and various Foundations.

Limitations: Not a full economic evaluation since QALYs were not calculated. Uncertainty as to whether the organization of care of patients with stroke in Sweden is comparable to the UK health system. This would have implications on the volume of resource use as well as the cost components included in the analysis. In addition, the costing is based on the practice of one hospital. There is a possibility that care of patients could vary depending on the size and region of the hospital, so these results may not be transferrable to the UK setting. The major costs drivers were due to the differences in resource use for the following items- hospitalisations in geriatric ward, home for the elderly costs and home assistant costs. The costs of informal care have been excluded from the results presented above. This is in line with the NICE reference case.

Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: NR = not reported; CI = confidence interval; ICER = incremental cost-effectiveness ratio; † Informal care time was also included in analysis but has been excluded from results reported here in line with NICE reference case; ‡Based on NCGC calculation; * Converted using 1996 Purchasing Power Parities²⁵

I.1.5 Donnelly M, Power M, Russell M, et al. Randomized controlled trial of an early discharge rehabilitation service: the Belfast community stroke trial. Stroke 2004;35:127-33.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CCA	Population: Patients with stroke admitted to hospital	Total costs over 12 months† (mean per patient) Intvn 1: £25,071	See clinical review – Donnelly 2004 ¹² Barthel 0-20: 0.25 (-1.62,	Primary ICER (Intvn 2 versus Intvn 1): ICER: n/a

I.1.5 Donnelly M, Power M, Russell M, et al. Randomized controlled trial of an early discharge rehabilitation service: the Belfast community stroke trial. Stroke 2004;35:127-33.

<p>Study design: Within-RCT analysis</p> <p>Approach to analysis: Analysis of individual level resource use from subgroup of trial, with unit costs applied.</p> <p>Perspective: UK NHS and PSS</p> <p>Time horizon: 12 months</p> <p>Treatment effect duration: n/a</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p>	<p>N (total/resource use subgroup) = 113/38</p> <p>M = NR</p> <p>Mean age = NR</p> <p>Country = UK</p> <p>Intervention 1: Hospital-based rehabilitation</p> <p>N (total/resource use subgroup) = 54/20</p> <p>Mean age = NR (median 71)</p> <p>M/F = NR</p> <p>Drop-outs = 8 (4 died+4 missing)</p> <p>Intervention 2: Community-based MDR multidisciplinary stroke team (CST)</p> <p>N (total/resource use subgroup) = 59/18</p> <p>Mean age = NR (median 68)</p> <p>M/F: NR</p> <p>Drop-outs: 8 (1 died+7 missing)</p>	<p>Intvn 2: £21,439</p> <p>Incremental (2-1): -£3632 (CI: -£12,115, £4851; p=NR)</p> <p>Total costs first 6 months (mean per patient):</p> <p>Intvn 1: £13,337</p> <p>Intvn 2: £11,759</p> <p>Incremental (2-1): -£1578 (CI: -£5035 to £8189.1 ; p=0.916)</p> <p>Total costs second 6 months (mean per patient):</p> <p>Intvn 1: £11,374</p> <p>Intvn 2: £9,680</p> <p>Incremental (2-1): -£1694 (CI: -£3455.4 to £10266.9 ; p=0.817)</p> <p>Currency & cost year: UK pounds. Cost year assumed to be 1999 (one unit cost source is from 1999)</p> <p>Cost components incorporated: Hospital inpatient costs Community rehabilitation team Community services (social work, meals-on-wheels; GP and hospital</p>	<p>1.13)0.24 (-0.16,0.64)</p> <p>Nottingham ADL (MD): 1.57 (-0.87, 4.01)</p> <p>SF-36 (MD): physical functioning 0.92 (-11.71, 13.55); mental health 2.19 (-5.48, 9.86)</p> <p>EuroQol VAS‡: -1.85 (-9.60, 5.90)</p> <p>Caregiver strain (SMD): 0.03 (-0.52, 0.57)</p>	<p>CI: n/a</p> <p>Probability cost-effective: n/a</p> <p>Other: n/a</p> <p>Subgroup analyses: n/a</p> <p>Analysis of uncertainty: NR</p>
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1.1.5 Donnelly M, Power M, Russell M, et al. Randomized controlled trial of an early discharge rehabilitation service: the Belfast community stroke trial. *Stroke* 2004;35:127-33.

	outpatient visits; day hospital visits; district and community nursing; privately provided home help, day centre care)		
Data sources			
Health outcomes: Within-RCT analysis (reported in same paper). Quality-of-life weights: Within RCT analysis – EuroQol. Cost sources: Resource use: within-trial analysis. Unit costs: hospital financial accounts, PSSRU 1999.			
Comments			
Source of funding: South and East Belfast Health and Social Services Trust; Northern Ireland Chest Heart and Stroke Association. Limitations: EuroQol reported but unclear if EQ5D or visual analogue scale part of tool used. Some uncertainty about the applicability of resource use and unit costs from over 10 years ago. RCT-based analysis so from one study by definition therefore not reflecting all evidence in area. Some local costs used; some uncertainty as to whether these will reflect national costs. Some uncertainty about whether time horizon is sufficient. No sensitivity analysis was undertaken. Other: n/a.			
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations			

Abbreviations: CCA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; RCT = randomised clinical trial

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious Limitations / Very serious limitations

† Total costs over 12 months, difference and CI calculated by NCGC as paper total reports the two 6 month periods separately. Calculation of CI is considered likely to underestimate uncertainty due to not accounting for covariance. ‡ It was not stated if the EuroQol measure used was the EuroQol five dimensions (EQ5D) or visual analogue scale (VAS) but is assumed to be VAS as was reported on a scale of 0-100.

1.1.6 Fjaertoft H, Indredavik B, Magnussen J, et al. Early supported discharge for stroke patients improves clinical outcome. Does it also reduce use of health services and costs? One-year follow-up of a randomized controlled trial. *Cerebrovascular Diseases* 2005;19:376-83

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CCA	Population: Acute stroke patients admitted to a hospital stroke unit.	Total costs per patient (mean): Intvn 1: £11,271	From clinical review – Indredavik 2000 ¹⁷ and Fjaertoft 2004 ¹⁴ Barthel (MD): 1.72 (1.10-	Primary ICER (Intvn 2 versus Intvn 1): ICER: n/a CI: n/a

I.1.6 Fjaertoft H, Indredavik B, Magnussen J, et al. Early supported discharge for stroke patients improves clinical outcome. Does it also reduce use of health services and costs? One-year follow-up of a randomized controlled trial. *Cerebrovascular Diseases* 2005;19:376-83

Study design: Within-RCT analysis	N = 340 Mean age = 73.9	Intvn 2: £9780 Incremental (2-1): -£1491 (CI=NR ; p=0.127)	2.70) Mortality (RR): 0.87 (0.43, 1.76) Caregiver strain index (SMD): 0.24 (-0.00, 0.49)	Probability cost-effective: n/a Other: n/a
Approach to analysis: Analysis of individual level resource use, with unit costs applied.	M = 49% Drop-outs = 37 Country = Norway	Currency & cost year: Norwegian Euro; cost year unclear – assumed to be 2005 (presented here as 2005 UK pounds£).		Subgroup analyses: Stratification by functional level Incremental costs: RS 0-1 = £1477 (CI NR, p=0.200) RS 2-3 = -£2743 (CI NR, p=0.099) RS4-5 = -£2962 (CI NR, p=0.301) Analysis of uncertainty: Simple sensitivity analyses with the five most expensive cost components increased/decreased by 25% - Author states that only marginally impacted results (not shown).
Perspective: Norwegian health service Time horizon: 52 weeks Treatment effect duration: n/a Discounting: Costs: n/a; Outcomes: n/a	Intervention 1: Treatment in stroke unit with no early supported discharge (OSUS) N = 160 Mean age = 73.8 M = 44% Drop-outs = 26 Intervention 2: Treatment in stroke unit followed by early supported discharge (ESUS) N = 160 Mean age = 74.0 M = 54% Drop-outs = 21	Cost components incorporated: Acute care in stroke unit, inpatient and home-based rehabilitation, nursing home/assisted living, hospital readmission, mobile team.		
Data sources				
Health outcomes: Within-RCT analysis (reported in a separate paper ^{14,17}). Quality-of-life weights: n/a Cost sources: National average costs (DRG-Norway).				
Comments				

I.1.6 Fjaertoft H, Indredavik B, Magnussen J, et al. Early supported discharge for stroke patients improves clinical outcome. Does it also reduce use of health services and costs? One-year follow-up of a randomized controlled trial. Cerebrovascular Diseases 2005;19:376-83

Source of funding: Norwegian Foundation for Health and Rehabilitation. Limitations: QALYs not used. Some uncertainty about the applicability of Norwegian resource use and unit costs. Resource use from >10 years ago year; unit cost year unclear. RCT-based analysis so from one study by definition therefore not reflecting all evidence in area. Some uncertainty about whether time horizon is sufficient. Limited sensitivity analysis. Other: n/a.

Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported;; RCT = randomised clinical trial

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations

Dysphagia

I.1.7 K. Marsh, E. Bertranou, H. Suominen, and M. Venkatachalam. An economic evaluation of speech and language therapy. Anonymous. Anonymous.

London: Matrix Evidence. 2010.

Study details	Population & interventions	Costs‡	Health outcomes	Cost effectiveness
Economic analysis: cost analysis	Population: Patients with stroke within the previous 7 days with a clinical diagnosis of swallowing difficulty and no history of swallowing treatment or surgery of the head or neck.	Intervention cost per patient: Intvn 1: £219 Intvn 2: £59 Incremental (2-1): saves £160	NR	NR
Study design: Decision tree model		Cost of chest infections: Intvn 1: £440 Intvn 2: £813 Incremental (2-1): £373		Analysis of uncertainty: Analysis was undertaken to observe the sensitivity of the total cost to a change in 2 parameters - the probability of developing chest infection with SLT and the cost of chest infections.
Approach to analysis: Patients received the intervention and could	Cohort settings: Age = 69-72 years M = NR			The probability of developing a chest

I.1.7 K. Marsh, E. Bertranou, H. Suominen, and M. Venkatachalam. An economic evaluation of speech and language therapy. Anonymous. Anonymous.

London: Matrix Evidence. 2010.

<p>go on to develop a chest infection or not. Patients with a chest infection could be treated in either the community or hospital.</p> <p>Perspective: UK NHS</p> <p>Time horizon: 1 year</p> <p>Treatment effect duration: maximum of one month</p> <p>Discounting: NA</p>	<p>Intervention 1: Standard 'low intensity swallowing therapy - 7.8 sessions equivalent to 3.22 hours. Intervention delivered by a Band 7 hospital SLT.</p> <p>Intervention 2: Usual care - 4.8 sessions equivalent to 1.28 hours for one month. Intervention delivered by an NHS hospital day nurse (non-specialised staff).</p> <p>See Canarby study in clinical review section.</p>	<p>Total costs per patient Intvn 1: £659 Intvn 2: £872 Incremental (2-1): £213</p> <p>Currency & cost year: 2009 UK pounds</p> <p>Cost components incorporated: Costs of staff time, costs of treating chest infections in hospital and community.</p>	<p>infection with standard therapy was varied between 25% and 40%. Standard low intensity swallowing therapy was cost saving as long as this probability was below 38%.</p> <p>The cost of chest infection requiring hospital admission was varied between £1,800 and £5,100. Standard low intensity swallowing therapy was cost saving as long as the costs were above £2,000.</p>
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Data sources

Health outcomes: treatment effect (probability of developing a chest infection) from Carnaby et al 2006⁹ (included in the review), probability of receiving either hospital or community treatment from Guest et al 1997.

Cost sources: staff time- PSSRU 2009, treatment of chest infection - Guest et al 1997 (updated to 2009 prices).

Comments

Source of funding: Royal College of Speech and Language Therapists

Limitations: The probability of requiring hospital or community care for chest infection was based on data not specific to people with dysphagia. Effectiveness data on chest infections is based on one RCT so does not reflect all the evidence in this area as our clinical review included more studies.

I.1.7 K. Marsh, E. Bertranou, H. Suominen, and M. Venkatachalam. An economic evaluation of speech and language therapy. Anonymous. Anonymous.

London: Matrix Evidence. 2010.

Others: the authors labelled this study as a cost-benefit analysis, however it is in fact a cost analysis taking into account initial and future costs.

Overall applicability*: Partially applicable Overall quality**: Minor limitations

Abbreviations: Intvn = intervention; NR = not reported;

‡ costs per patient were calculated by NCGC based on the overall costs of a population of ~63,000 patients.

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious Limitations / Very serious limitations

Aphasia

I.1.8 K. Marsh, E. Bertranou, H. Suominen, and M. Venkatachalam. An economic evaluation of speech and language therapy. Anonymous. Anonymous.

London: Matrix Evidence. 2010.

Study details	Population & interventions	Costs‡	Health outcomes	Cost effectiveness
<p>Economic analysis: cost-utility analysis</p> <p>Study design: Decision tree model based on an RCT.⁶</p> <p>Patients entering the model received either intervention. Following</p>	<p>Population: First time stroke patients (mean days post stroke onset: 31) with a score of <93.8 on Western Aphasia Battery.</p> <p>Patients characteristics in the RCT: See study by Bakheit et al (2007) in clinical review section.</p> <p>Cohort settings:</p>	<p>Total costs per patient Intvn 1: £469 Intvn 2: £1313 Incremental (2-1): £844</p> <p>Currency & cost year: 2009 UK pounds</p>	<p>Primary outcome measure: Improvement in Western Aphasia Battery score: Intvn 1: 42.58% Intvn 2: 79.42% Incremental (2-1): 36.84%</p>	<p>ICER (Intvn 2 versus Intvn 1): £14,807 per QALY gained CI: NR</p> <p>Analysis of uncertainty: Analysis was undertaken to observe the sensitivity of the net benefit to a change in 2 parameters improvement in WAB scores and the incremental QALY gain.</p>

I.1.8 K. Marsh, E. Bertranou, H. Suominen, and M. Venkatachalam. An economic evaluation of speech and language therapy. Anonymous. Anonymous.

London: Matrix Evidence. 2010.

<p>this, a WAB test was conducted. The improvement in WAB test scores (from baseline to 24 weeks) was calculated and converted to aphasia test scores. These scores were then translated to the Barthel index. The QALY gain was obtained by mapping from the Barthel index to QALY values.</p> <p>Perspective: UK NHS Time horizon: 1 year Treatment effect duration: NR Discounting: NA</p>	<p>70-73 years old M = NR</p> <p>Intervention 1: Standard SLT for 2 hours a week for 12 weeks; in practice however usual SLT was 6.9 hours per patient over 12 weeks.</p> <p>Intervention 2: Enhanced SLT for 2 hours a week for 12 weeks; in practice however enhanced SLT was 19.3 hours per patient over 12 weeks.</p>	<p>Cost components incorporated: Community SLT costs (band 7)</p>	<p>QALY gain: Intvn 1: 0.120 Intvn 2: 0.177 Incremental (2-1): 0.057</p>	<p>The percentage improvement in WAB test following enhanced SLT was varied between 70% and 80%. Enhanced SLT remained cost-effective as long as the improvement was above 72%.</p> <p>The change in QALY gain was varied between 0.040 and 0.058. Enhanced SLT remained cost-effective as long as the incremental QALY gain was above 0.042.</p>
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Data sources

Health outcomes: treatment effect (Improvement in Western Aphasia Battery score) from Bakheit 2007⁶ (included in the review),
 Quality-of-life weights: QALY gains were obtained by mapping from the Barthel index to EQ5D using a linear regression analysis reported in a paper by Exel et al (2004).³¹
 Resource use: Bakheit et al 2007⁶
 Cost sources: staff time- PSSRU 2009 (cost of £67 per hour client contact with a community speech and language therapist Band 7 was used).¹⁰

I.1.8 K. Marsh, E. Bertranou, H. Suominen, and M. Venkatachalam. An economic evaluation of speech and language therapy. Anonymous. Anonymous.

London: Matrix Evidence. 2010.

Comments

Source of funding: Royal College of Speech and Language Therapists

Limitations: The conversion of WAB test scores into QALY gains was based on a number of assumptions. For example, it assumed that the WAB test is comparable to the Aphasia test and that both scales have a similar distribution. The WAB test is scored out of 1 to 100, while the aphasia test is scored between 0 and 20. Issues around translation aphasia scales to the Barthel index which measures function.

The effectiveness data used in the analysis is based on one RCT, however the NCGC clinical review has identified additional relevant studies.

Others: The original RCT compared enhanced SLT also with intensive SLT; however intensive SLT had no significant effect over and above enhanced SLT, therefore intensive SLT was not considered in the economic analysis (it would be dominated by enhanced SLT).

Overall applicability*: Directly applicable Overall quality**: Potentially serious limitations

Abbreviations: Intvn = intervention; NR = not reported; QALY=quality-adjusted life year; SLT=speech and language therapy.

‡ costs per patient were calculated by NCGC based on the overall costs of a population of ~63,000 patients.

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations

I.1.9 MCNAMEE PAUL, CHRISTENSEN JAKO, SOUTTER JENN, et al. Cost analysis of early supported hospital discharge for stroke. Age and Ageing 1998 May 1;27:345-51.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA</p> <p>Study design: Within-RCT analysis</p> <p>Approach to analysis: Analysis of individual level resource use,</p>	<p>Population: Patients admitted with acute stroke within 72 h of onset from their own homes with no co-morbidity likely to affect rehabilitation</p> <p>N = 92</p> <p>M /F = 50/42</p>	<p>Total costs (mean per patient):</p> <p>Intvn 1: £7480</p> <p>Intvn 2 (2-1): £7155</p> <p>Incremental (2-1): -£325 (CI NR; p=NR)</p>	<p>From clinical review – Rodgers 1997²⁶</p> <p>Mortality (RR): 0.25 (0.03, 2.15)</p>	<p>Primary ICER (Intvn 2 versus Intvn 1): ICER: n/a</p> <p>CI: n/a</p> <p>Probability cost-effective: n/a</p> <p>Other: n/a</p>

I.1.9 MCNAMEE PAUL, CHRISTENSEN JAKO, SOUTTER JENN, et al. Cost analysis of early supported hospital discharge for stroke. Age and Ageing 1998 May 1;27:345-51.

<p>with unit costs applied.</p> <p>Perspective: UK NHS and PSS</p> <p>Time horizon: 6 months</p> <p>Treatment effect duration: n/a</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p>	<p>Mean age = NR</p> <p>Country = UK</p> <p>Intervention 1: Conventional hospital care (CHC)</p> <p>N = 46</p> <p>Mean age = NR</p> <p>M/F = 24/22</p> <p>Drop-outs = NR</p> <p>Intervention 2: Early supported discharge (ESD)</p> <p>N = 46</p> <p>Mean age = NR</p> <p>M/F = 26/20</p> <p>Drop-outs = NR</p>	<p>Hospital inpatient costs (mean per patient):</p> <p>Intvn 1: £5453</p> <p>Intvn 2: £3091</p> <p>Incremental (2-1): -£2362 (CI NR; p=NR)</p> <p>Rehabilitation costs/Additional service costs (mean per patient):</p> <p>Intvn 1: £1279</p> <p>Intvn 2: £3613</p> <p>Incremental: £2334 (CI NR; p=NR)</p> <p>Other service costs (mean per patient):</p> <p>Intvn 1: £748</p> <p>Intvn 2: £451</p> <p>Incremental (2-1): -£297 (CI NR; p=NR)</p> <p>Currency & cost year: 1995 UK pounds</p> <p>Cost components</p>		<p>Subgroup analyses:</p> <p>Patients were divided into three sub-groups based on three bands of 7-day Barthel ADL scores.</p> <p>Band 7-day Barthel score of 0 -8</p> <p>ESD (N = 11); Median Barthel score: 6; average cost: £14,643</p> <p>CHC (N = 10); Median Barthel score: 7; average cost: £15,975</p> <p>P value= ns</p> <p>Band 7-day Barthel score of 9-12</p> <p>ESD (N = 9); Median Barthel score: 11; average cost: £5713</p> <p>CHC (N = 13); Median Barthel score: 9; average cost: £6397</p> <p>P value= ns</p> <p>Band 7-day Barthel score of 13-20</p> <p>ESD (N = 26); Median Barthel score: 17; average cost: £3598</p> <p>CHC (N = 23); Median Barthel score: 17; average cost: £1198</p> <p>P value = 0.001</p> <p>Analysis of uncertainty: Two one-way sensitivity analyses were performed. Bed-day costs were varied using the highest and lowest average bed day cost estimates provided by Newcastle and North Tyneside Health Authority. In the lower band ESD was no longer cost saving (incremental</p>
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1.1.9 MCNAMEE PAUL, CHRISTENSEN JAKO, SOUTTER JENN, et al. Cost analysis of early supported hospital discharge for stroke. Age and Ageing 1998 May 1;27:345-51.

incorporated:
Hospital inpatient costs
Rehabilitation staff costs
(physiotherapy; occupational
therapy; speech therapy;
district nursing; social work;
home care)
Other services (day-hospital
care; outpatient care; general
practitioner care).

cost: £578), while application of the upper
band increased the cost saving with ESD to -
£1126.
Second, service coordinator and
implementation costs were excluded to
provide an estimate of recurrent costs. This
reduced costs for ESD by £800 to £6355 per
patient.

Data sources

Health outcomes: Within-RCT analysis (reported separately in Rodgers 1997²⁶ study included in clinical review). Quality-of-life weights: n/a. Cost sources: Resource use: Within-RCT analysis. Unit costs: Inpatient costs valued using local weighted average specialty costs per bed day based on 1995/6 contract prices. Weights reflected relative physical dependency measured by the average of 7-day and discharge Barthel ADL scores. Local staff unit costs for rehabilitation programmes. Unit costs of other services derived from PSSRU 1995.

Comments

Source of funding: National CVD and Stroke Research and Development Programme. Limitations: QALYs not used. Some uncertainty about the applicability of resource use and unit costs from over 10 years ago. RCT-based analysis so from one study by definition therefore not reflecting all evidence in area. Local costs used; some uncertainty as to whether these will reflect national costs. Some uncertainty about whether time horizon is sufficient. Doesn't report if residential care has been considered in analysis. Other: n/a.

Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; RCT = randomised clinical trial

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious Limitations / Very serious limitations

I.1.10 M. Moodie, D. Cadilhac, D. Pearce, C. Mihalopoulos, R. Carter, S. Davis, and G. Donnan. Economic evaluation of Australian stroke services: a prospective, multicentre study comparing dedicated stroke units with other care modalities. Stroke 37 (11):2790-2795, 2006.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA</p> <p>Study design: Within-trial analysis</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied.</p> <p>Perspective: Australian health care system</p> <p>Time horizon: 28 weeks</p> <p>Treatment effect duration: n/a</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p>	<p>Population:</p> <p>Patients presenting to hospital within three days of onset of first-ever or recurrent attacks of stroke.</p> <p>N = 395†</p> <p>Country = Australia</p> <p>Intervention 1:</p> <p>Conventional care (defined as general medical ward care with no dedicated stroke service or health professional team)</p> <p>N = 84</p> <p>M = 45%</p> <p>Median age = 77</p> <p>Intervention 2:</p> <p>Stroke care unit (defined as a designated ward where a dedicated multidisciplinary stroke team focuses its expertise.</p> <p>N = 102</p> <p>M = 61%</p>	<p>Total costs</p> <p>Intvn 1: £6073</p> <p>Intvn 2: £7626</p> <p>Incremental (2-1): £1553</p> <p>Currency & cost year: Costs reported as 1998 Australian dollars (presented here as 1998 UK pounds‡)</p> <p>Cost components incorporated:</p> <p>Pre-hospital (referral and transport costs)</p> <p>Acute admission costs</p> <p>Post- acute care (rehabilitation, community support)</p> <p>The costs of visits to a general practitioner and allied health professionals were also captured.</p>	<p>Primary outcome measure</p> <p>Thorough adherence to defined process of care measures (number per 1000)</p> <p>Intvn 1: 36</p> <p>Intvn 2: 353</p> <p>Incremental (2-1): 317</p> <p>Rates of severe medical complications (number per 1000)</p> <p>Intvn 1: 158</p> <p>Intvn 2: 59</p> <p>Incremental (2-1): -99</p>	<p>Primary ICER (Intvn 2 vs. Intvn 1): £4891 per patient with thorough adherence gained</p> <p>£8116 per patient with severe complications avoided.</p> <p>CI: NR</p> <p>Probability cost-effective: NR</p> <p>Subgroup analyses: N/A</p> <p>Analysis of uncertainty: NR</p>

I.1.10 M. Moodie, D. Cadilhac, D. Pearce, C. Mihalopoulos, R. Carter, S. Davis, and G. Donnan. Economic evaluation of Australian stroke services: a prospective, multicentre study comparing dedicated stroke units with other care modalities. Stroke 37 (11):2790-2795, 2006.

Median age = 75

Data sources

Health outcomes: Within-study analysis

Quality-of-life weights: n/a

Cost sources: Hospital Finance departments, Professional associations, Nation references e.g. Medicare Benefits Schedule

Comments

Source of funding: Department of Human Services Victoria, the Ian Potter Foundation and the National Stroke Foundation of Australia

Limitations: Not a full economic evaluation since QALYs were not calculated. Uncertainty as to whether the care of patients with stroke in Australia is comparable to the UK health system. This would have implications for the cost components included in the analysis. The age of this study also means that it may not reflect current practice. There is some uncertainty about the comparability of the health outcomes in the analysis to those specified in the review protocol. The primary health outcome was defined as adherence to 15 process indicators including CT scan, swallowing assessment, neurological observations and the use of anti-platelet agents. The results can be interpreted as stroke units providing a higher quality of care as there was higher adherence to the process indicators. It could be inferred that higher quality of care would impact on factors such as mortality and length of hospital stay, however, the magnitude is unknown. The major cost drivers were nursing and medical costs which were higher in the stroke units. This could be due to the use of more specialised staff on stroke units.

Overall applicability*: Partially applicable Overall quality**: Very serious limitations

Abbreviations: NR = not reported; N/A= not applicable; ‡ Converted using 1998 Purchasing Power Parities²⁵; †trial included a third arm (mobile service) which has been excluded from results presented here as it is not a relevant comparator.

I.1.11 National Audit Office. Progress in Improving Stroke Care: report by the Comptroller and Auditor General. London: National Audit Office; 2010. Report No.: HC 291.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis:	Population:	Total costs (mean per	0.13 QALYs	Primary ICER (Intvn 2 versus Intvn 1):

1.1.11 National Audit Office. Progress in Improving Stroke Care: report by the Comptroller and Auditor General. London: National Audit Office; 2010. Report No.: HC 291.

<p>CUA</p> <p>Study design: Decision analytic model</p> <p>Approach to analysis: Discrete event simulation model comparing current with pre National Stroke Strategy (2006) provision of ESD. Health states modelled were severe, moderate and mild disability, depending on a patient's Barthel score.</p> <p>Treatment effects (probability of being mild, moderate or severe) determined at 1 year.</p> <p>Perspective: UK NHS and PSS</p> <p>Time horizon: 10 years</p> <p>Treatment effect duration: Unclear – possibly 1 year.</p> <p>Discounting: Costs:</p>	<p>Patients who have suffered a stroke and who require post-discharge therapy. Mild stroke patients were excluded.</p> <p>Cohort settings: Start age = 69.89 M = NR</p> <p>Intervention 1: Conventional discharge route (inpatient and community-based care)</p> <p>Intervention 2: Early supported discharge (ESD): program of home-based care (physiotherapy; occupational therapy and speech therapy) available up to a period of 3 months, with no more than one visit per day from each type of therapist.</p>	<p>patient):</p> <p>Intvn 1: £24,855</p> <p>Intvn 2: £25, 659</p> <p>Incremental (2-1): £804 (CI NR ; p=NR)</p> <p>Currency & cost year: UK pounds. Cost year unclear: cost analysis based on Beech et al (1999). Not clear whether the cost figures were updated using inflation indexes.</p> <p>Cost components incorporated: Length of stay in acute ward; physiotherapy; occupational therapy; speech therapy; non-inpatient services (annual contacts with hospital physician; GP home visits; visits at GP surgery). Community-based services (meals on wheels; home help; district nurse; lunch club; day hospital).</p>	<p>Other outcome measures (mean): n/a</p>	<p>ICER: £6,184 per QALY</p> <p>CI: NR</p> <p>Probability cost-effective: NR</p> <p>Other: n/a</p> <p>Subgroup analyses: n/a</p> <p>Analysis of uncertainty: Deterministic uncertainty conducted on the level of discount rate (varying it from 0 to 6%) and on the extent of coverage of the ESD scheme to all stroke patients. The model findings were not sensitive to these changes.</p> <p>Not clear as to whether probabilistic sensitivity analysis was conducted.</p>
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1.1.11 National Audit Office. Progress in Improving Stroke Care: report by the Comptroller and Auditor General. London: National Audit Office; 2010. Report No.: HC 291.

3%; Outcomes: 1.5%

Data sources

Health outcomes: Barthel index disability levels based on an RCT by Rudd et al (1997)²⁷. Barthel scores converted to EQ5D using van Exel et al (2004)³¹. Quality-of-life weights: EQ5D UK tariff; Cost sources: Hospital financial records; PSSRU 2008.

Comments

Source of funding: Department of Health. Limitations: Costs and outcomes discounted at a different rate. EQ5D data not available so mapped from disease-specific measure. Unclear how the health outcomes, health and social care costs of each health states were calculated. Not clear whether the study considered the costs of long-term care such as residential care (nursing homes and residential homes). Unclear as to whether the unit costs used from Beech et al (1997) were updated to take into account of inflation or whether recent official data were used (e.g. unit costs from PSSRU). Other: n/a.

Overall applicability*: partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CUA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported;

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious Limitations / Very serious limitations

1.1.12 Teng J, Mayo NE, Latimer E, et al. Costs and caregiver consequences of early supported discharge for stroke patients. Stroke 2003;34:528-36. Ref ID: 152

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA</p> <p>Study design: Within-RCT analysis</p> <p>Approach to analysis: Analysis of individual level resource use,</p>	<p>Population: Stroke patients requiring rehabilitation who had a caregiver at home</p> <p>N = 114</p> <p>M/F = 77/37</p> <p>Mean age = 70</p> <p>Country = Canada</p>	<p>Total costs (mean per patient):</p> <p>Intvn 1: £5715</p> <p>Intvn 2: £4020</p> <p>Incremental (2-1): -£1694 (CI NR; p<0.0001)</p> <p>Currency & cost year:</p>	<p>From clinical review – Mayo 2000²⁰</p> <p>SF36 (MD): physical component 5.00 (0.82, 9.18); mental health -0.20 (-4.73, 4.33)</p> <p>Barthel 0-100 (MD): 2.0 (-1.72, 5.72)</p>	<p>Primary ICER (Intvn 2 versus Intvn 1): ICER: n/a</p> <p>CI: n/a</p> <p>Probability cost-effective: n/a</p> <p>Other: n/a</p> <p>Subgroup analyses: Analyses were</p>

I.1.12 Teng J, Mayo NE, Latimer E, et al. Costs and caregiver consequences of early supported discharge for stroke patients. Stroke 2003;34:528-36. Ref ID: 152

with unit costs applied.				
Perspective: Canadian health care system Time horizon: 3 months. Treatment effect duration: n/a Discounting: Costs: n/a; Outcomes: n/a.	Intervention 1: Usual care practices for discharge planning and referral for follow-up services N = 56 Mean age = 69.6 M = 71% Intervention 2: Early Supported Discharge (ESD) for 4 weeks from randomization. N = 58 Mean age = 70.3 M = 63%	Canadian dollars; cost year unclear – assumed to be 2000 (presented here as 2000 UK pounds#). Cost components incorporated: Acute hospitalisation, readmission, emergency room visits, outpatient visits, health and social care home visits.		undertaken looking at whether the impact of ESD on costs varied across levels of disability (Barthel score). Cost was found to have an effect on cost but this did not depend on group i.e. ESD was no more (or less) expensive for those with greater function limitation than for those with less. Analysis of uncertainty: The author's state that multiway sensitivity analysis was performed to test the robustness of the unit cost estimates but it is unclear what was done and what the result was. Only analysis reported is variation of overhead rates varied between 0% and 20% (30% in base case). The lower costs of the ESD group remained.

Data sources

Health outcomes: Within-RCT analysis (reported separately in Mayo 2000²⁰ study included in clinical review). Quality-of-life weights: n/a. Cost sources: Resource use: within-RCT analysis. Unit costs: Estimates from Quebec Hospital Association weighted average costs. Rehabilitation professionals' costs from relevant professional associations assuming 4-5years experience. Costs of physician visits based on billing records.

Comments

Source of funding: NR. Limitations: QALYs not used. Some uncertainty about the applicability of Canadian resource use and unit costs from over 10 years ago. RCT-based analysis so from one study by definition therefore not reflecting all evidence in area. Local costs used; some uncertainty as to whether these will reflect national costs. Some uncertainty about whether time horizon is sufficient. Doesn't report if residential care has been considered in analysis. Other: n/a.

Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; RCT = randomised clinical trial

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious Limitations / Very serious limitations

Converted using 2000 Purchasing Power Parities²⁵

I.1.13 von Koch L, de Pedro-Cuesta J, Kostulas V, et al. Randomized controlled trial of rehabilitation at home after stroke: one-year follow-up of patient outcome, resource use and cost. Cerebrovascular Diseases 2001;12:131-8.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA</p> <p>Study design: Within-RCT analysis</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied.</p> <p>Perspective: Swedish health care sector</p> <p>Time horizon: 12 months</p> <p>Treatment effect duration: n/a</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p>	<p>Population: Patients after stroke moderately impaired</p> <p>N = 83</p> <p>M = 55%</p> <p>Mean age = 72</p> <p>Country = Sweden</p> <p>Intervention 1: Routine rehabilitation</p> <p>N = 41</p> <p>Mean age = NR</p> <p>M/F = NR</p> <p>Drop-outs = 3 (at 12 months)</p> <p>Intervention 2: Home rehabilitation</p> <p>N = 42</p> <p>Mean age = NR</p> <p>M/F = NR</p> <p>Drop-outs = 3 (at 12 months)</p>	<p>Total costs (mean per patient):</p> <p>Intvn 1: £6252</p> <p>Intvn 2: £4919</p> <p>Incremental (2-1): -£1333 (CI NR; p=NR)</p> <p>Currency & cost year: Swedish Kroner; cost year unclear – assumed 1995 (presented here as 1995 UK sterling#)</p> <p>Cost components incorporated: Inpatient hospital care; outpatient health care; use of health-related services; informal care.</p>	<p>From clinical review – von Koch 2000, 2001^{33,34}.</p> <p>Barthel ADL (MD): 2.75 (0.77, 9.77)</p> <p>Falls (RR): 1.02 (0.72, 1.43)</p>	<p>Primary ICER (Intvn 2 versus Intvn 1): ICER: n/a</p> <p>CI: n/a</p> <p>Probability cost-effective: n/a</p> <p>Other: n/a</p> <p>Subgroup analyses: n/a</p> <p>Analysis of uncertainty: NR</p>

Data sources

Health outcomes: Within-RCT analysis (reported in same paper and included in clinical review; 6 month outcomes reported separately in von Koch 2000³⁴ and also included in clinical review). Quality-of-life weights: n/a. Cost sources: Health care and rehabilitation costs based on the official Stockholm County Council statistics and the National (Swedish) Social Insurance Board. Since the cost of home rehabilitation service delivered by the Department of Geriatrics was not available, the mean cost of a similar visit from the Department of Neurology was used.

I.1.13 von Koch L, de Pedro-Cuesta J, Kostulas V, et al. Randomized controlled trial of rehabilitation at home after stroke: one-year follow-up of patient outcome, resource use and cost. *Cerebrovascular Diseases* 2001;12:131-8.

Comments

Source of funding: Swedish Medical Research Council, the National Board of Health and Welfare, the Swedish Association of Neurologically Disabled, the Swedish Stroke Association, the Karolinska Institute and the Carlos III Institute of Public Health (Madrid). Limitations: QALYs not used. Some uncertainty about the applicability of Swedish resource use and unit costs from over 10 years ago. RCT-based analysis so from one study by definition therefore not reflecting all evidence in area. Some local costs used; some uncertainty as to whether these will reflect national costs. Some uncertainty about whether time horizon is sufficient. Doesn't report if residential care has been considered in analysis. No sensitivity analysis. Other: n/a.

Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; RCT = randomised clinical trial

** Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious Limitations / Very serious limitations*

‡ Converted using 1995 Purchasing Power Parities²⁵

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J.1 In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and/or visual neglect?

J.1.1 Cognitive rehabilitation for spatial awareness and/or neglect and visual neglect versus usual care

Figure 2: BIT (total) (post-treatment effect)

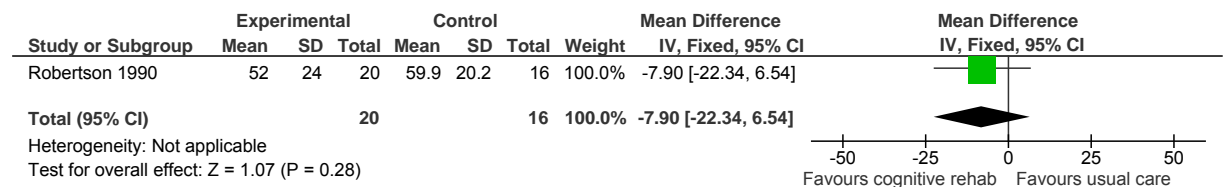


Figure 3: BIT (total) (1 month follow-up)

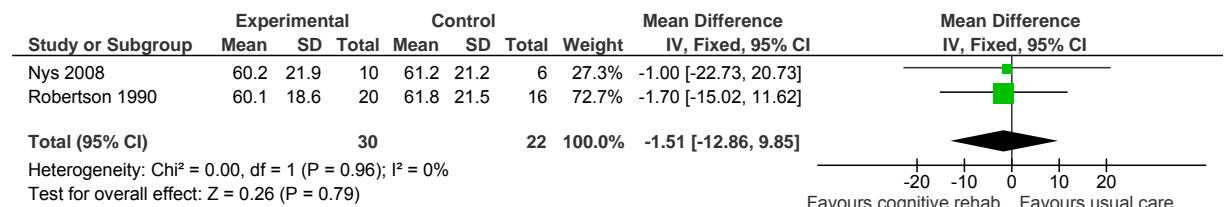


Figure 4: BIT conventional (post treatment effect)

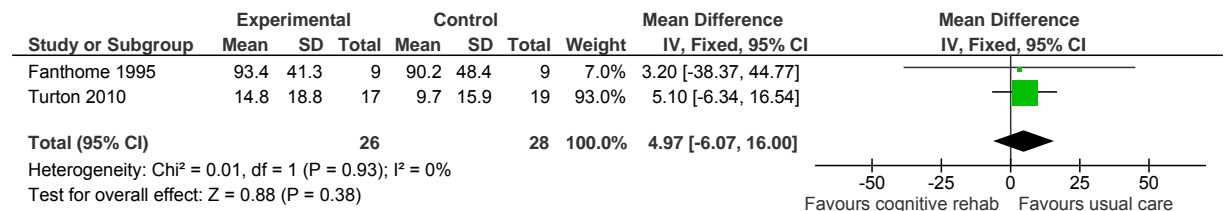


Figure 5: BIT conventional (1-2 months follow-up)

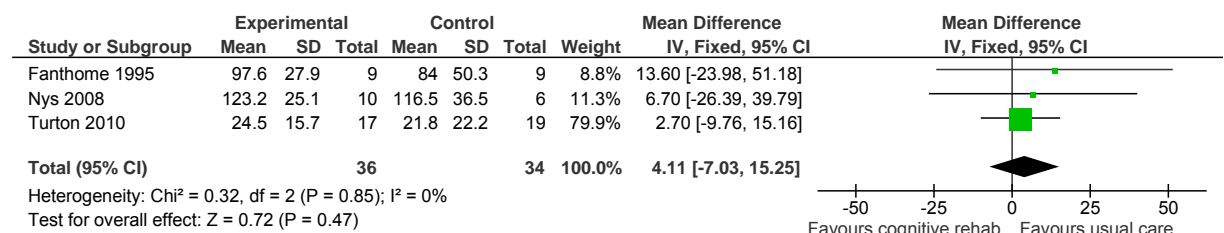
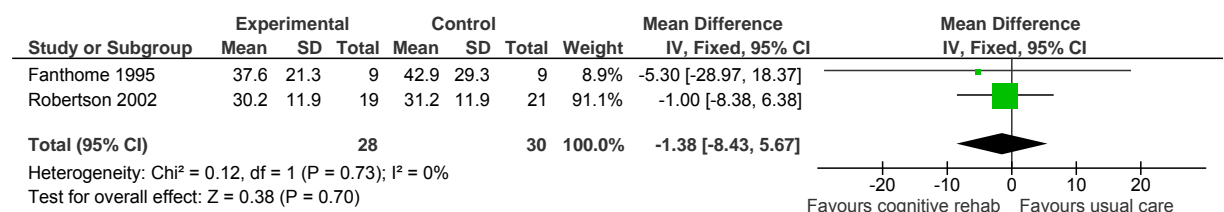


Figure 6: BIT behavioural (post-treatment effect)



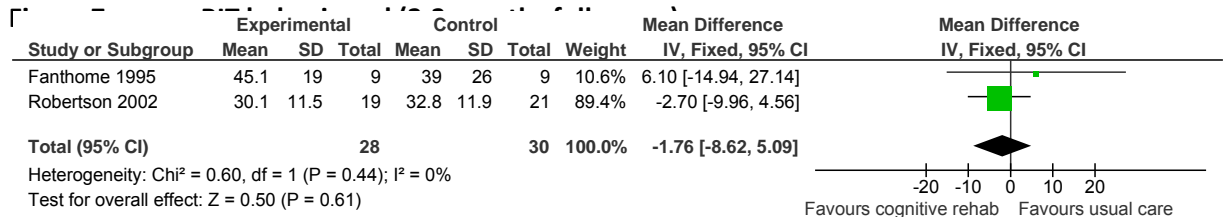


Figure 8: BIT behavioural (6 months follow-up)

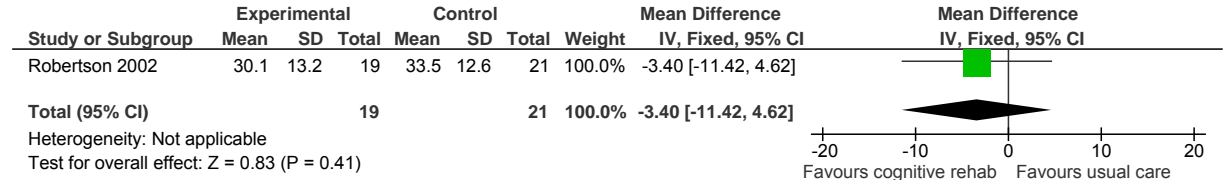


Figure 9: Line bisection (post-treatment effect)

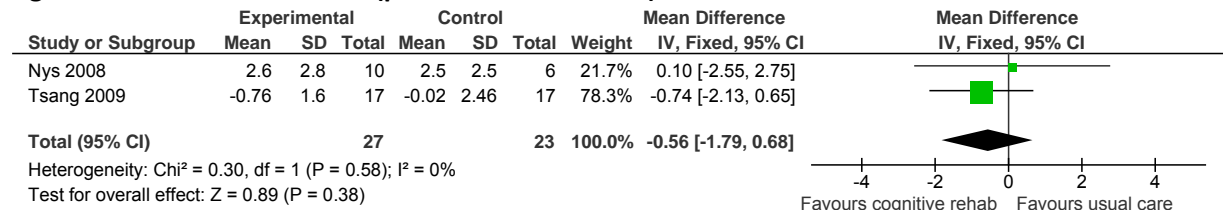


Figure 10: Line bisection (1 month follow-up)

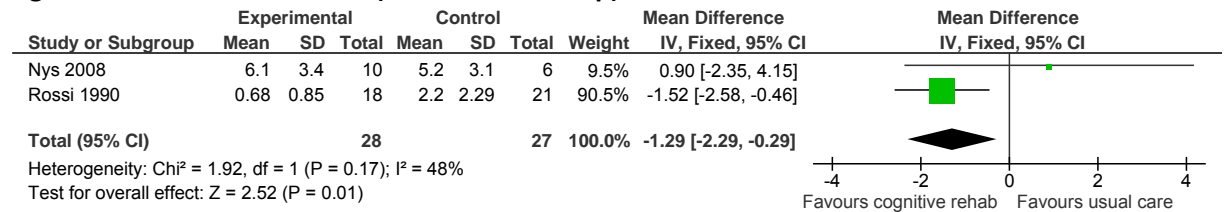


Figure 11: Star cancellation (post-treatment effect)

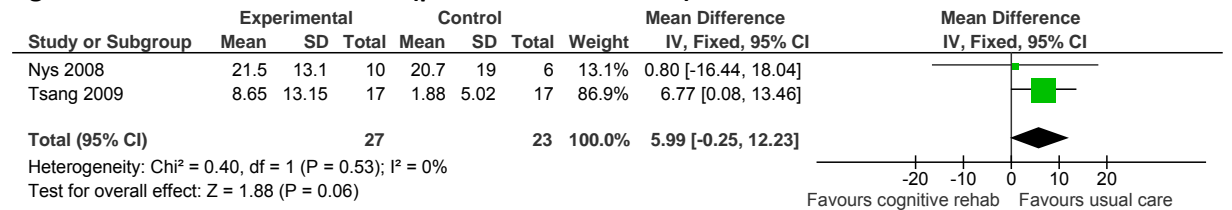


Figure 12: Star cancellation (1 month follow-up)

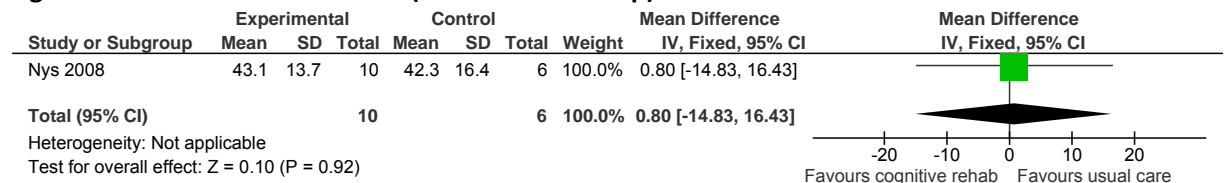


Figure 13: RPAB (total score) (post-treatment effect)

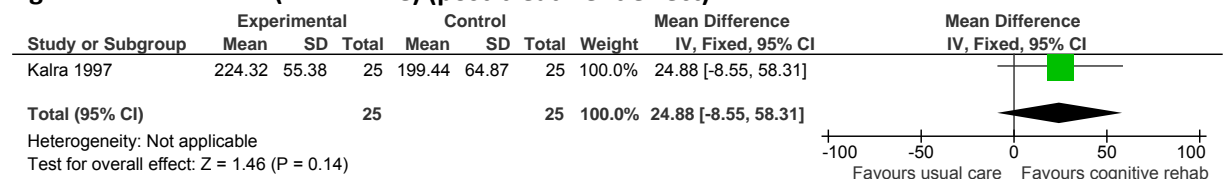


Figure 14: RPAB (cancellation subtest) (post-treatment effect)

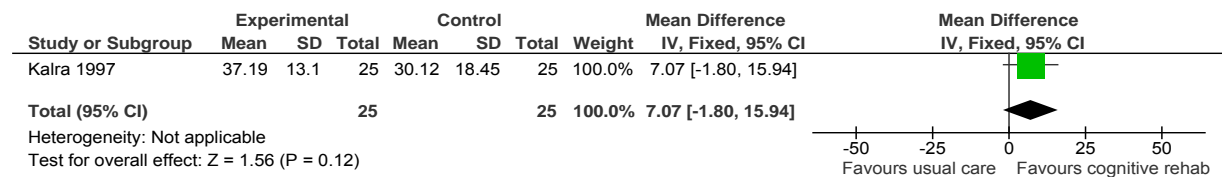


Figure 15: RPAB (body image subtest) (post-treatment effect)

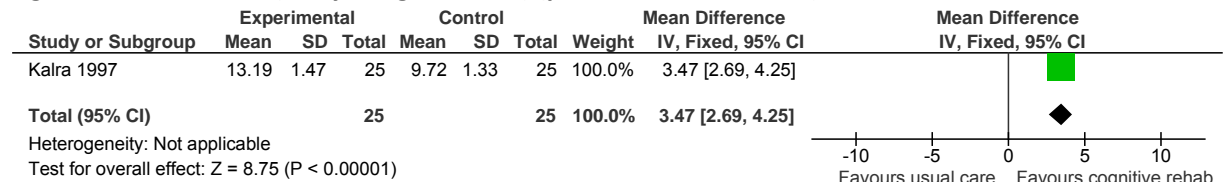


Figure 16: Letter cancellation (post-treatment effect)

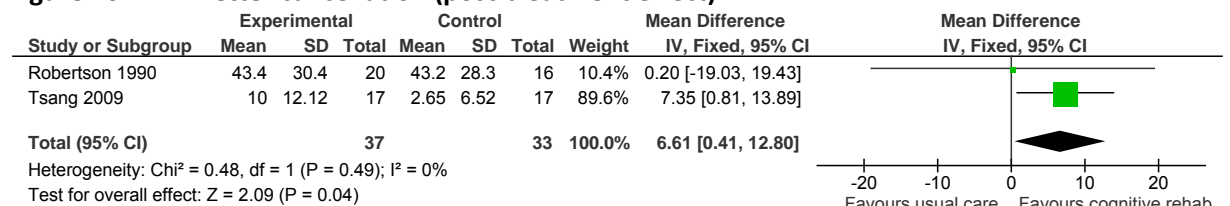


Figure 17: Letter cancellation (6 months follow-up)

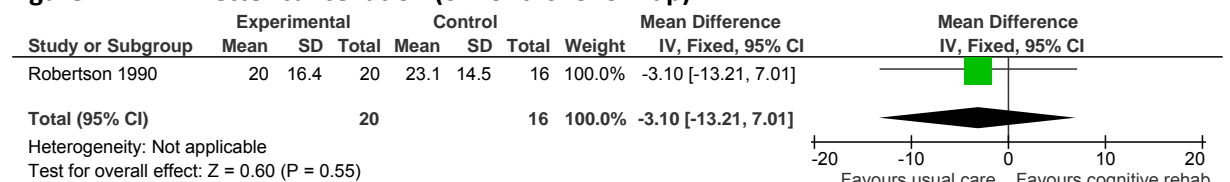


Figure 18: Tangent screen examination (post-treatment effect)

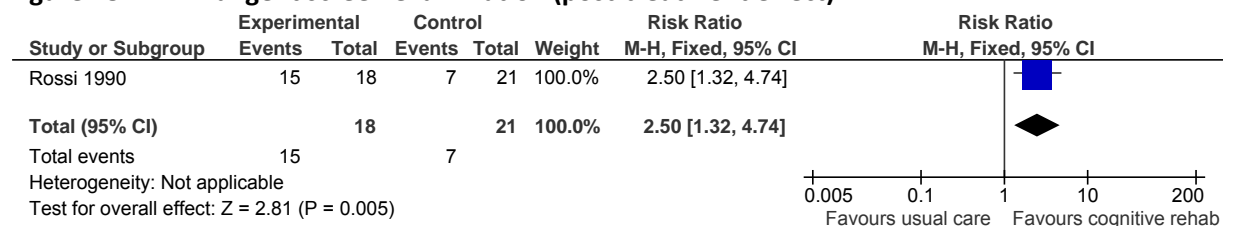


Figure 19: Line cancellation (post-treatment effect)

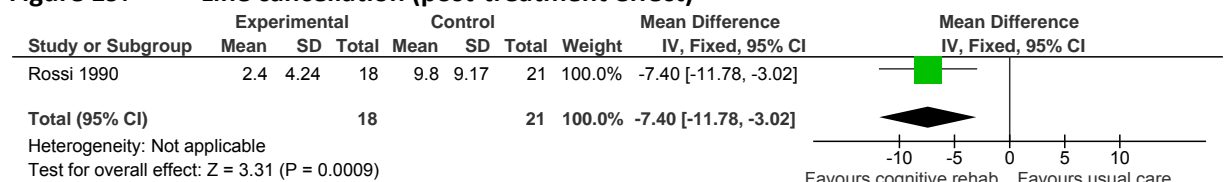
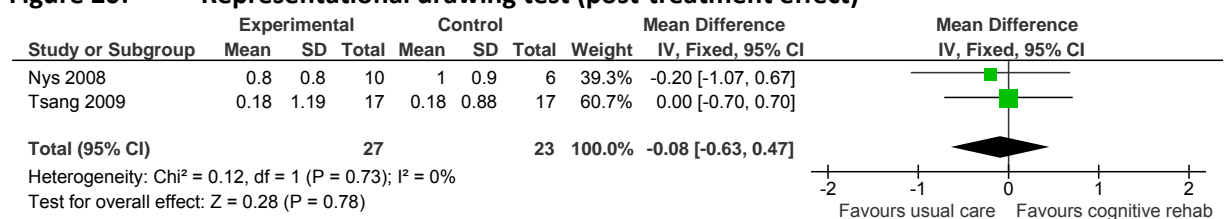
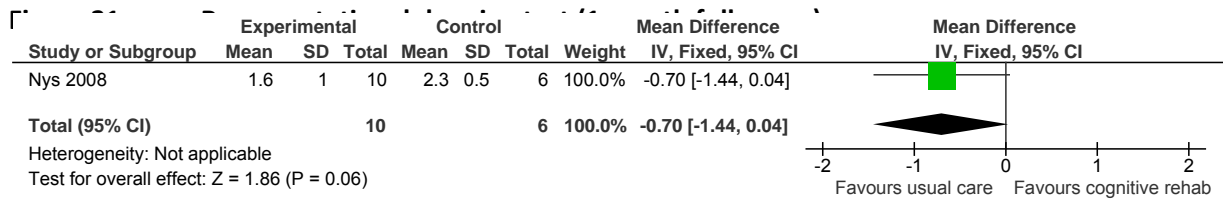


Figure 20: Representational drawing test (post-treatment effect)





J.2 In people after stroke what is the clinical and cost-effectiveness of memory strategies versus usual care to improve memory?

Figure 22: Delayed recall AVLT (Baseline adjusted beta –value for mean difference)

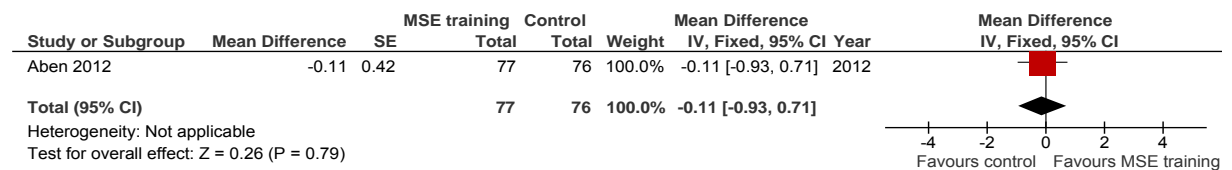


Figure 23: Delayed recall RBMT (Baseline adjusted beta –value for mean difference)

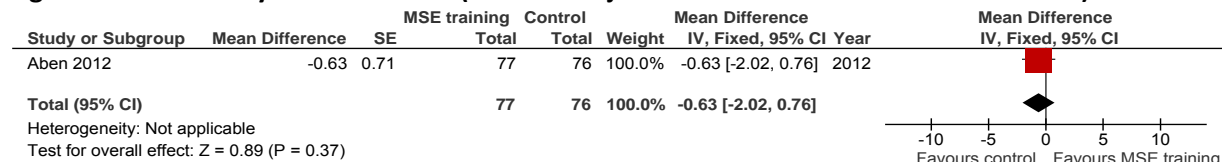


Figure 24: Memory efficacy score (baseline adjusted beta value for mean difference)

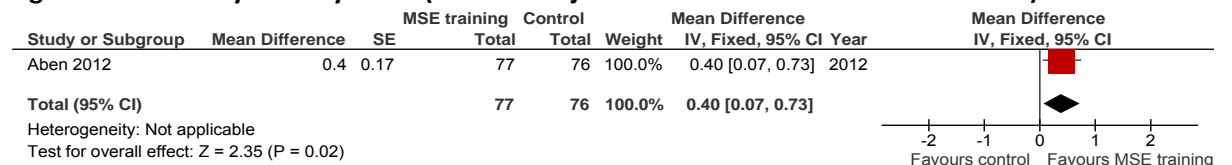
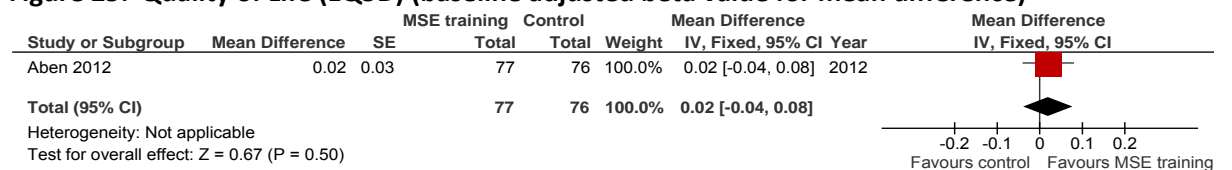


Figure 25: Quality of Life (EQ5D) (baseline adjusted beta value for mean difference)



J.3 In people after stroke what is the clinical and cost-effectiveness of sustained attention training versus usual care to improve attention?

J.3.1 Sustained attention training versus usual care

Figure 26: IVA-CPT (full attention) changes (5 weeks follow-up)

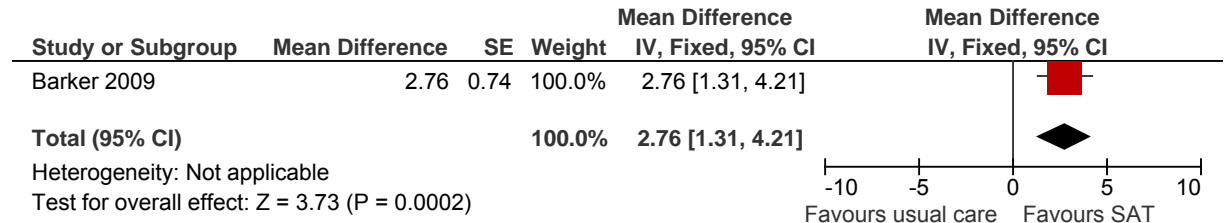


Figure 27: IVA-CPT (full attention) changes (6 months follow-up)

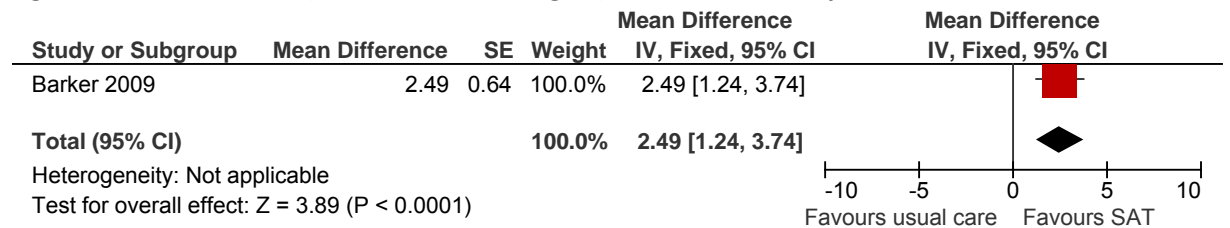


Figure 28: IVA-CPT (auditory attention) changes (5 weeks follow-up)

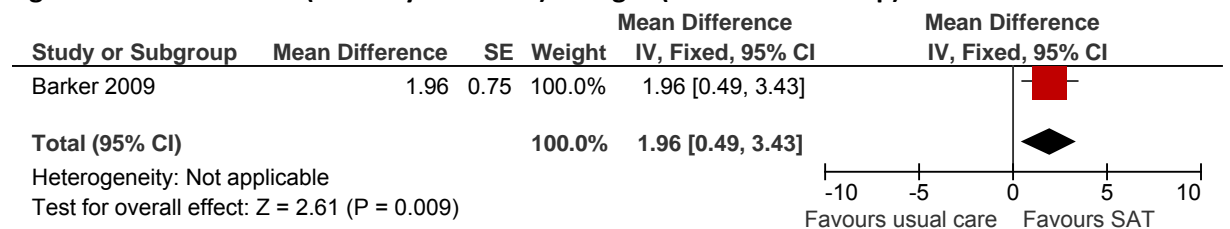


Figure 29: IVA-CPT (auditory attention) changes (6 months follow-up)

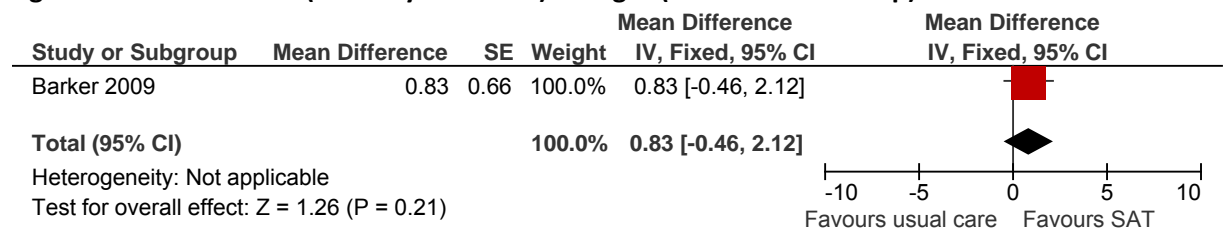
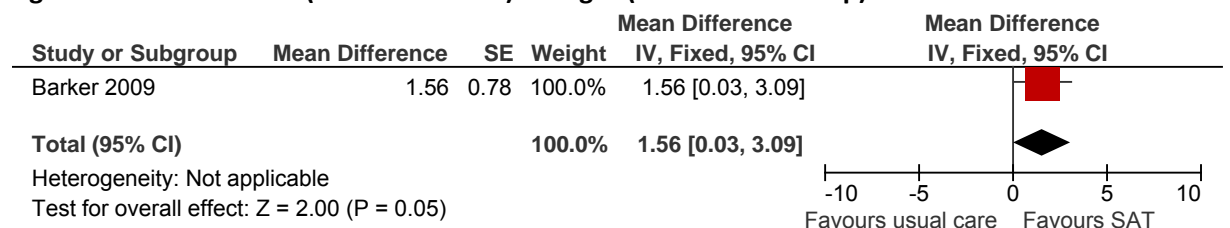
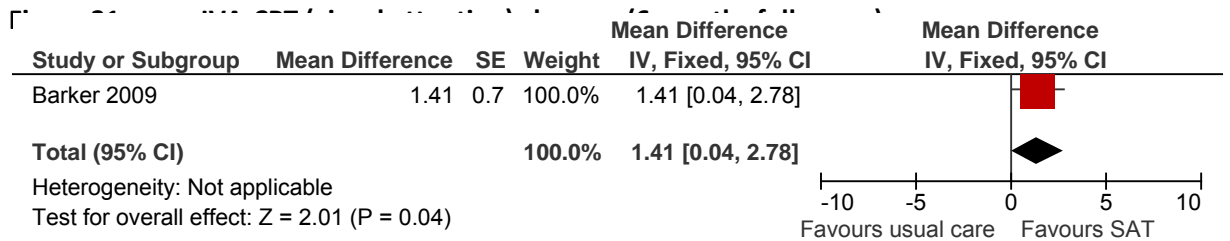


Figure 30: IVA-CPT (visual attention) changes (5 weeks follow-up)





J.3.2 Computerised working memory training versus usual care

Figure 32: Wechsler Adult intelligence Scale-Revised Spa

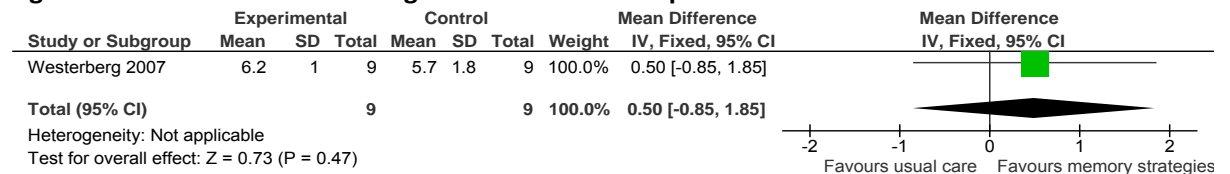


Figure 33: Wechsler Adult Intelligence Scale-Revised Digit Span (post-treatment effect)

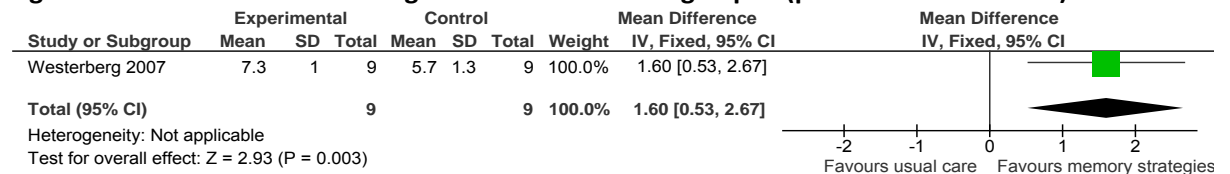


Figure 34: Stroop time (sec) (post-treatment effect)

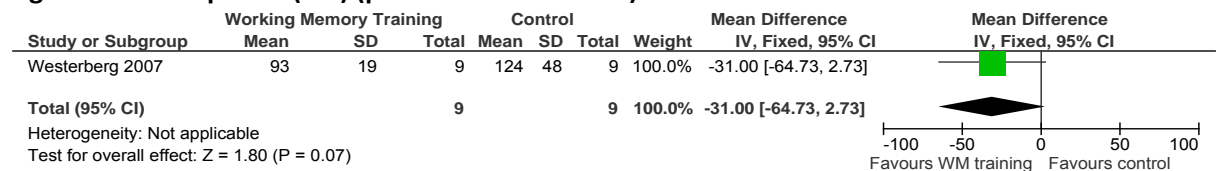


Figure 35: Stroop raw score (post-treatment effect)

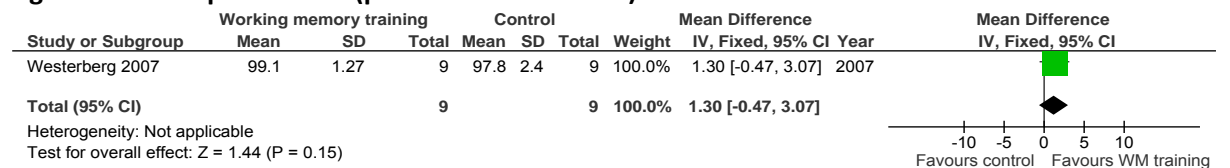
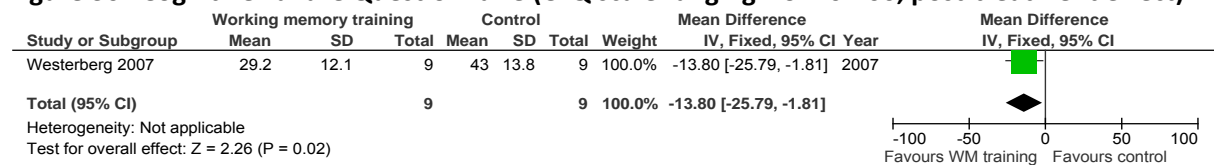


Figure 36: Cognitive Failure Questionnaire (CFQ scale ranging from 0-100, post-treatment effect)



J.4 In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?

Figure 37: Eye movement therapy (EMT) for visual field loss versus usual care

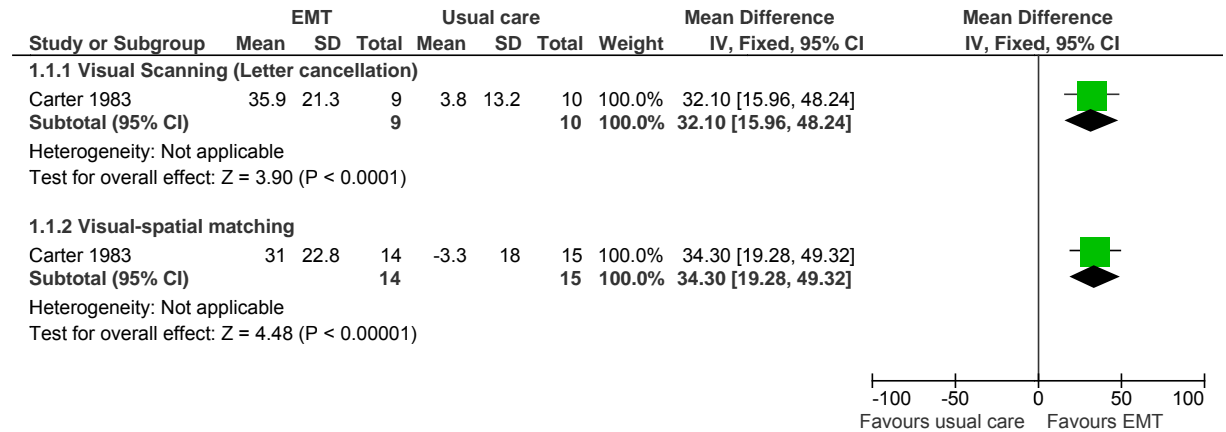


Figure 38: Visual field enlargement (TAP visual field assessment)

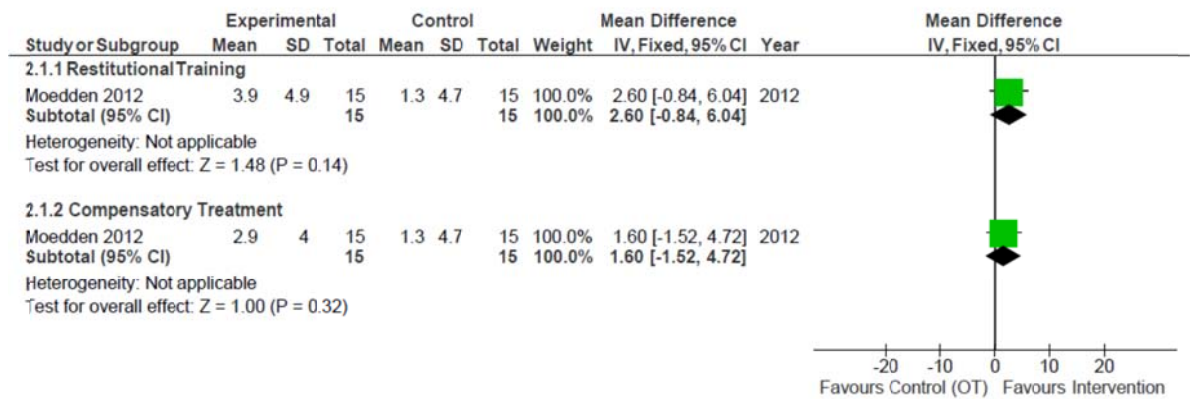


Figure 39: Visual search (BIT cancellation task)

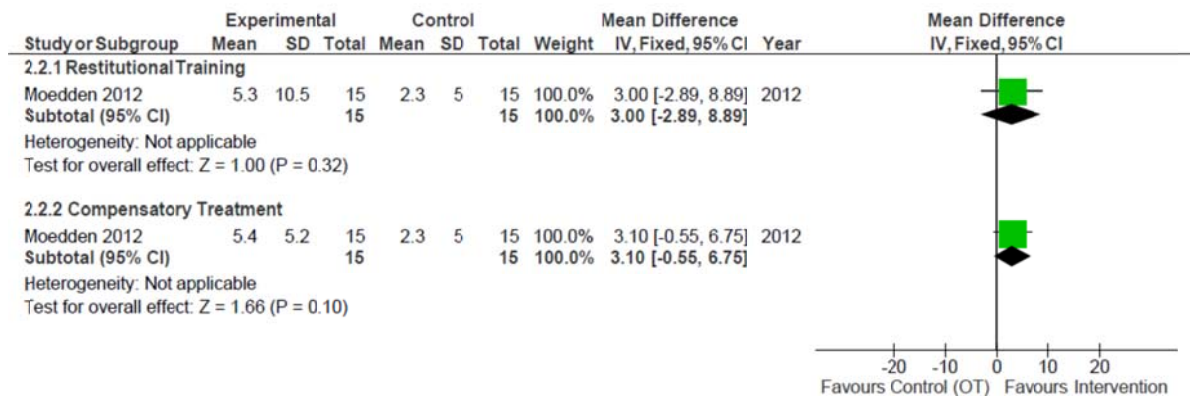


Figure 40: Reading performance (text from the Wechsler Memory Test)

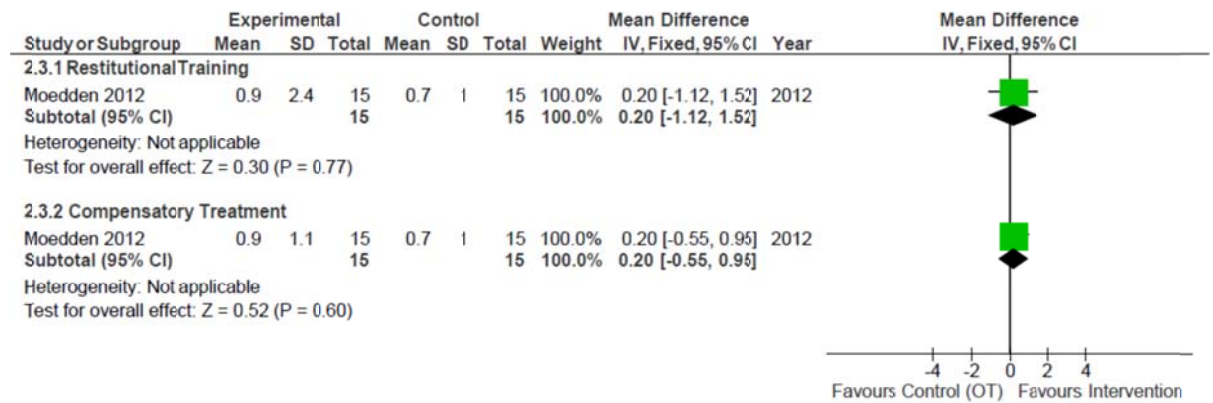


Figure 41: Attention (TAP phasic alertness)

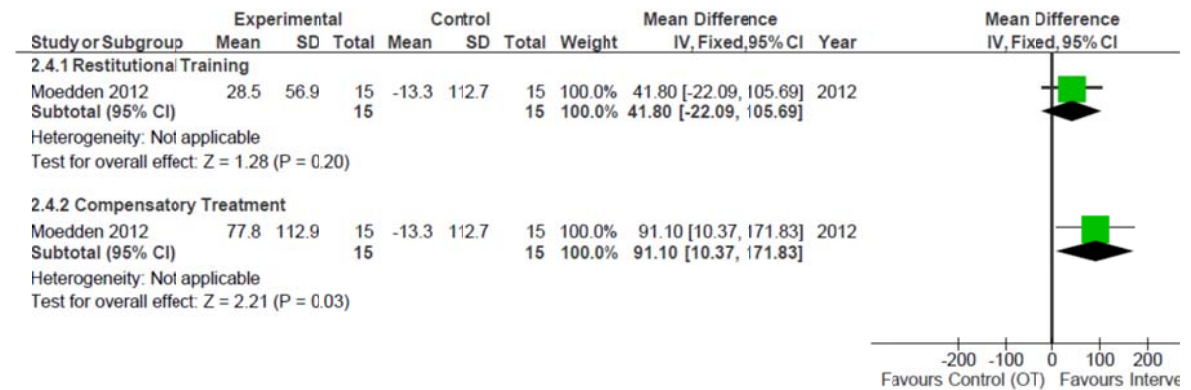


Figure 42: Visual conjunction search (TAP visual scanning)

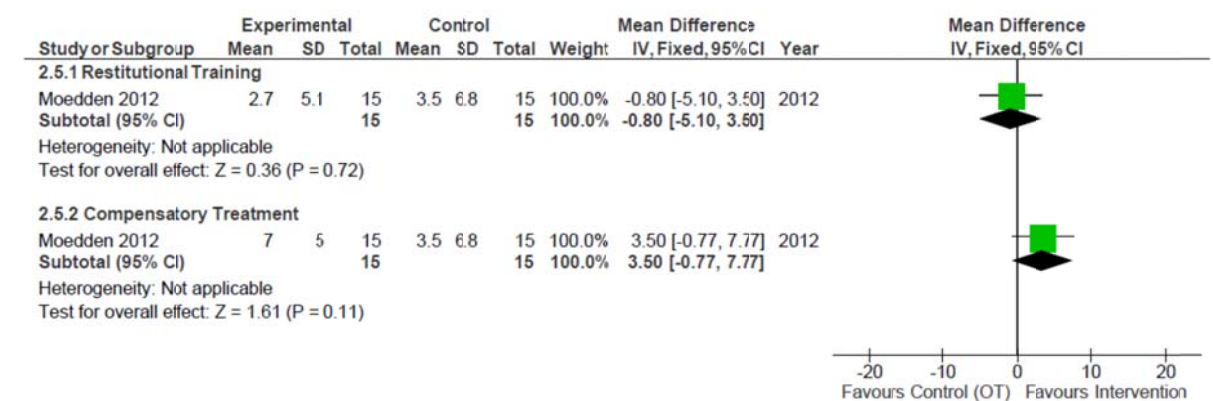
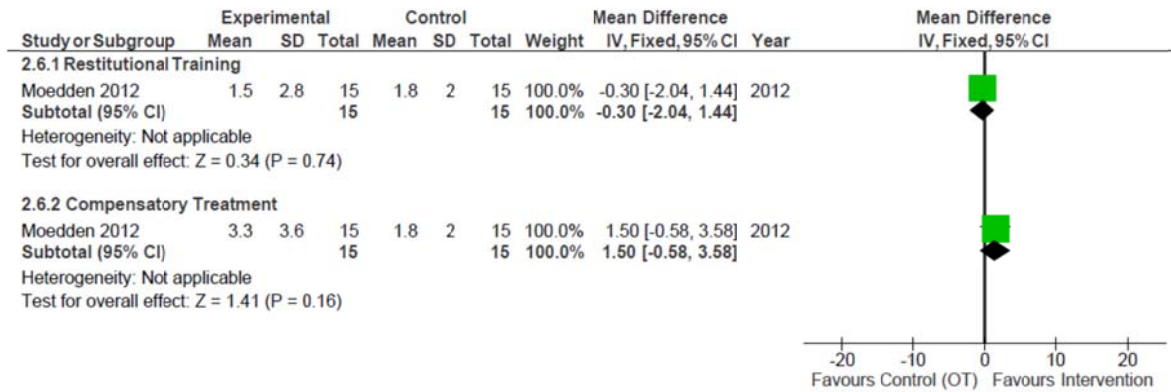


Figure 43: Extended Barthel Index



J.5 In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions/usual care to improve difficulty swallowing (dysphagia)?

J.5.1 Standard low intensity swallowing therapy (SWT) for dysphagia versus usual care

Figure 44: Return to pre stroke diet at 6 months

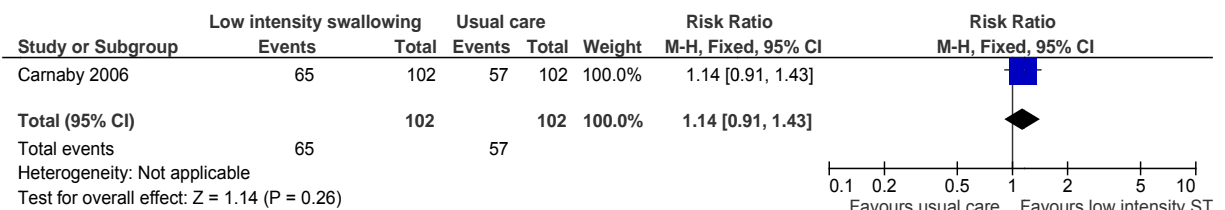
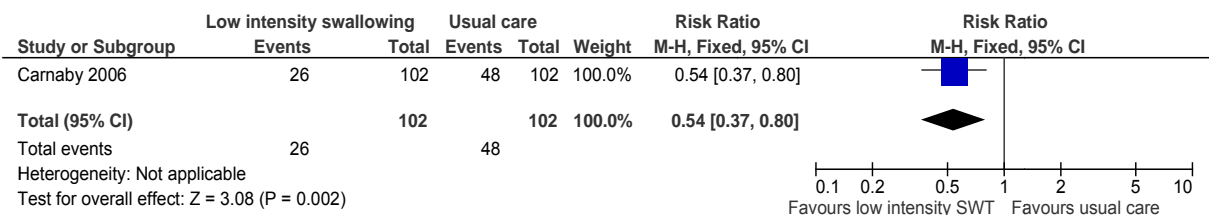


Figure 45: Incidence of severe chest infection



J.5.2 Standard high intensity swallowing therapy (SWT) for dysphagia versus usual care

Figure 46: Return to pre stroke diet at 6 months

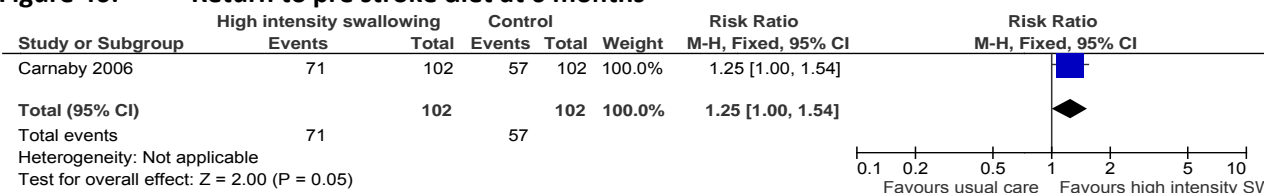
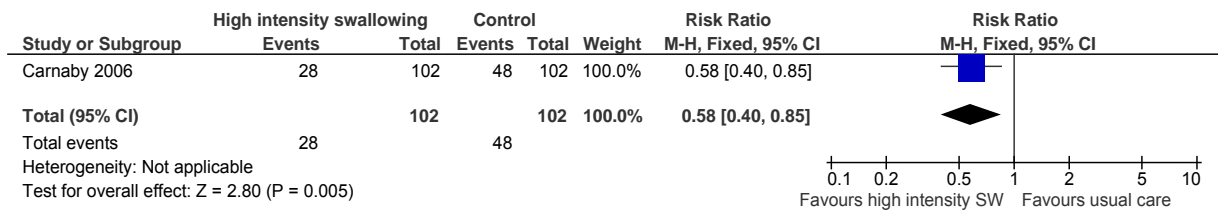
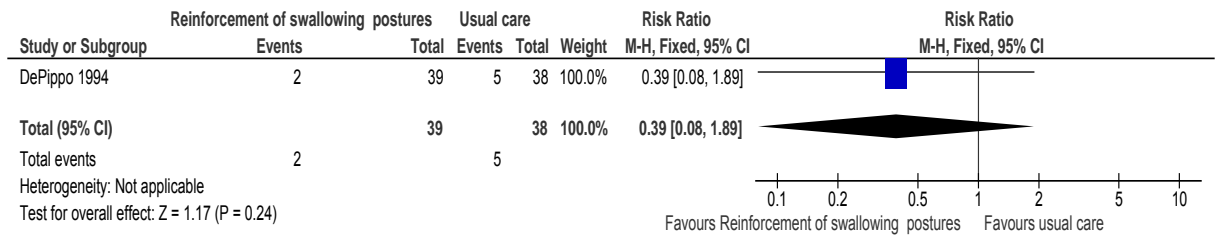


Figure 47: Incidence of severe chest infection



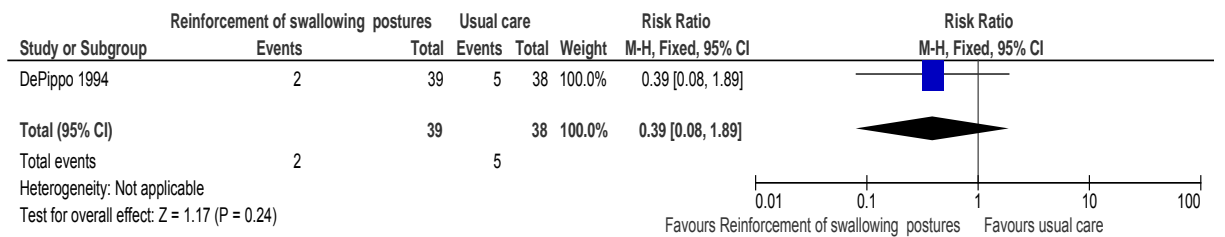
J.5.3 Reinforcement of swallowing postures versus usual care

Figure 48: Incidence of pneumonia



J.5.4 Unlimited oral intake of water in addition to thickened liquids versus thickened liquids only

Figure 49: Incidence of aspiration pneumonia



J.6 In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?

J.6.1 Functional strength training (upper, lower limb) versus usual care

Figure 50: Barthel Index (6 months follow-up)

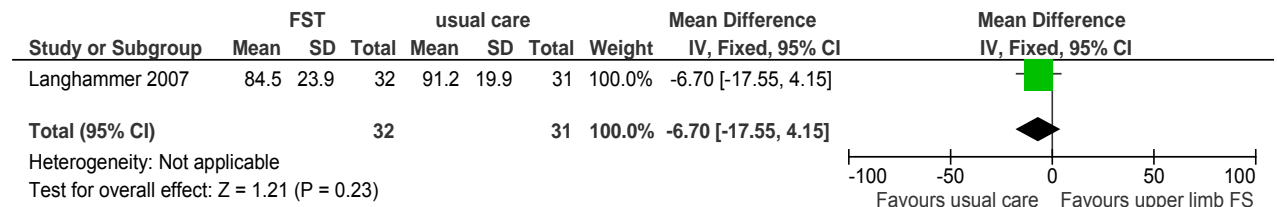


Figure 51: Grip strength paretic hand (6 months follow-up)

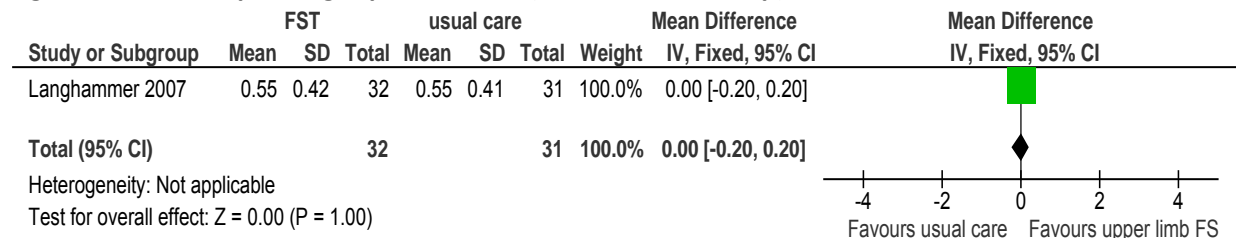


Figure 52: Grip strength non-paretic hand (6 months follow-up)

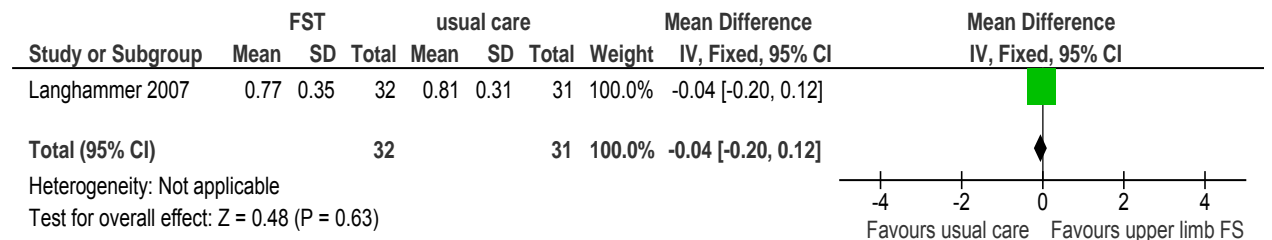


Figure 53: Barthel Index (1 year follow-up)

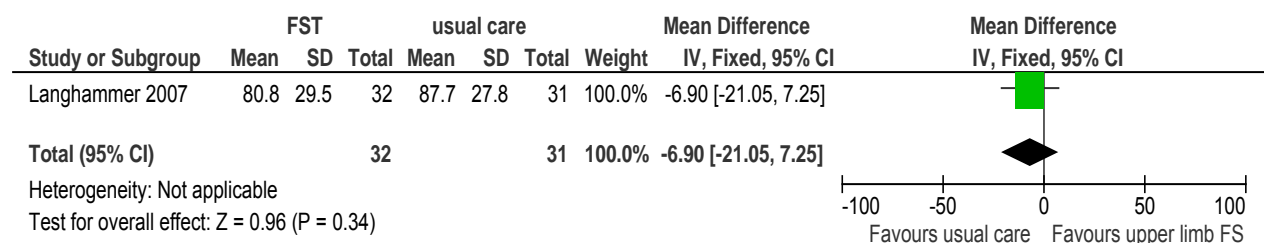


Figure 54: Grip strength paretic hand (1 year follow-up)

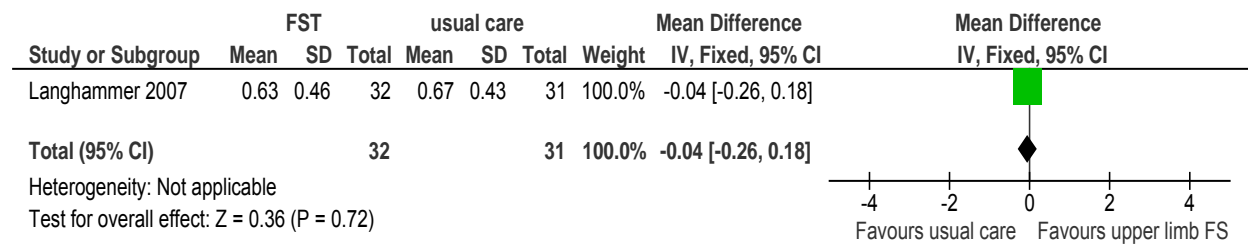


Figure 55: Grip strength non-paretic hand (1 year follow-up)

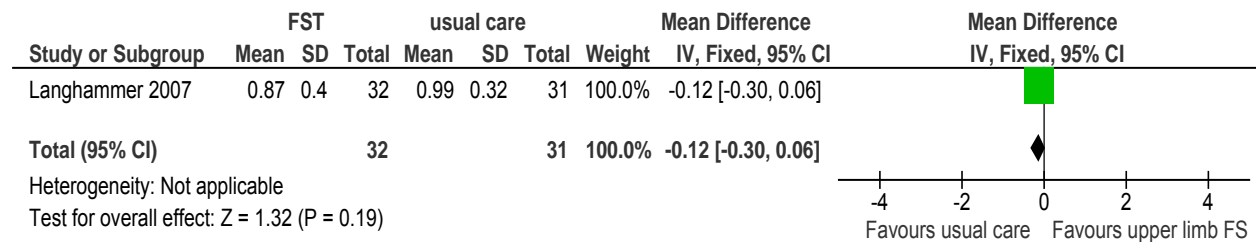


Figure 56: Action Research Arm Test (ARAT) (3 months follow-up)

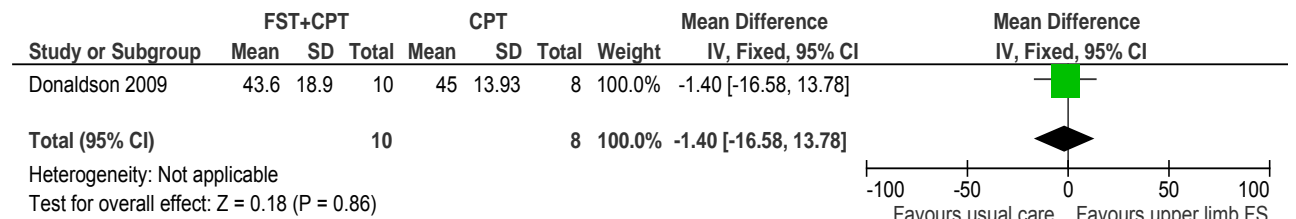


Figure 57: Grip force (N) (3 months follow-up)

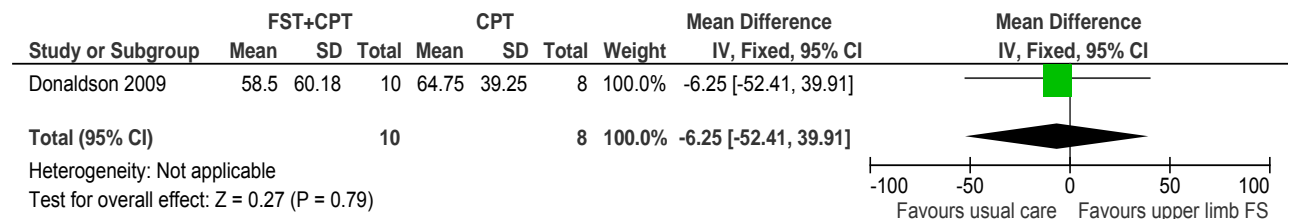
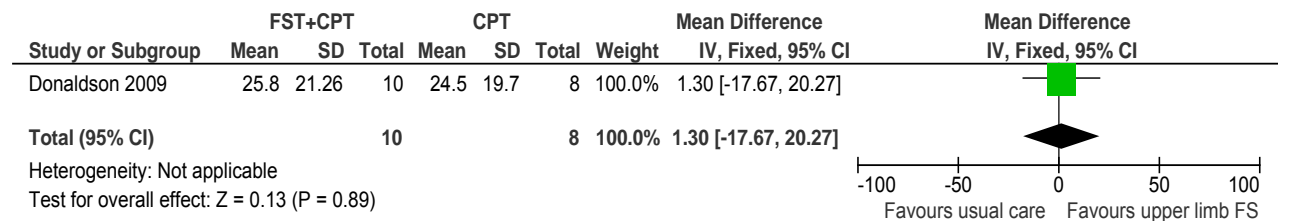


Figure 58: Pinch force (N) (3 months follow-up)



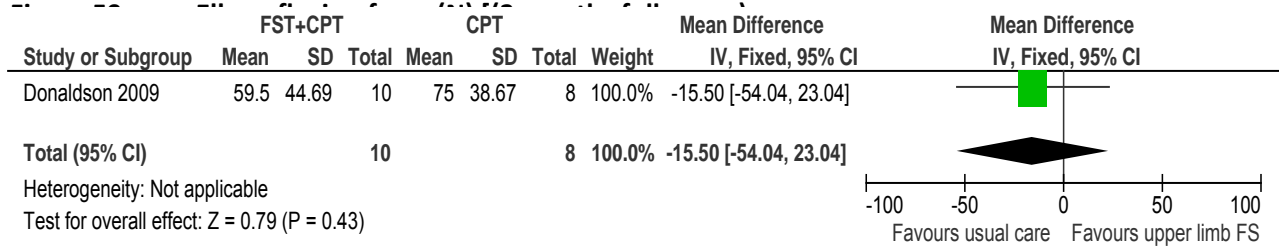
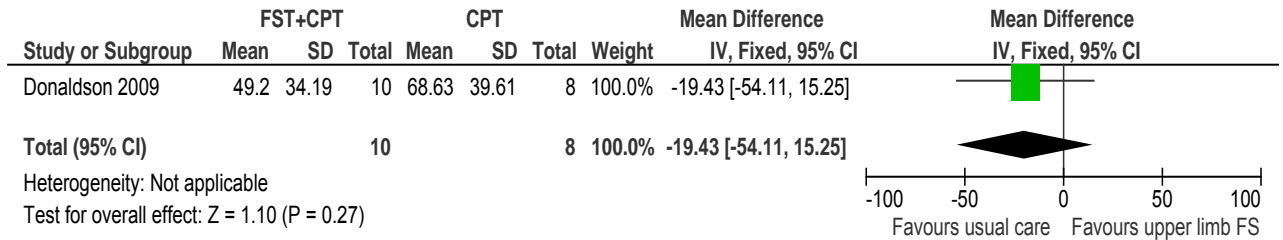


Figure 60: Elbow extension force (N) (3 months follow-up)



J.6.2 Lower limb functional strength training versus usual care.

Figure 61: Walking speed (m/sec) (3 months follow-up)

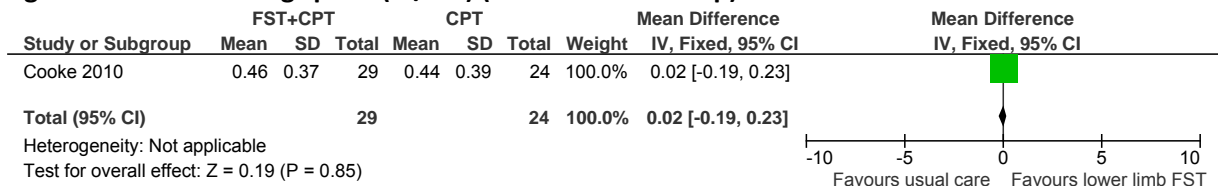


Figure 62: Knee flexion peak torque (3 months follow-up)

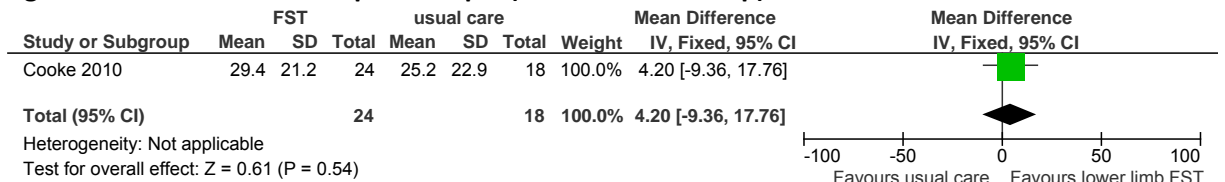
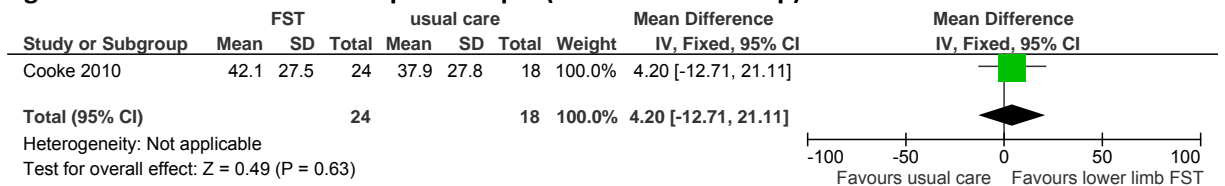
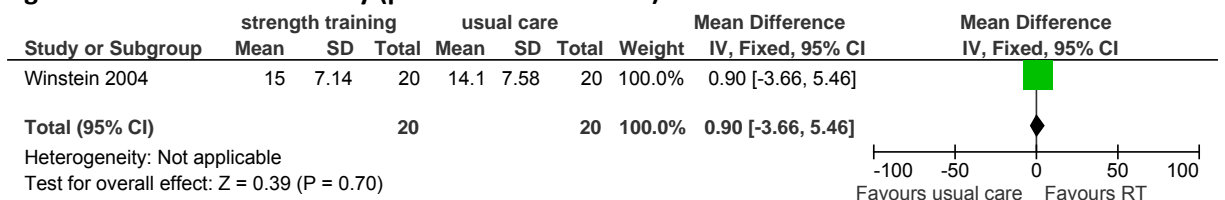


Figure 63: Knee extension peak torque (3 months follow-up)



J.6.3 Resistance training versus usual care

Figure 64: FIM – mobility (post-treatment effect)



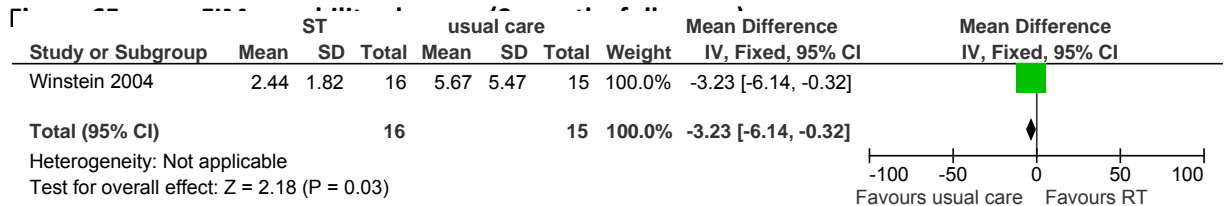


Figure 66: FIM – self-care (post-treatment effect)

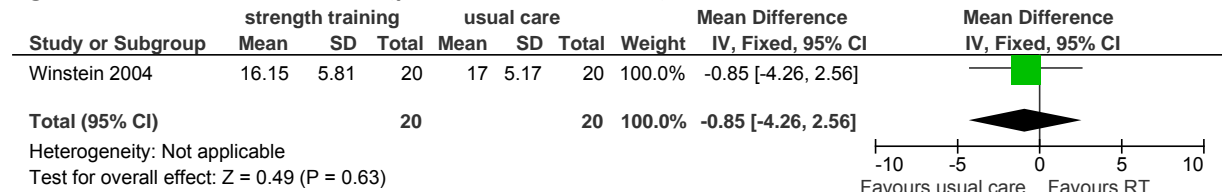


Figure 67: FIM – self-care (9 months follow-up)

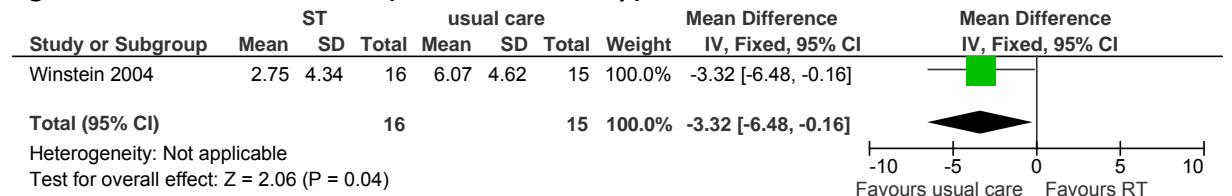


Figure 68: Fugl-Meyer – ROM (post-treatment effect)

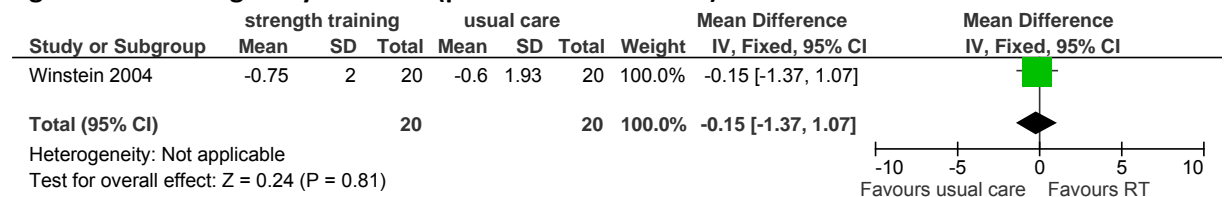


Figure 69: Fugl-Meyer – ROM (9 months follow-up)

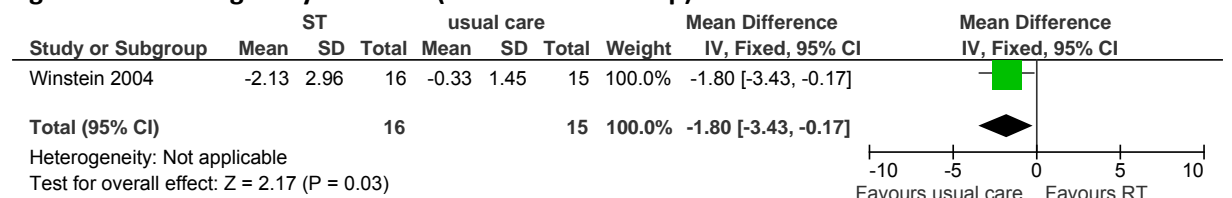


Figure 70: Fugl-Meyer – Pain (post-treatment effect)

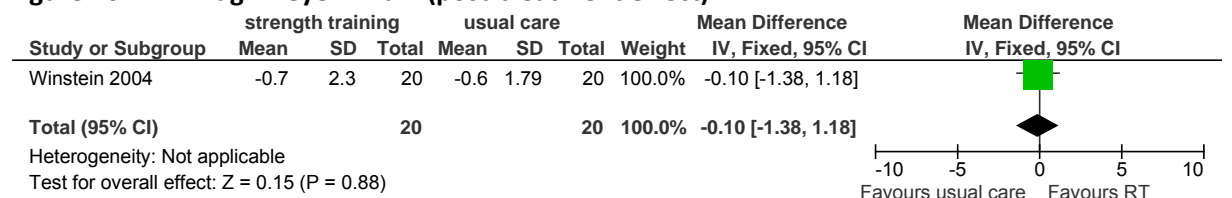
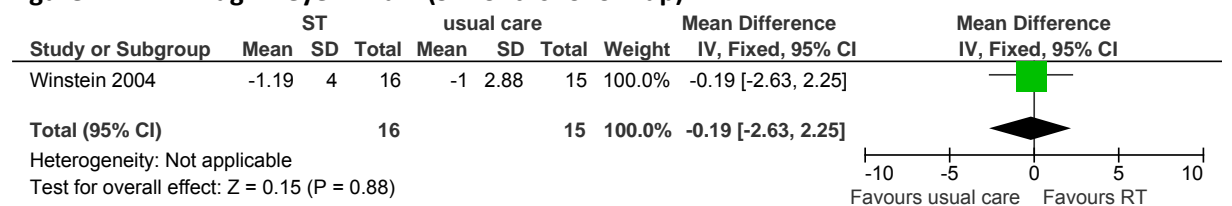


Figure 71: Fugl-Meyer – Pain (9 months follow-up)



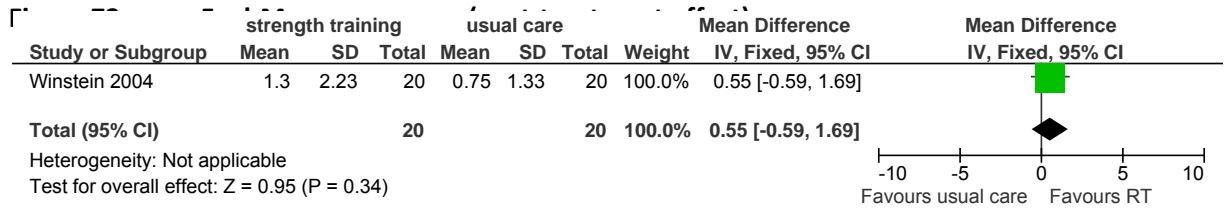


Figure 73: Fugl-Meyer – sensory (9 months follow-up)

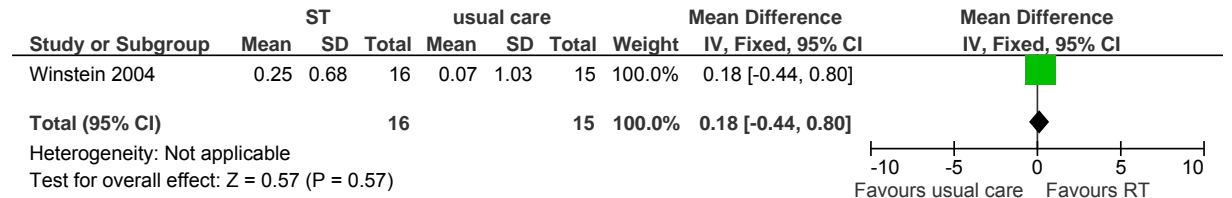


Figure 74: Fugl-Meyer – motor function (post-treatment effect)

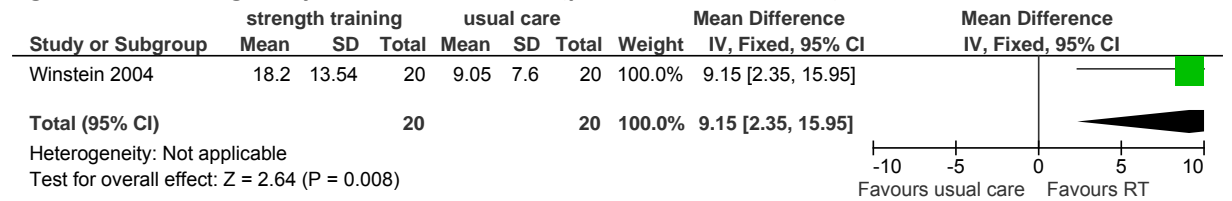


Figure 75: Fugl-Meyer – motor function (9 months follow-up)

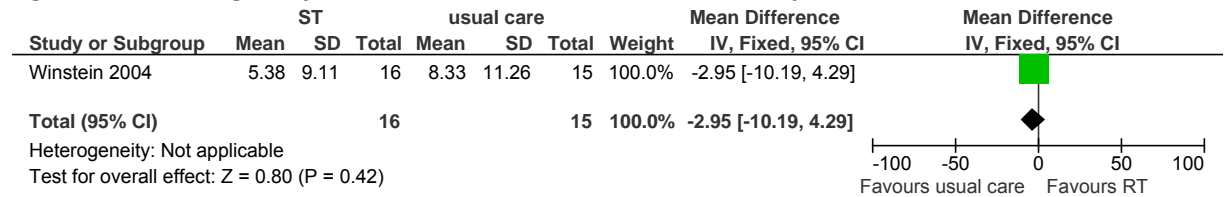


Figure 76: Timed up and go (sec) (5 months follow-up)

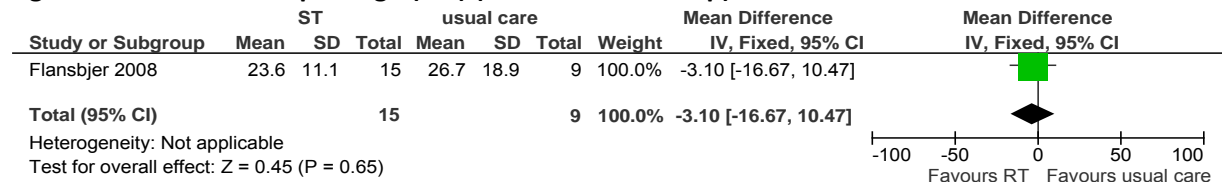


Figure 77: Fast gait speed (m/sec) (5 months follow-up)

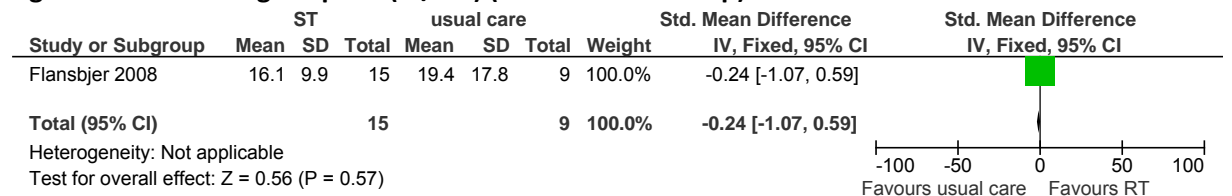


Figure 78: 6 minute walk test (m) (3 and 5 months follow-up)

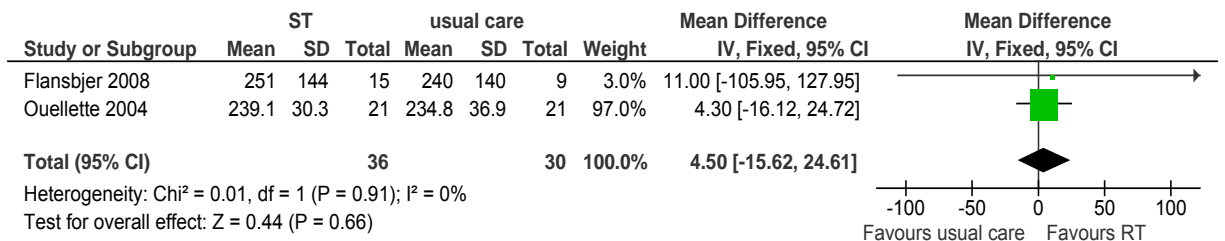


Figure 79: 2 minute walk test (m) (6 months follow-up)

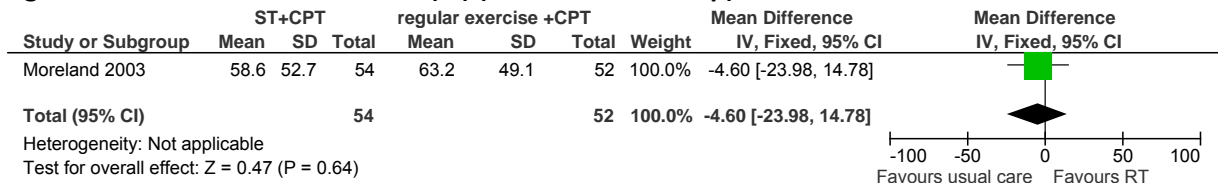


Figure 80: Self-selected/habitual gait speed (m/sec)

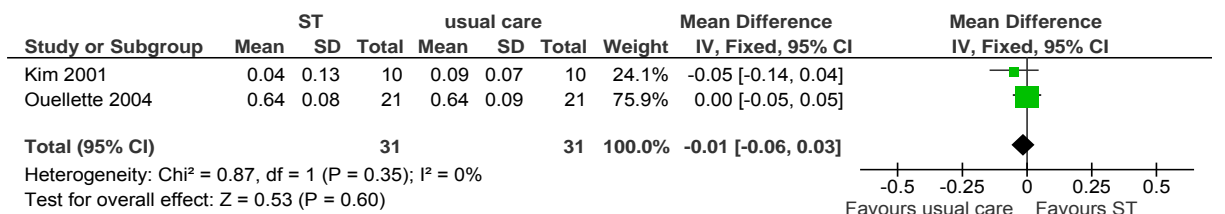
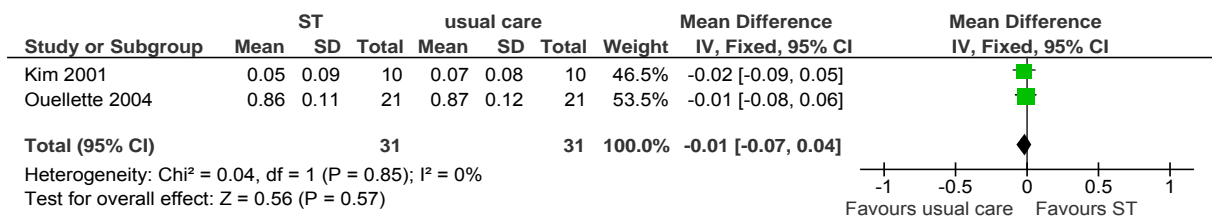


Figure 81: Maximal gait speed (m/sec)



J.6.4 Family mediated exercise intervention versus usual care

Figure 82: Lower Limb Fugl-Meyer – change scores

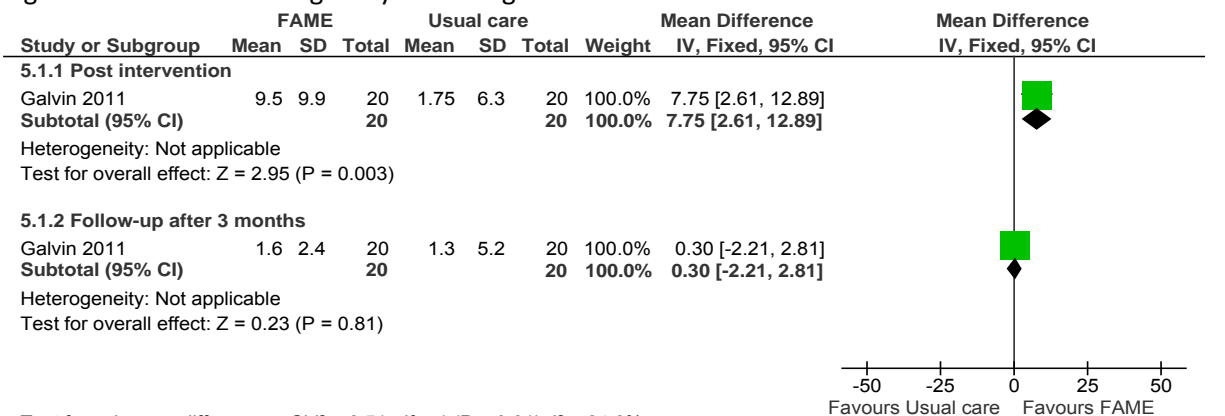


Figure 83: Motor assessment scale – change scores

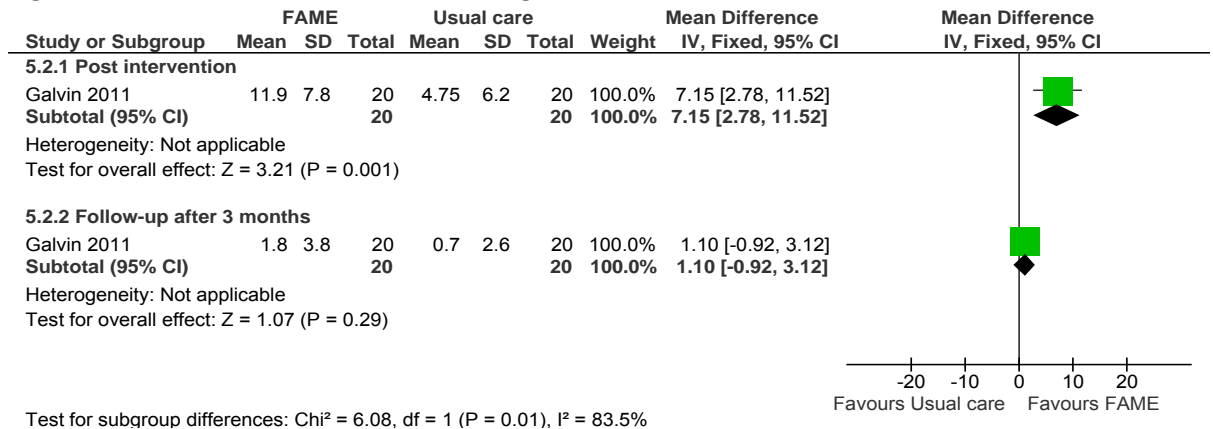


Figure 84: Berg Balance Scale – change scores

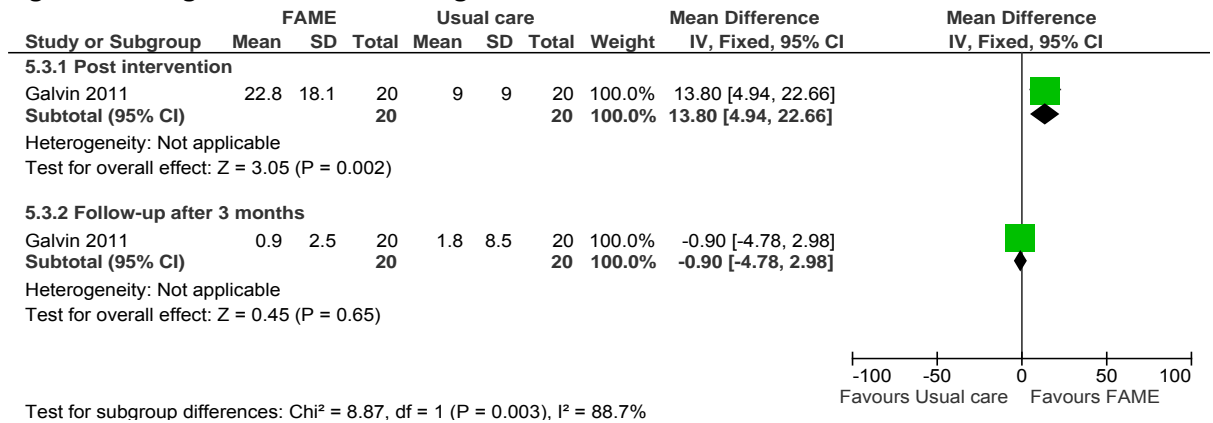


Figure 85: 6 Minute Walk Test – change scores

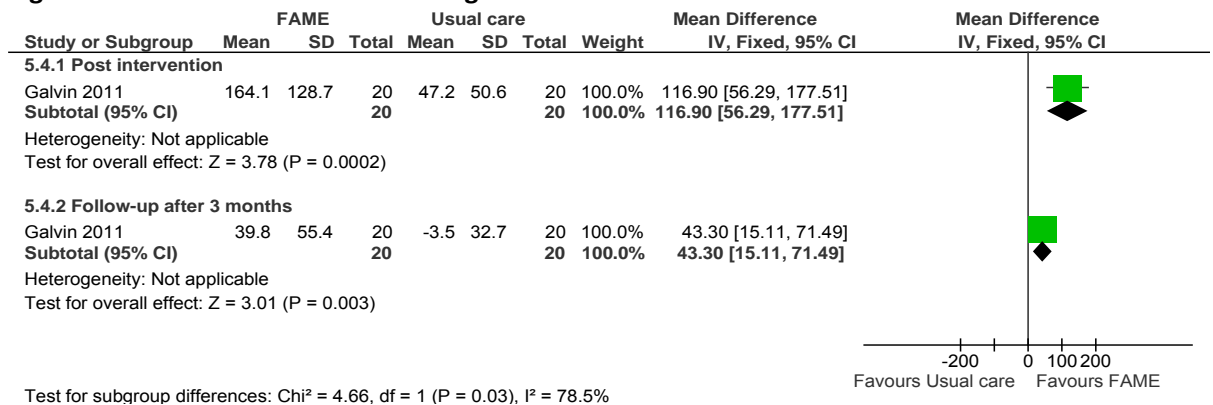
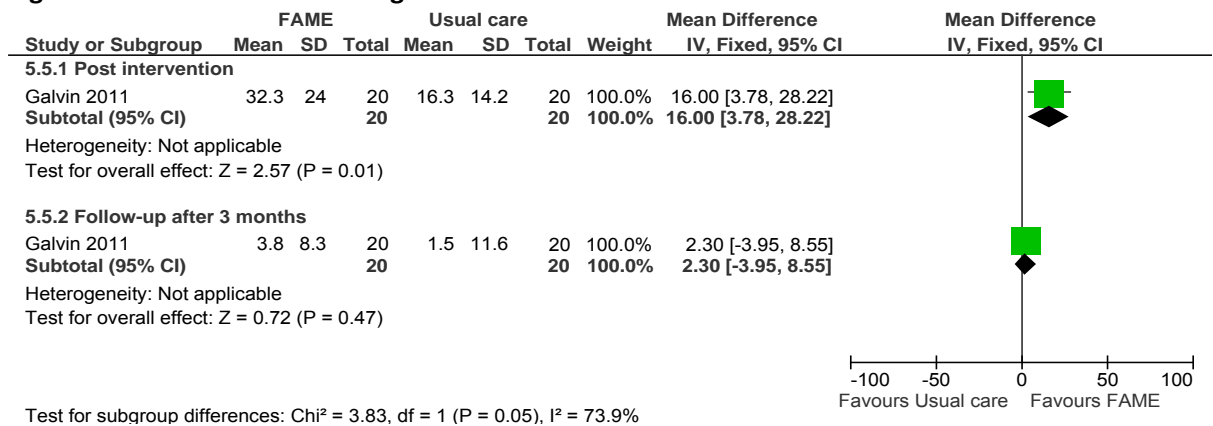


Figure 86: Barthel Index – change scores



J.7 In people after stroke, does cardiorespiratory or resistance fitness training improve outcome (fitness, function, quality of life and mood) and reduce disability?

J.7.1 Cardiorespiratory training versus usual care – end of intervention

Figure 87: Disability - Functional Independence Measure

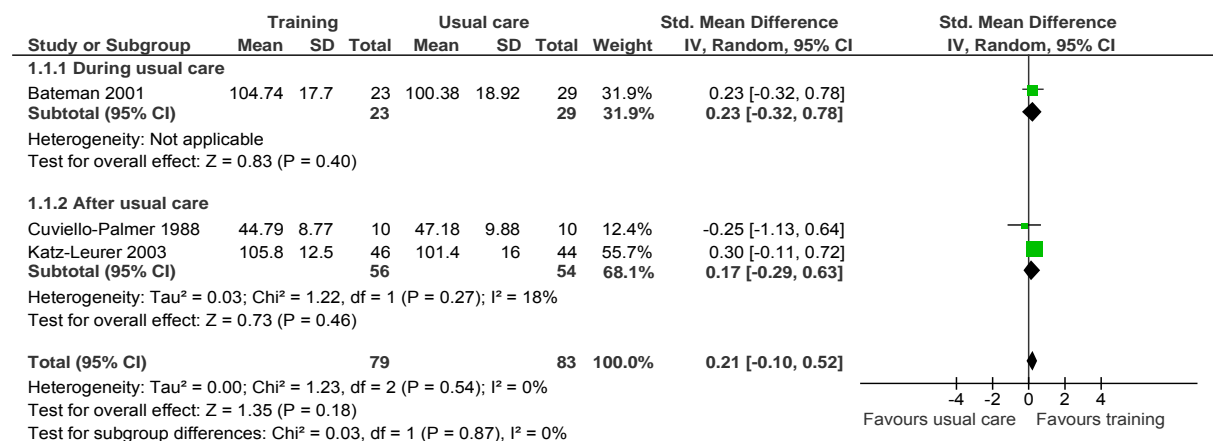


Figure 88: Disability - Rivermead Mobility Index

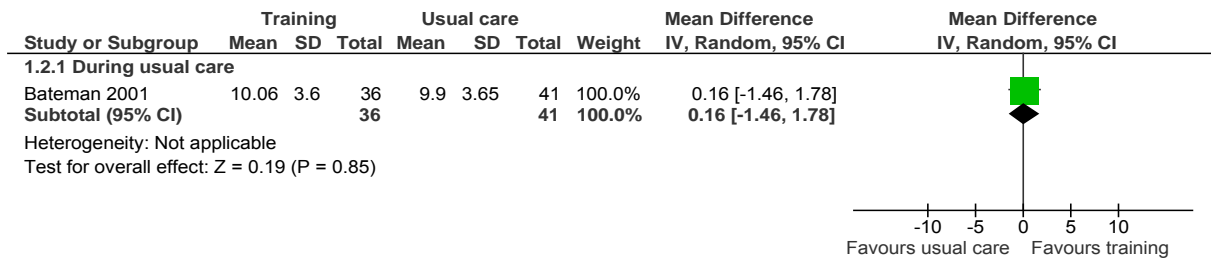


Figure 89: Disability - Physical Activity and Disability Scale

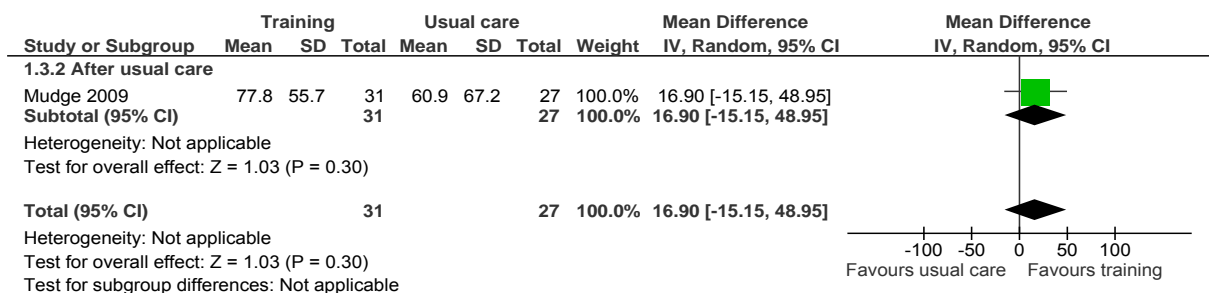


Figure 90: Risk factors - blood pressure, systolic

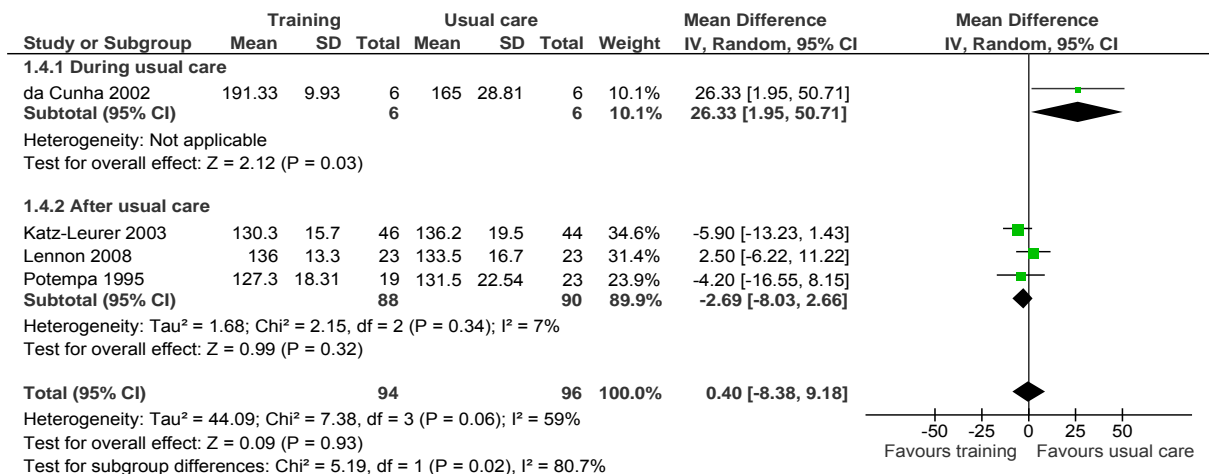


Figure 91: Risk factors - blood pressure, diastolic

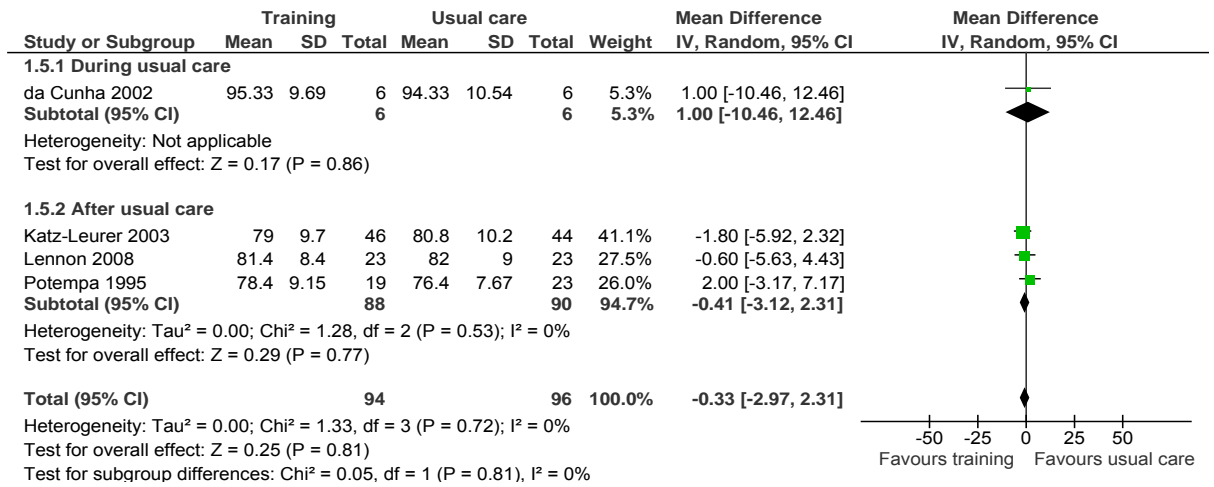


Figure 92: Physical fitness - peak VO₂ (ml/kg/min)

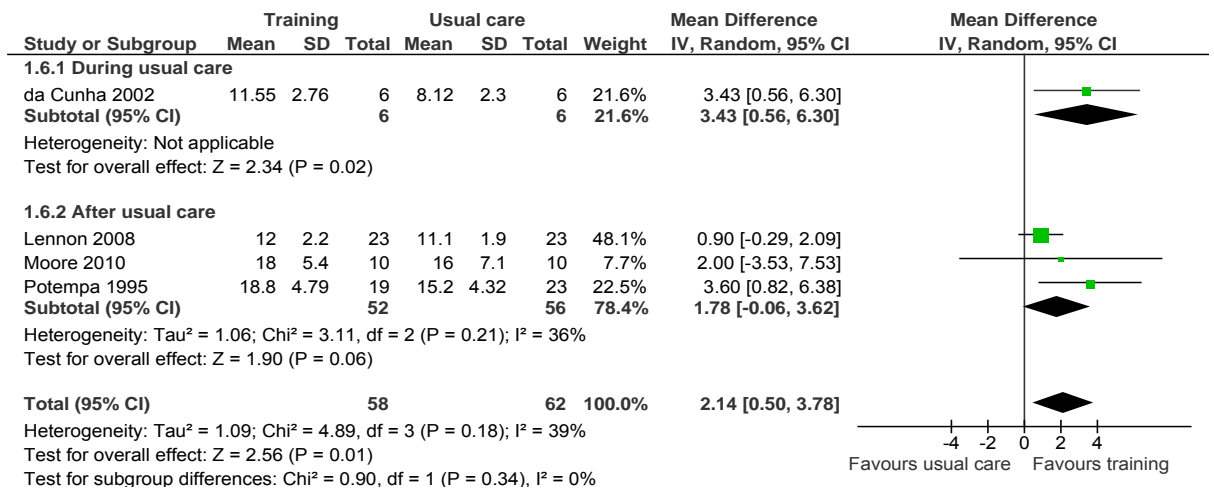


Figure 93: Physical fitness - gait economy, VO₂ (ml/kg/metre)

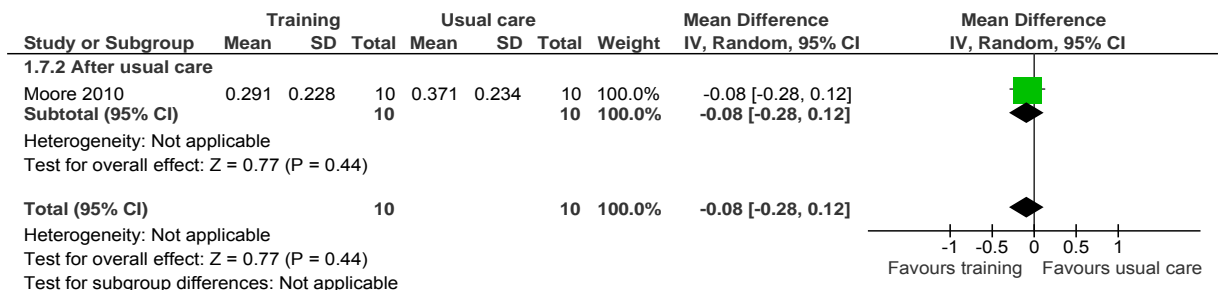


Figure 94: Physical fitness - maximum cycling work rate (Watts)

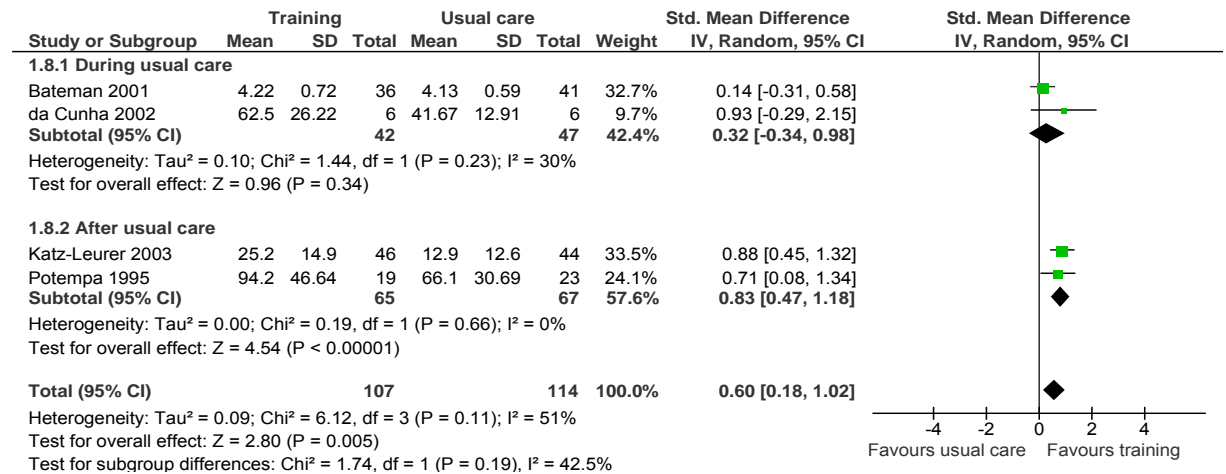


Figure 95: Physical fitness - Body Mass (Kg)

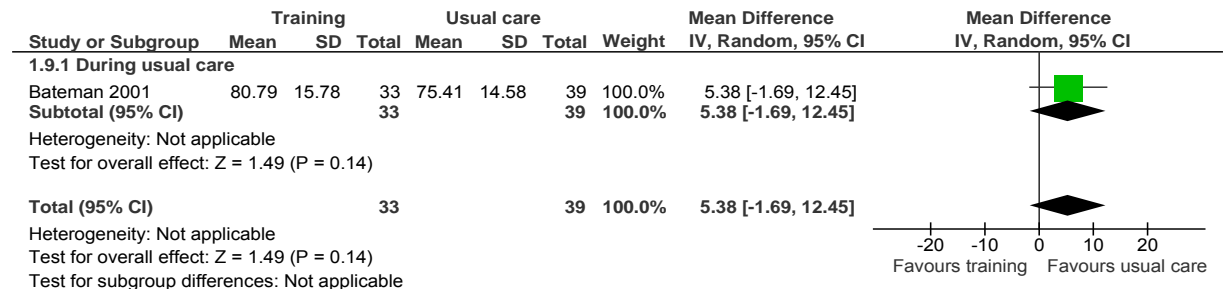


Figure 96: Mobility - functional ambulation categories

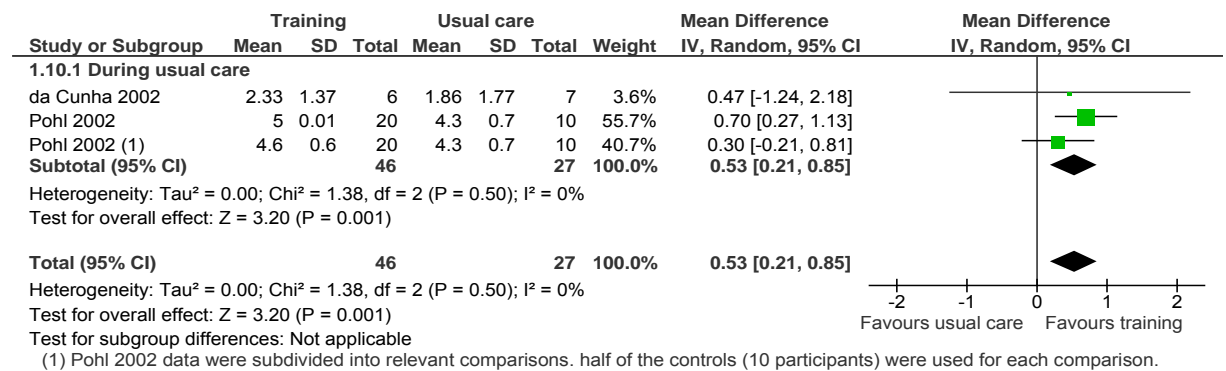


Figure 97: Mobility - maximal gait speed (m/min over 5 to 10 metres)

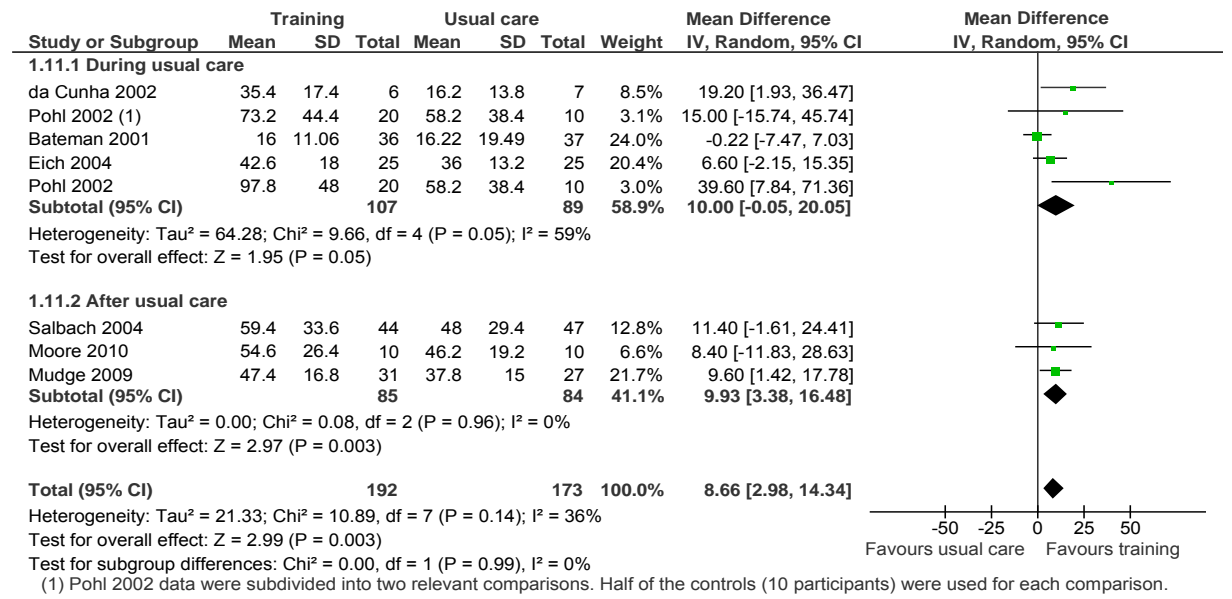


Figure 98: Mobility - preferred gait speed (m/min)

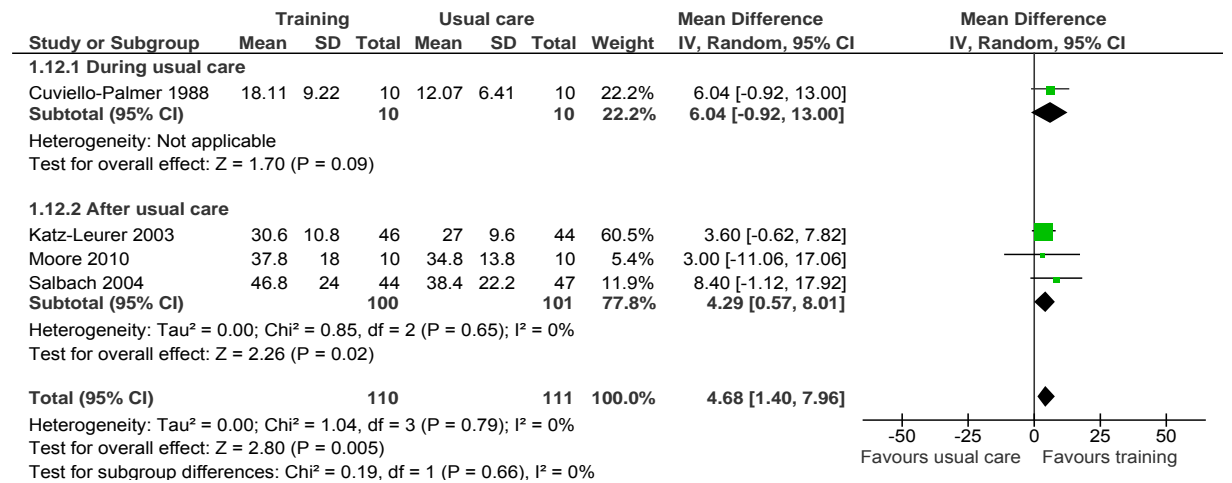


Figure 99: Mobility - gait endurance (6-MWT metres)

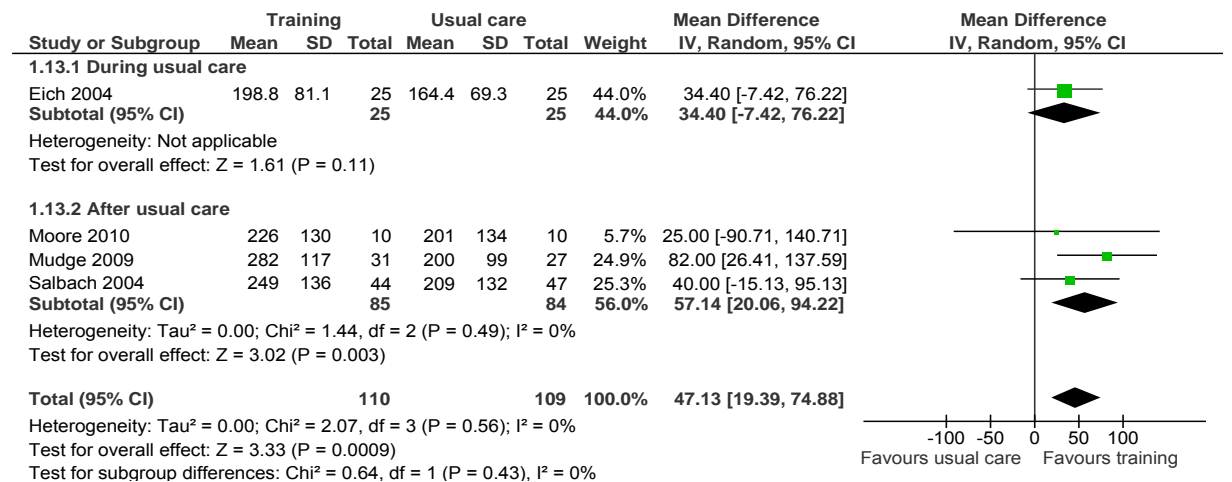


Figure 100: Mobility - gait endurance (m/min)

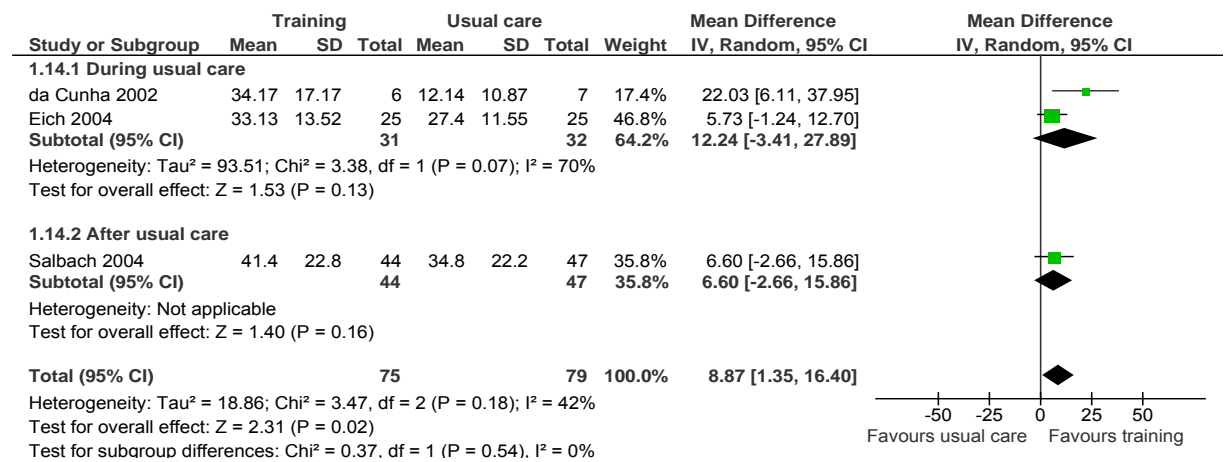


Figure 101: Mobility - 6-metre walking time (sec)

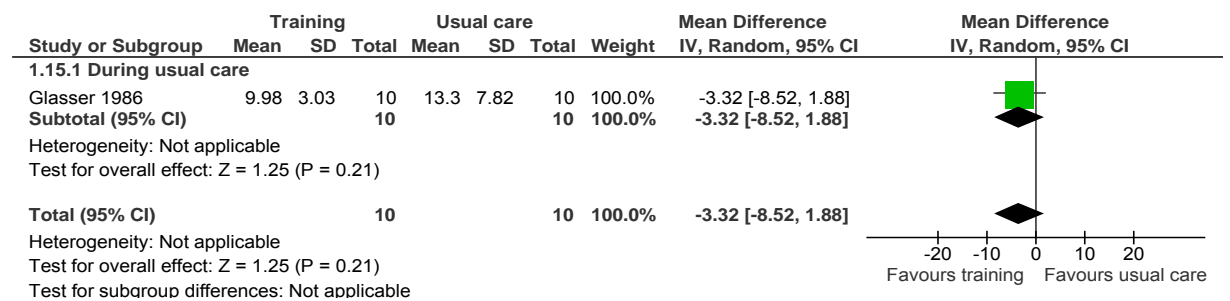


Figure 102: Mobility - Stroke Impact Scale (mobility domain)

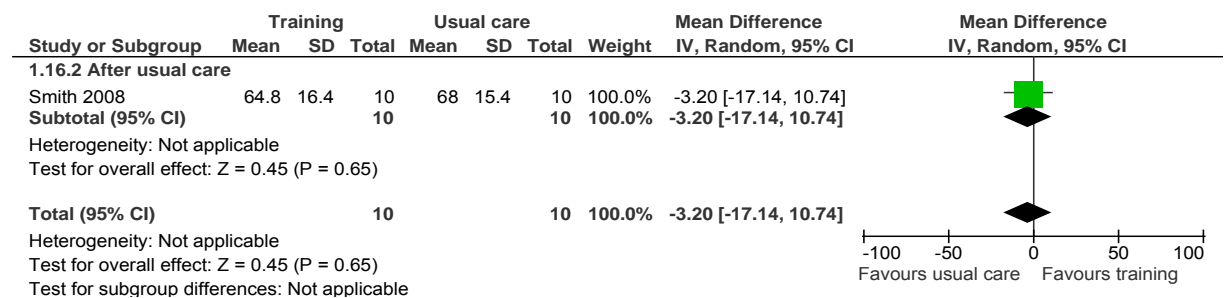


Figure 103: Mobility - peak activity index (steps/min)

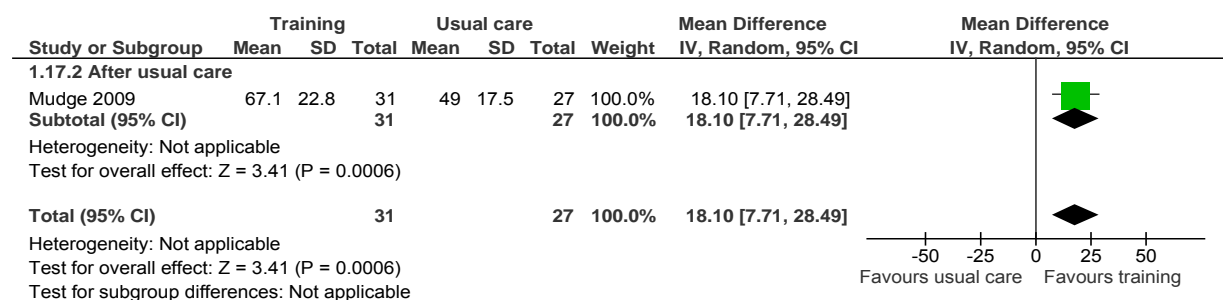


Figure 104: Mobility - max step rate in 1 min

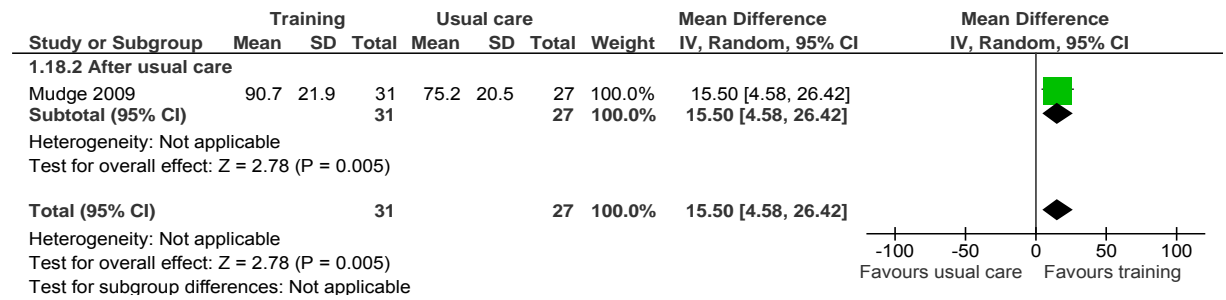


Figure 105: Physical function - Berg Balance scale

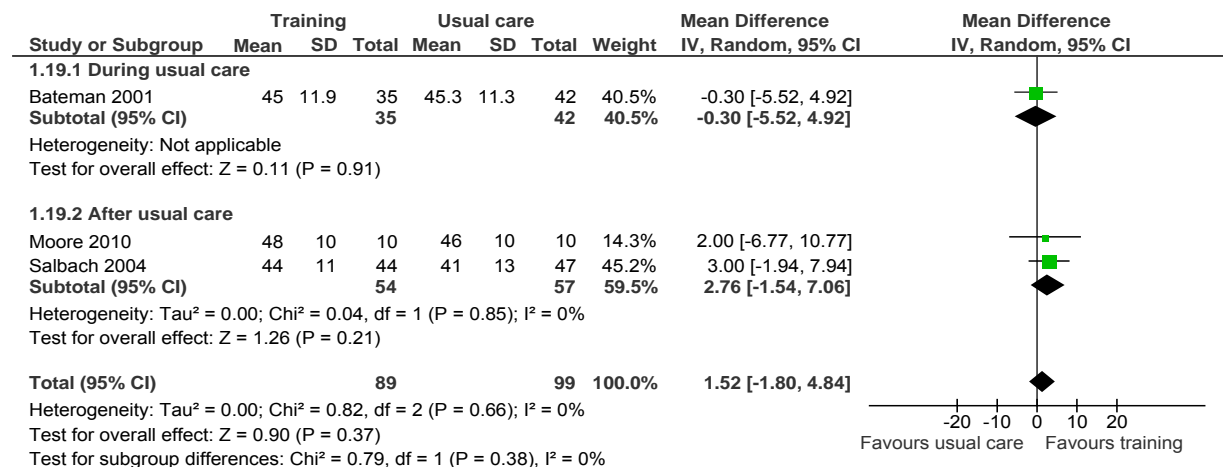


Figure 106: Physical function - Timed Up and Go (sec)

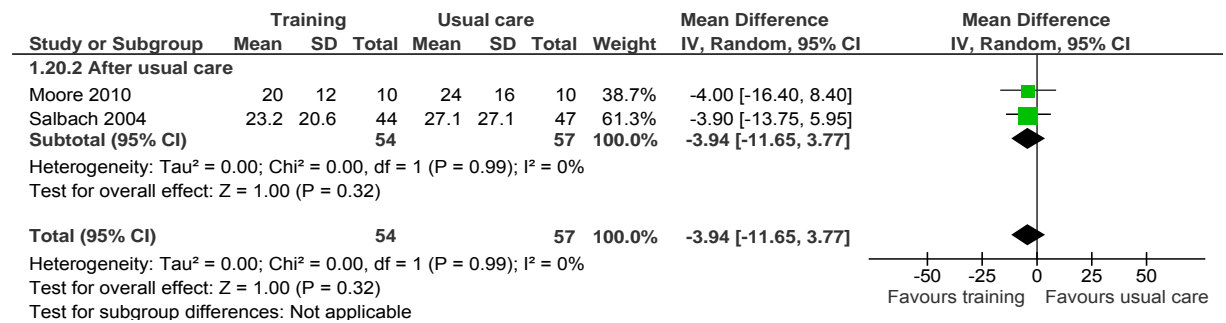


Figure 107: Health related QoL - SF-36 physical functioning

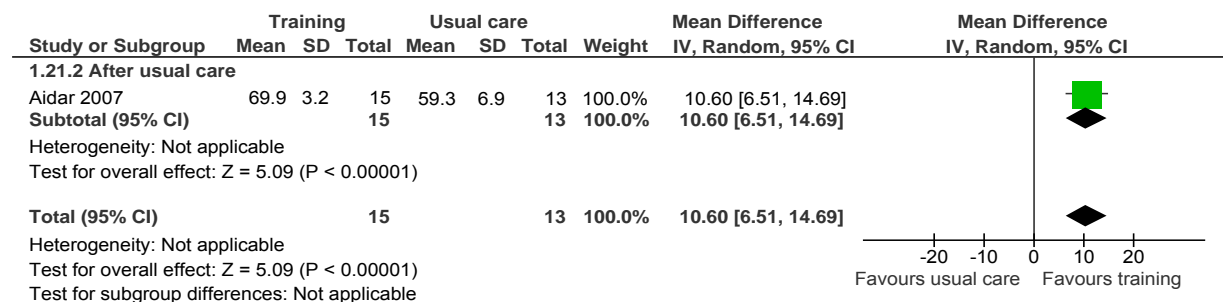


Figure 108: Health related QoL - SF-36 emotional role functioning

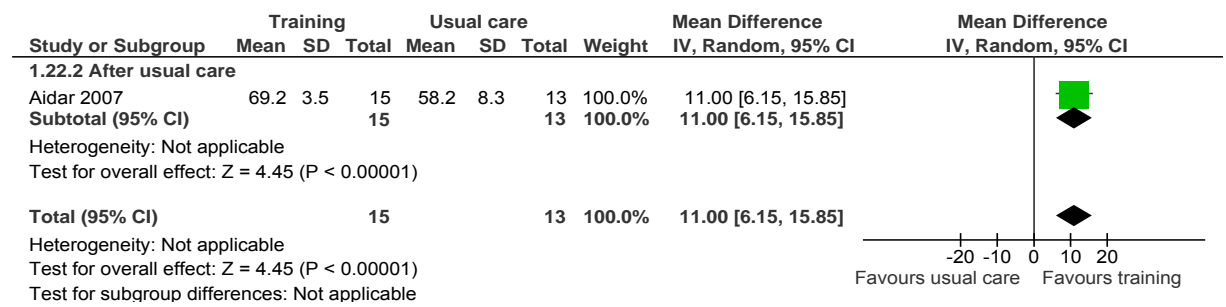


Figure 109: Health related QoL - SF-36 physical functioning

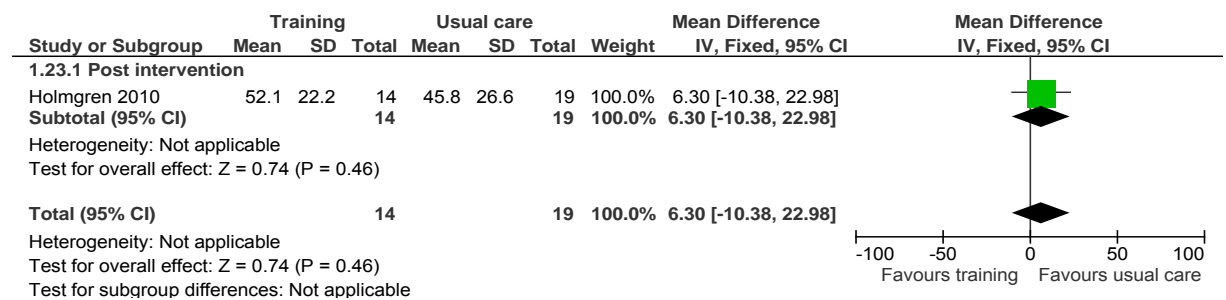


Figure 110: Health related QoL - SF-36 emotional role functioning

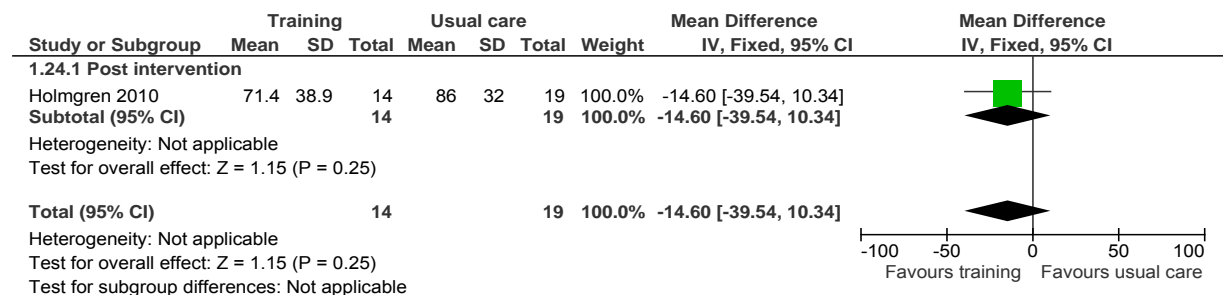


Figure 111: Health related QoL - SF-36 mental health

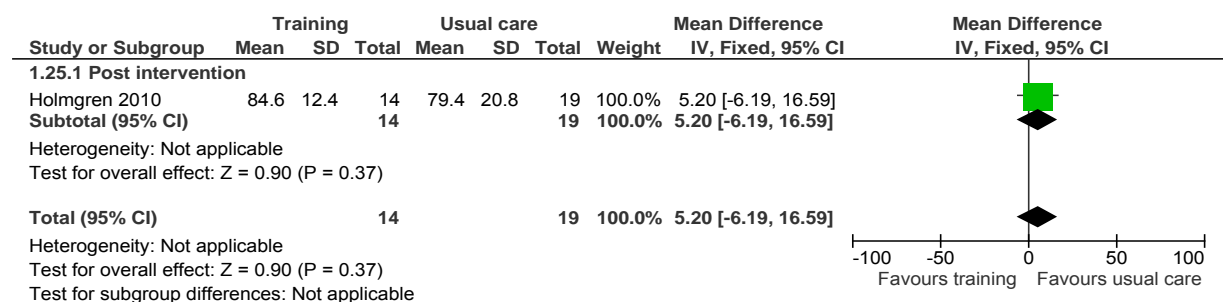


Figure 112: Health related QoL - SF-36 Physical Component Scale

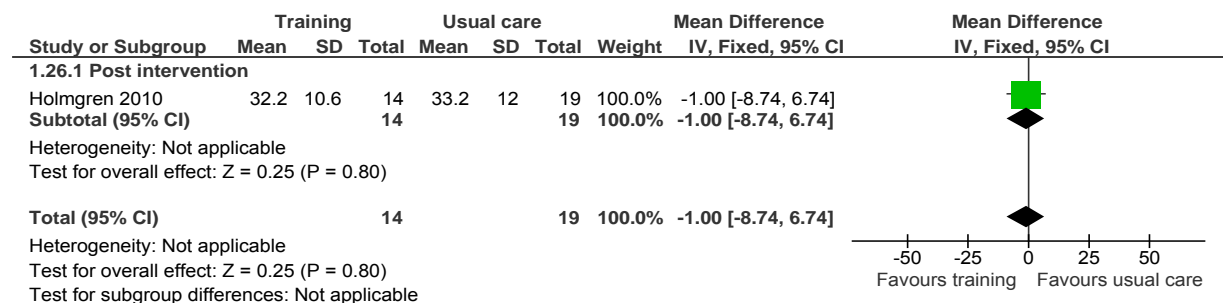


Figure 113: Health related QoL - SF-36 Mental Component Scale

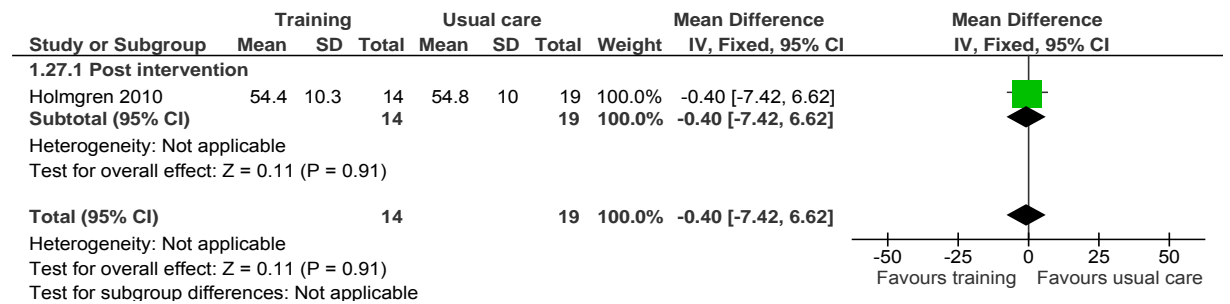


Figure 114: Mood - Beck Depression Index

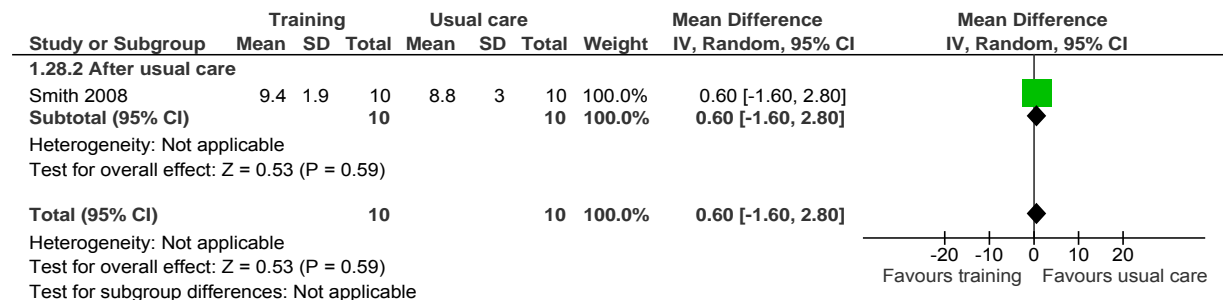


Figure 115: Hospital Anxiety and Depression Scale (HADS) - anxiety score

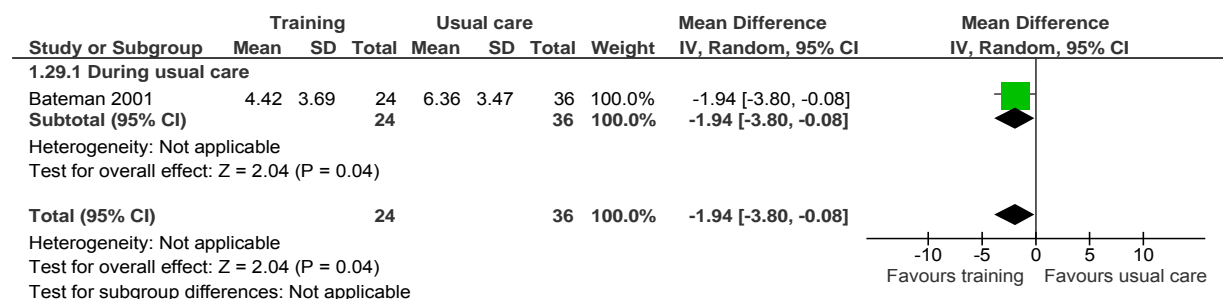


Figure 116: Mood - Hospital Anxiety and Depression Scale (HADS) - depression score

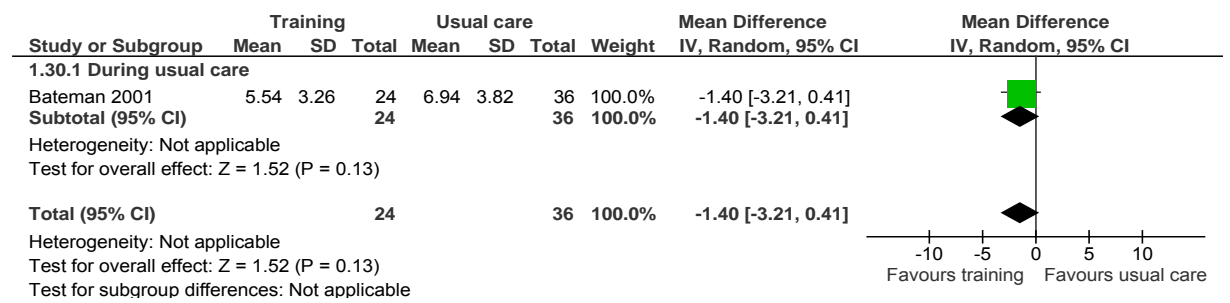
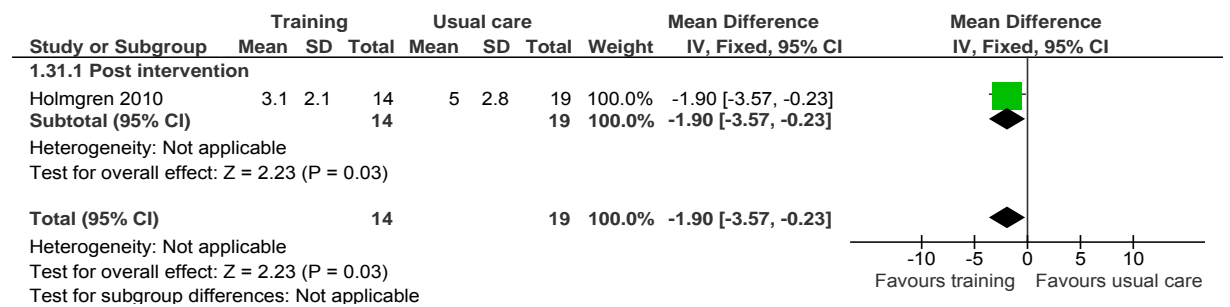


Figure 117: Geriatric Depression Scale – 15



J.7.2 Cardiorespiratory training versus usual care – end of retention follow up

Figure 118: Case fatality

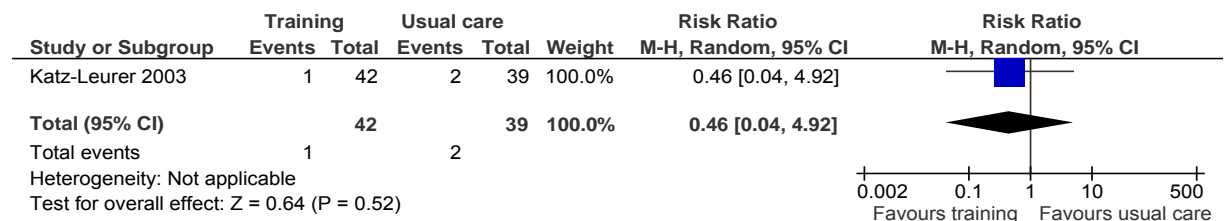


Figure 119: Rivermead Mobility Index

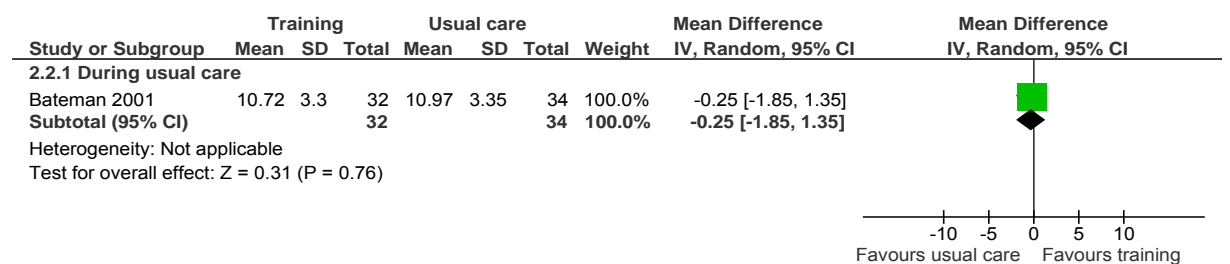


Figure 120: Disability - Nottingham Extended ADL

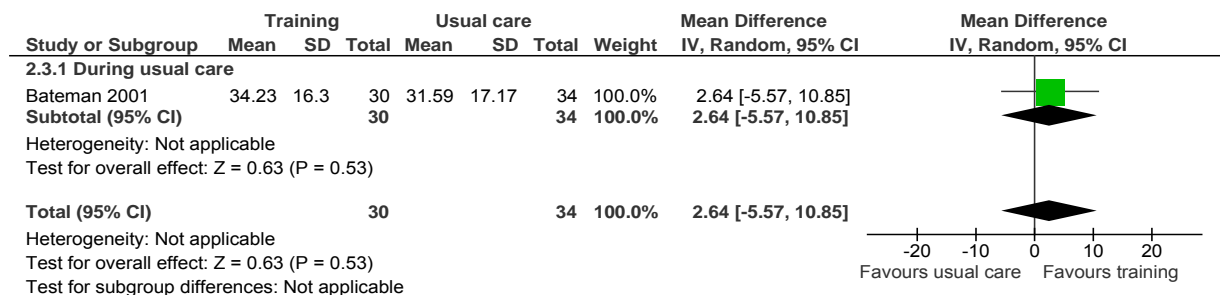


Figure 121: Physical Activity and Disability Scale

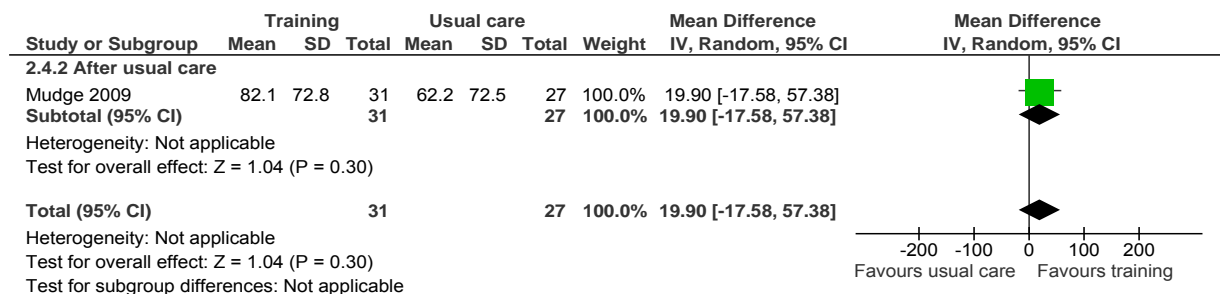


Figure 122: Disability - Frenchay Activities Index (FAI)

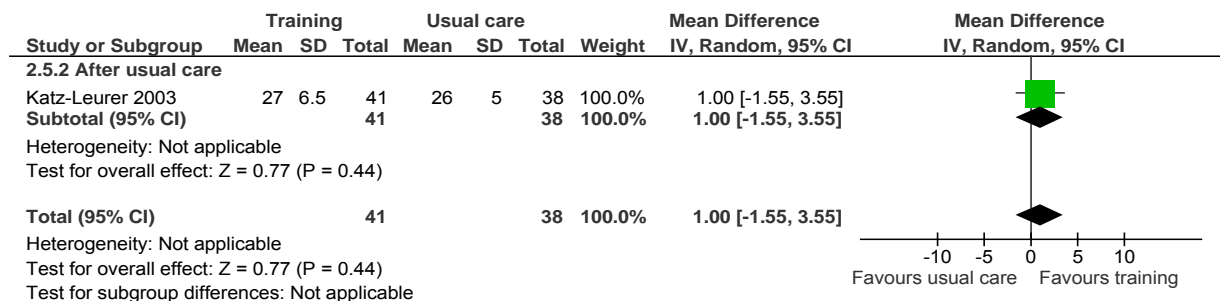


Figure 123: Physical fitness - maximum cycling work rate (Watts)

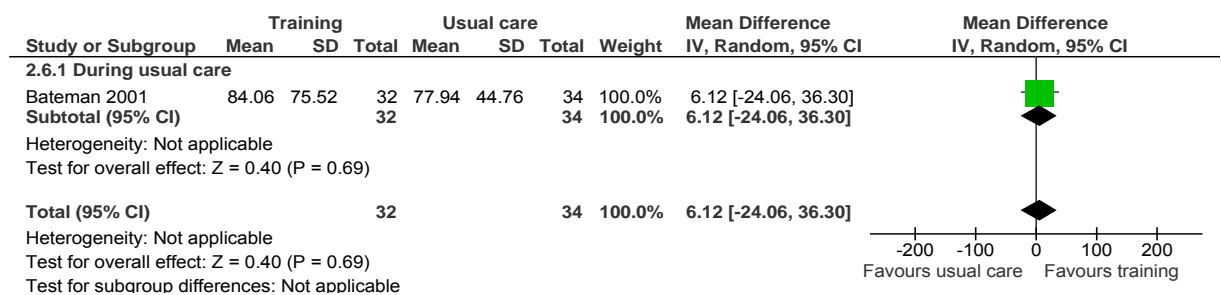


Figure 124: Physical fitness - Body Mass (Kg)

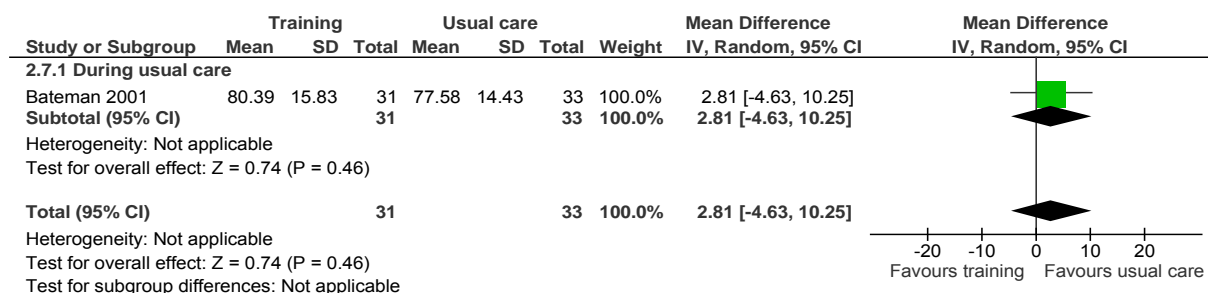


Figure 125: Mobility - maximal gait speed (m/min)

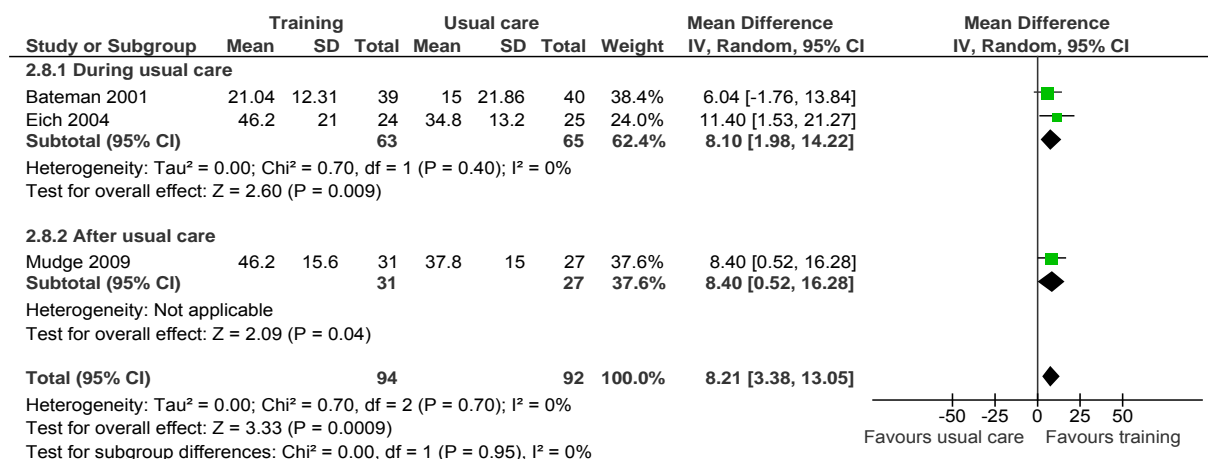


Figure 126: Mobility - gait endurance (6-MWT metres)

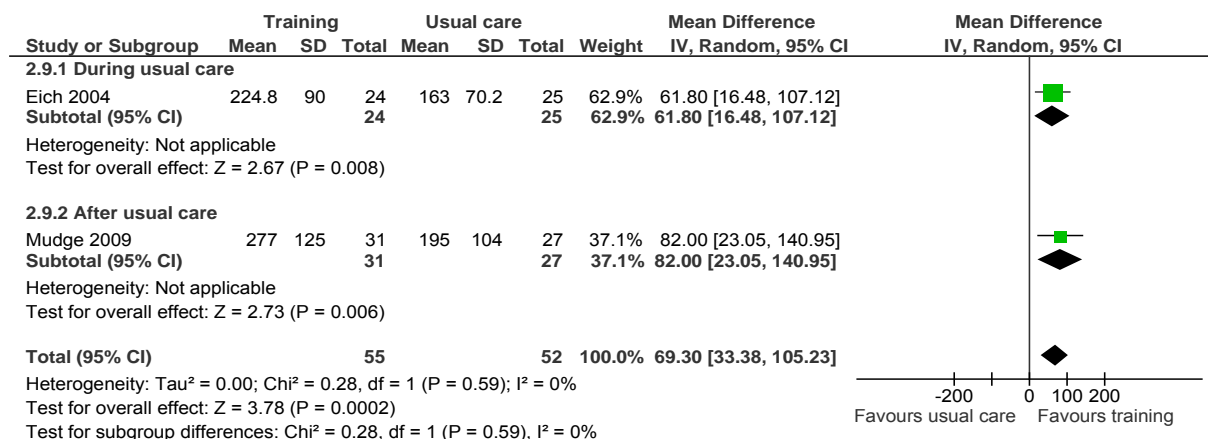


Figure 127: Mobility - peak activity index (steps/min)

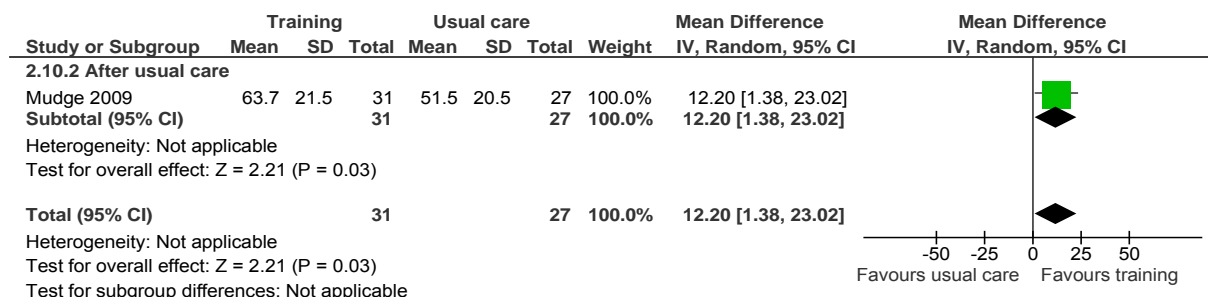


Figure 128: max step rate in 1 min

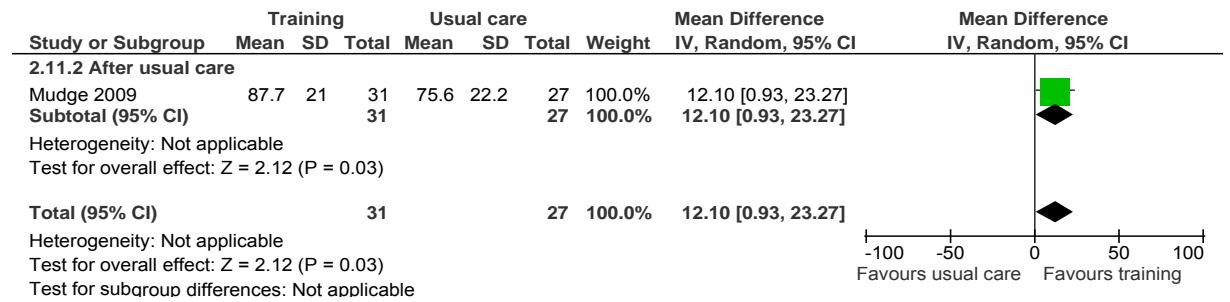


Figure 129: Mobility - Stroke Impact Scale (mobility domain)

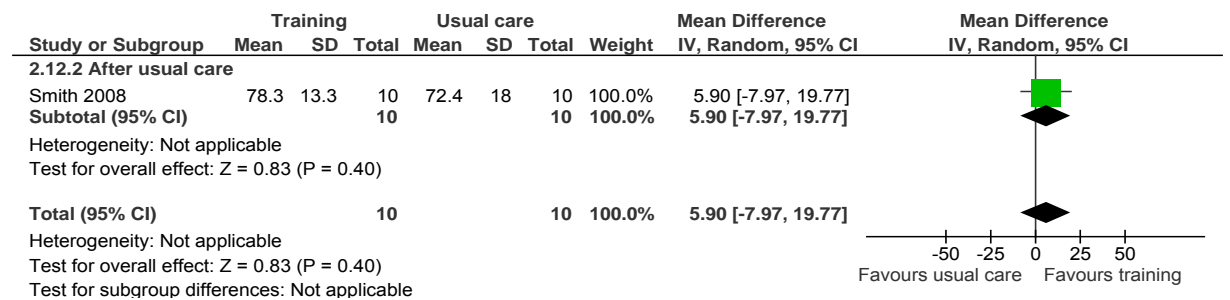


Figure 130: Physical function - Berg Balance scale

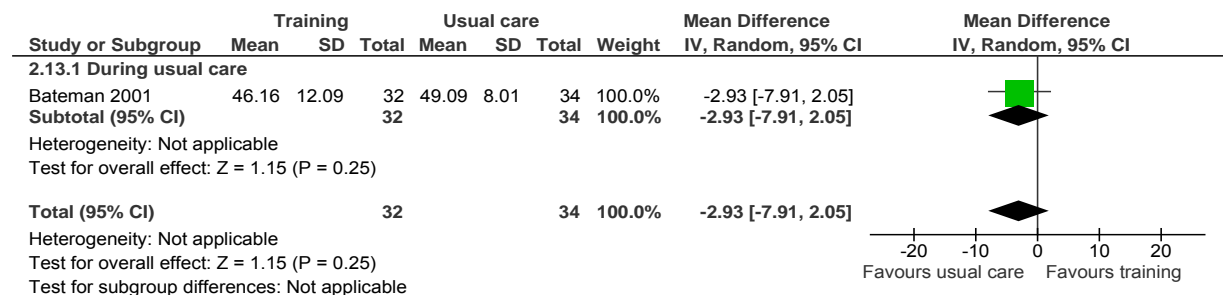


Figure 131: Mood - Beck Depression Index

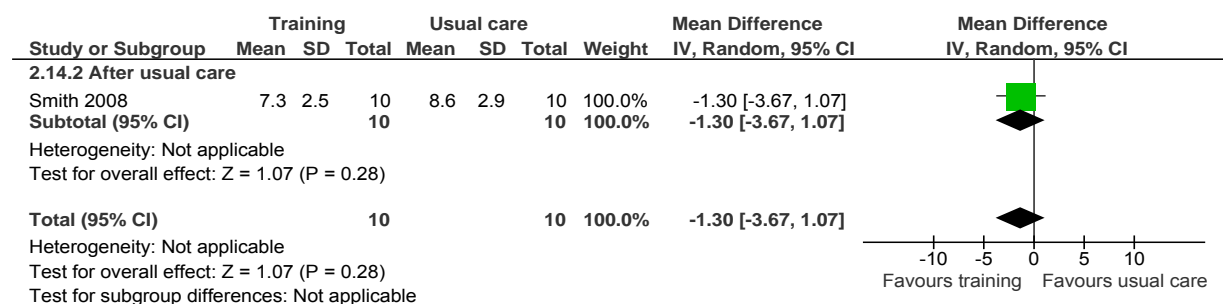


Figure 132: Hospital Anxiety and Depression Scale (HADS) - anxiety score

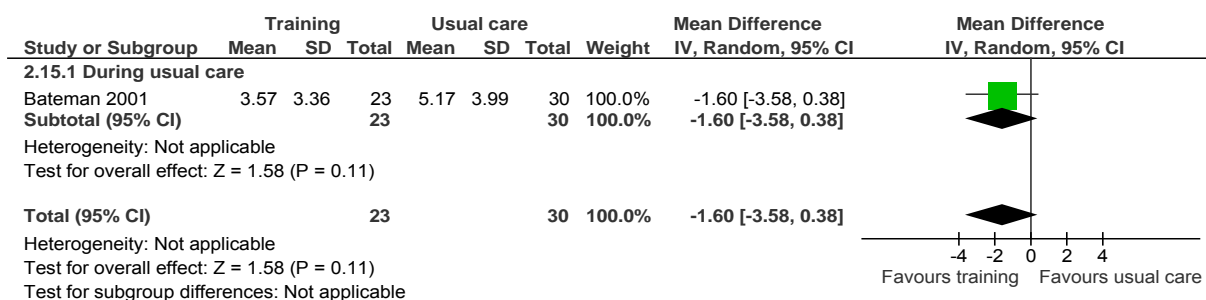


Figure 133: Mood - Hospital Anxiety and Depression Scale (HADS) - depression score

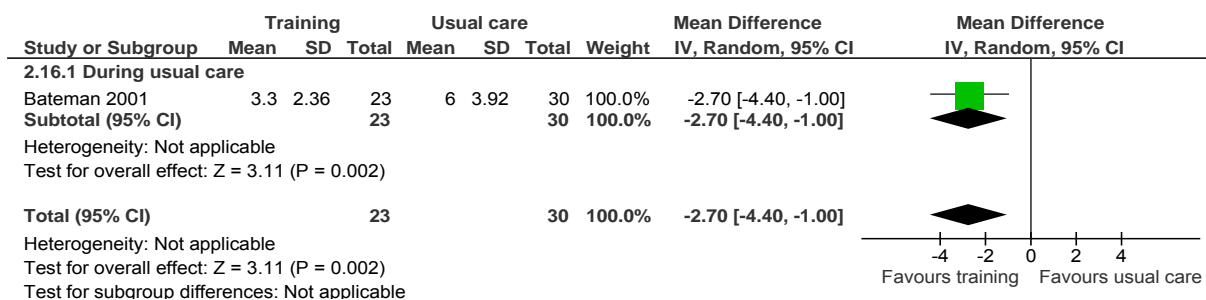


Figure 134: Health related QoL - SF-36 Physical Component Scale

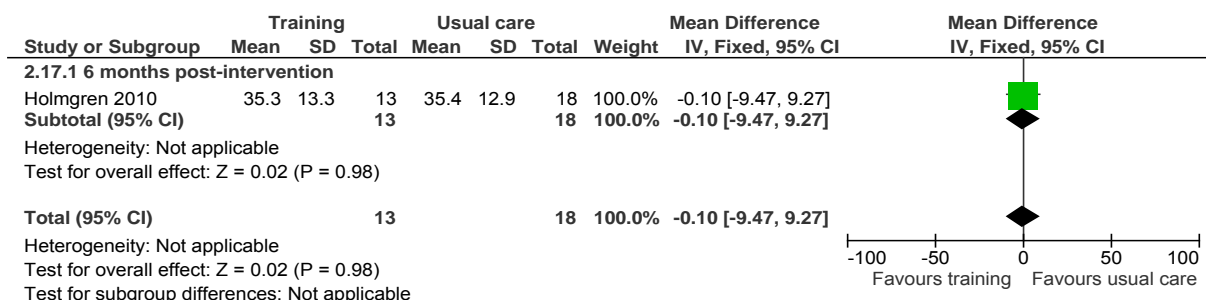


Figure 135: Health related QoL - SF-36 Mental Component Scale

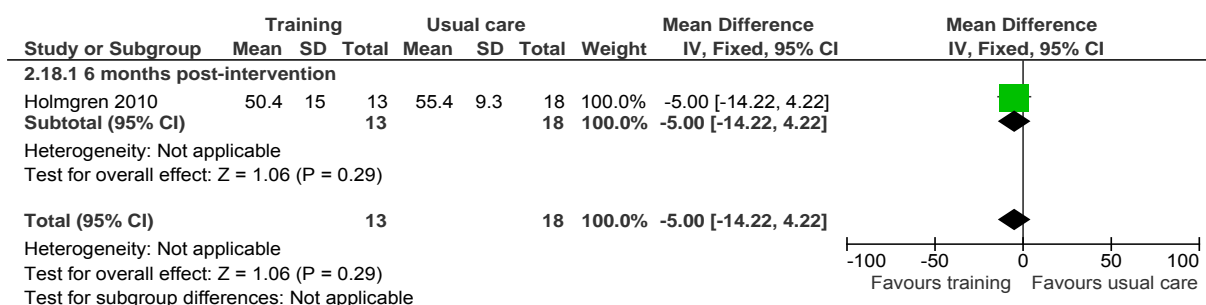


Figure 136: Health related QoL - SF-36 physical functioning

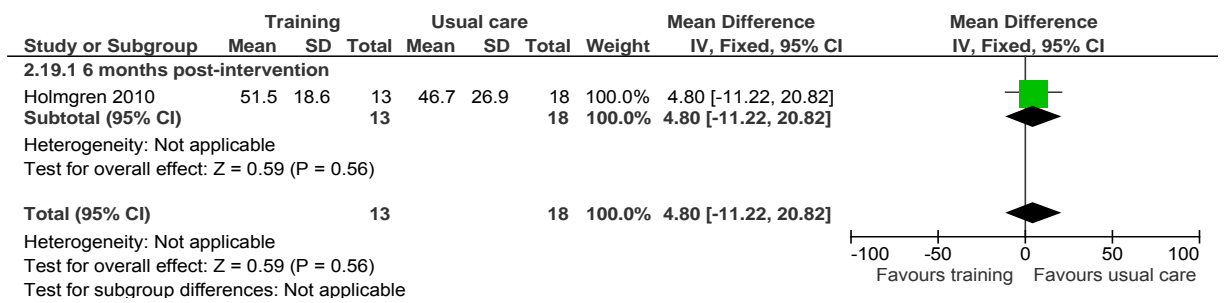


Figure 137: Health related QoL - SF-36 emotional role functioning

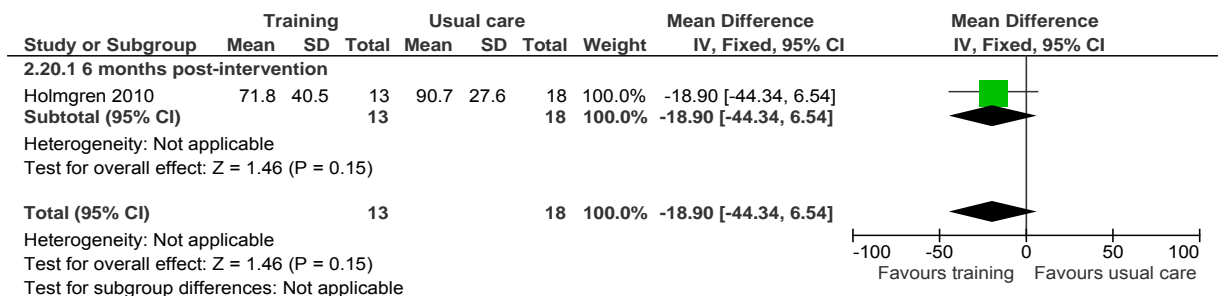


Figure 138: Health related QoL - SF-36 mental health

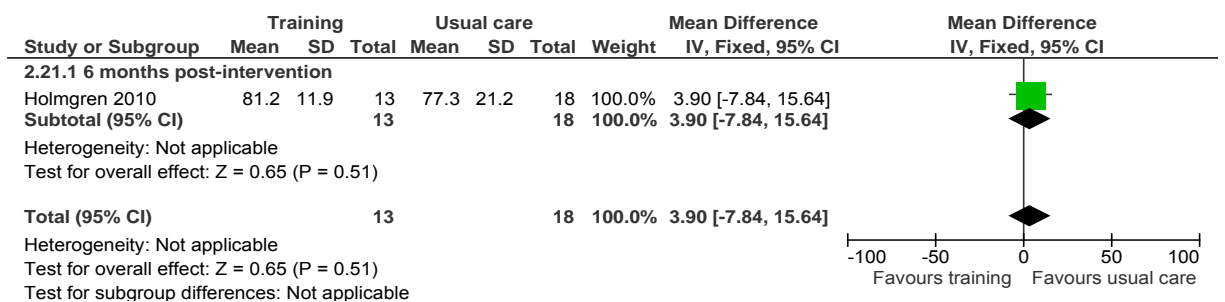
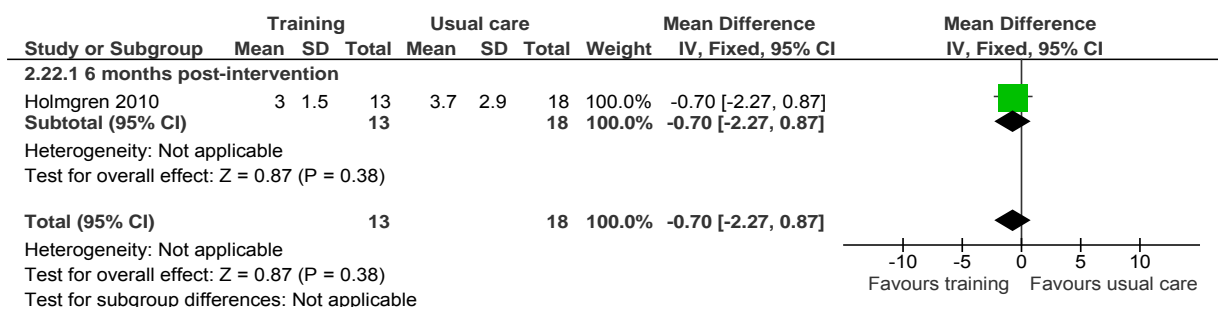


Figure 139: Mood - Geriatric Depression Scale – 15



J.7.3 Resistance training versus usual care – end of intervention

Figure 140: Physical fitness - composite measure of muscle strength

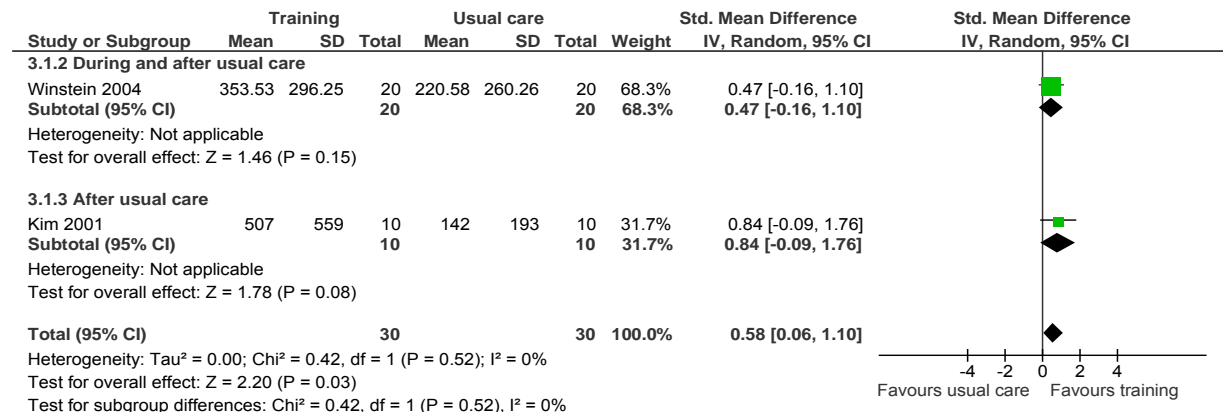


Figure 141: Physical fitness - muscle strength, knee extension (Nm)

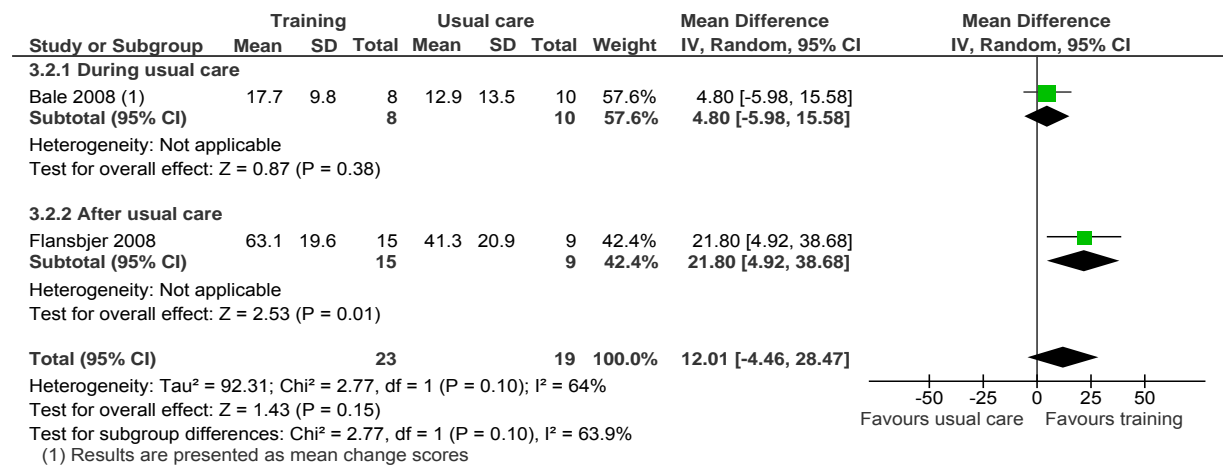


Figure 142: Physical fitness - muscle strength, knee flexion (Nm)

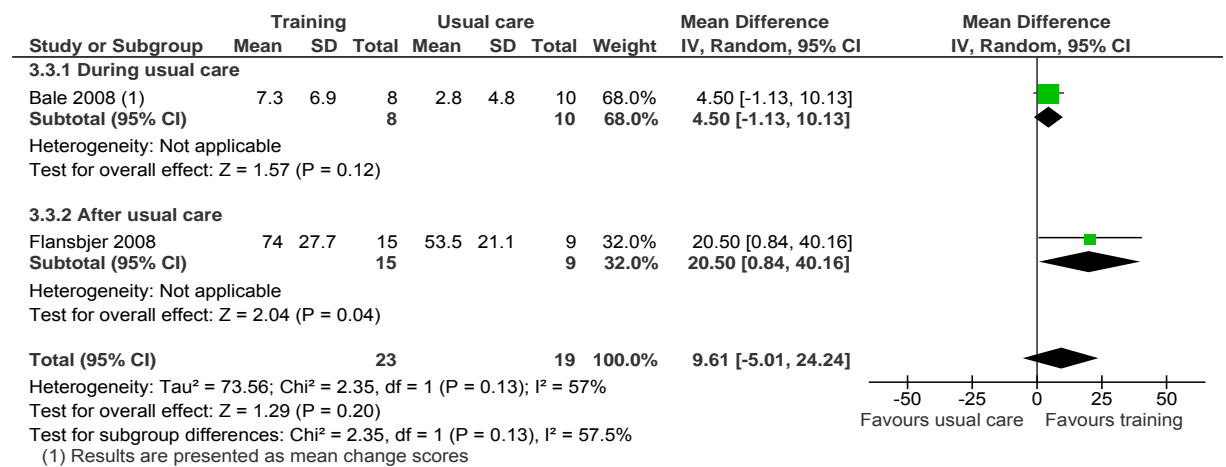


Figure 143: Mobility - maximal gait speed (m/min)

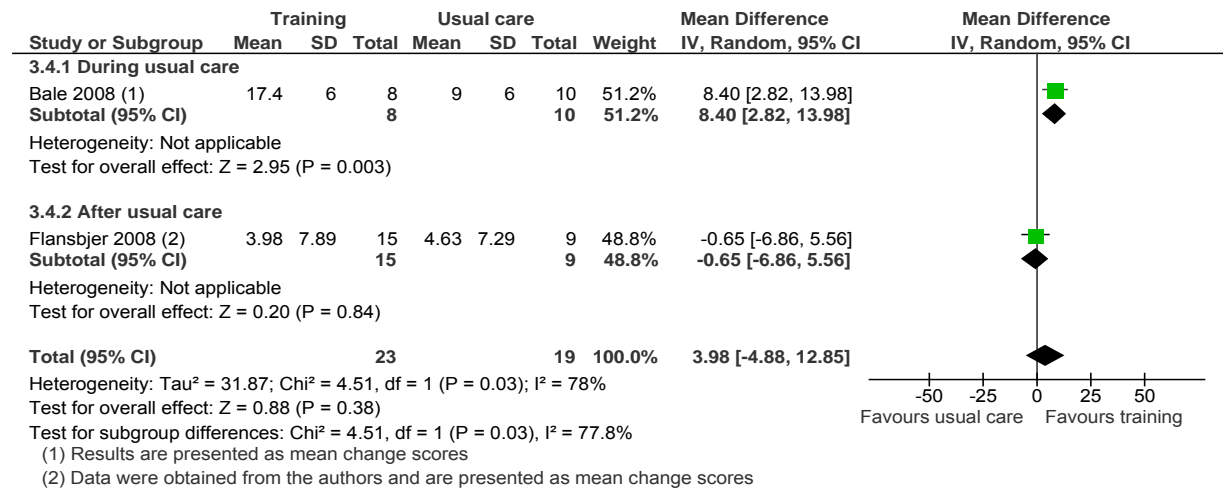


Figure 144: Mobility - preferred gait speed (m/min)

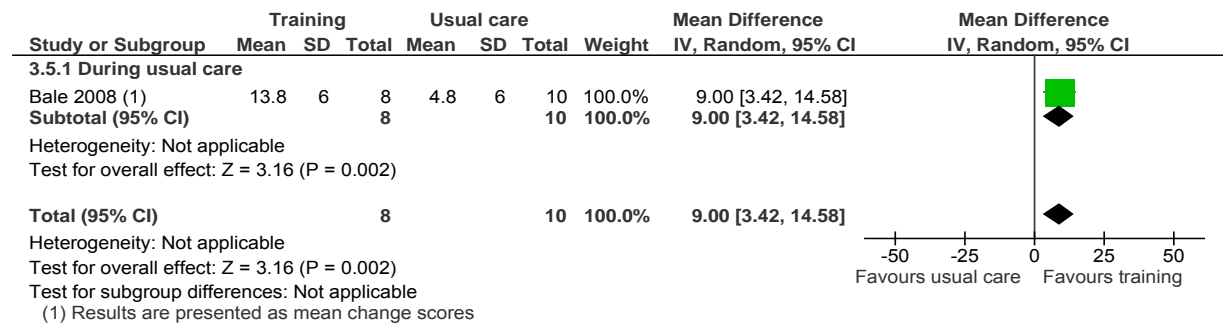


Figure 145: Mobility – Rivermead

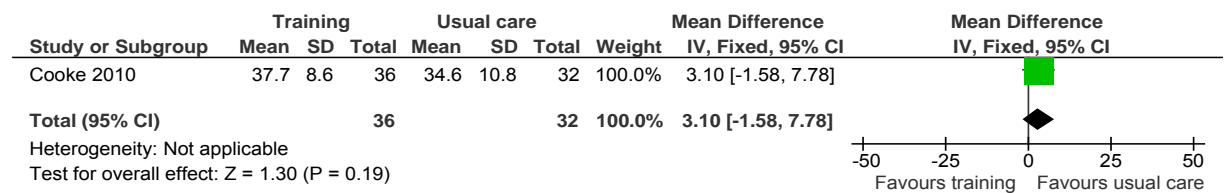


Figure 146: Physical function - weight-bearing (% body weight - affected side)

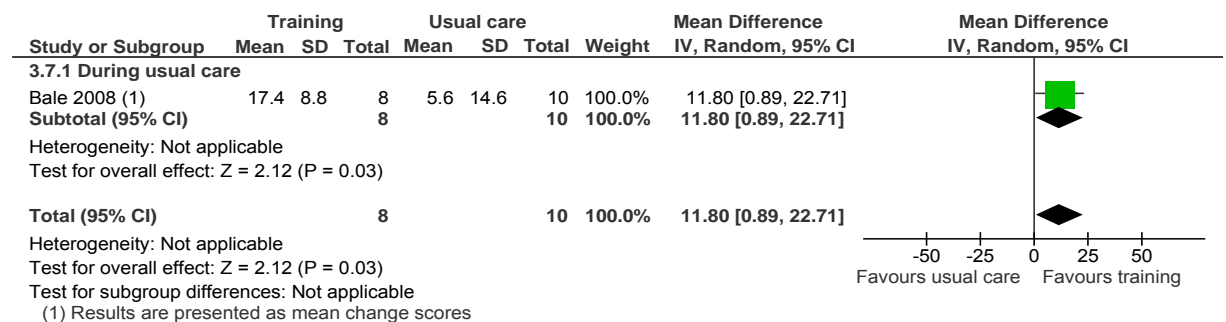


Figure 147: Physical function - stair climbing, maximal (sec/step)

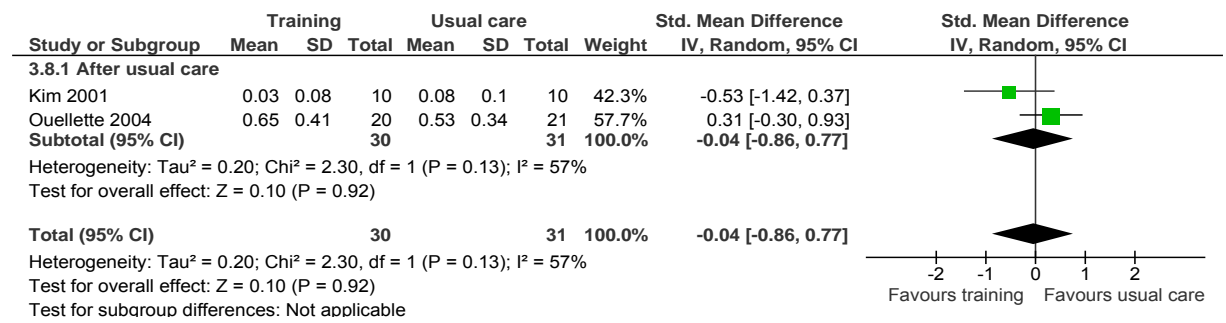


Figure 148: Physical function - Timed Up and Go (sec)

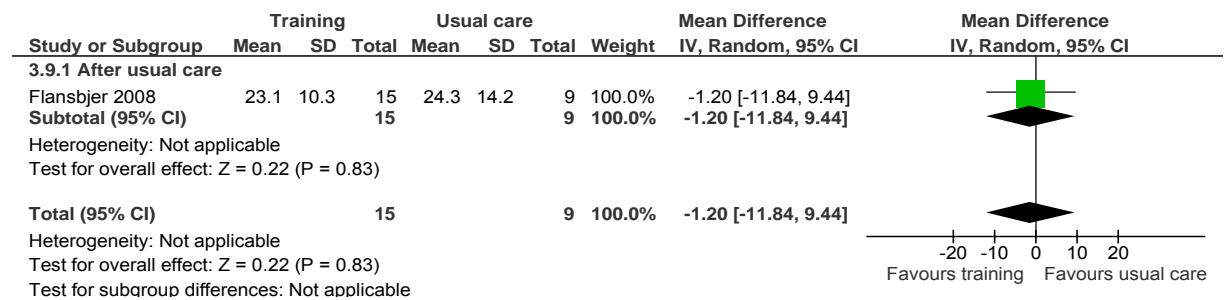


Figure 149: Health related QoL - SF-36 physical functioning

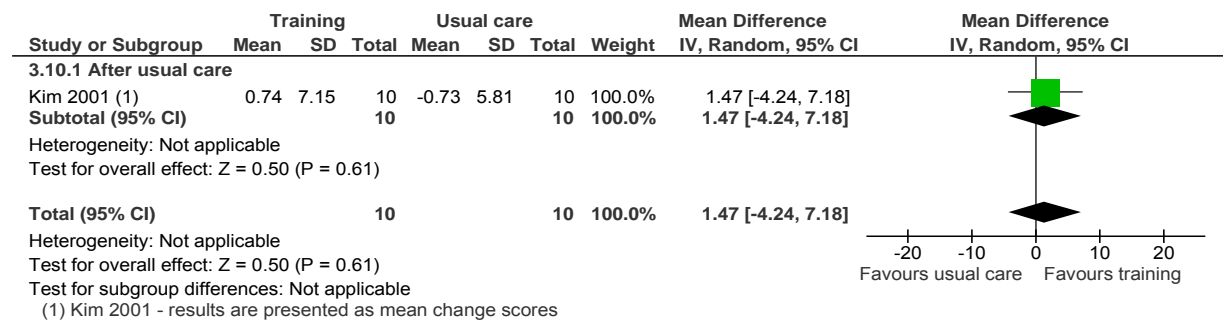


Figure 150: Health related QoL - SF-36 mental health

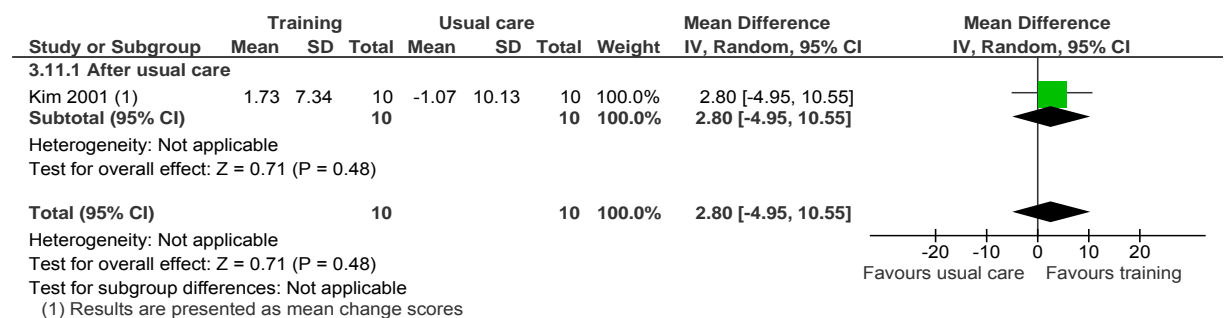


Figure 151: EuroQol Self-perceived health

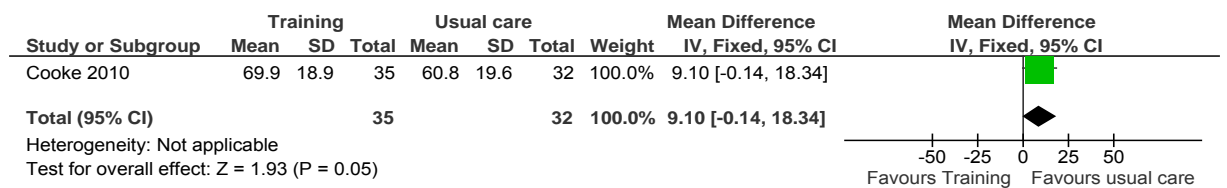
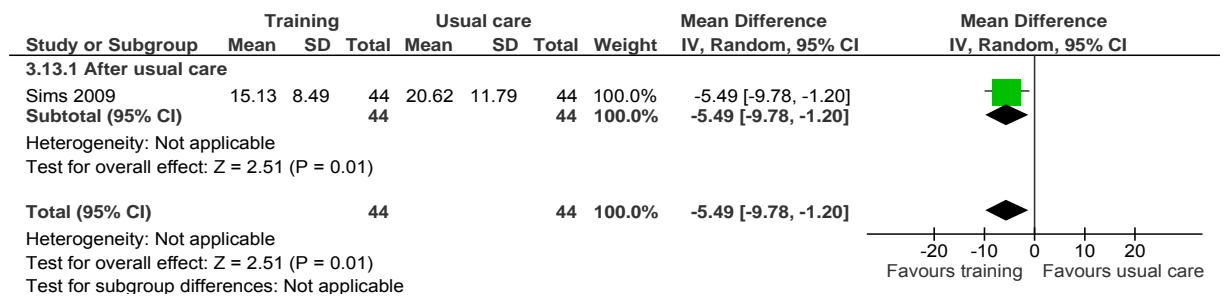


Figure 152: Mood - Centre for Epidemiologic Studies for Depression scale (CES-D)



J.7.4 Resistance training versus usual care – end of retention follow-up

Figure 153: Physical fitness - muscle strength, knee extension (Nm)

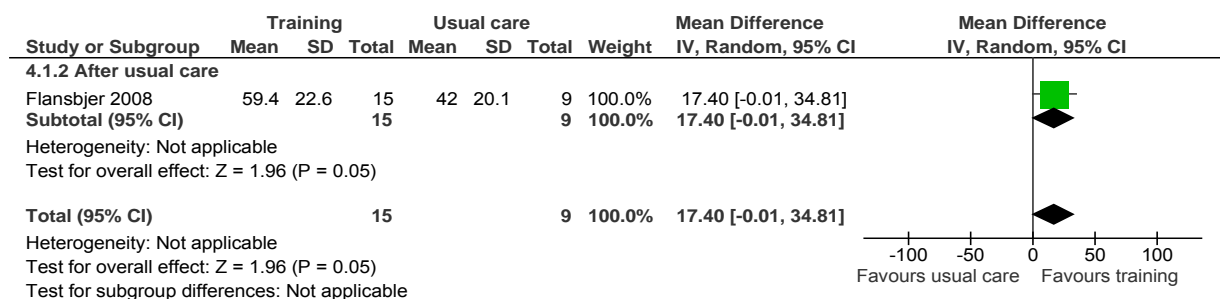


Figure 154: Physical fitness - muscle strength, knee flexion (Nm)

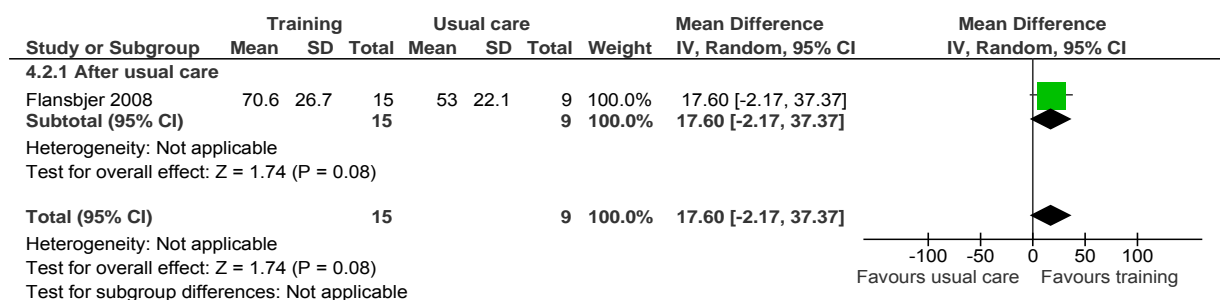


Figure 155: Mobility - maximal gait speed (m/min)

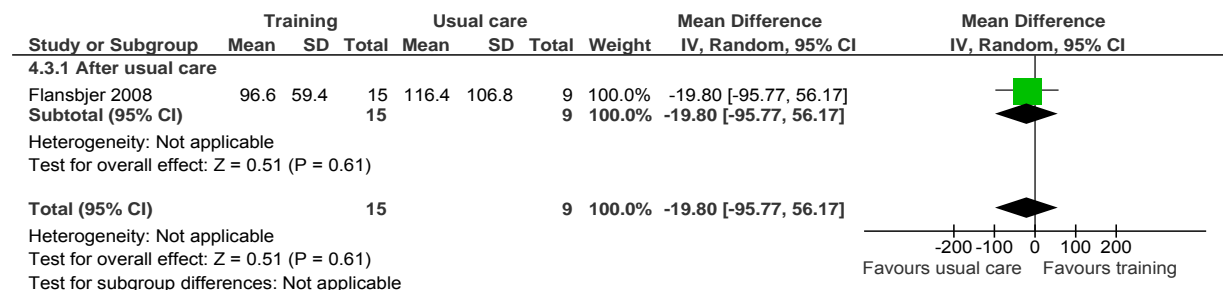


Figure 156: Mobility – Rivermead

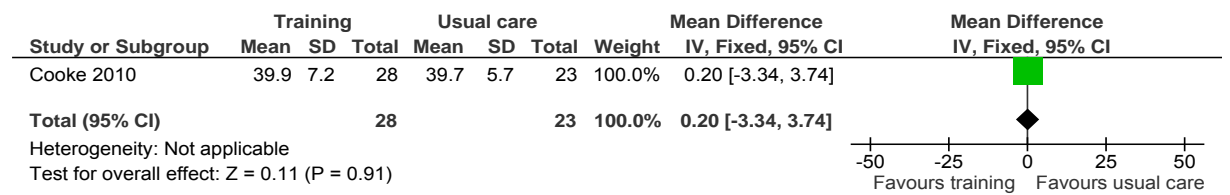


Figure 157: Physical function - Timed Up and Go (sec)

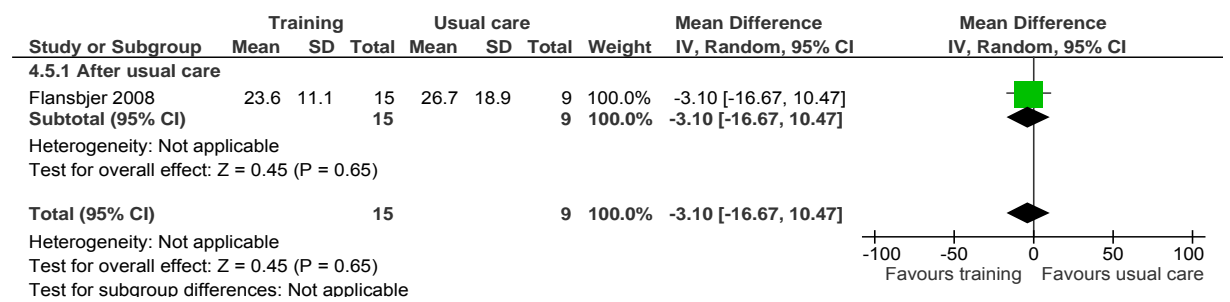


Figure 158: Mood - Centre for Epidemiologic Studies for Depression scale (CES-D)

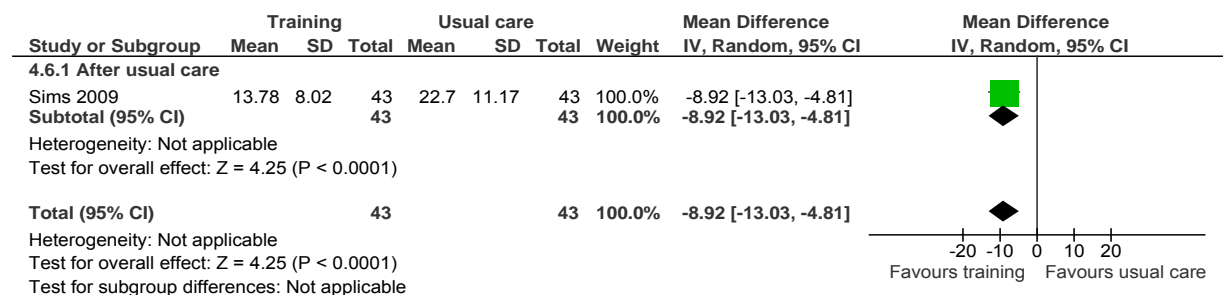
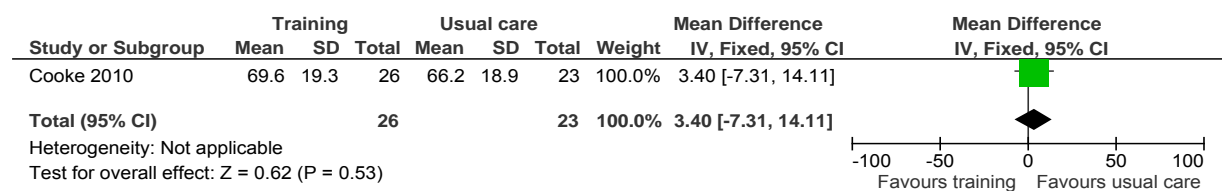
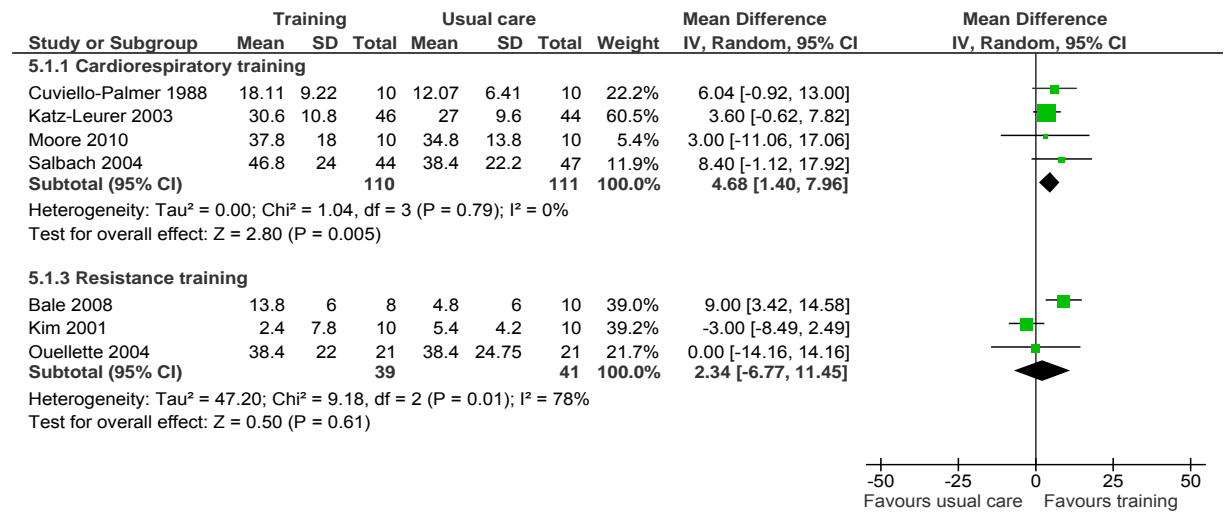


Figure 159: EuroQuol Self-perceived health



J.7.5 Cardiorespiratory versus resistance training

Figure 160: Mobility - gait preferred speed (m/min)



J.8 What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?

J.8.1 Listener advice/information versus usual care

Figure 161: Measure of skill (of listener) in providing supported conversation for adults with aphasia (acknowledge competence) (Post-test)

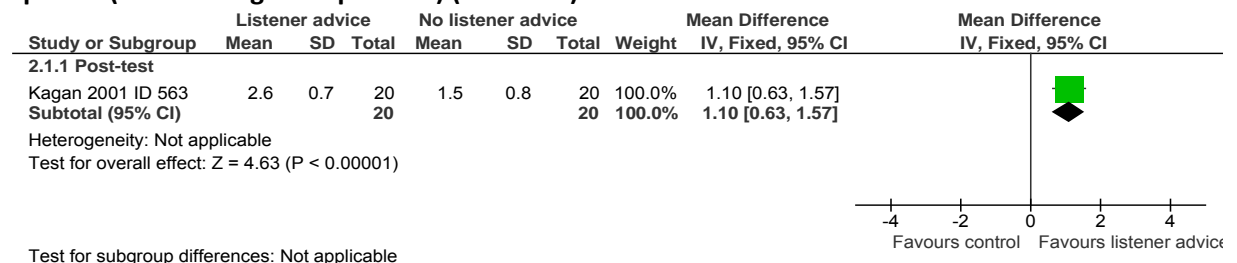


Figure 162: Measure of skill (of listener) in providing supported conversation for adults with aphasia (reveal competence) (Post-test)

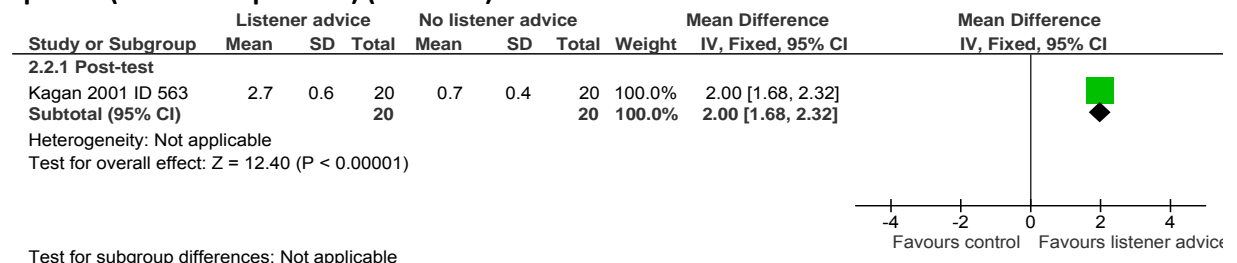


Figure 163: Measure of participation (of person with aphasia) in conversation for adults with

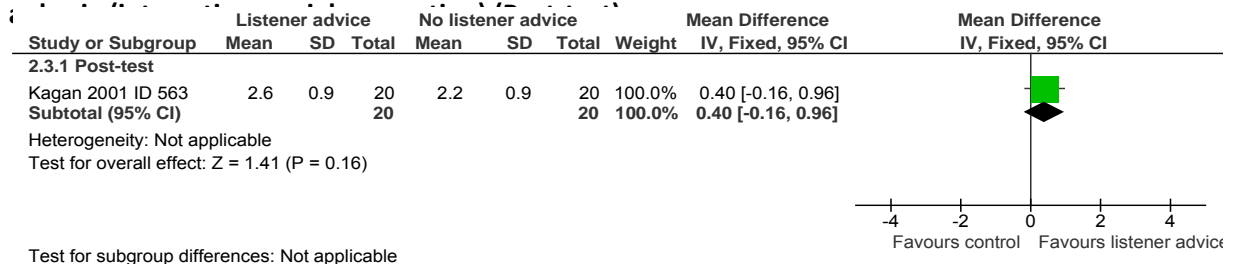
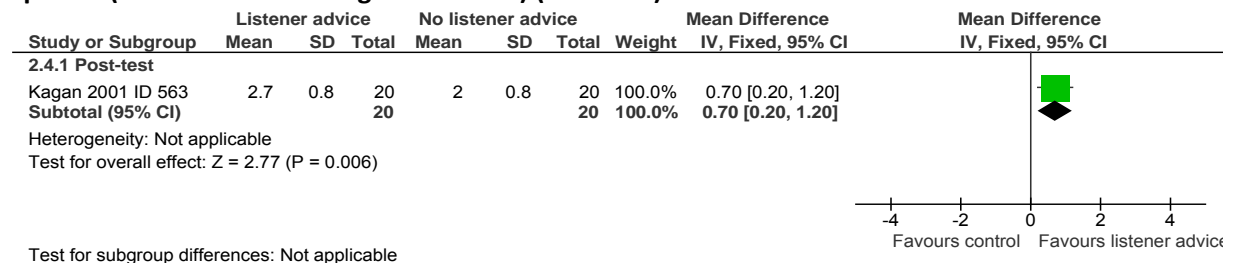


Figure 164: Measure of participation (of person with aphasia) in conversation for adults with aphasia (transaction: exchange of content) (Post-test)



J.9 In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?

J.9.1 Neutral splint versus usual care

Figure 165: Wrist extensibility in 4 weeks

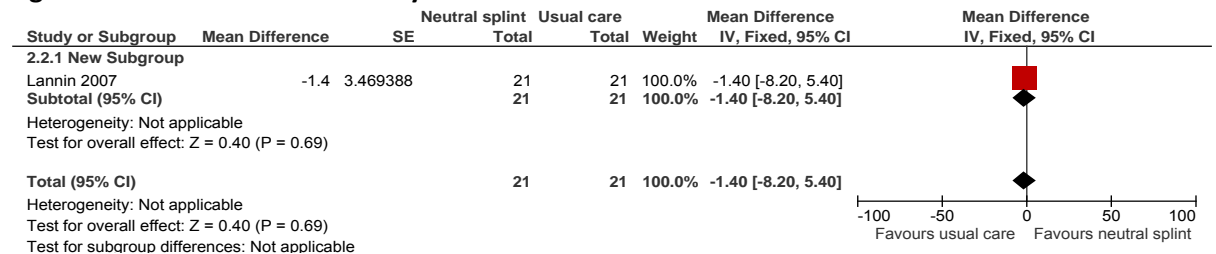
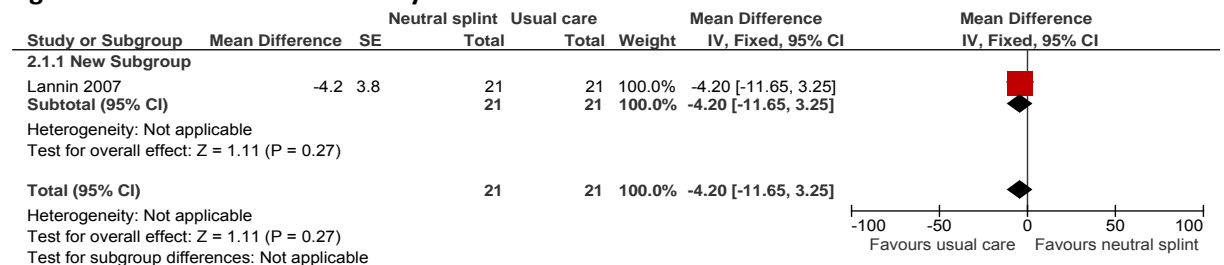


Figure 166: Wrist extensibility in 6 weeks



J.9.2 Extension splint versus usual care

Figure 167: Wrist extensibility in 4 weeks

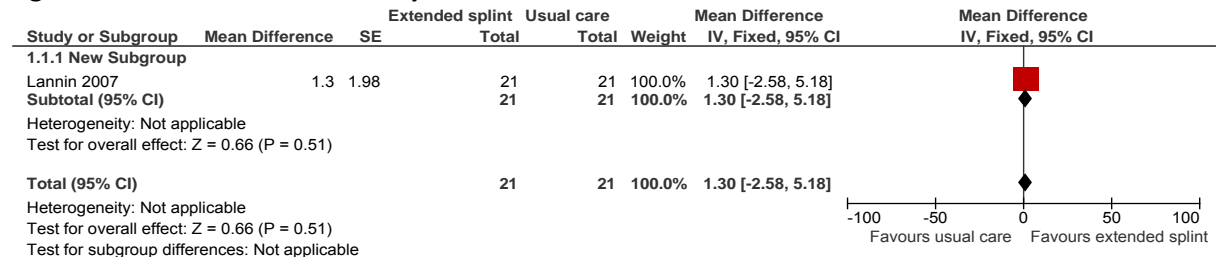


Figure 168: Wrist extensibility in 6 weeks

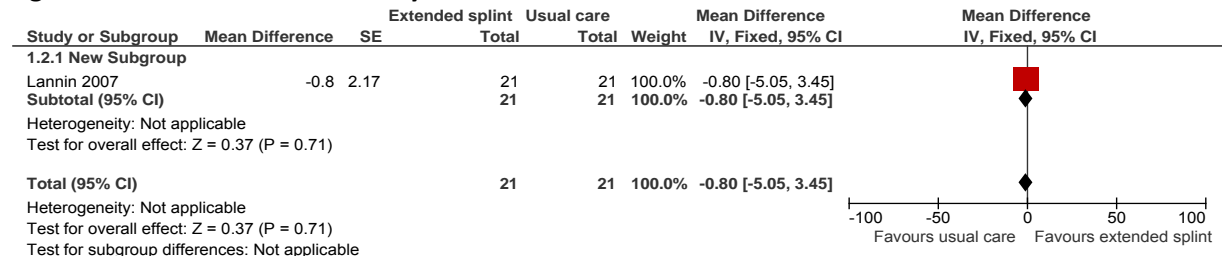
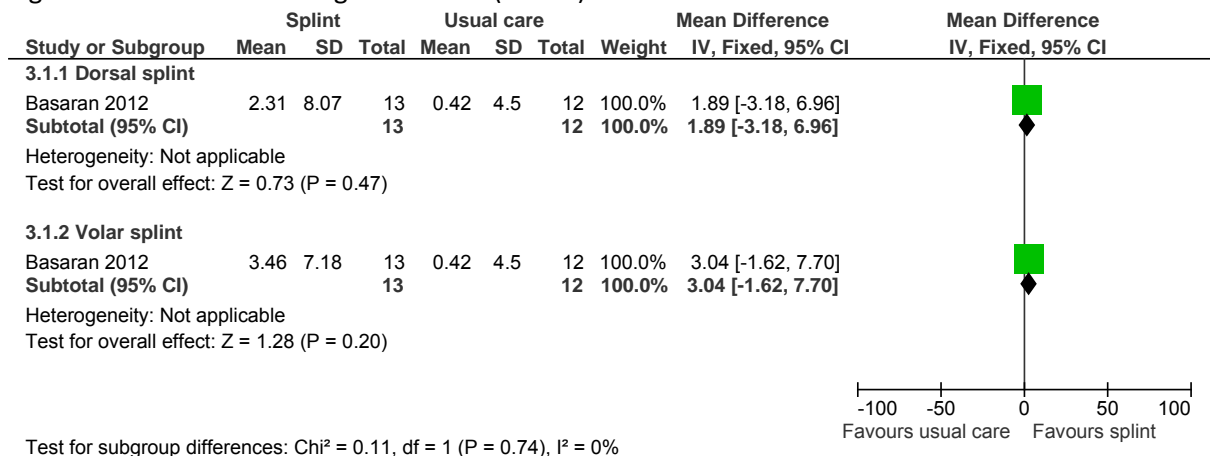
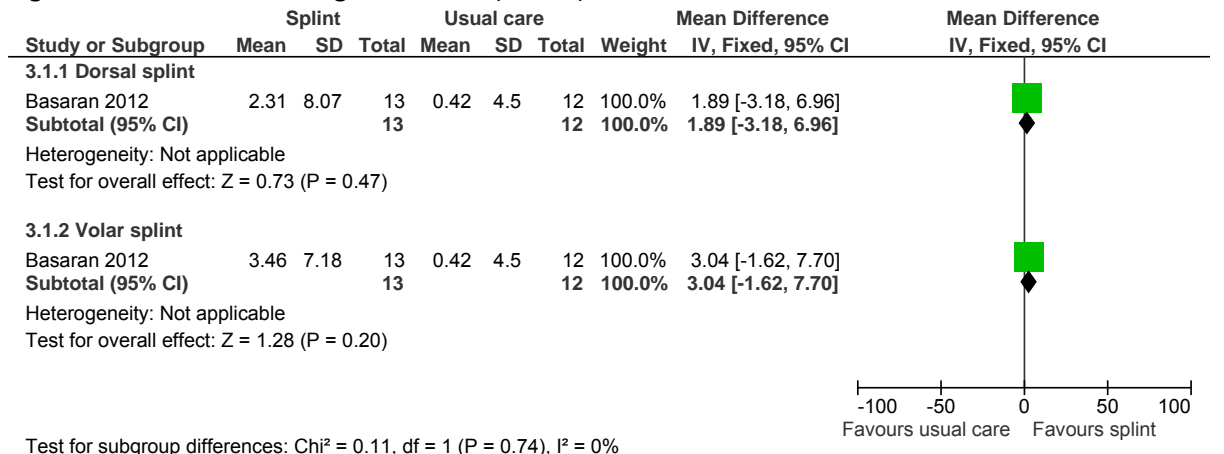


Figure 169: Passive range of motion (PROM) of wrist extension



J.9.3 Static dorsal / volar splint versus usual care

Figure 170: Passive range of motion (PROM) – wrist extension



J.10 In people after stroke what is the clinical and cost-effectiveness of functional electrical stimulation (FES) for hand function versus usual care?

J.10.1 Functional electrical stimulation versus usual care

Figure 171: Box and Blocks (number of blocks moved in 1 minute)

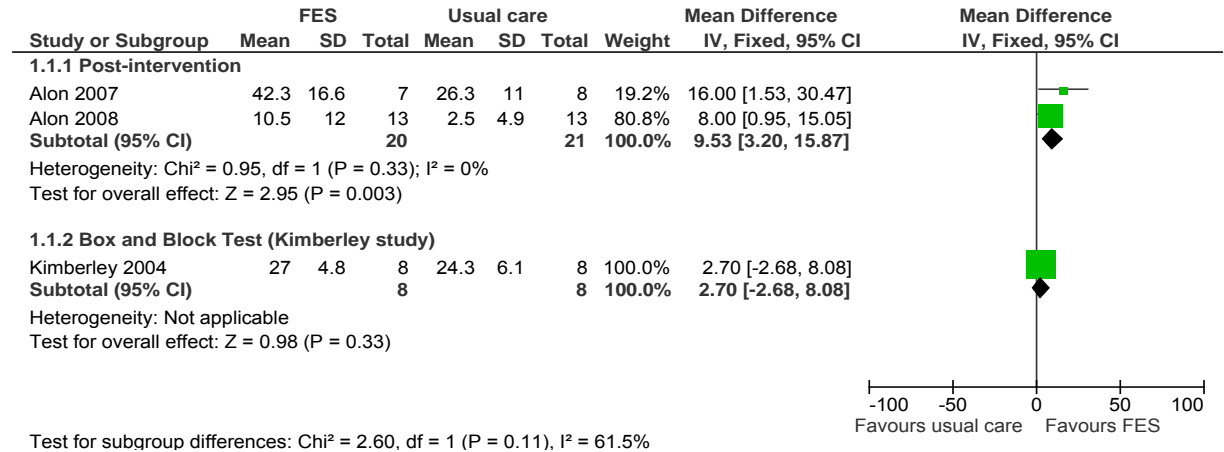


Figure 172: Jepsen-Taylor light object lift test (time to move 5 large empty cans)

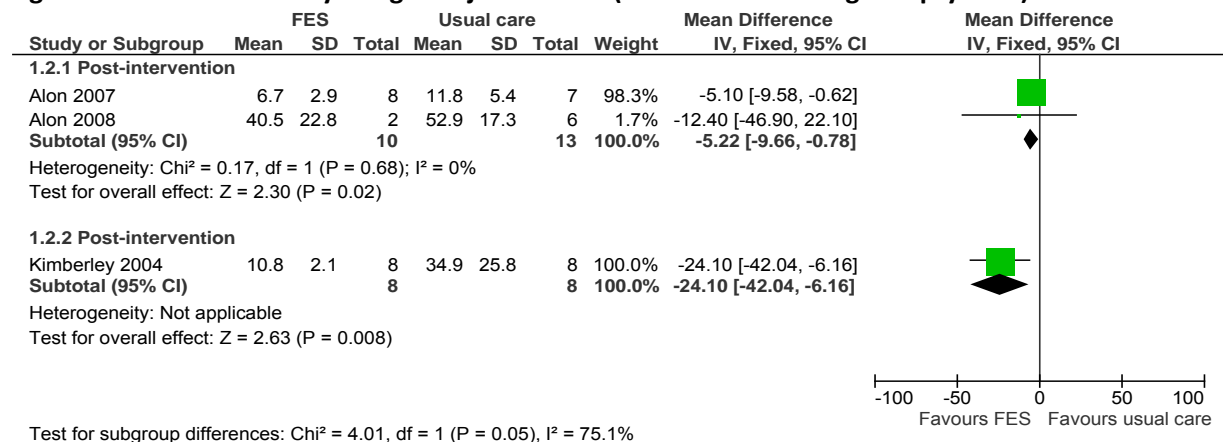
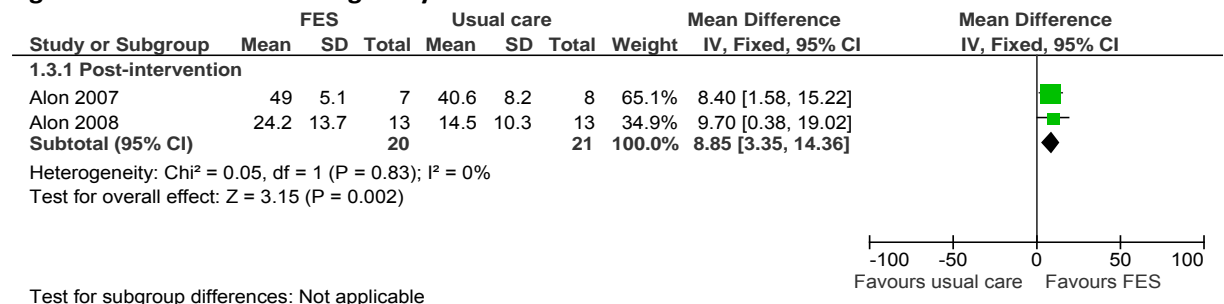


Figure 173: Modified Fugl-Meyer Assessment



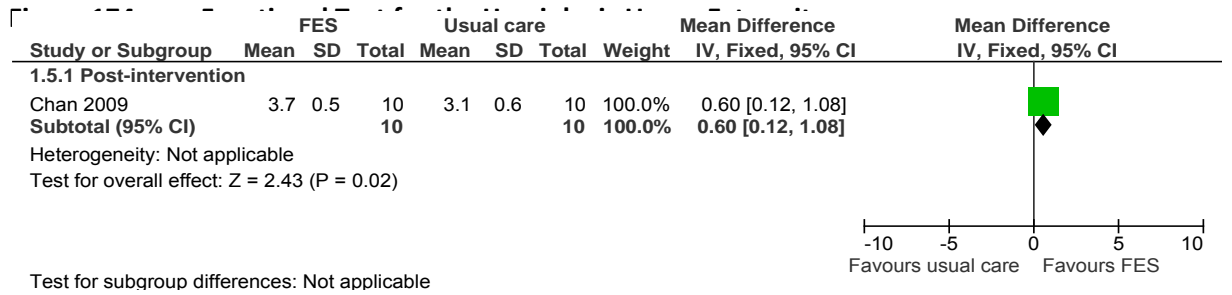


Figure 175: Forward reach distance (cm)

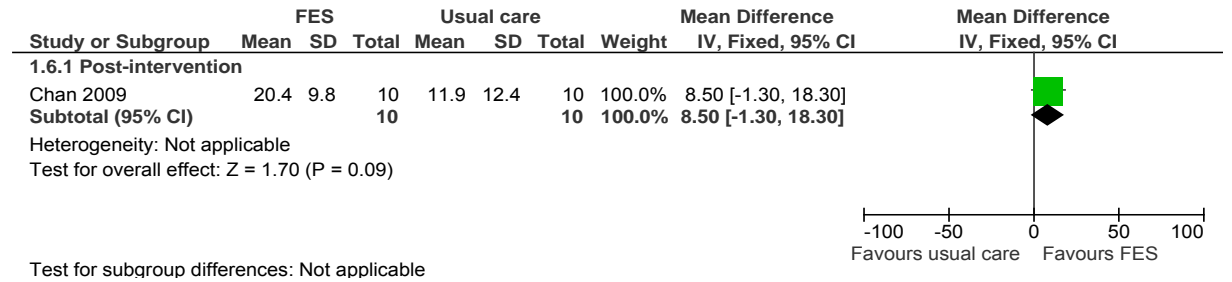


Figure 176: Range of motion wrist extension (degrees)

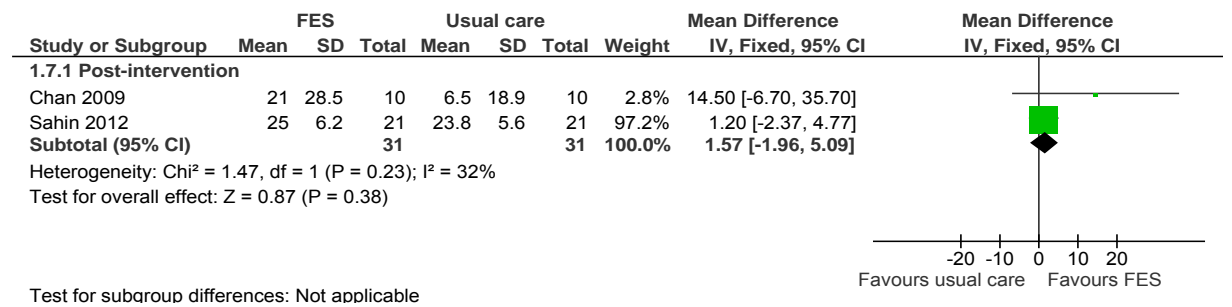


Figure 177: Grip power (kg)

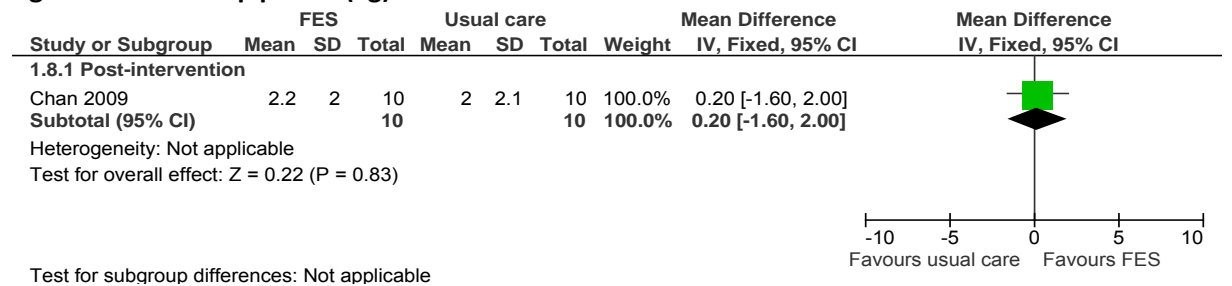
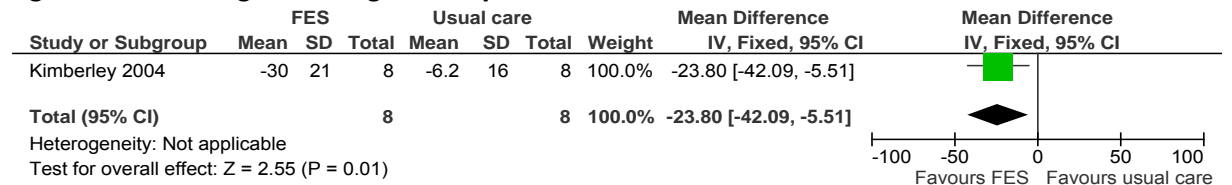


Figure 178: Finger tracking accuracy test



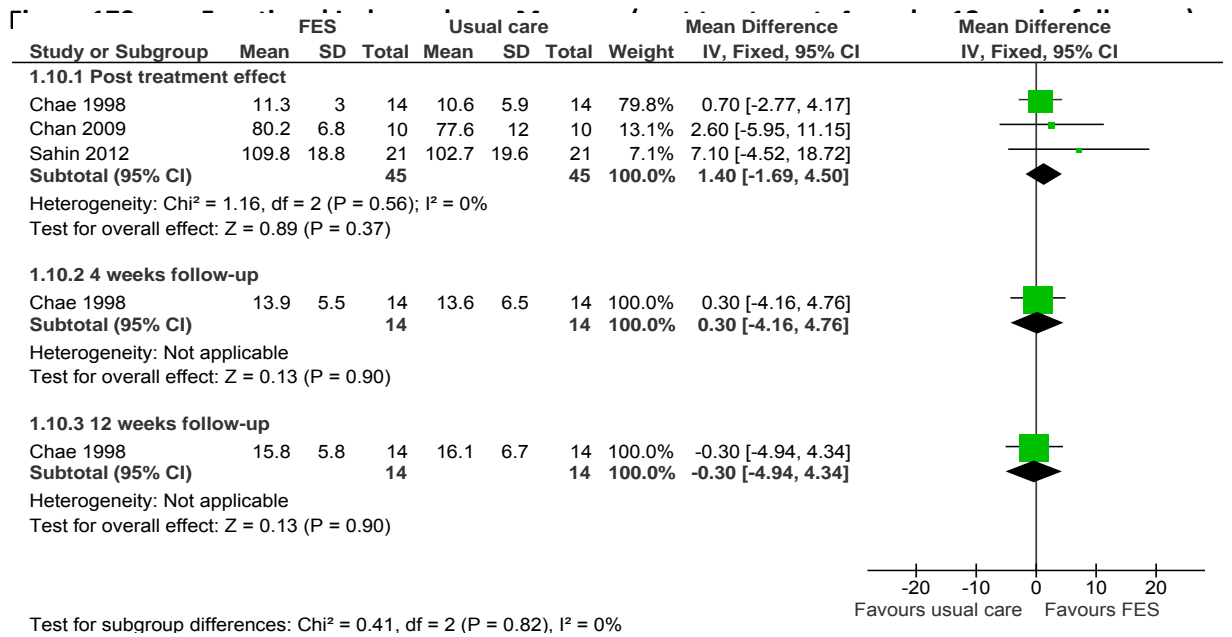


Figure 180: MAS of shoulder

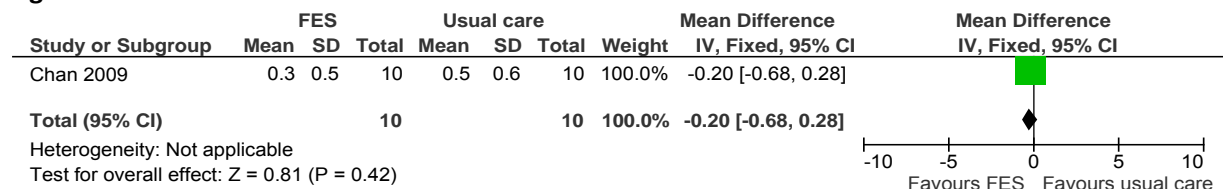


Figure 181: MAS of elbow

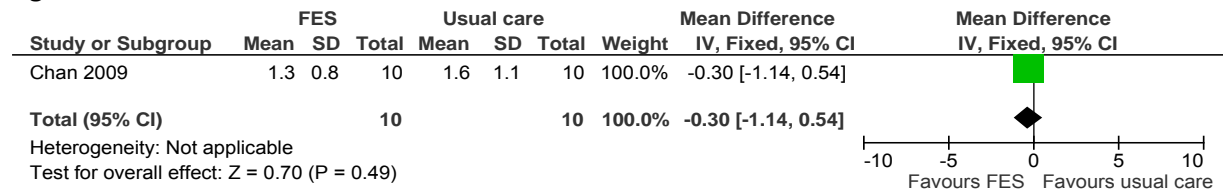


Figure 182: Strength of finger extension (Newtons)

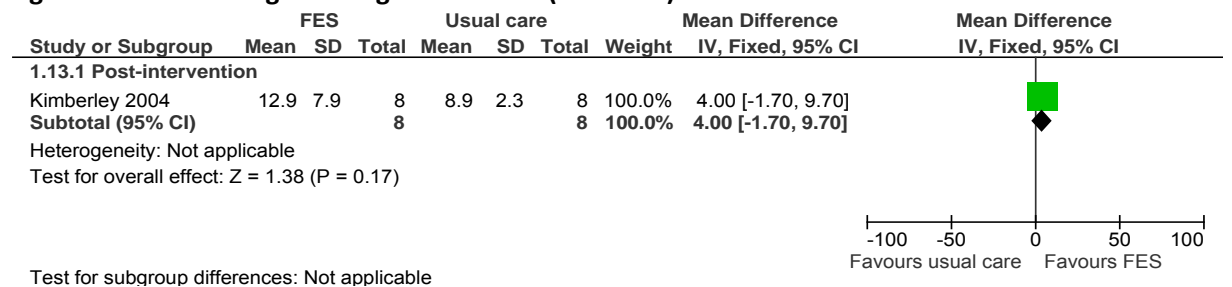
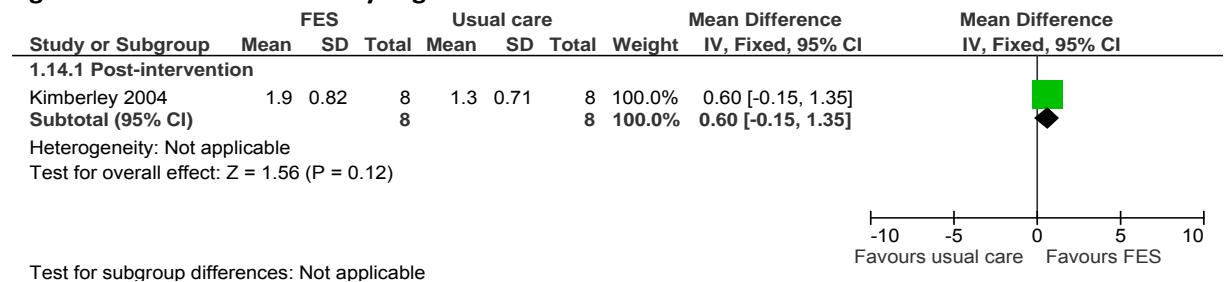


Figure 183: Motor Activity Log- amount of use score



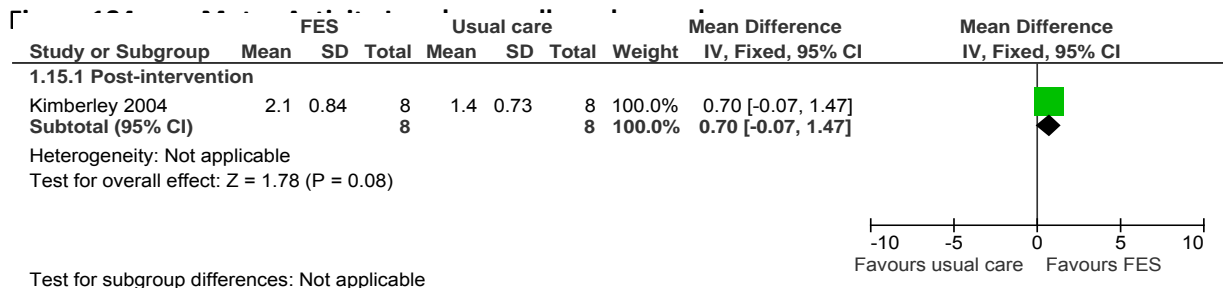


Figure 185: Motor Activity Log – how well used scored and quality of movement (low and high dose)

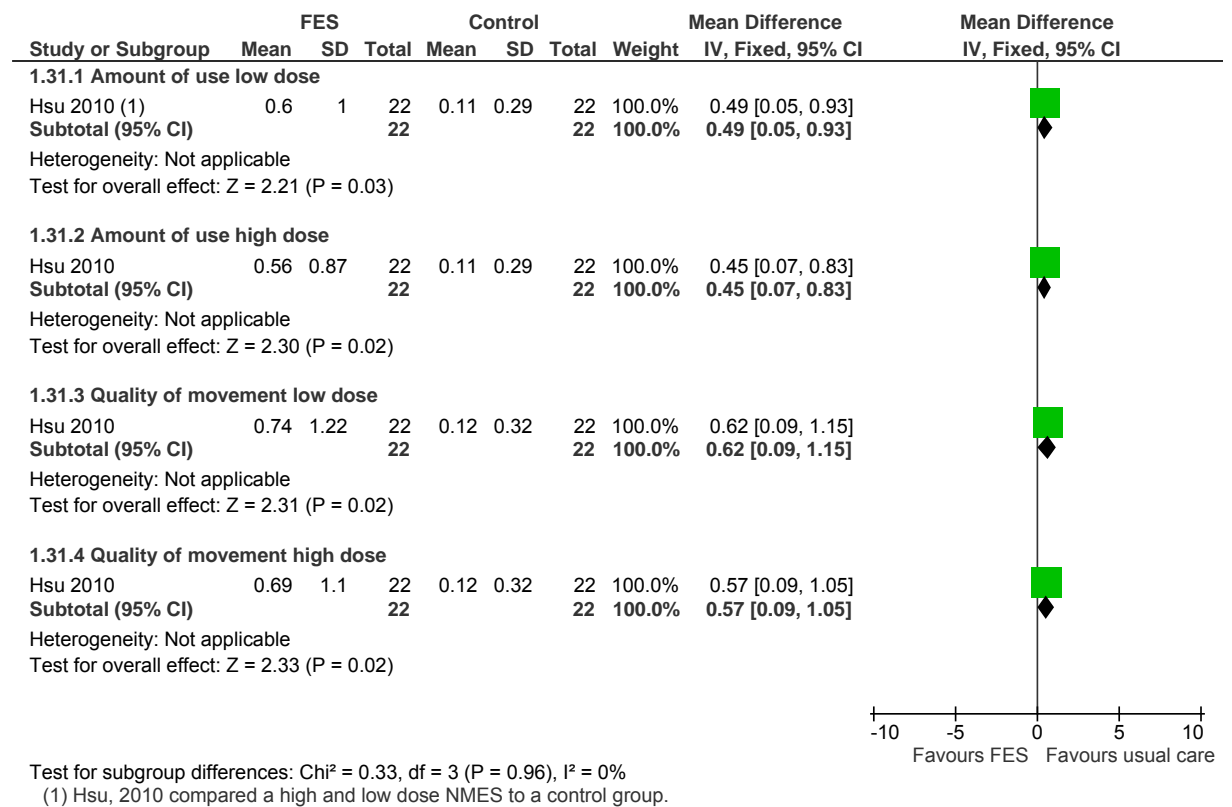
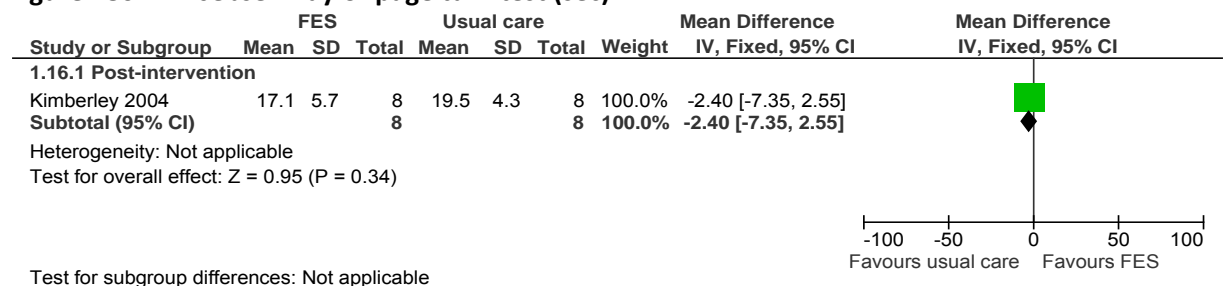


Figure 186: Jebsen-Taylor page turn test (sec)



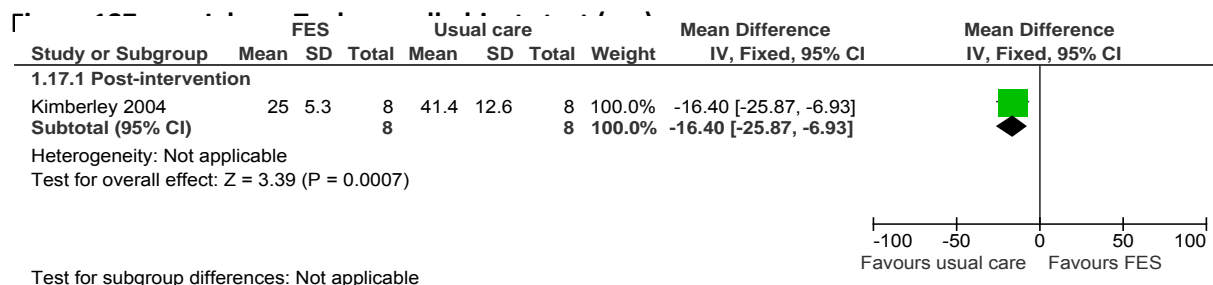


Figure 188: Jebsen-Taylor feeding test (sec)

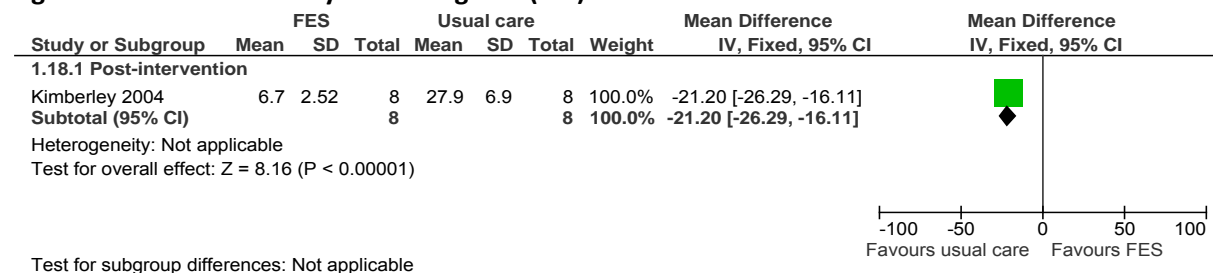


Figure 189: Jebsen-Taylor stacking test (sec)

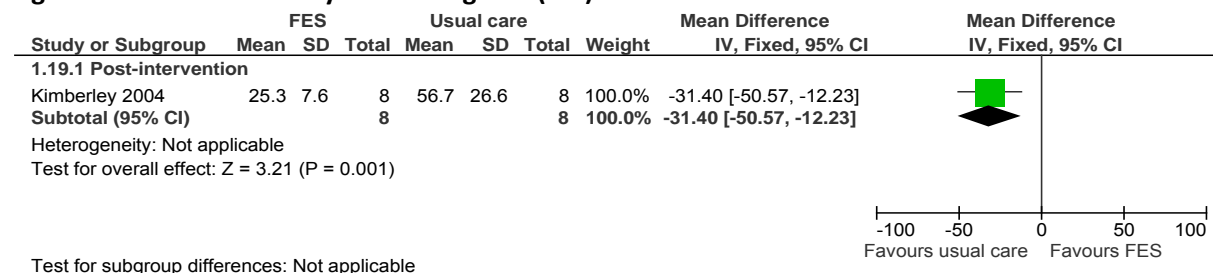
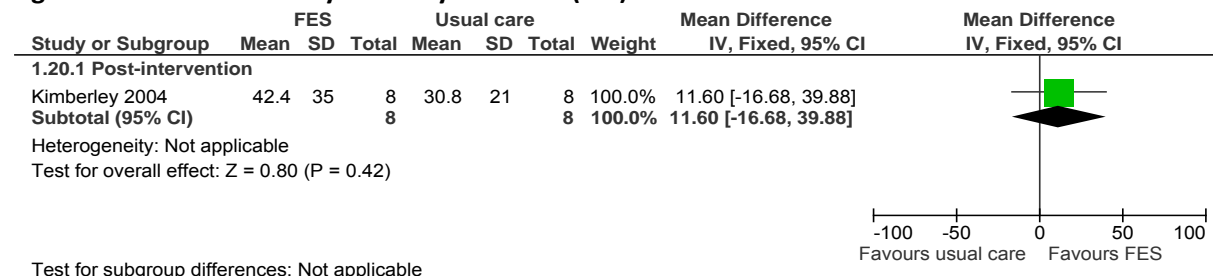


Figure 190: Jebsen-Taylor heavy cans test (sec)



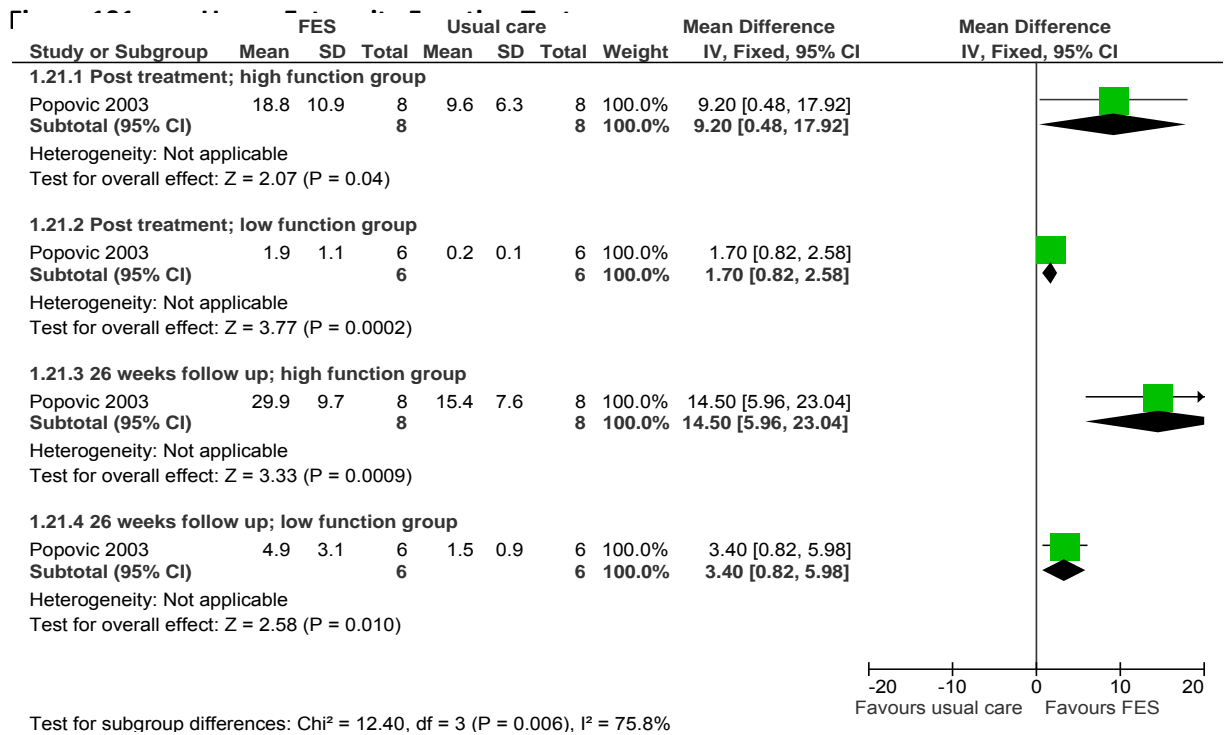
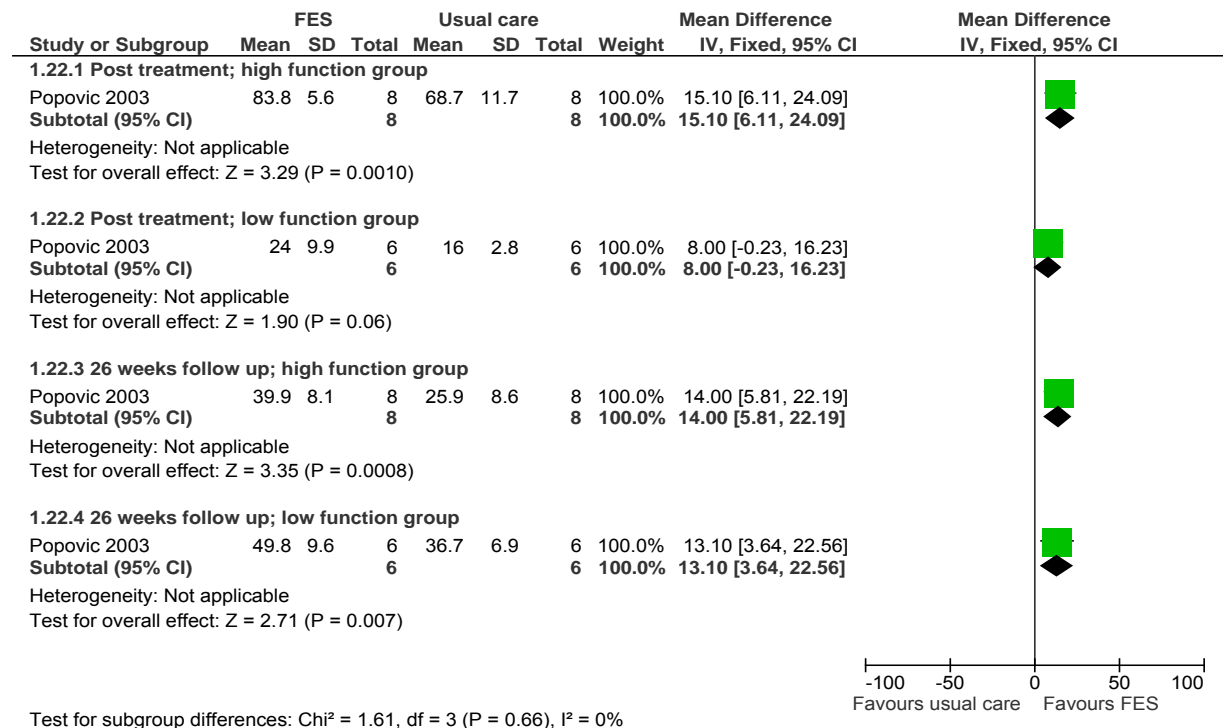


Figure 192: Drawing test (% area compared with target square)



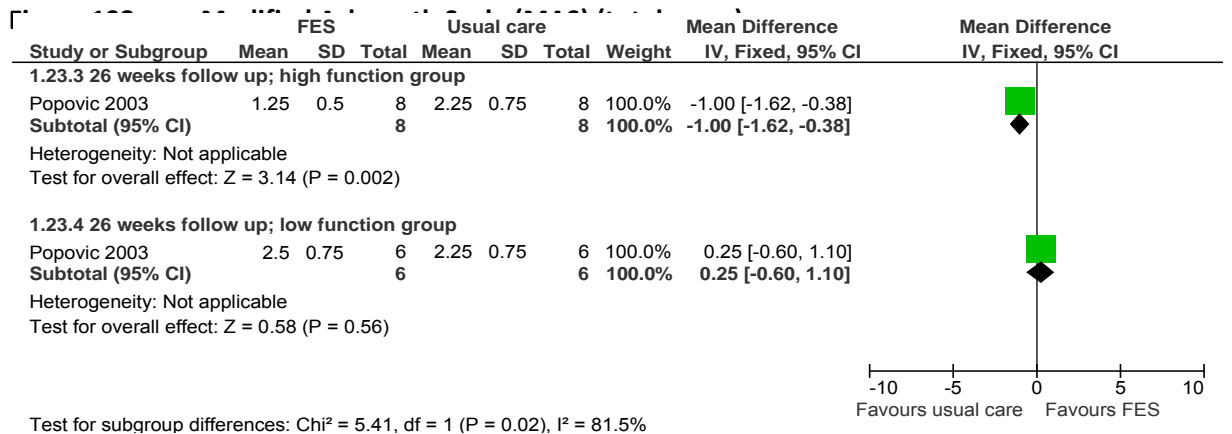


Figure 194: MAS of wrist

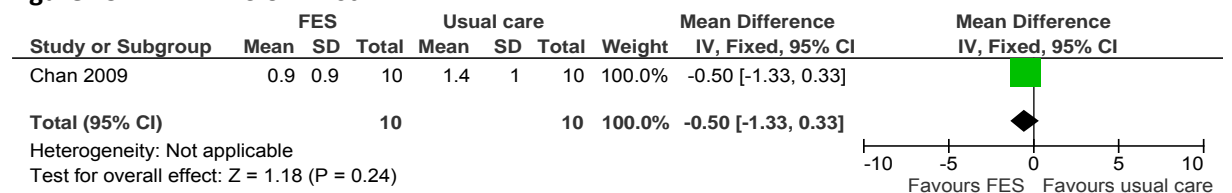


Figure 195: Reduced Upper Extremity Motor Activity Log questionnaire – Amount Scale

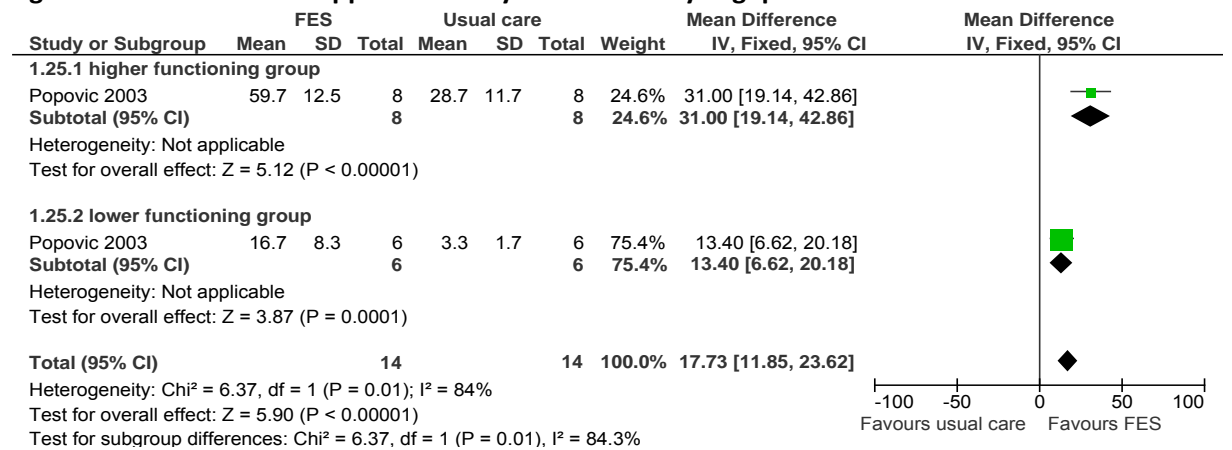
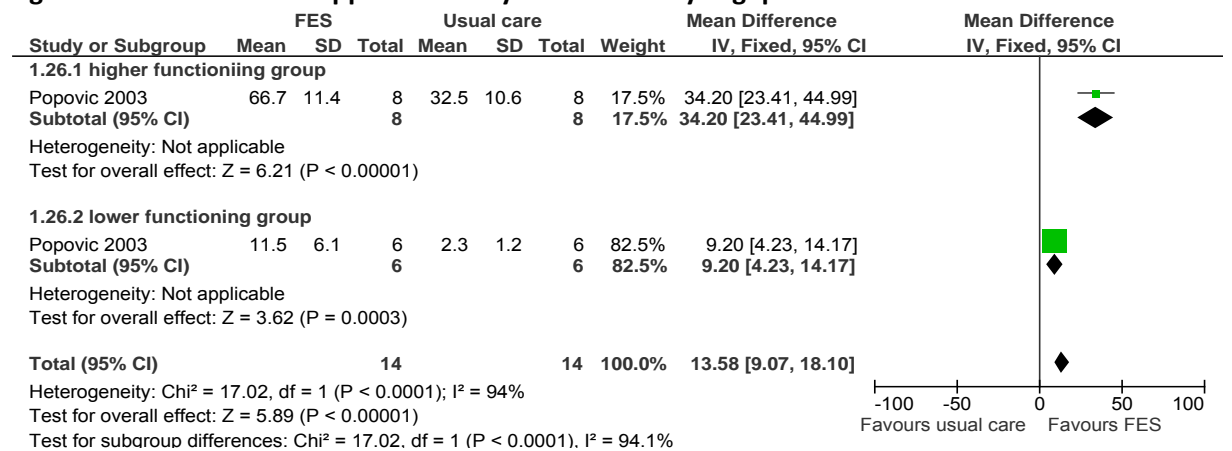


Figure 196: Reduced Upper Extremity Motor Activity Log questionnaire – How well scale



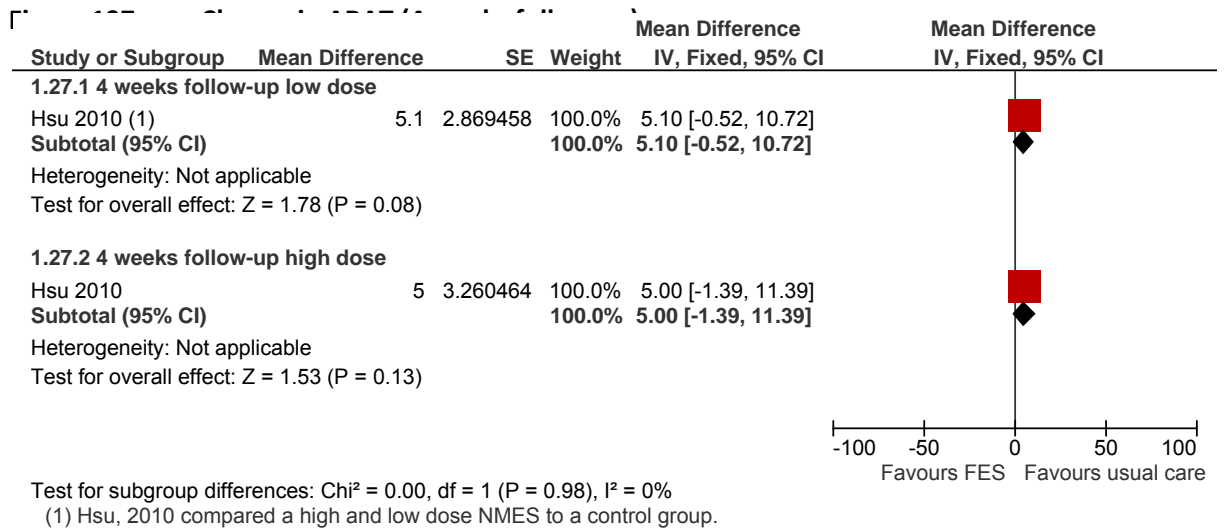


Figure 198: Change in ARAT (12 weeks follow up)

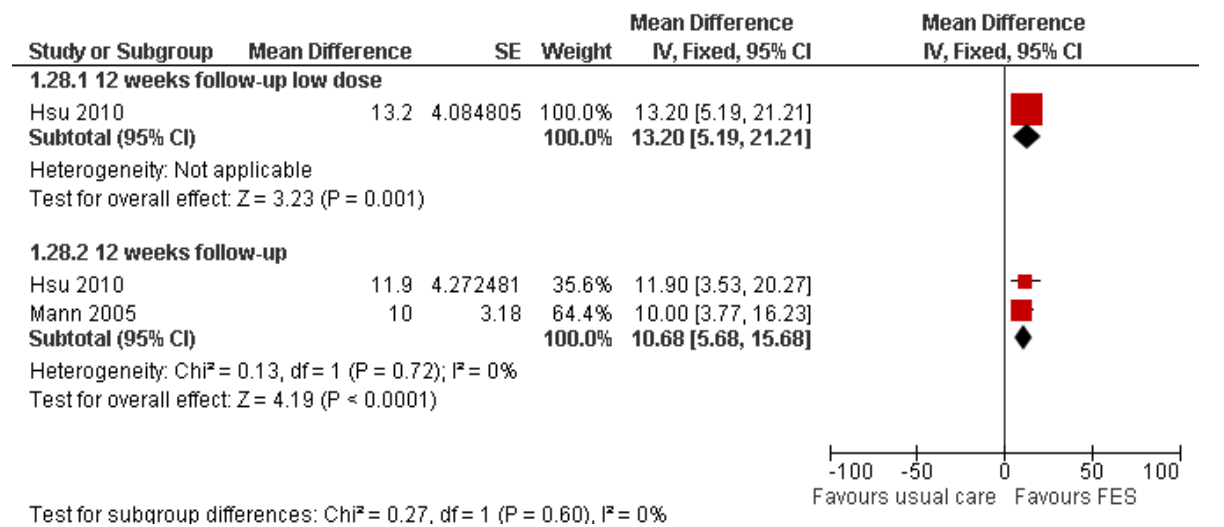


Figure 199: Change in ARAT (24 weeks follow up)

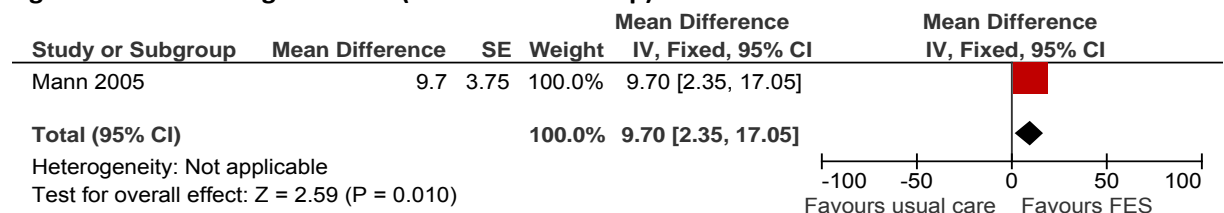
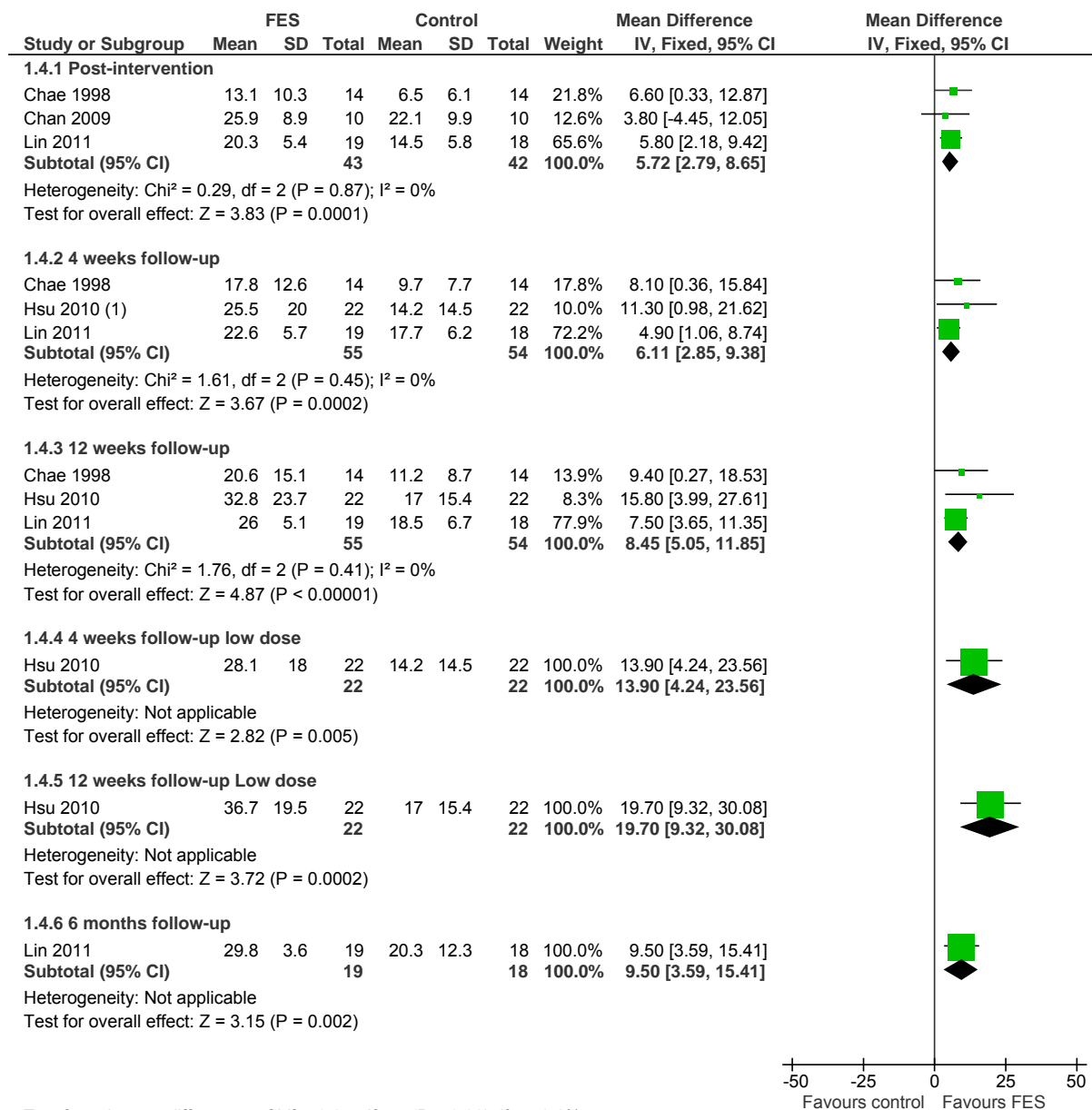


Figure 200: Upper limb section of the Fugl-Meyer Assessment (post treatment, 1 month, 3 months, and 6 months follow up)



Test for subgroup differences: Chi² = 9.84, df = 5 (P = 0.08), I² = 49.2%
(1) Hsu, 2010 compared a high and low dose NMES to a control group.

Figure 201: Modified Ashworth Scale (post treatment, 1 month, 3 months, and 6 months)

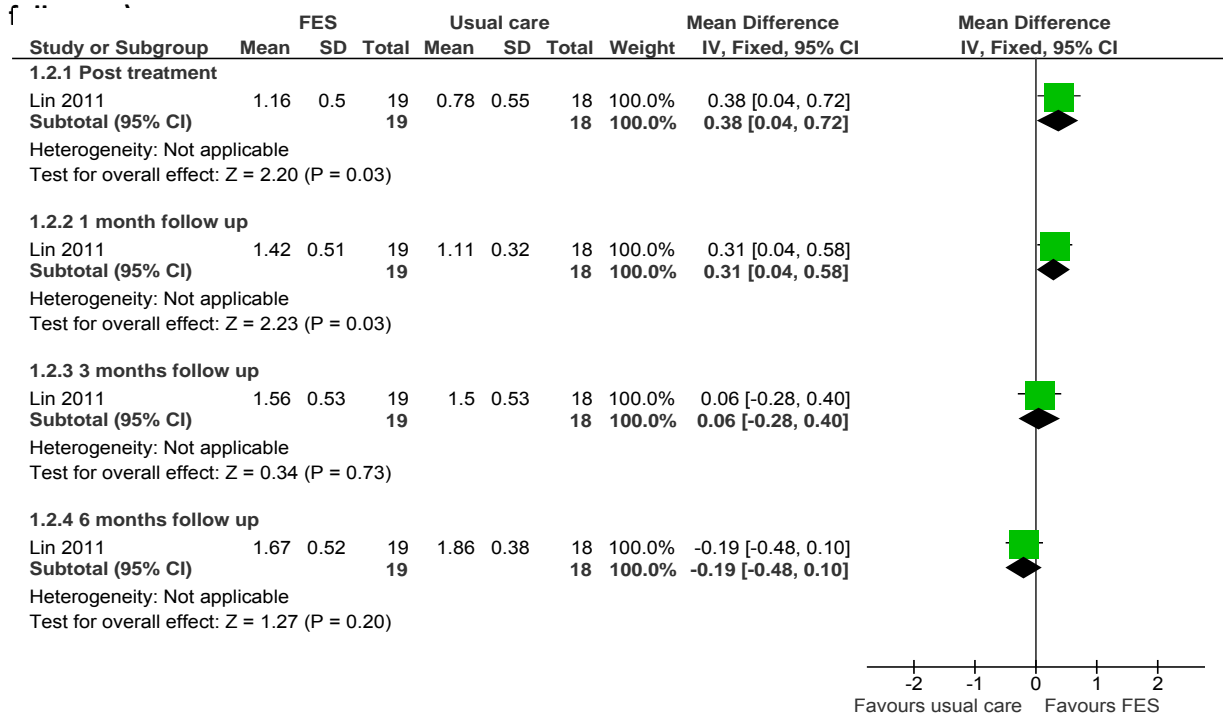
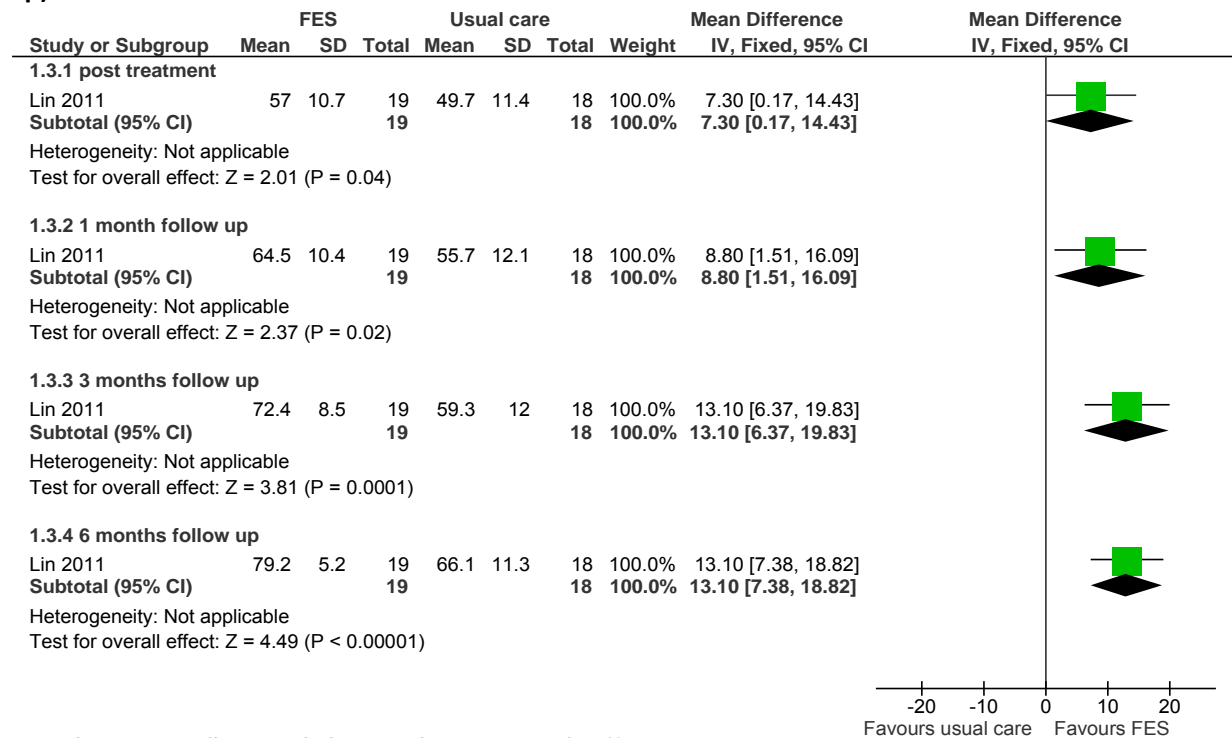
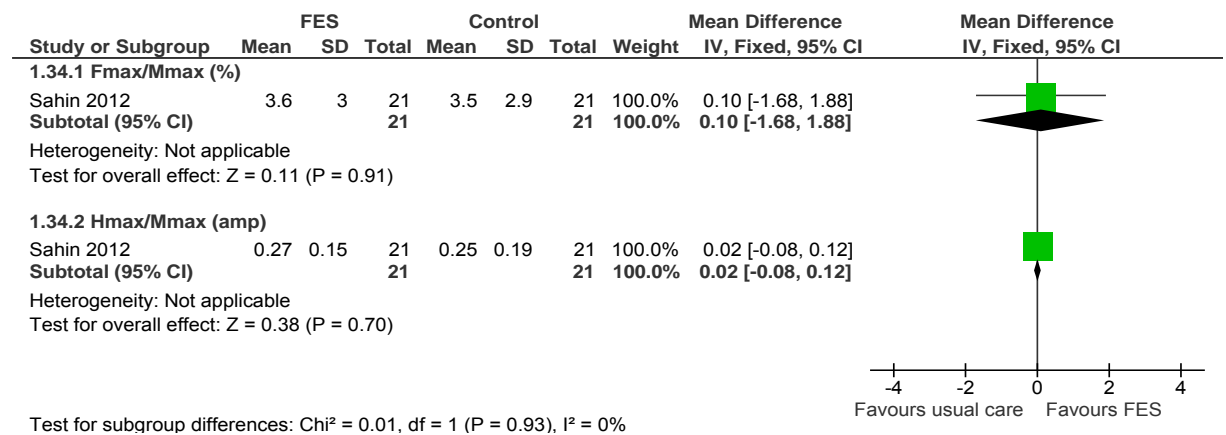


Figure 202: Modified Barthel Index (post treatment, 1 month, 3 months, and 6 months follow up)



Test for subgroup differences: Chi² = 2.27, df = 3 (P = 0.52), I² = 0%

Figure 203: Electrophysiological evaluation (Post treatment)



J.11 In people after stroke what is the clinical and cost effectiveness of constraint induced therapy versus usual care on improving function and reducing disability?

J.11.1 Constraint induced therapy versus usual care

Figure 204: Action Research Arm Test (post-intervention)

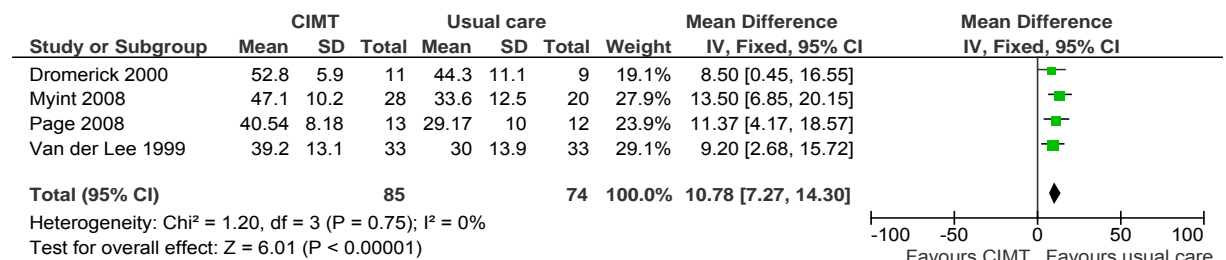


Figure 205: Action Research Arm Test (4 week follow up)

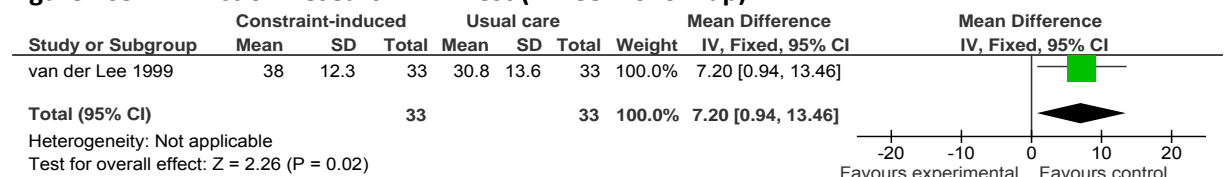
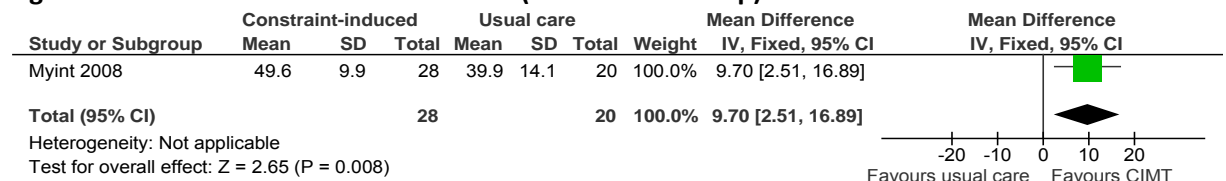


Figure 206: Action Research Arm Test (12 week follow up)



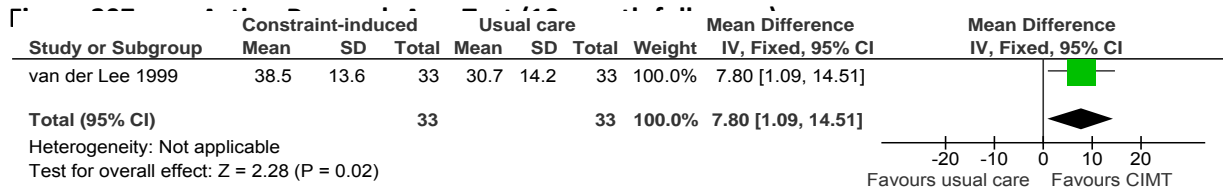


Figure 208: Wolf Motor Function Test (performance time) (post-intervention)

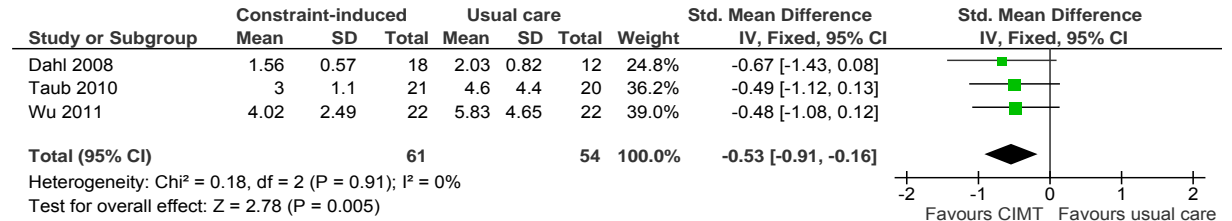


Figure 209: Wolf Motor Function Test (performance time) (6 month follow up)

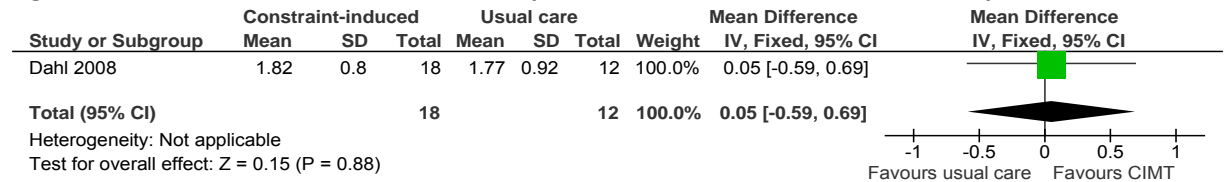


Figure 210: Change in Wolf Motor Function Test (performance time) (12 month follow up)

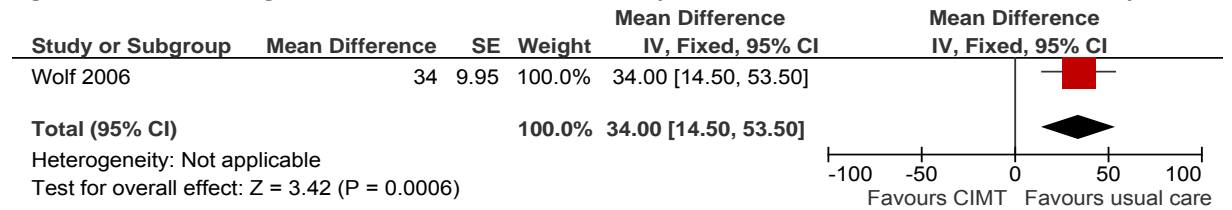


Figure 211: Wolf Motor Function Test (functional ability) (post-intervention)

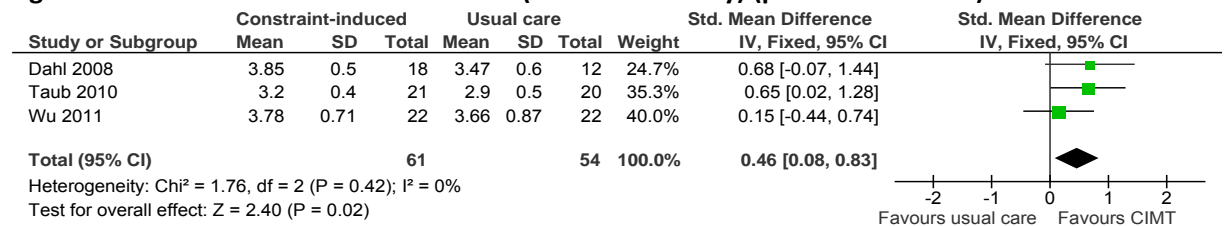


Figure 212: Wolf Motor Function Test (functional ability) (6 month follow up)

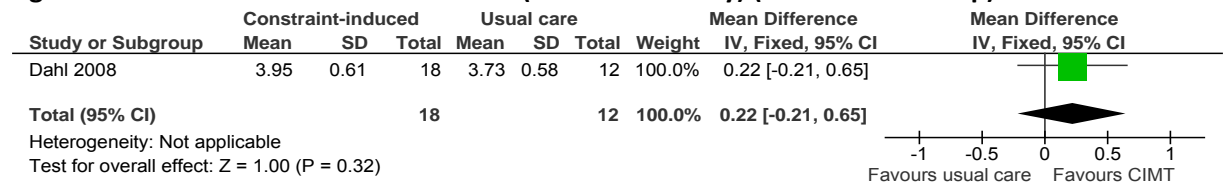
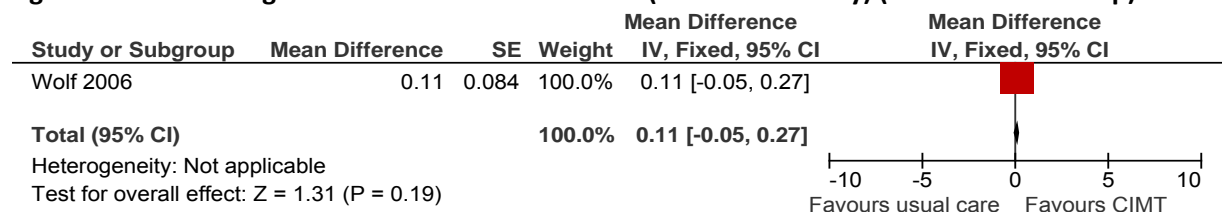


Figure 213: Change in Wolf Motor Function Test (functional ability) (12 month follow up)



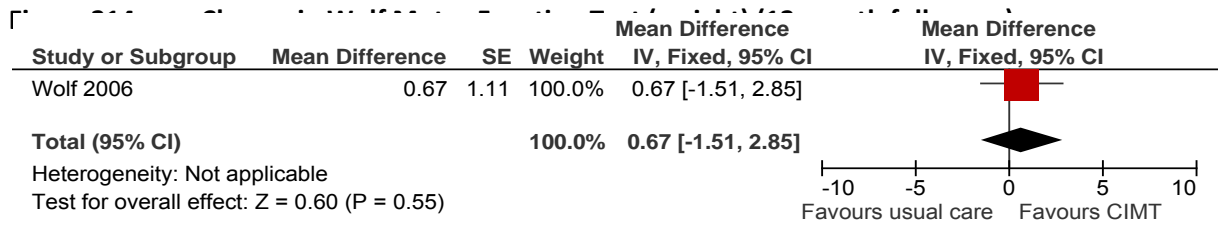


Figure 215: Change in Wolf Motor Function Test (grip) (12 month follow up)

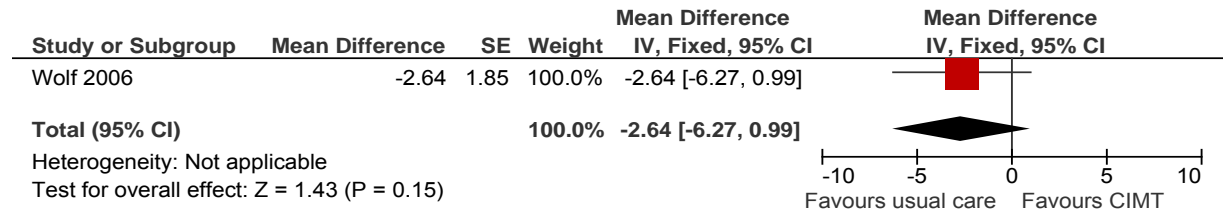


Figure 216: Total Functional Independence Measure (total score) (post-intervention)

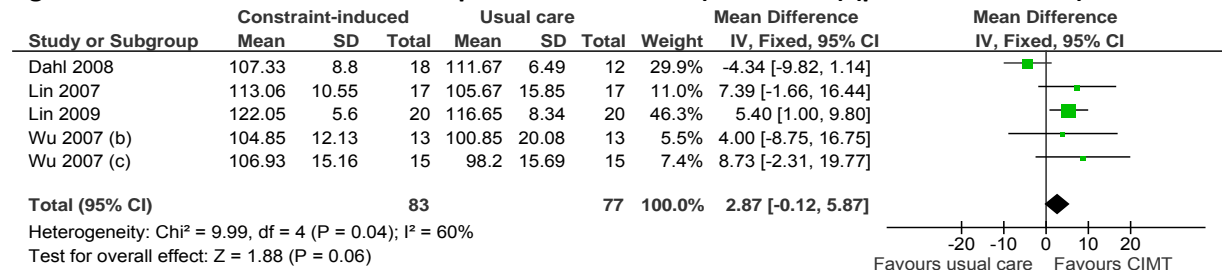


Figure 217: Total Functional Independence Measure (total score) (6 month follow up)

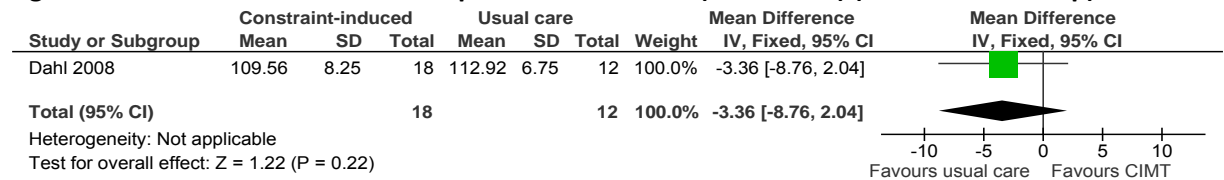


Figure 218: Functional Independence Measure (eating) (post-intervention)

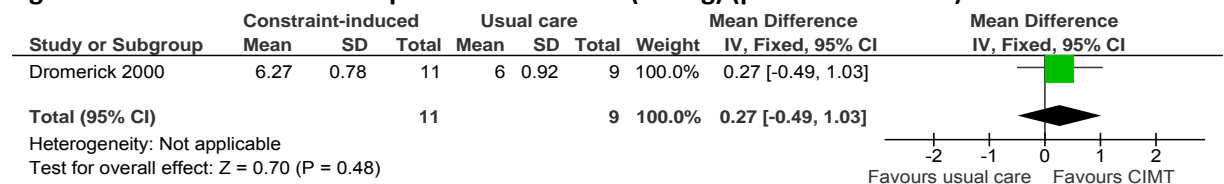
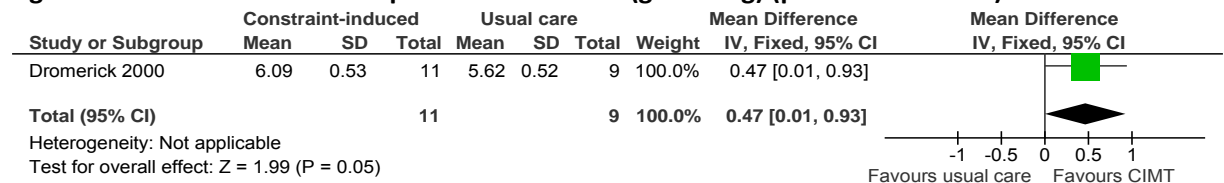


Figure 219: Functional Independence Measure (grooming) (post-intervention)



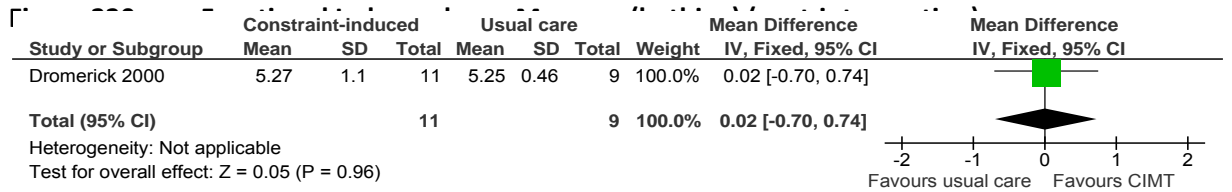


Figure 221: Functional Independence Measure (upper-extremity dressing) (post-intervention)

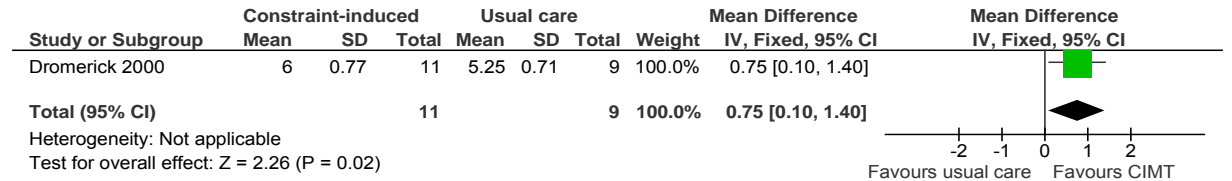


Figure 222: Fugl-Meyer assessment (post-intervention)

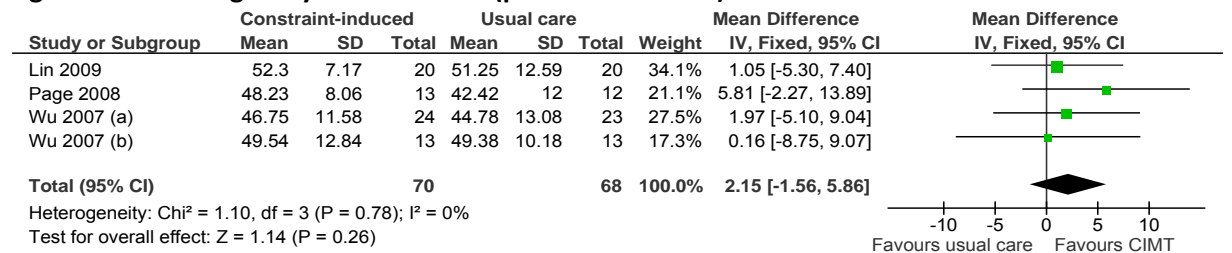


Figure 223: Fugl-Meyer assessment (3 week follow up)

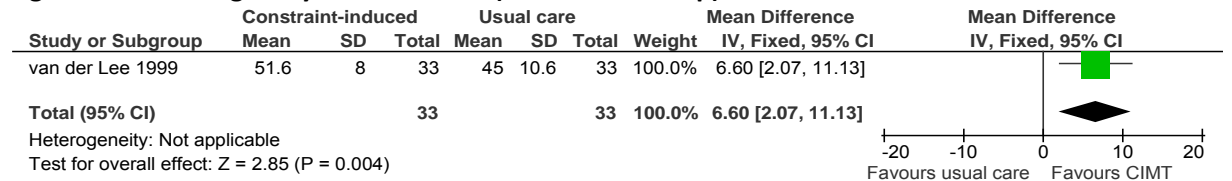


Figure 224: Fugl-Meyer assessment (6 week follow up)

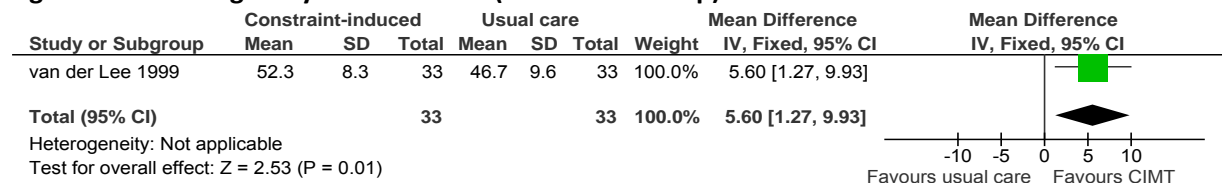


Figure 225: Fugl-Meyer assessment (1 year follow up)

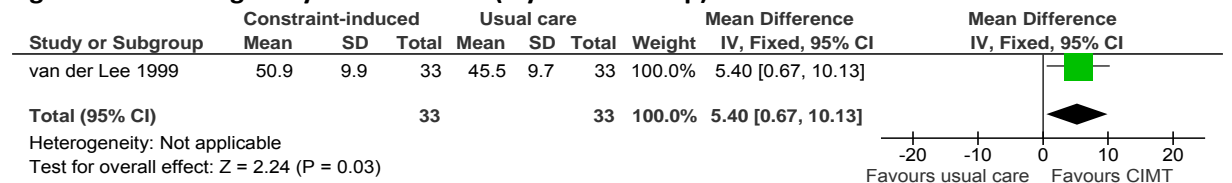
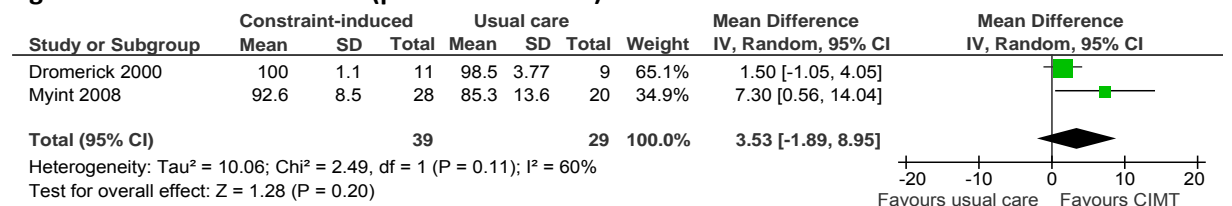


Figure 226: Barthel Index (post-intervention)



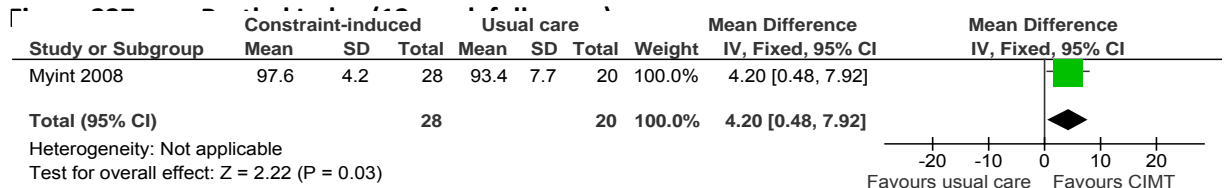


Figure 228: 9-hole Peg test (post-intervention)

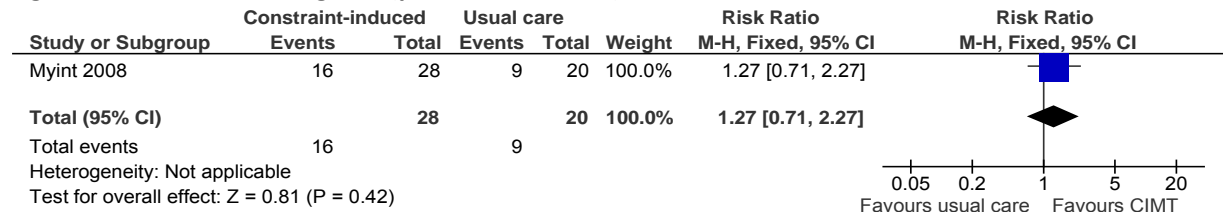


Figure 229: 9-hole Peg test (3 month follow up)

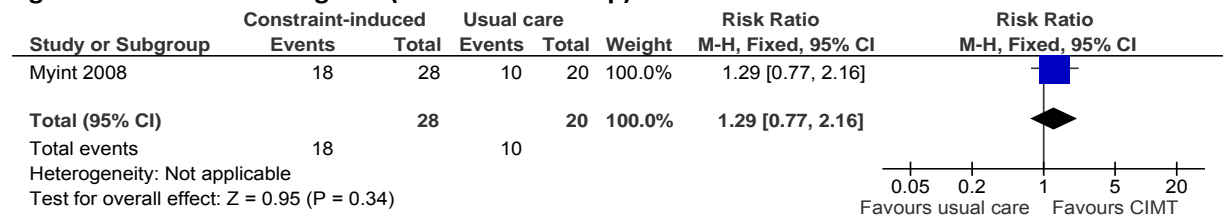
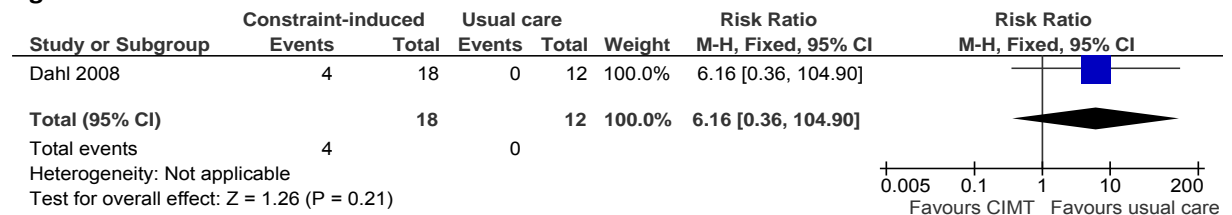


Figure 230: Adverse events- muscle tenderness in the affected arm



J.12 In people after stroke what is the clinical and cost effectiveness of repetitive task training versus usual care on improving function and reducing disability?

J.12.1 Lower limb training (repetitive task or function) versus usual care

Figure 231: 6-minute walk test (m) (post treatment effect)

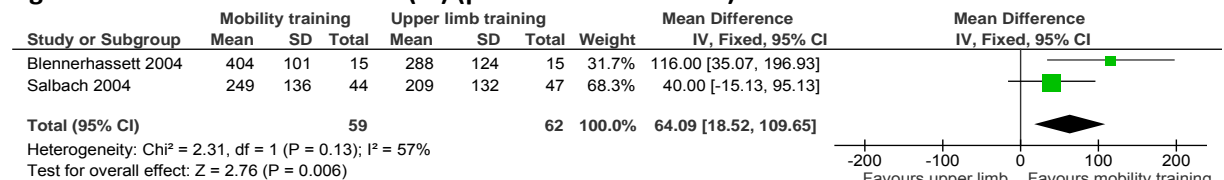
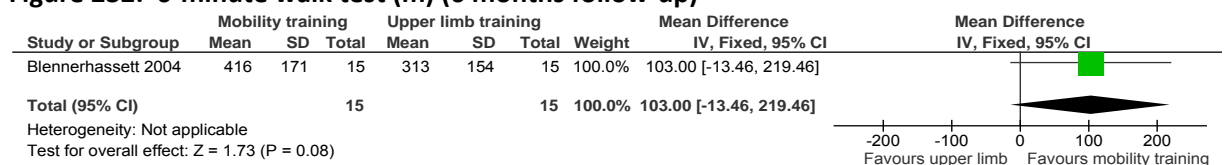


Figure 232: 6-minute walk test (m) (6 months follow-up)



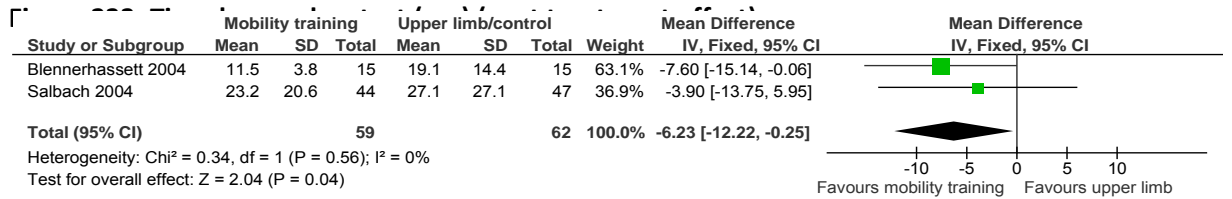


Figure 234: Timed up and go test (sec) (6 months follow-up)

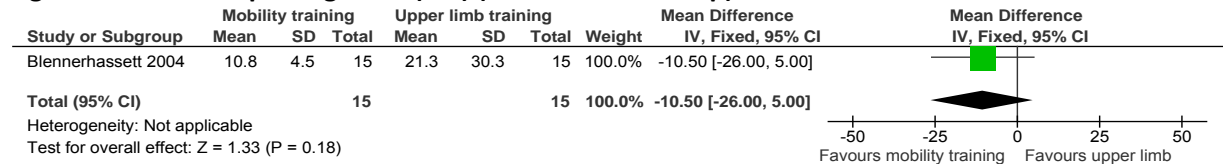


Figure 235: 5 and 10 metre timed walk test: comfortable speed (m/sec) (post treatment effect)

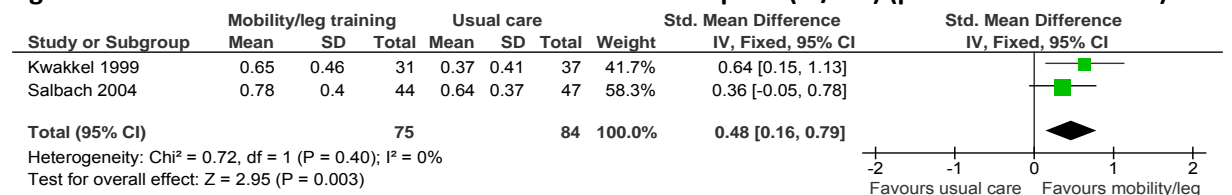


Figure 236: 5 and 10 metre timed walk test: maximum speed (m/sec) (post treatment effect)

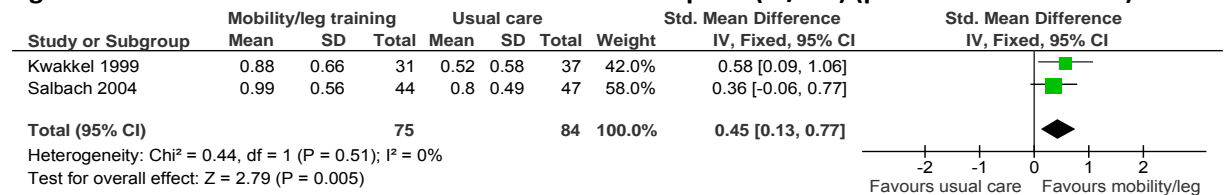


Figure 237: 10 metre timed walk test: comfortable speed (m/sec) (6 ½ months follow-up)

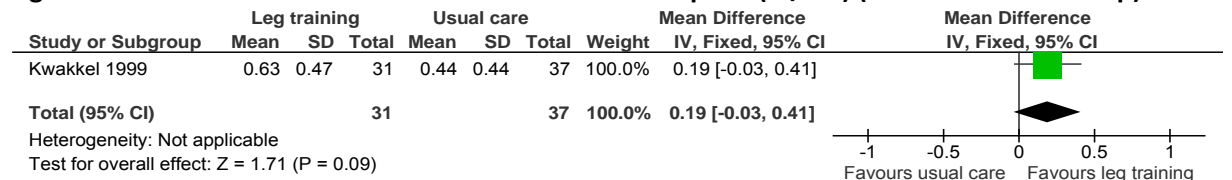
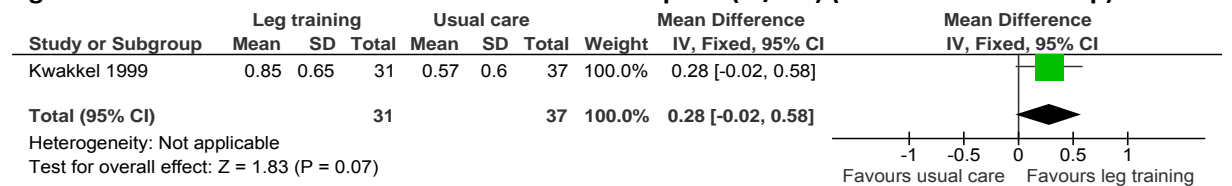


Figure 238: 10 metre timed walk test: maximum speed (m/sec) (6 ½ months follow-up)



J.12.2 Upper limb training (repetitive task or functional) versus usual care

Figure 9: 9-Hole-Peg-Test (post treatment effect) (1 ½ month follow-up)

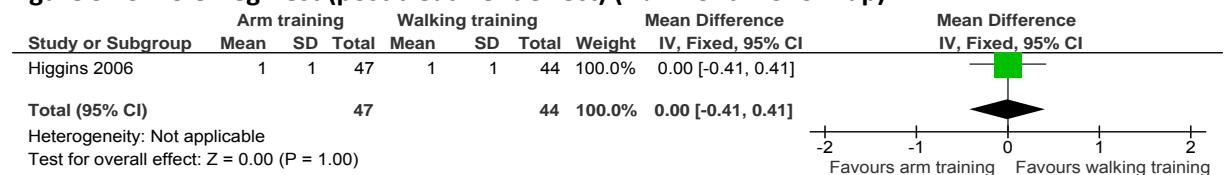


Figure 239: Motor Assessment Scale (MAS) – hand (post treatment effect)

No forest plot was performed.

Figure 240: Motor Assessment Scale (MAS) – hand (6 months follow-up)

No forest plot was performed.

Figure 241: Action research arm test (post treatment effect)

No forest plot was performed.

Figure 242: Action research arm test (6 ½ months follow up)

No forest plot was performed.

Figure 243: Fugl-Meyer score – range of motion (post treatment effect)

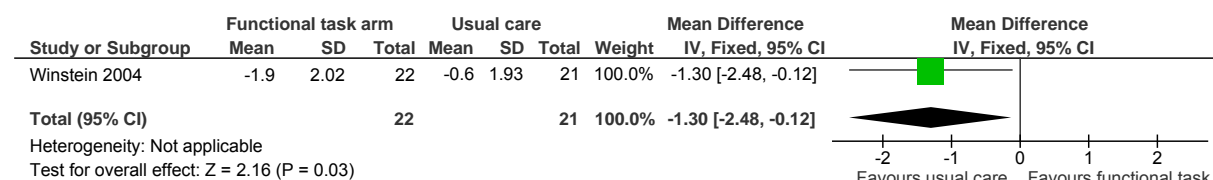


Figure 244: Fugl-Meyer score – pain (post treatment effect)

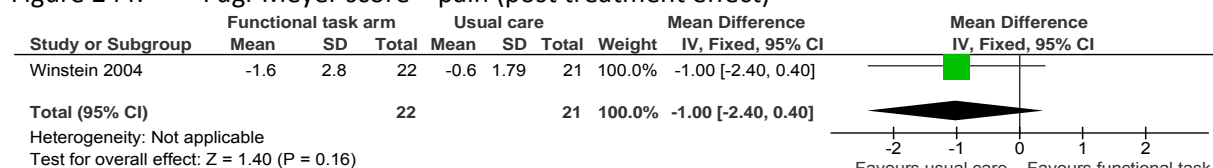


Figure 245: Fugl-Meyer score – sensory (post treatment effect)

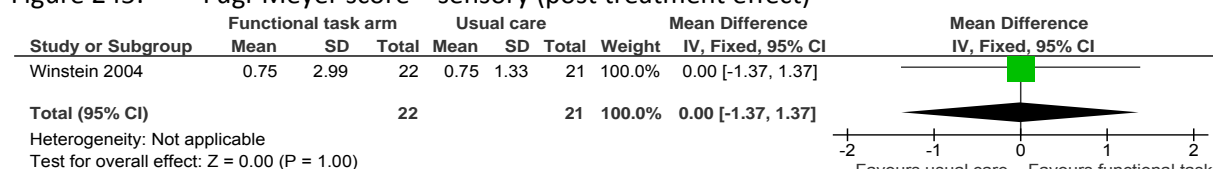


Figure 246: Fugl-Meyer score – motor function (post treatment effect)

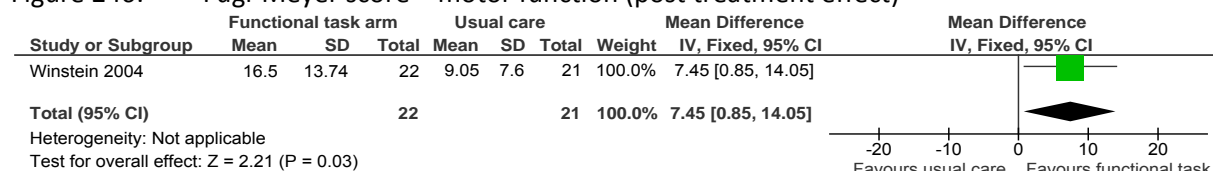


Figure 247: Fugl-Meyer score – range of motion (9 months follow-up)

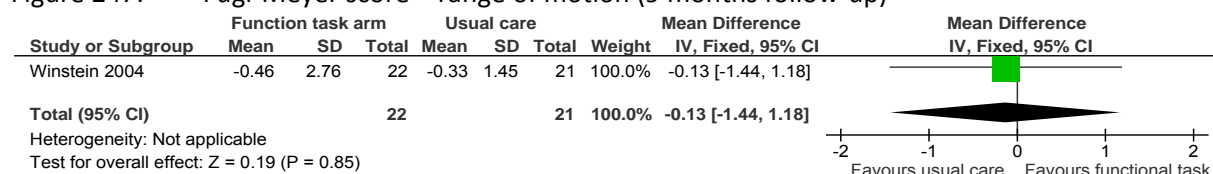


Figure 248: Fugl-Meyer score – pain (9 months follow-up)

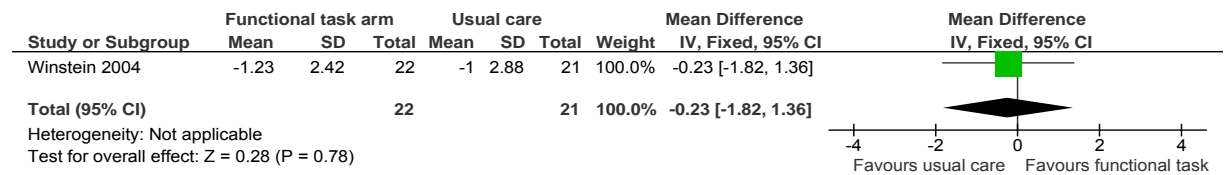


Figure 249: Fugl-Meyer score – sensory (9 months follow-up)

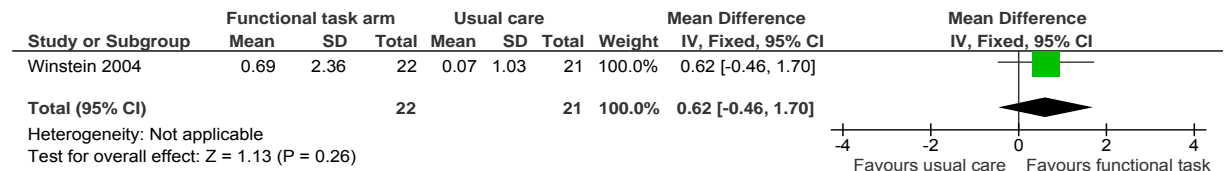
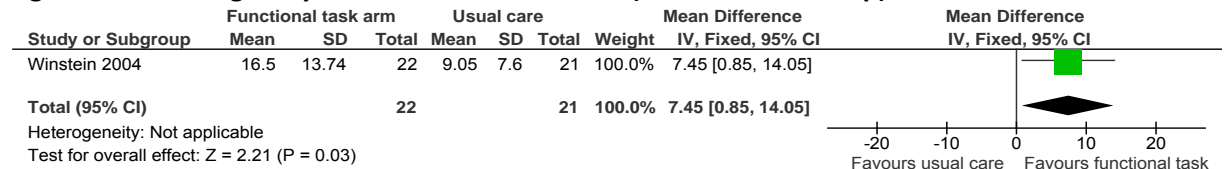


Figure 250: Fugl-Meyer score – motor function (9 months follow-up)



J.13 In people after stroke what is the clinical and cost-effectiveness of all treadmill versus usual care on improving walking?

J.13.1 All treadmill training (with or without body support) versus usual care

Figure 251: 10 metre timed walk test (m/sec): end of study

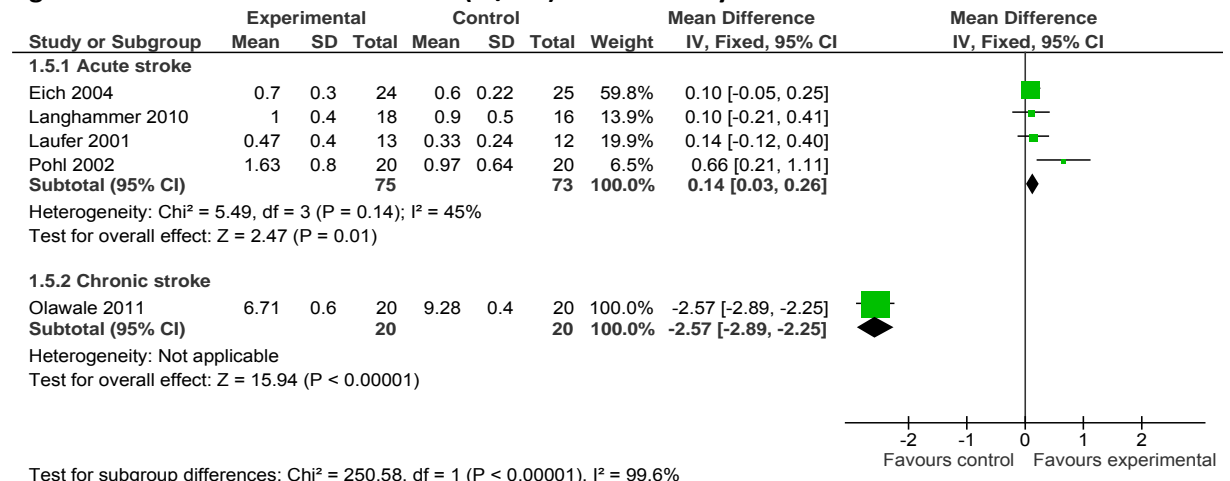


Figure 252: 10 metre timed walk test (m/sec): follow-up

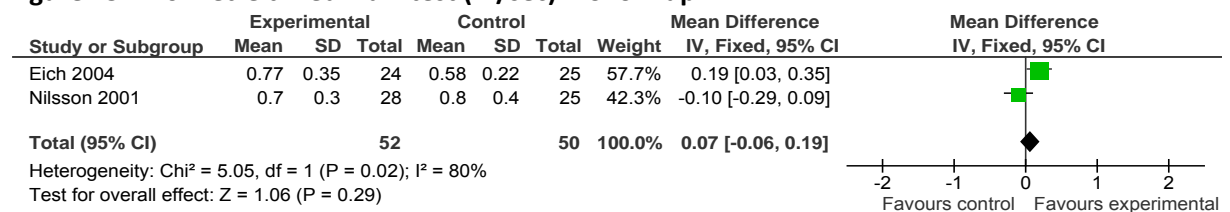


Figure 253: walking speed over a 2-minute test period (m/minute): end of study

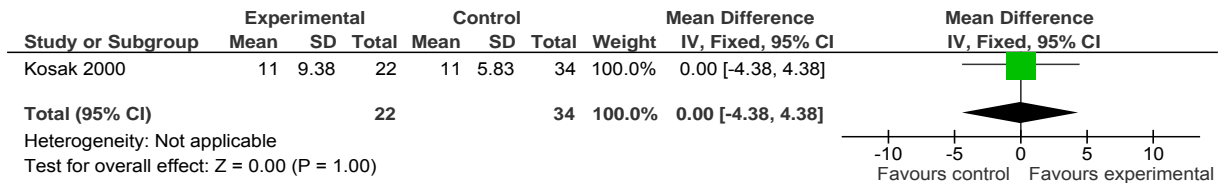


Figure 254: walking endurance (m): end of study

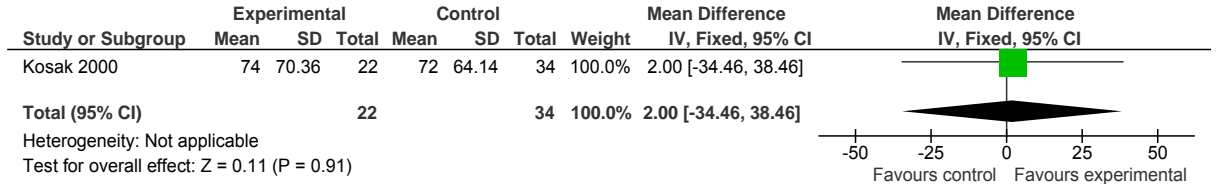


Figure 255: FIM motor items: 10 months follow-up

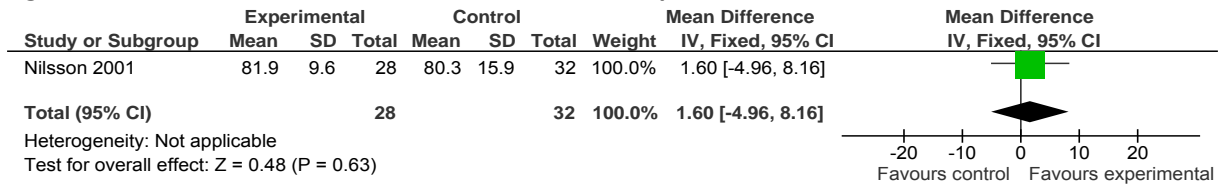


Figure 256: FIM cognitive items: 10 months follow-up

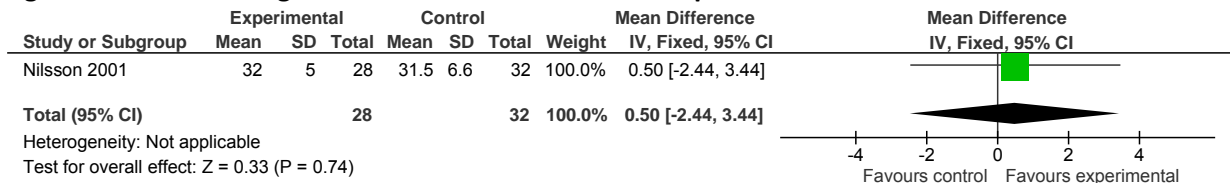


Figure 257: 6 minute walk test – end of study

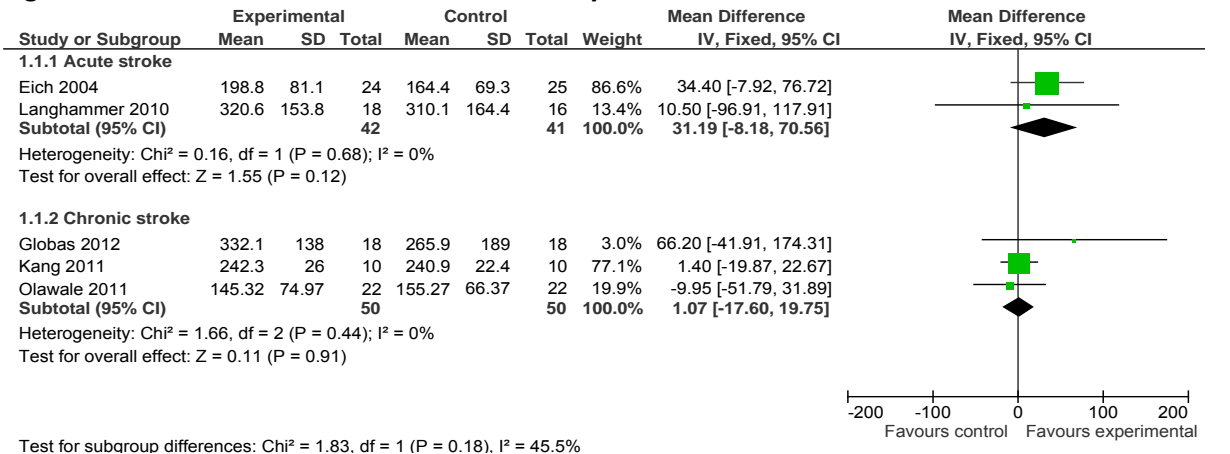
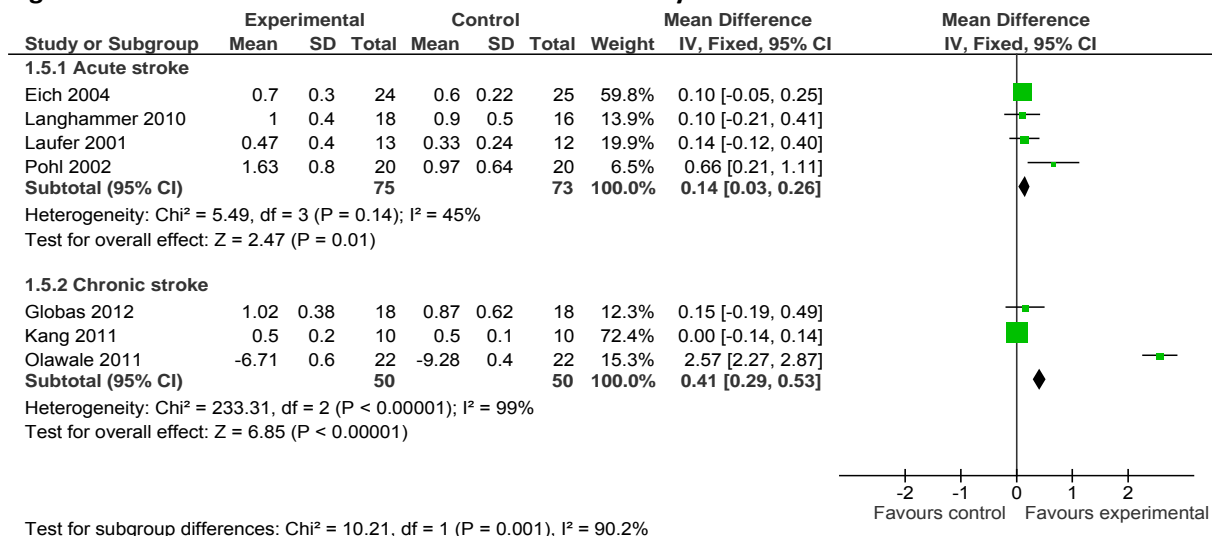


Figure 258: 10 metre timed walk test – end of study



J.13.2 Early treadmill training exercise (2 months after stroke) with body weight support versus home exercise program

Figure 259: 10 metre walk test (comfortable/usual walking speed) (m/sec): 6 months after stroke

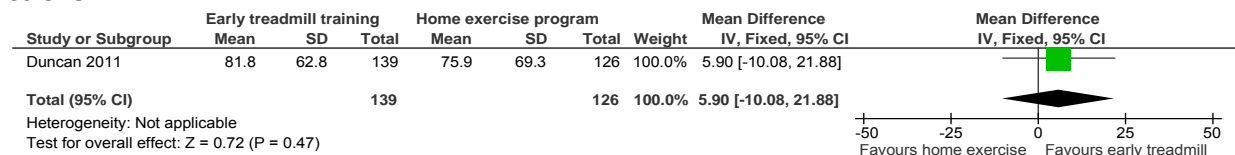


Figure 260: 10 metre walk test (comfortable/usual walking speed) (m/sec): 12 months after stroke

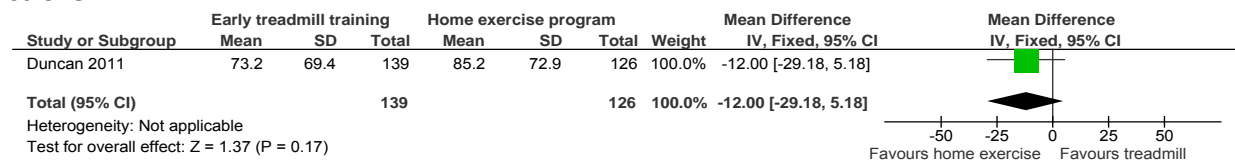


Figure 261: 6 minutes walk test (m): 6 months after stroke

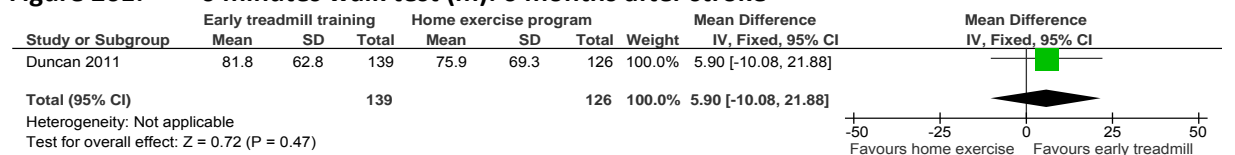
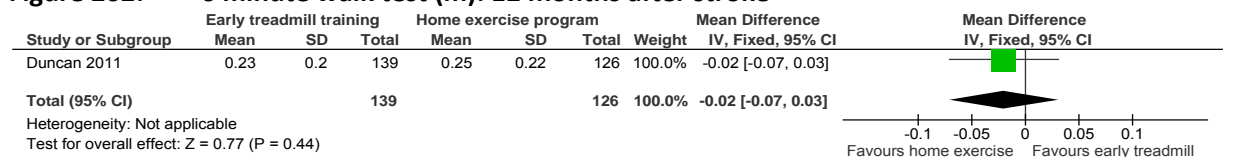


Figure 262: 6 minute walk test (m): 12 months after stroke



J.13.3 Treadmill plus body weight support versus treadmill only

Figure 263: 10 metre timed walk test (m/sec): Post treatment effect

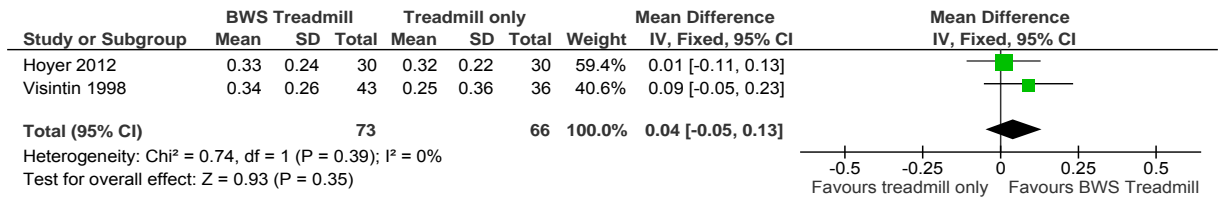


Figure 264: 10 metre timed walk test (m/sec): 11-12 weeks follow-up

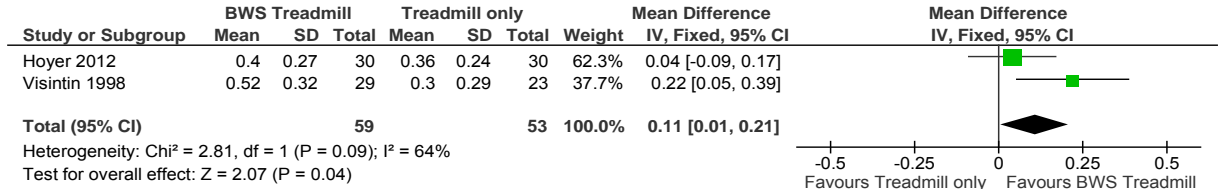


Figure 265: walking endurance (m): end of study

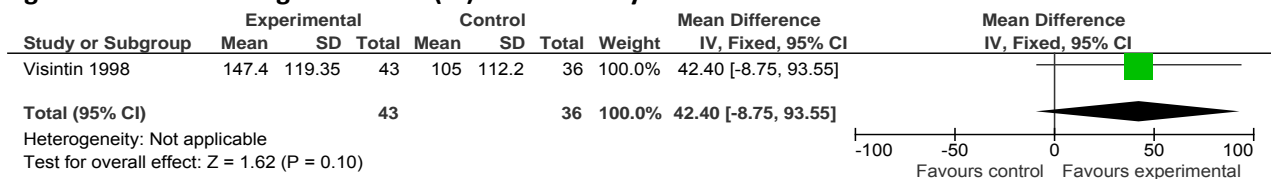


Figure 266: walking endurance (m): 3 months follow-up

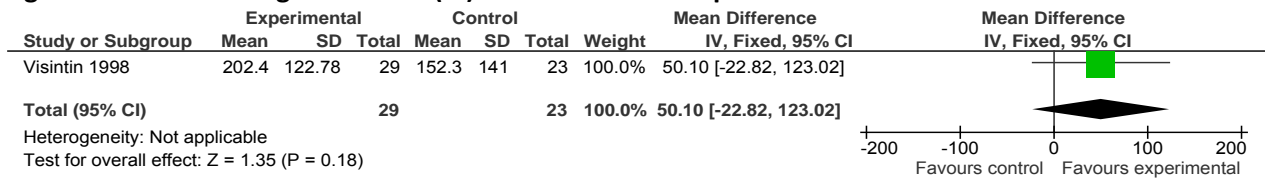


Figure 267: proportion of participants achieved walking speed over 0.2m/s (post treatment effect)

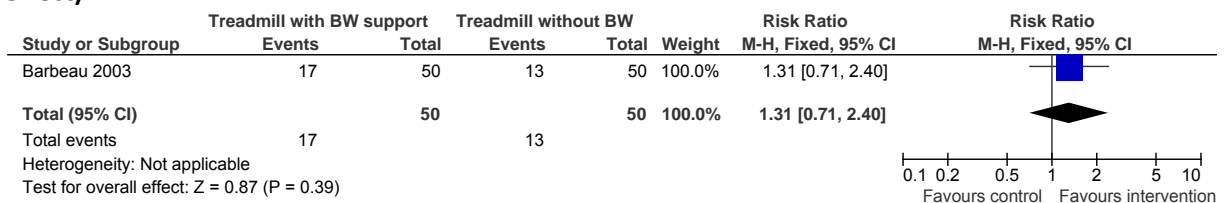


Figure 268: proportion of participants achieved walking endurance over 20m (post treatment effect)

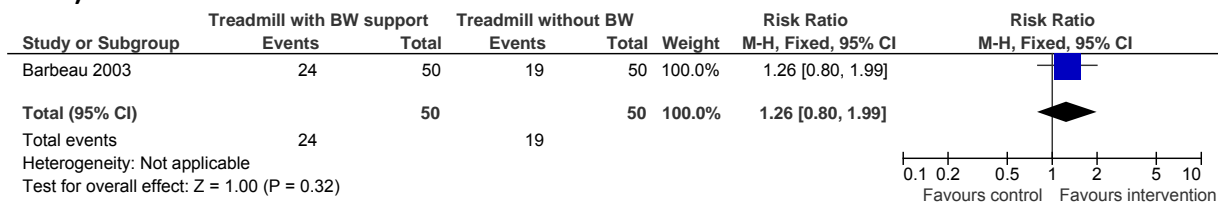


Figure 269: 6 metre walk test (post treatment effect)

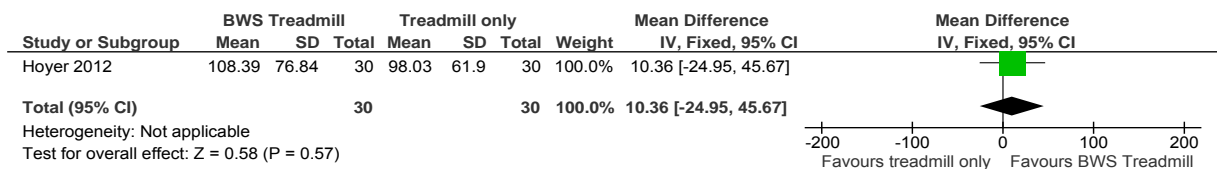


Figure 270: 6 metre walk test (11 weeks follow up)

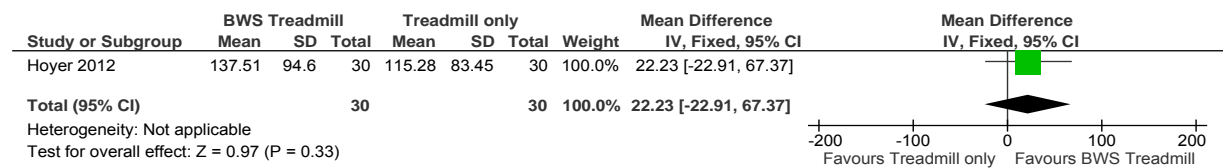


Figure 271: Functional Independence Measure (Post treatment effect)

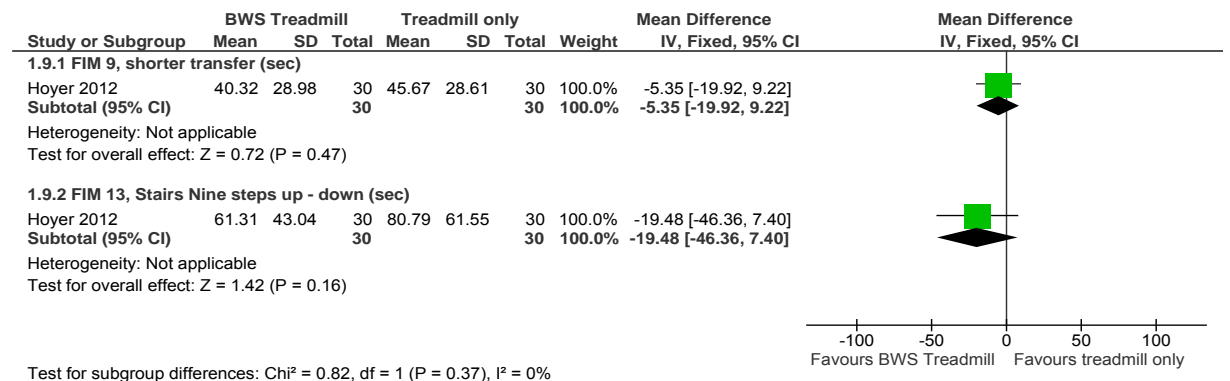
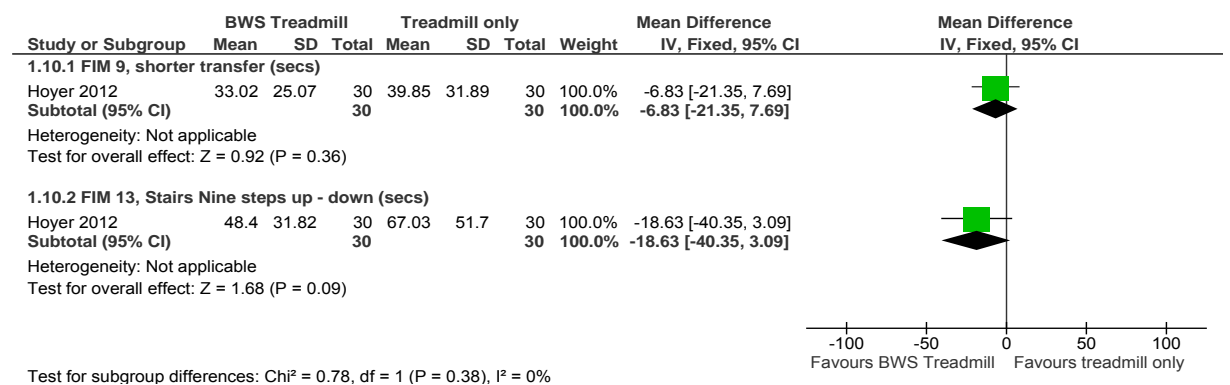


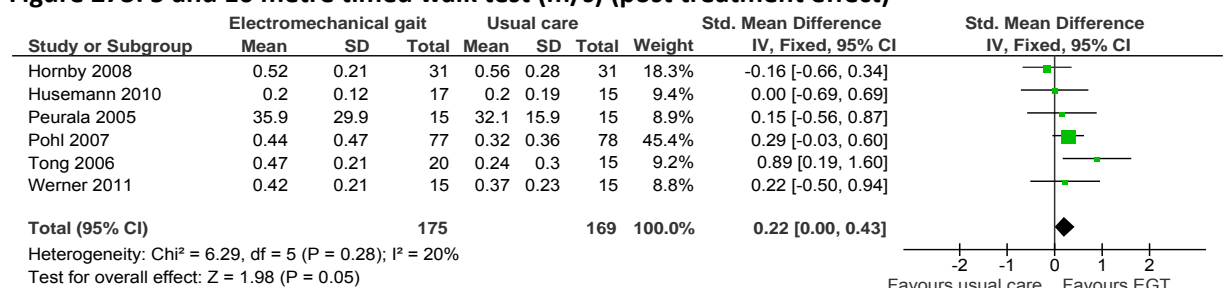
Figure 272: Functional Independence Measure (11 weeks follow up)



J.14 In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?

J.14.1 Electromechanical gait training versus usual care

Figure 273: 5 and 10 metre timed walk test (m/s) (post treatment effect)



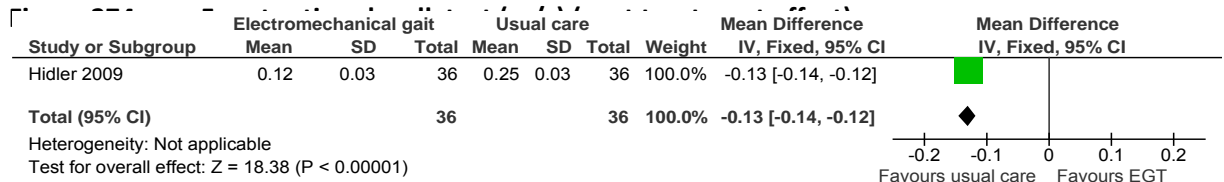


Figure 275: 5 metre timed walk test (m/s) (3 months follow up)

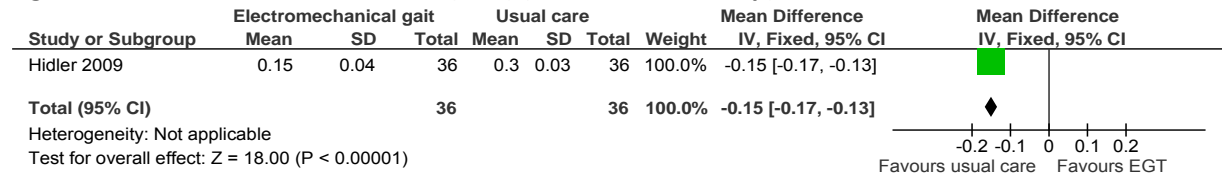


Figure 276: 10 metre timed walk test (m/s) (6 months follow up) (>6 months stroke onset)

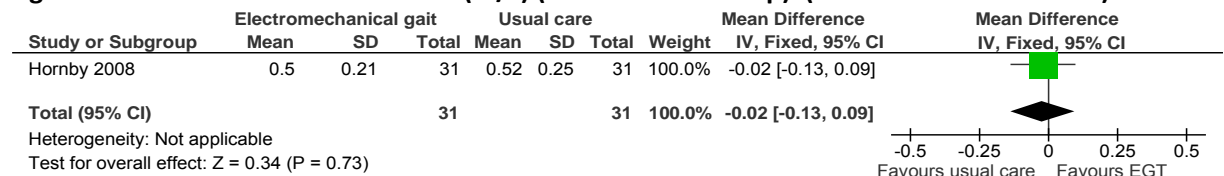


Figure 277: 10 metre timed walk test (m/s) (6 months follow up) (<2 months stroke onset)

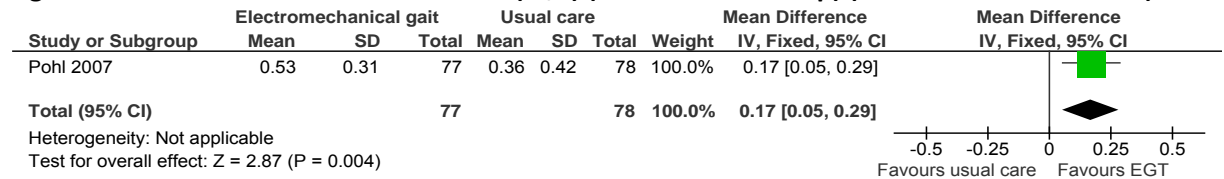


Figure 278: 6 minute walk test (m) (post treatment effect)

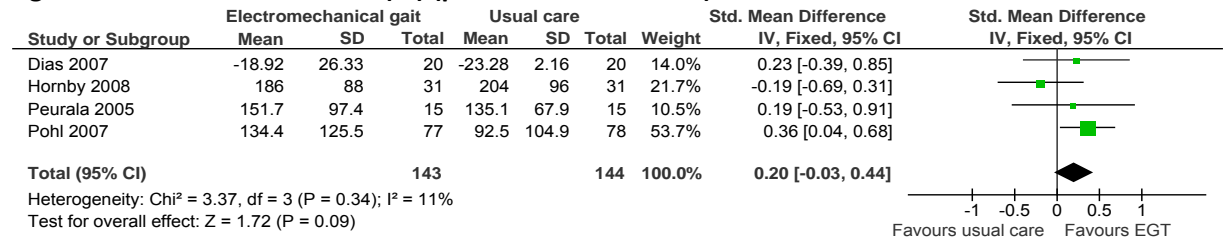


Figure 279: 6 minute walk test (m) (post treatment effect)

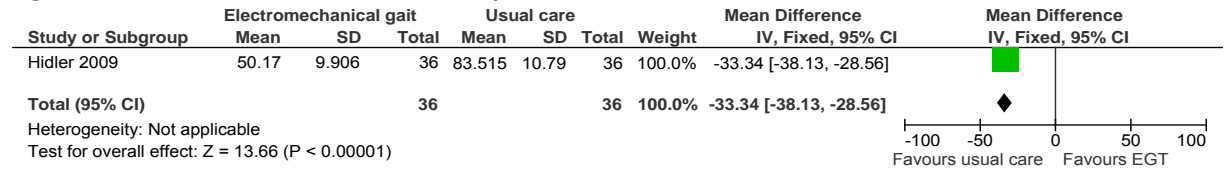
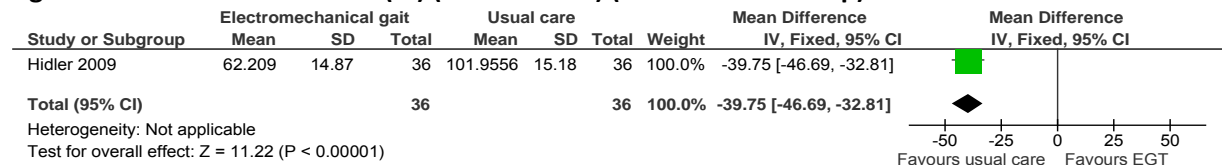


Figure 280: 6 minute walk test (m) (self-selected) (3 months follow up)



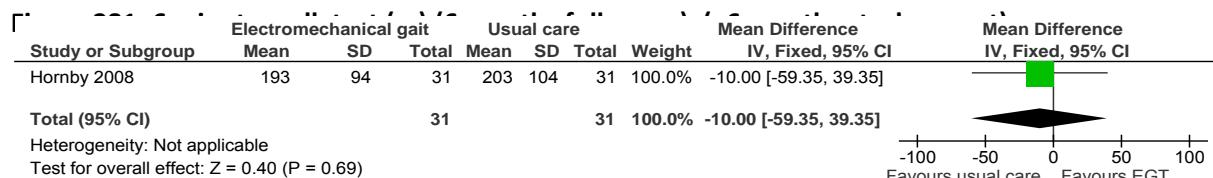


Figure 282: 6 minute walk test (m) (6 months follow up) (<2 months stroke onset)

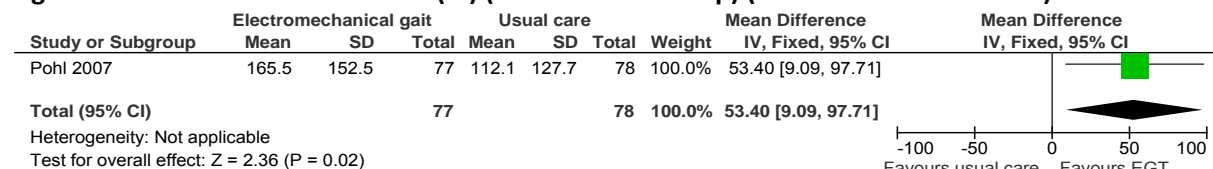


Figure 283: FIM (post treatment effect) (total score)

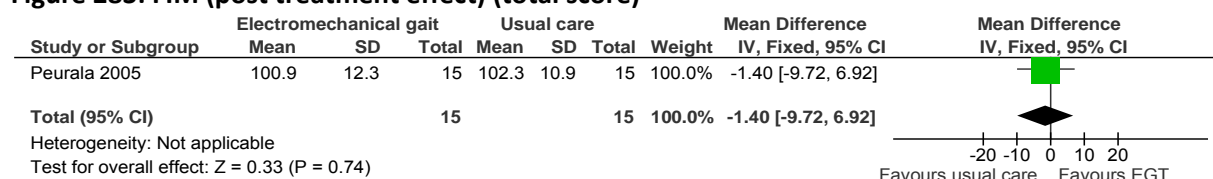


Figure 284: FIM (post treatment effect) (motor item)

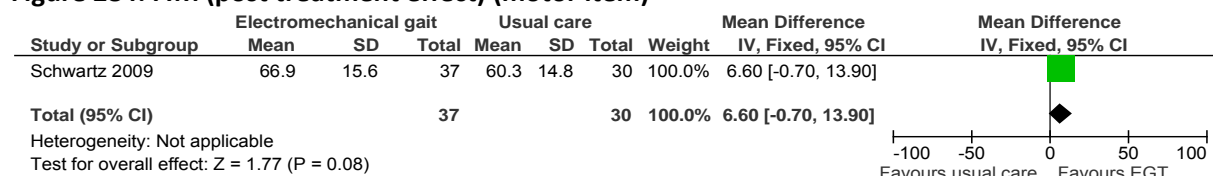


Figure 285: Rivermead Mobility Index (post treatment effect)

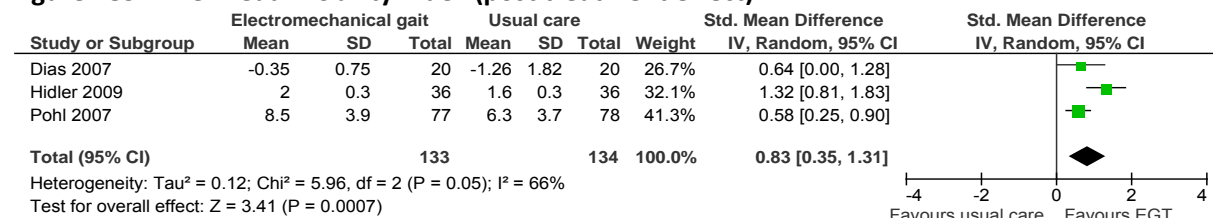


Figure 286: Rivermead Mobility Index (3 months follow up)

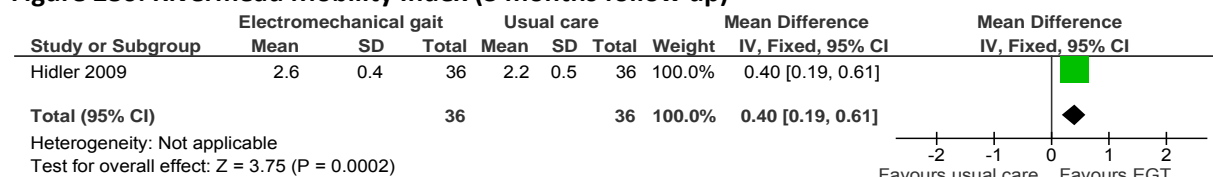
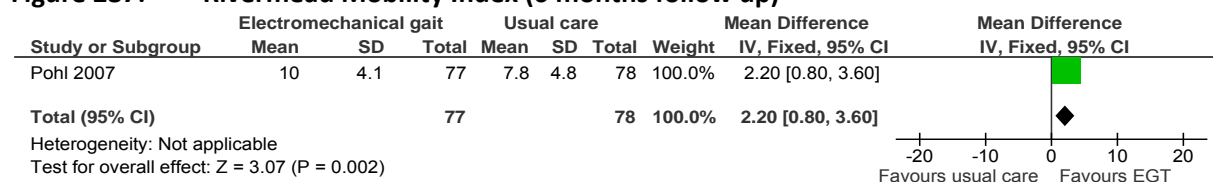


Figure 287: Rivermead Mobility Index (6 months follow up)



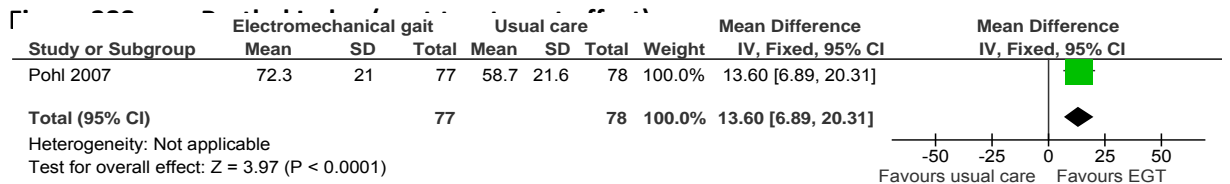
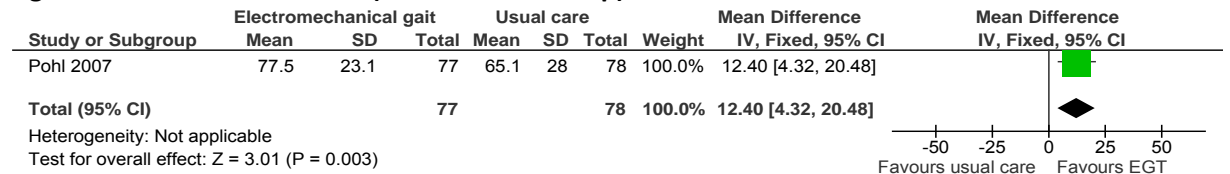


Figure 289: Barthel Index (6 months follow up)



J.14.2 Electromechanical gait training versus conventional gait training stratified by baseline level of motor impairment (LM=low motricity – greater level of impairment; HM = high motricity= lower levels of impairment)

Figure 290: Functional ambulation classification at discharge and 2 year follow-up

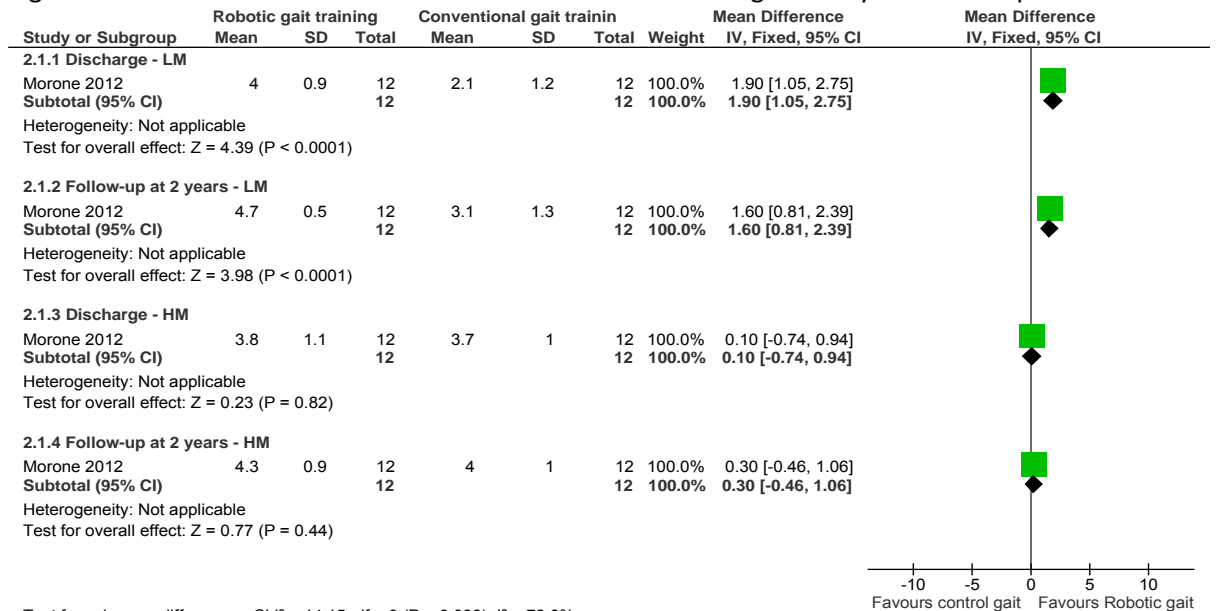


Figure 291: Barthel Index at discharge at discharge and 2 year follow-up

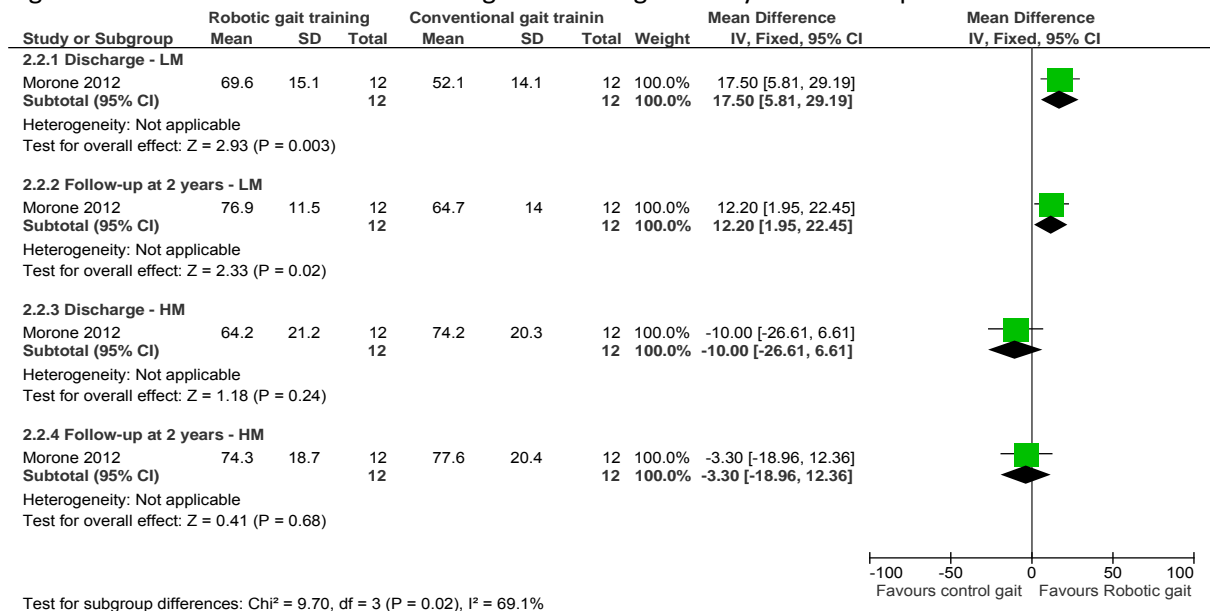
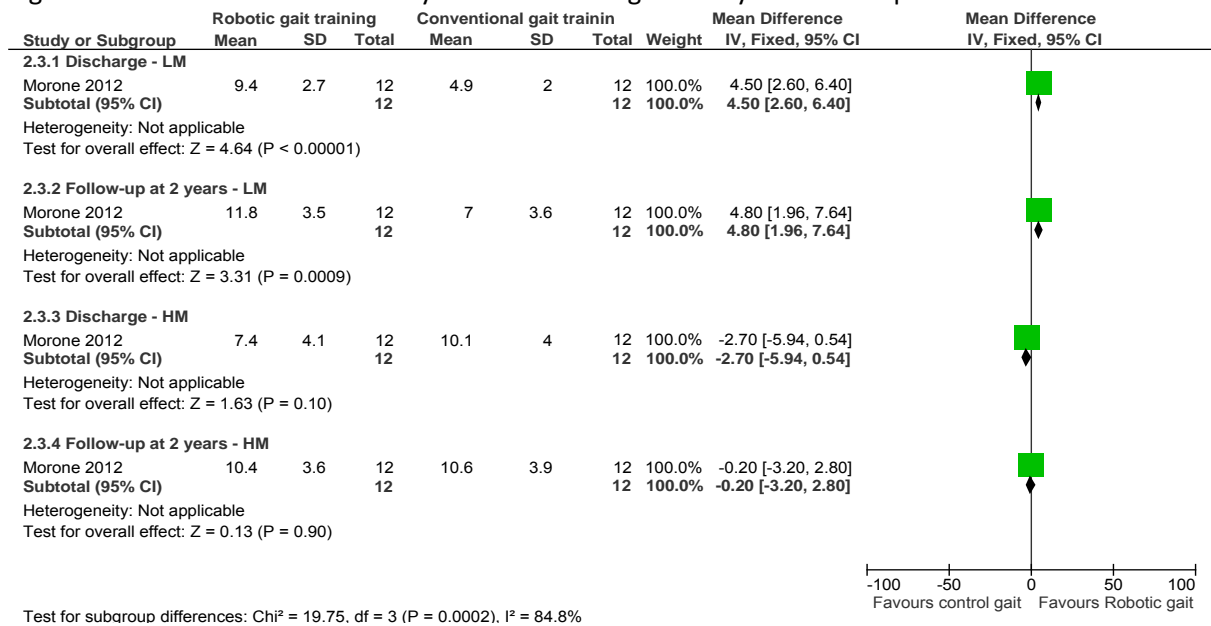


Figure 292: Rivermead mobility index at discharge and 2 year follow-up



J.15 In people after stroke what is the clinical and cost-effectiveness of ankle-foot orthoses of all types to improve walking function versus usual care?

J.15.1 Ankle Foot Orthosis of all types versus no usual care

Figure 293: Velocity (cm/sec) (post treatment effects)

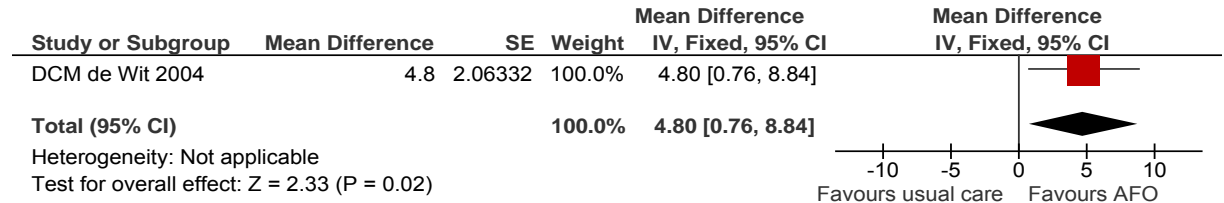


Figure 294: Timed up and go (sec) (post treatment effects)

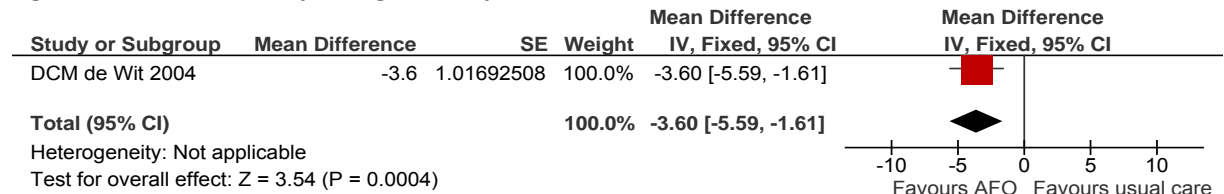


Figure 295: Stairs test (sec) (post treatment effects)

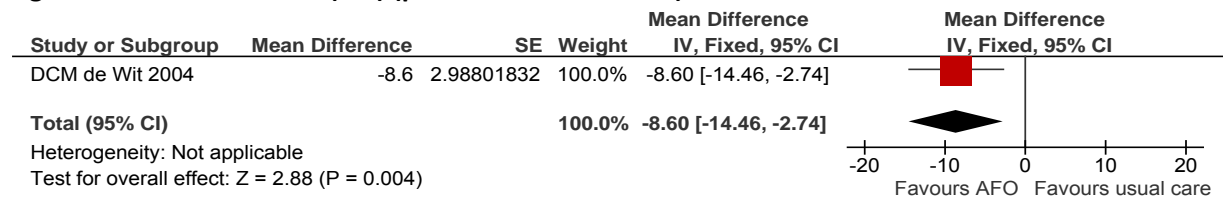
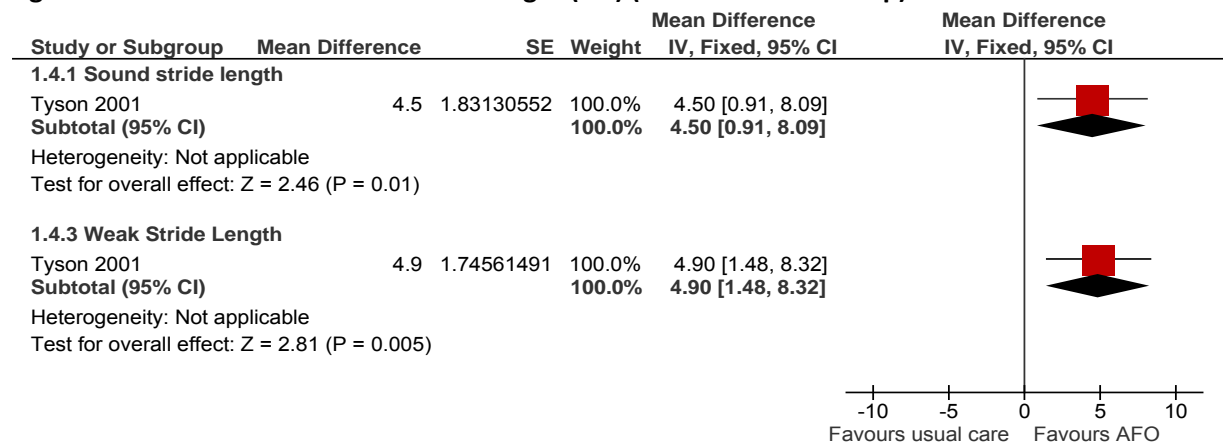


Figure 296: Sound and weak stride length (cm) (one month follow-up)



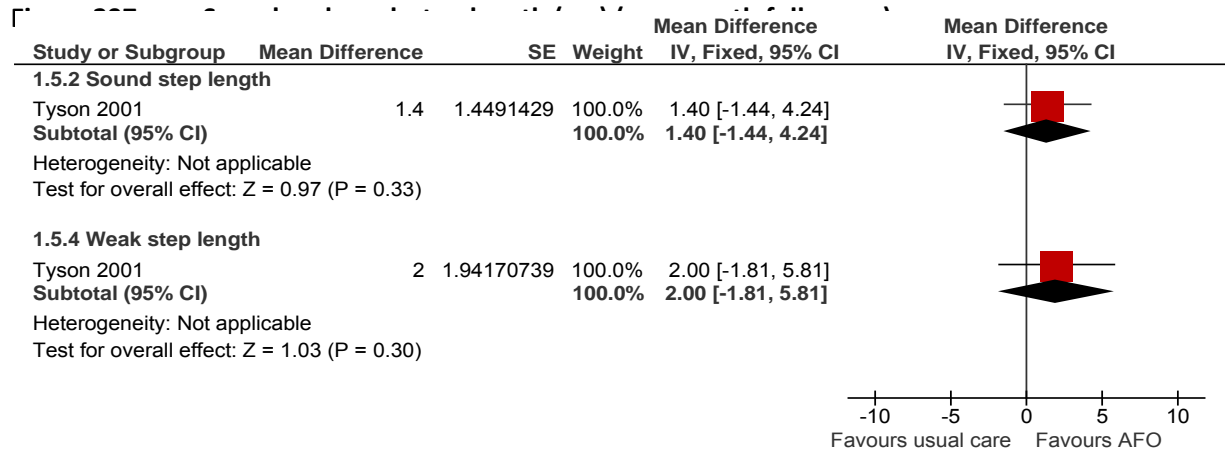


Figure 298: Step symmetry (one month follow-up)

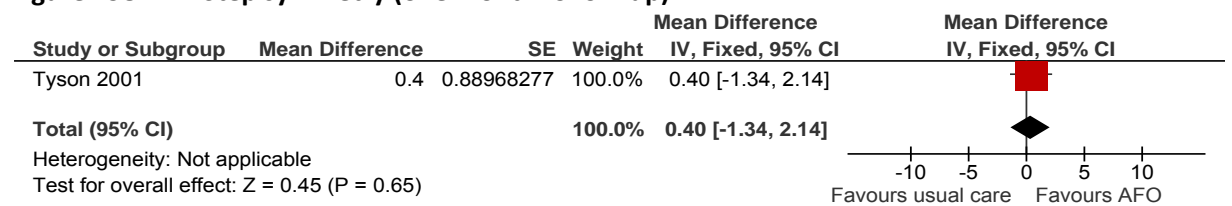


Figure 299: Cadence (steps/min) (one month follow-up)

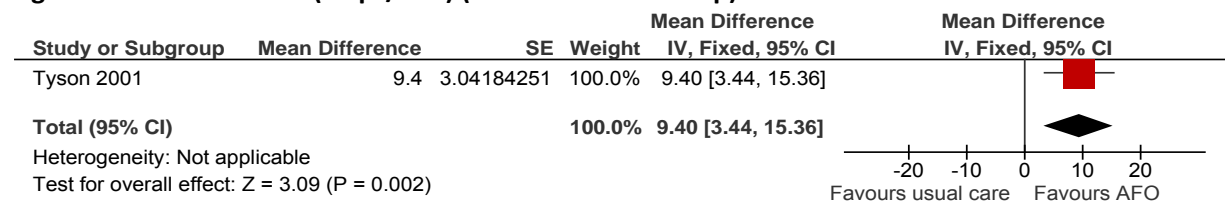


Figure 300: Velocity (m/sec) (one month follow-up)

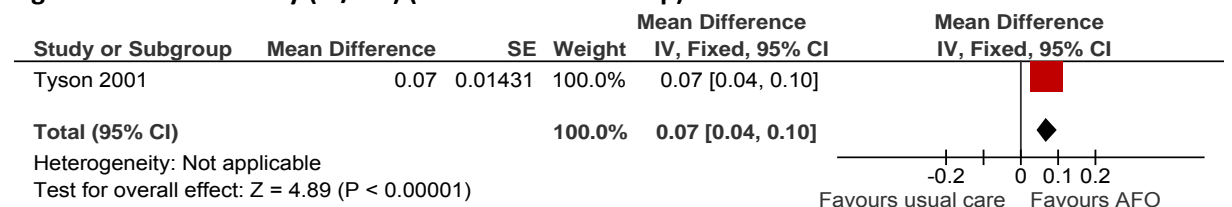


Figure 301: Sickness Impact Profile (SIP) ambulation, physical dimension and total score (3

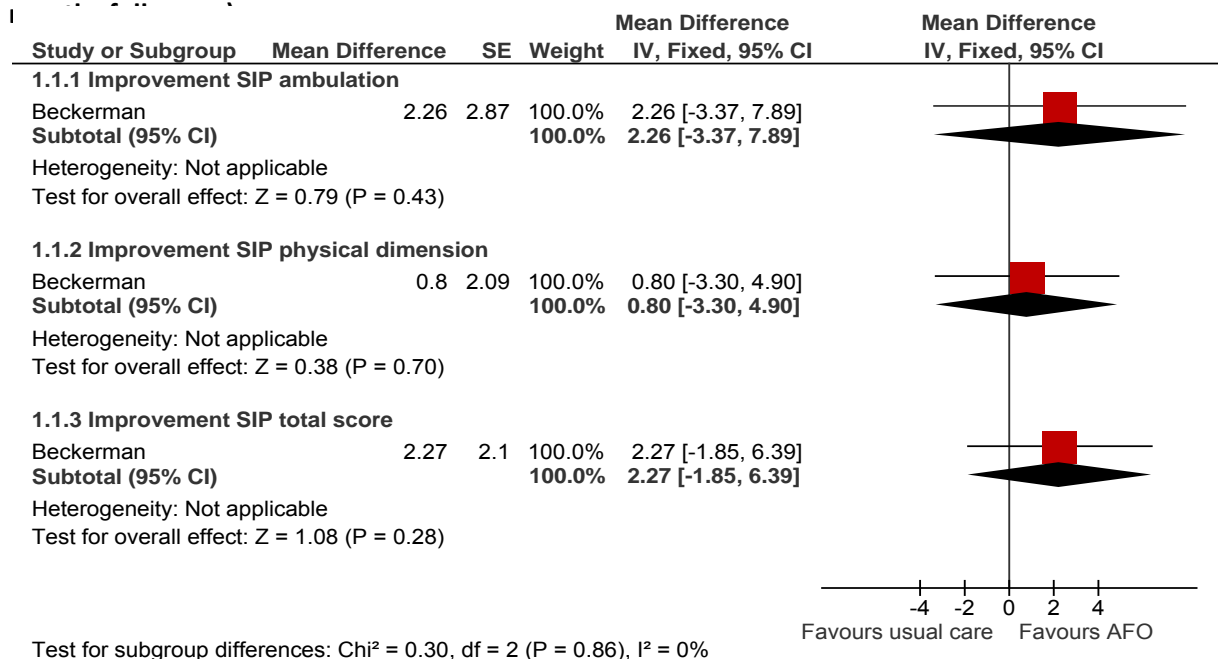


Figure 302: Walking speed - comfortable with shoes and maximal safe, with shoes (m/sec) (3 months follow-up)

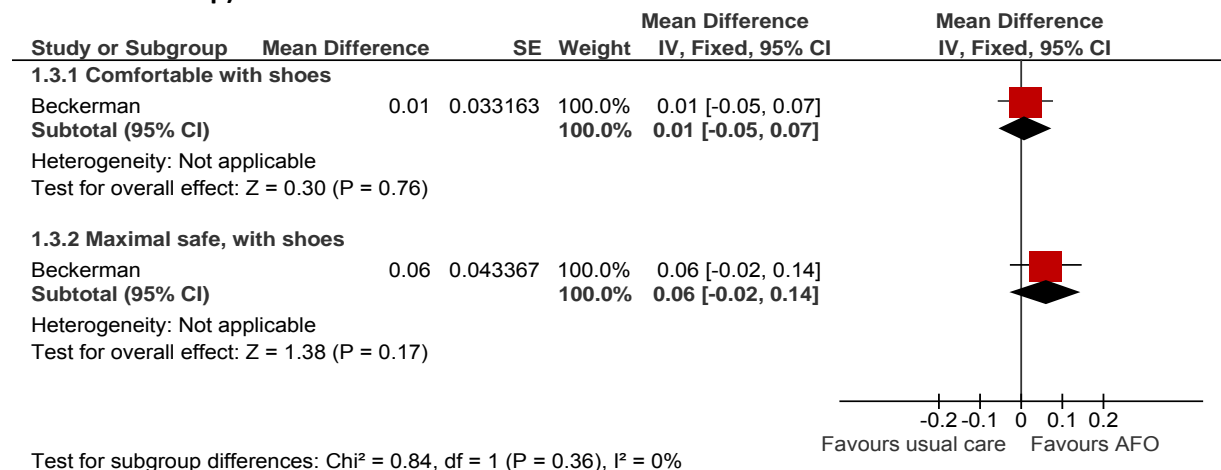


Figure 303: Timed up and go test (sec) (post treatment effects)

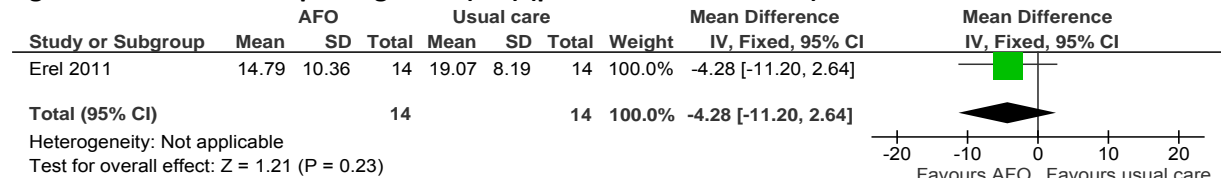
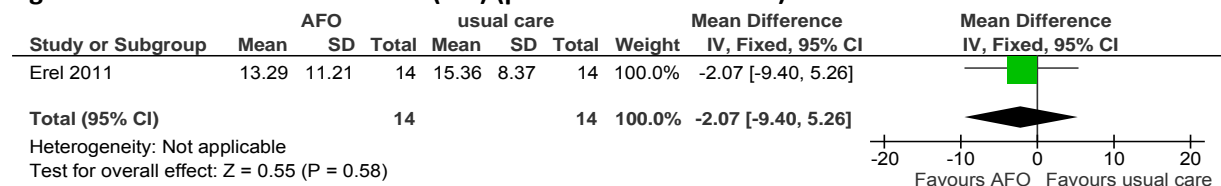


Figure 304: Timed down stairs (sec) (post treatment effects)



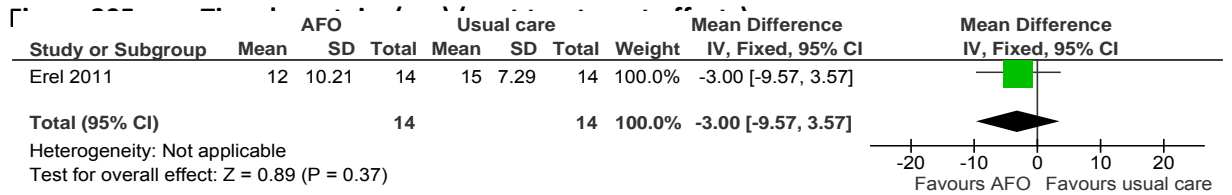
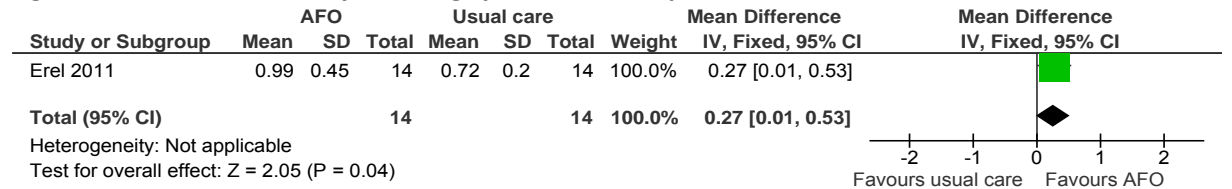


Figure 306: Gait velocity (walking speed) (m/sec) (post treatment effects)



J.16 In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing / others) versus usual care?

J.16.1 Occupational therapy versus usual care/no care

Figure 307: Functional Independence Measure (3 months follow-up)

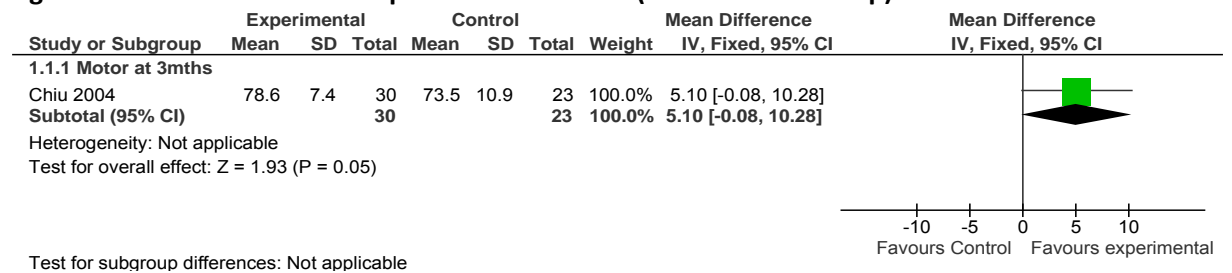


Figure 308: Barthel Index (2 months follow-up)

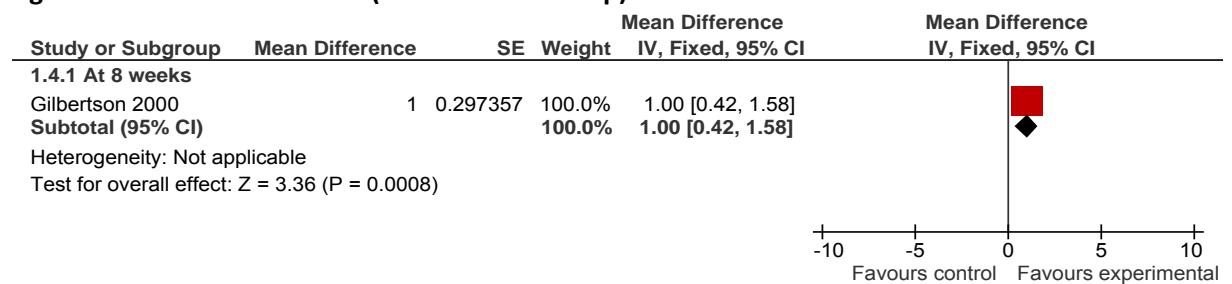
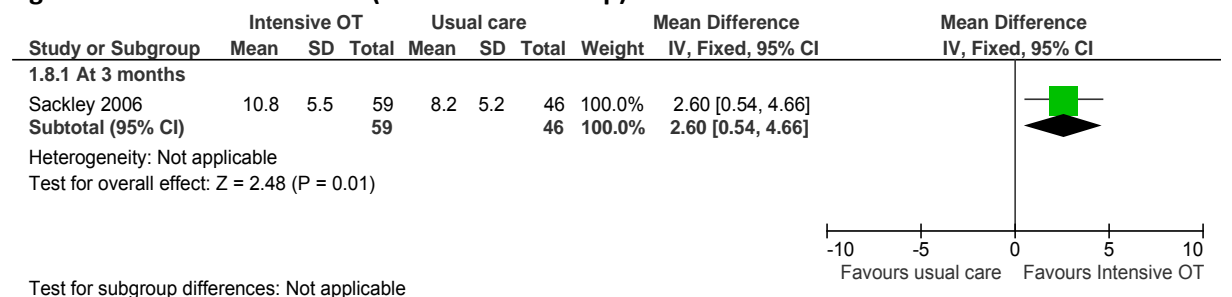


Figure 309: Barthel Index (3 months follow-up)



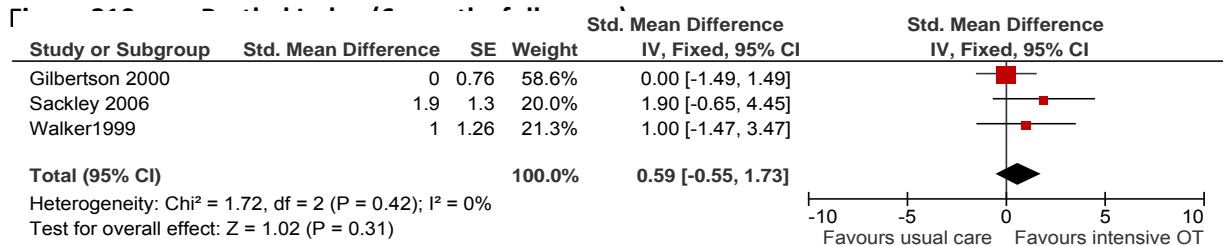


Figure 311: Barthel Index (score<12) (1 year follow-up)

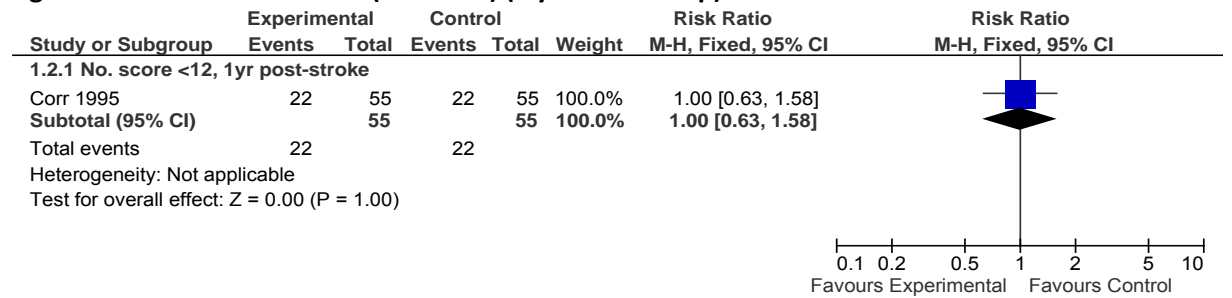


Figure 312: Nottingham Extended ADL (total)(2 months follow-up)

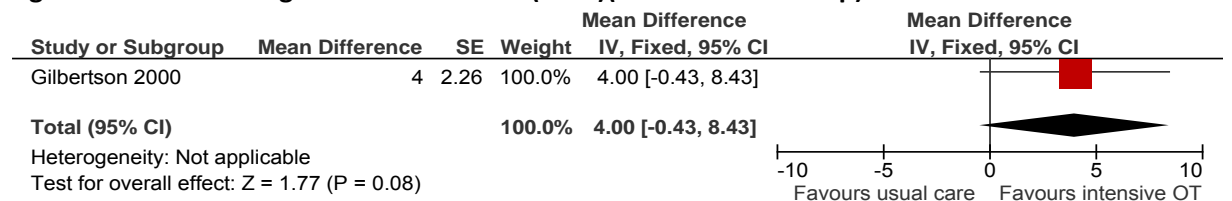


Figure 313: Nottingham Extended ADL (total)(6 months follow-up)

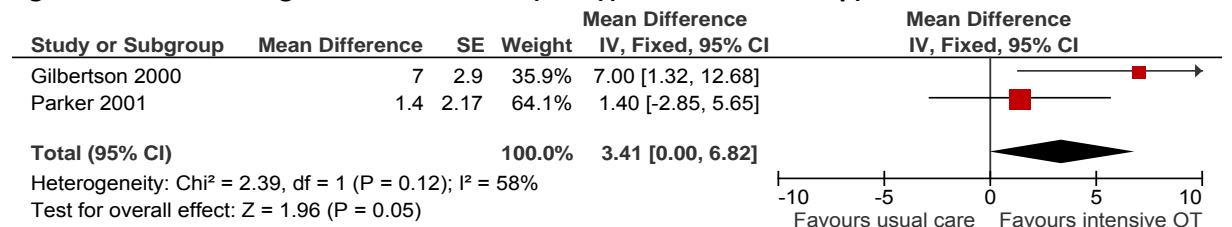
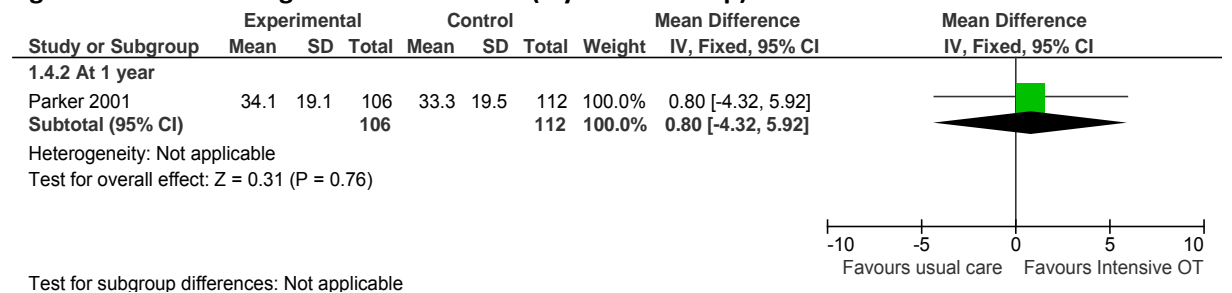


Figure 314: Nottingham Extended ADL (1 year follow-up)



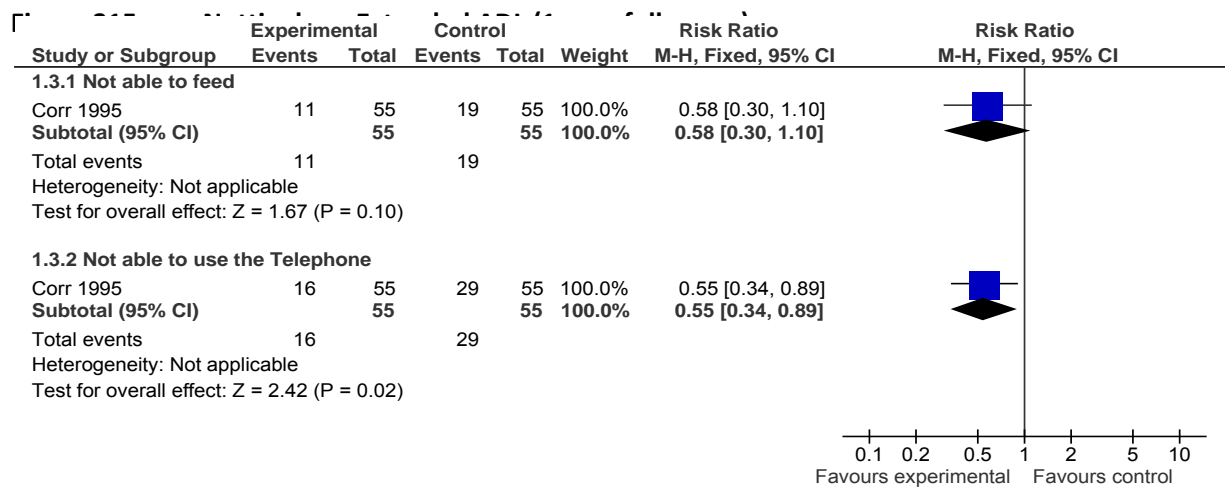


Figure 316: Rivermead Mobility Index (3 and 6 months follow-up)

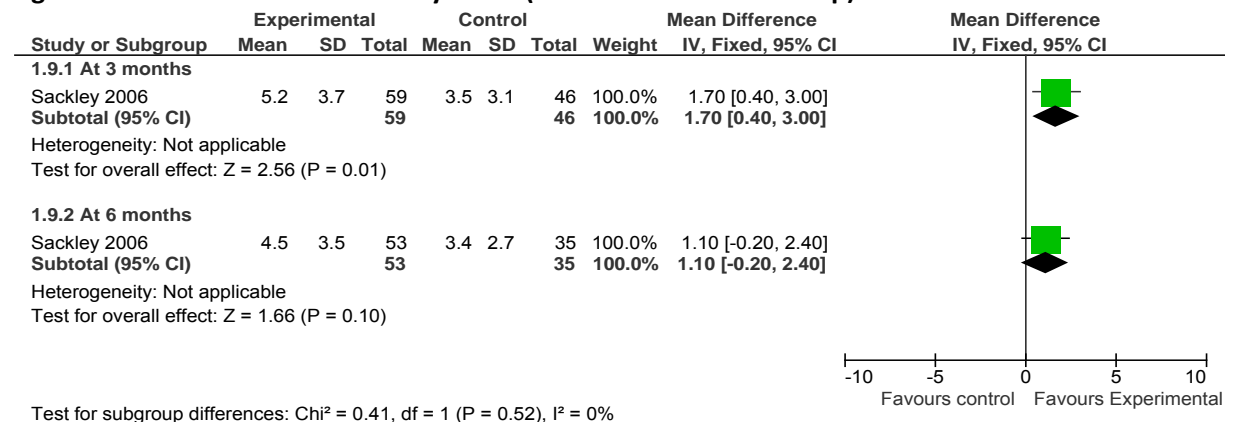
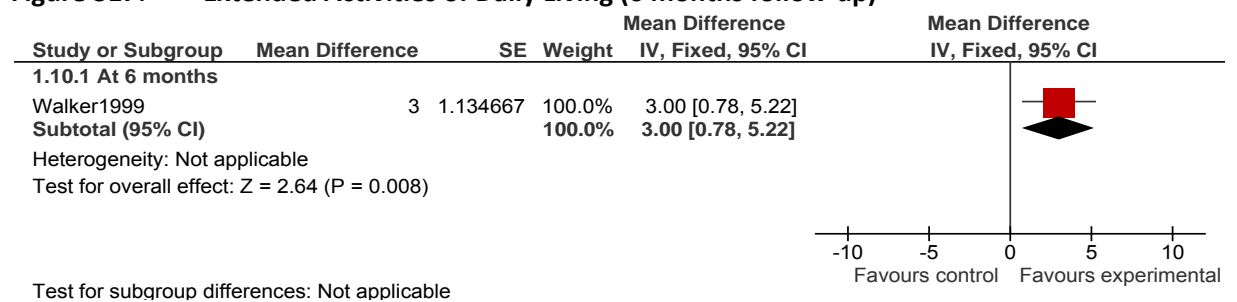


Figure 317: Extended Activities of Daily Living (6 months follow-up)



J.17 In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?

J.17.1 Comparison of resource facilitation intervention on return to work versus usual care

Figure 318: Full time employment

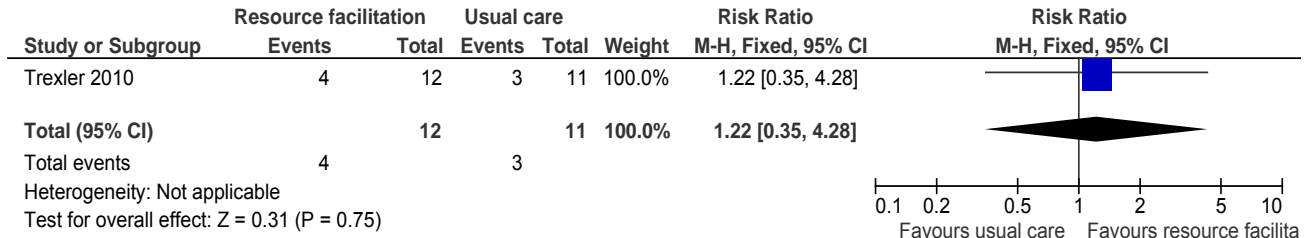


Figure 319: Part time employment

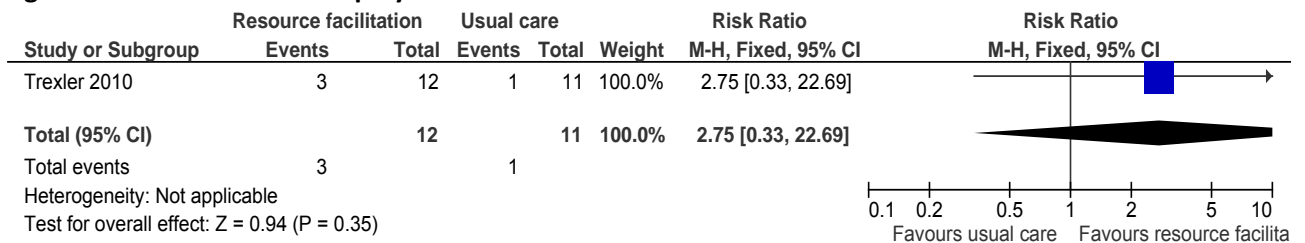


Figure 320: Anytime employment

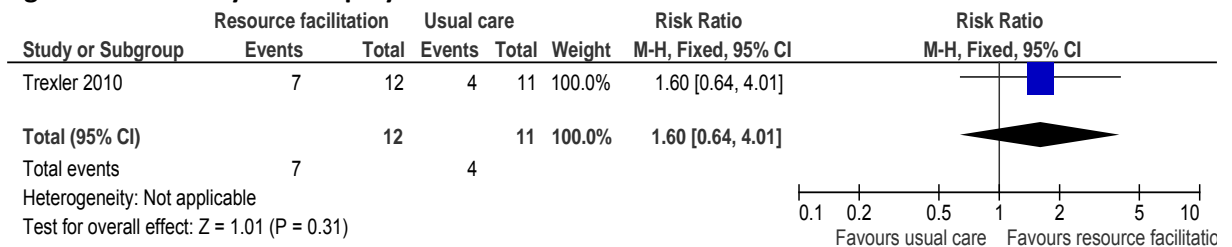
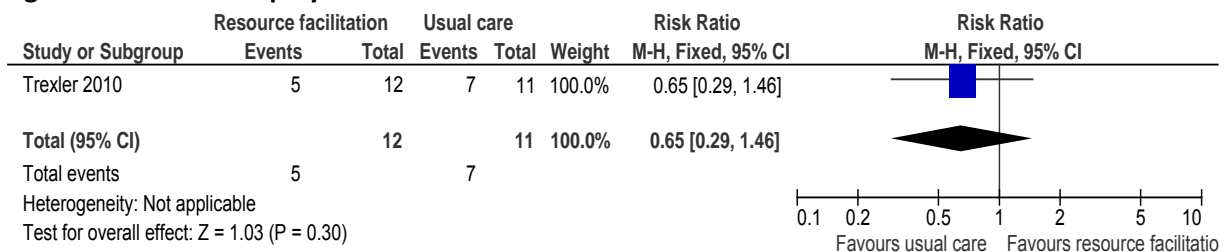


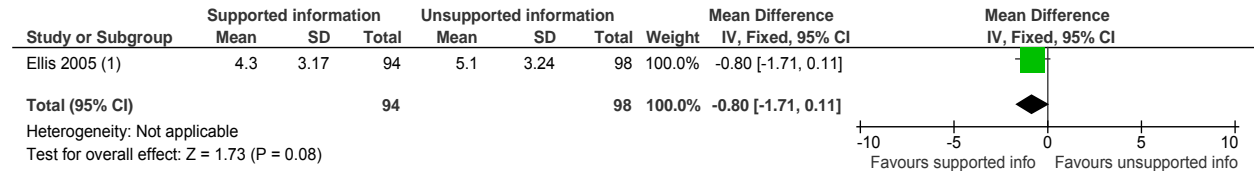
Figure 321: Unemployment



J.18 What is the clinical and cost-effectiveness of supported information provision versus unsupported information provision on mood and depression in people with stroke?

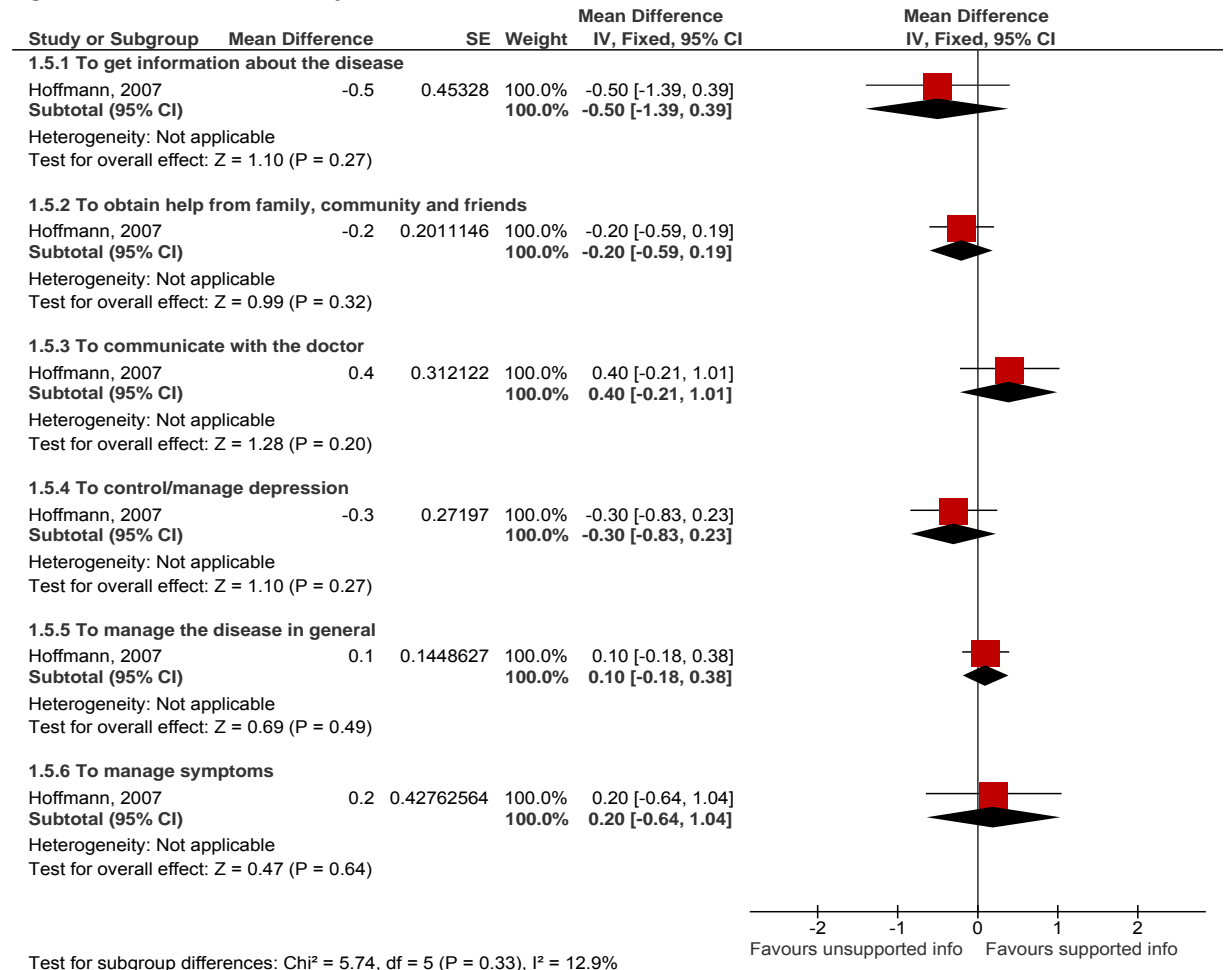
J.18.1 Supported information versus unsupported information

Figure 322: Geriatric depression at 5 months after stroke



(1) The lower the scores the better the outcome

Figure 323: Self efficacy at 3 months after stroke



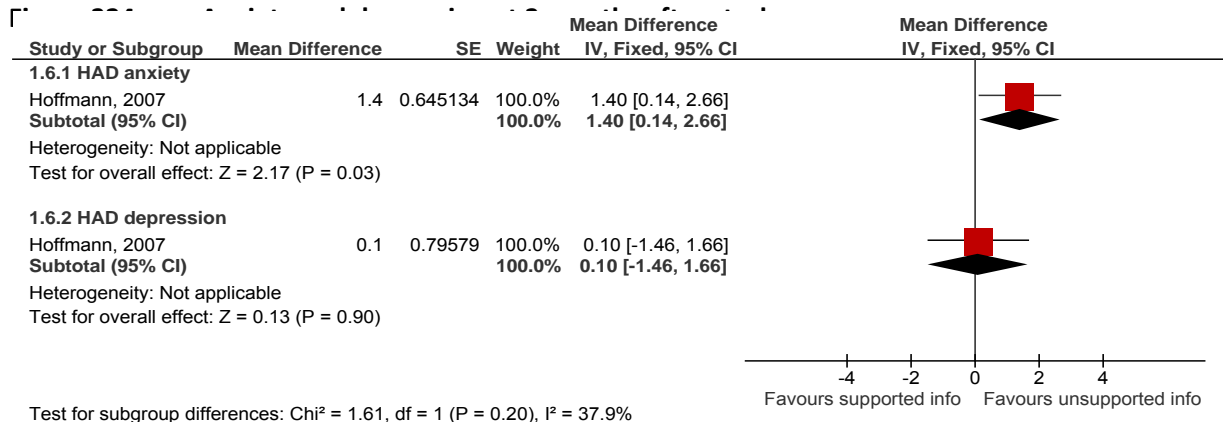
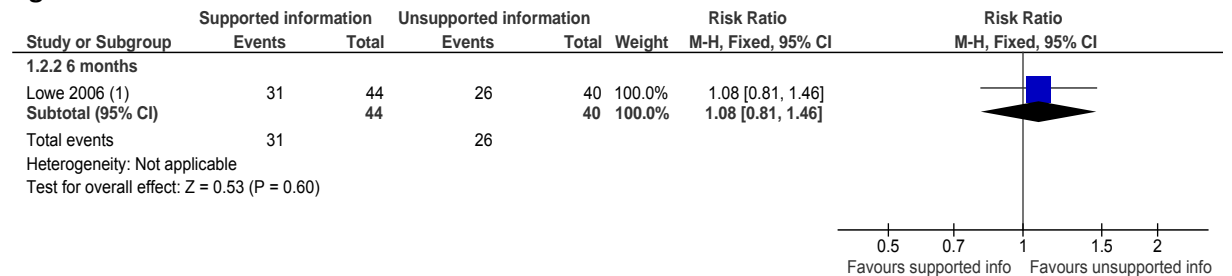
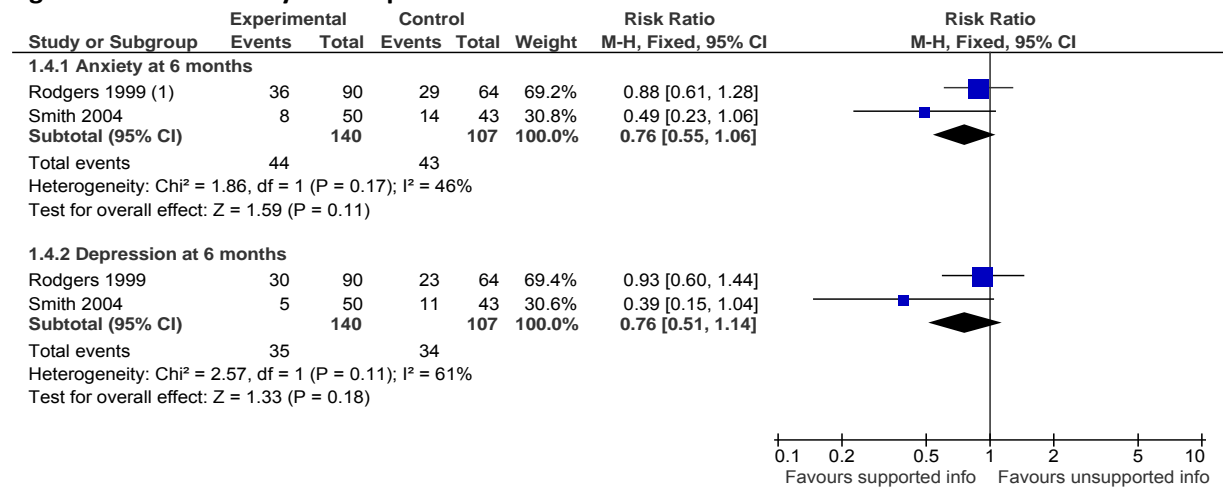


Figure 325: Mood at 6 months after stroke



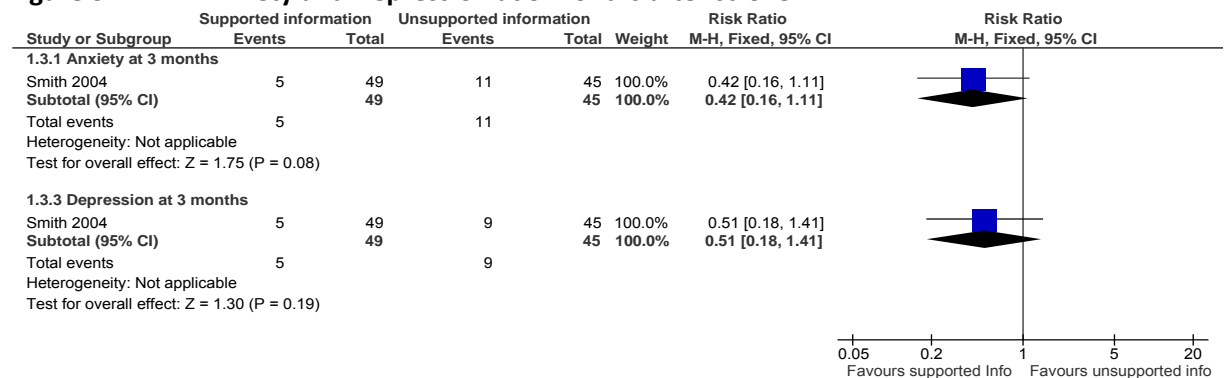
(1) Assuming no important difference in depression scale scores between groups with does lost to follow-up or were excluded from analysis.

Figure 326: Anxiety and Depression at 6 months after stroke



(1) Assuming no important difference in scores between groups with does lost to follow-up or were excluded from analysis.

Figure 327: Anxiety and Depression at 3 months after stroke



J.19 In people after stroke what is the clinical and cost-effectiveness of psychological therapies provided to the family (including the patient)?

Figure 328: Centre for Epidemiological Studies Depression scale (CESD) baseline adjusted values – Caregivers (Wives)

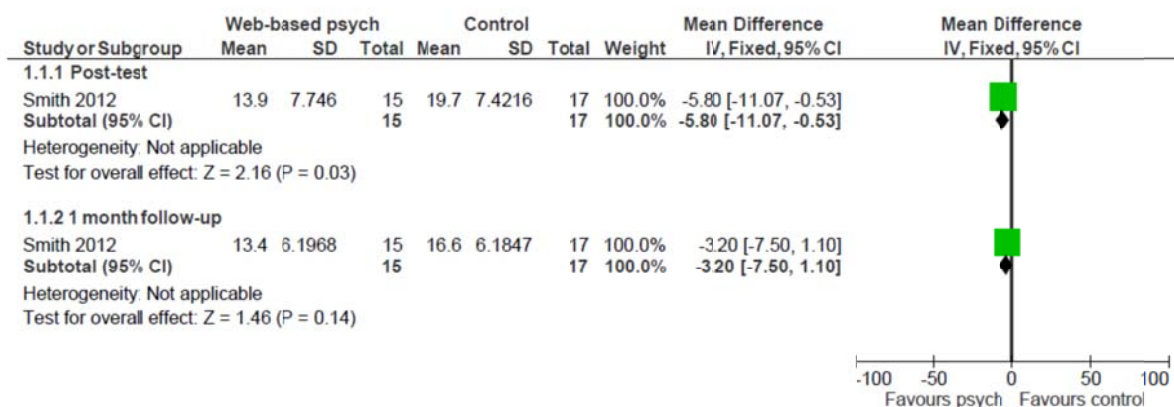


Figure 329: Centre for Epidemiological Studies Depression scale (CESD) baseline adjusted values – Persons with stroke (Husbands)

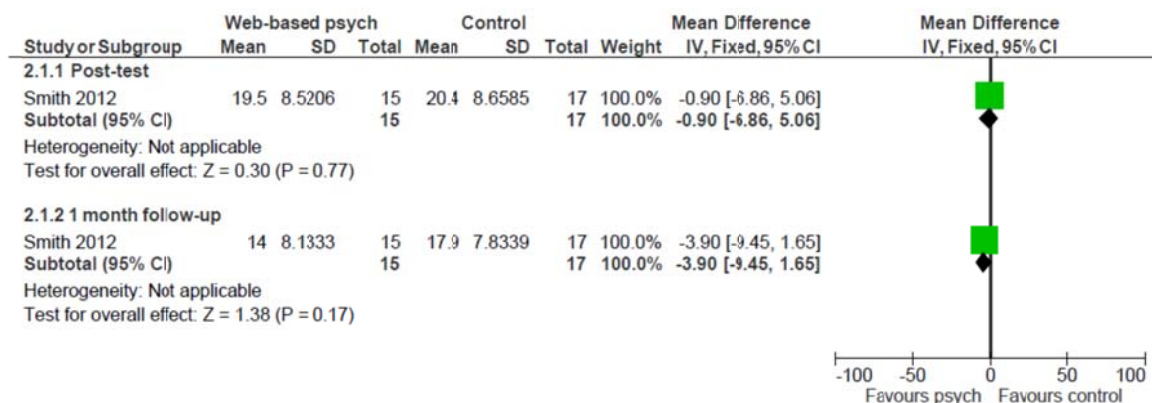


Figure 330: **Mastery scale baseline adjusted values – Caregivers (Wives)**

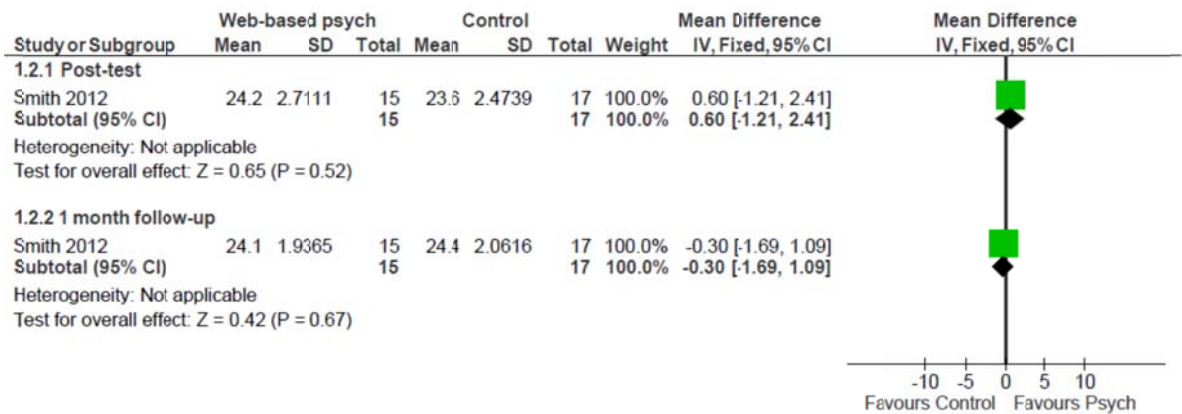


Figure 331: **Mastery scale baseline adjusted values – Persons with stroke (Husbands)**

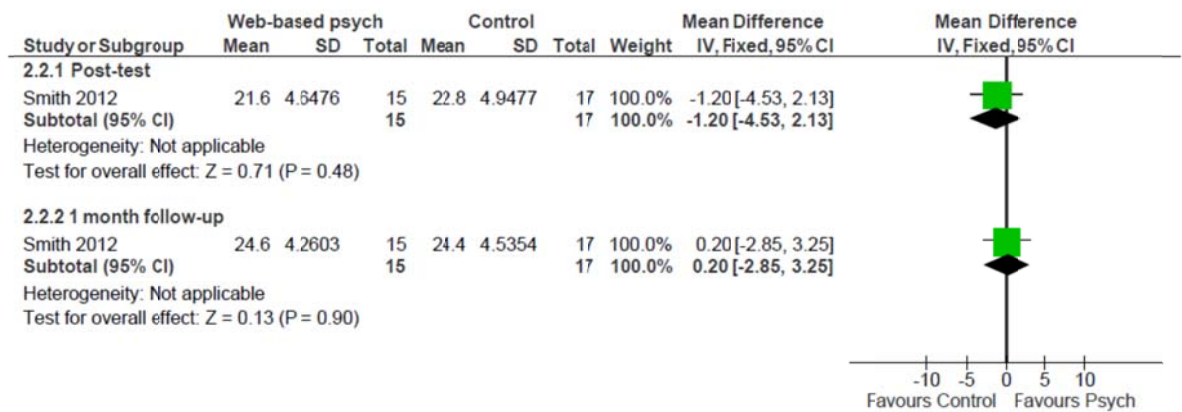


Figure 332: **Self-esteem scale baseline adjusted values – Caregivers (Wives)**

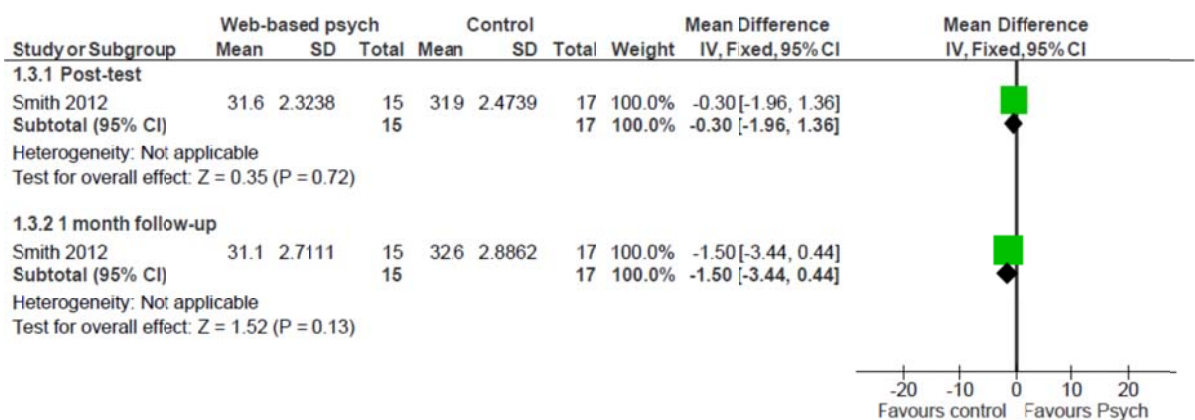


Figure 333: Self-esteem scale baseline adjusted values – Persons with stroke (Husbands)

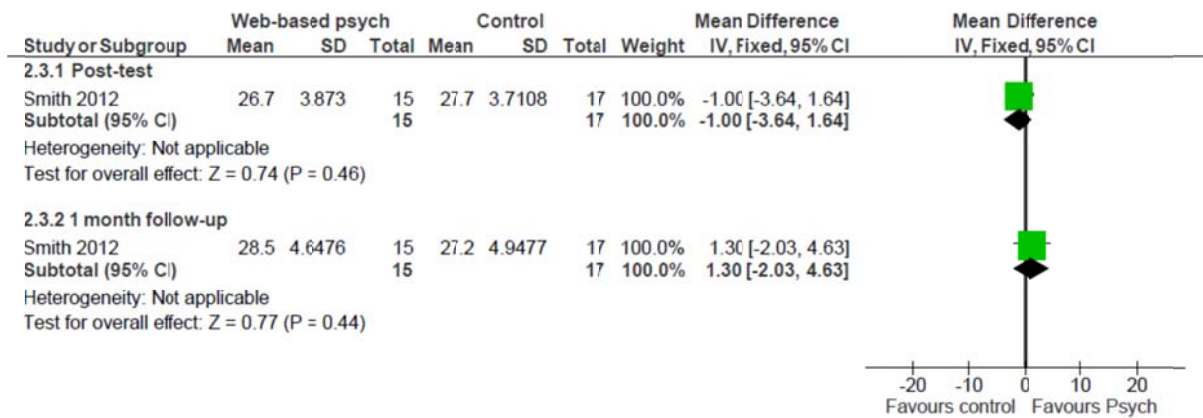


Figure 334: Medical Outcomes Study (MOS) Social Support survey baseline adjusted values – Caregivers (Wives)

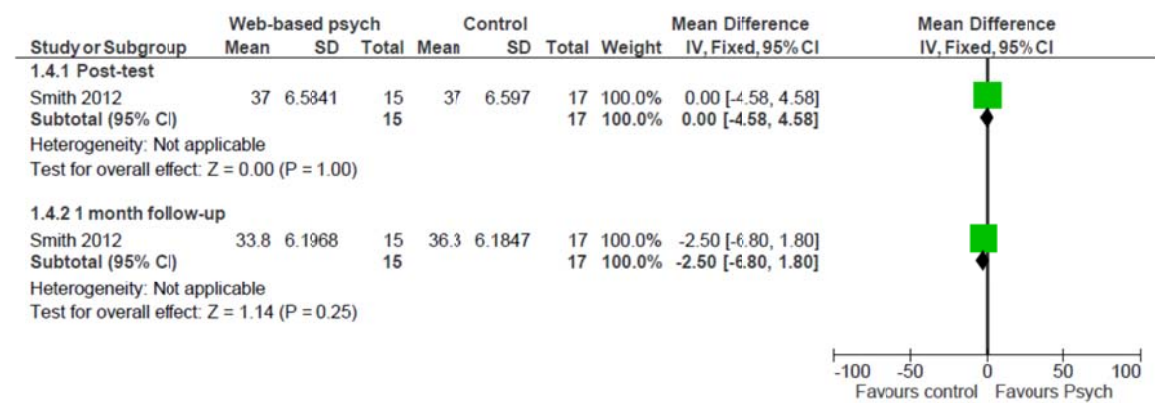
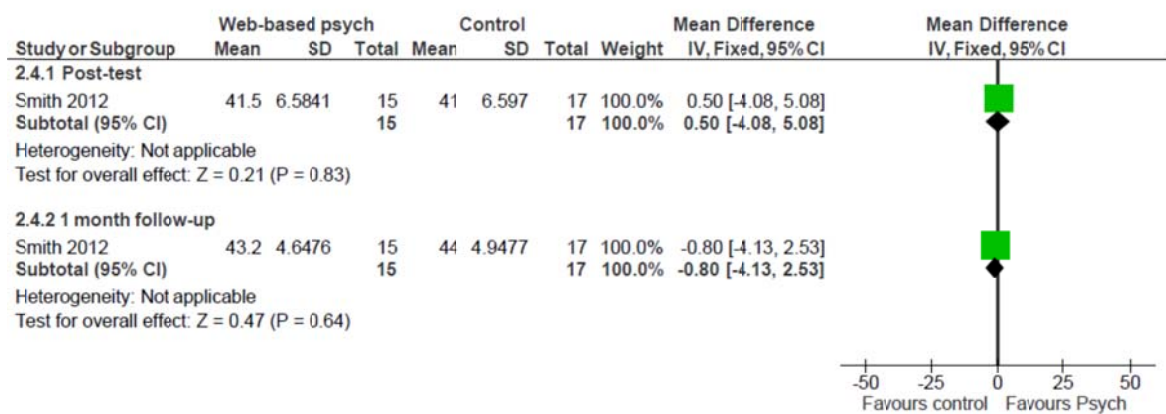


Figure 335: Medical Outcomes Study (MOS) Social Support survey baseline adjusted values – Persons with stroke (Husbands)



J.20 In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care ?

J.20.1 Early supported discharge versus usual care

Figure 336: Barthel Index Scale (6, 12, and 26 weeks follow-up)

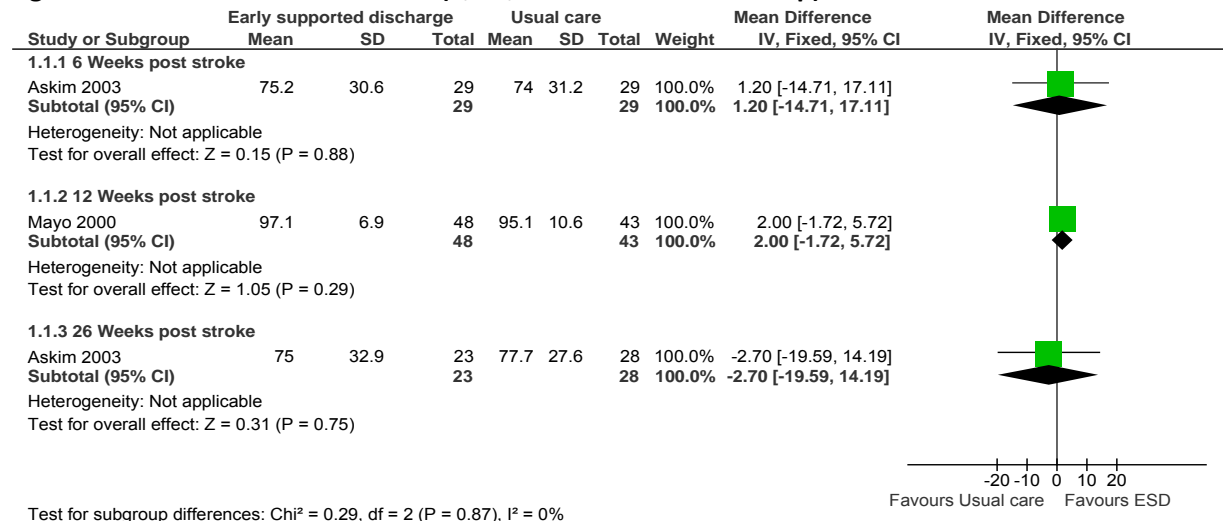


Figure 337: Barthel Index Scale (52 weeks follow-up)

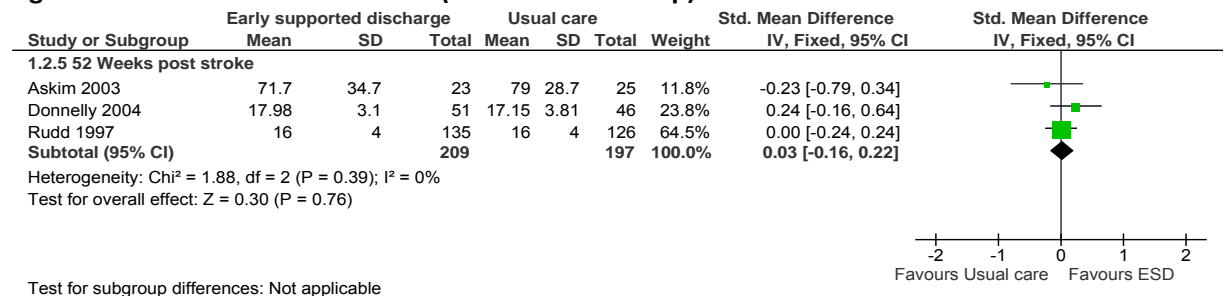
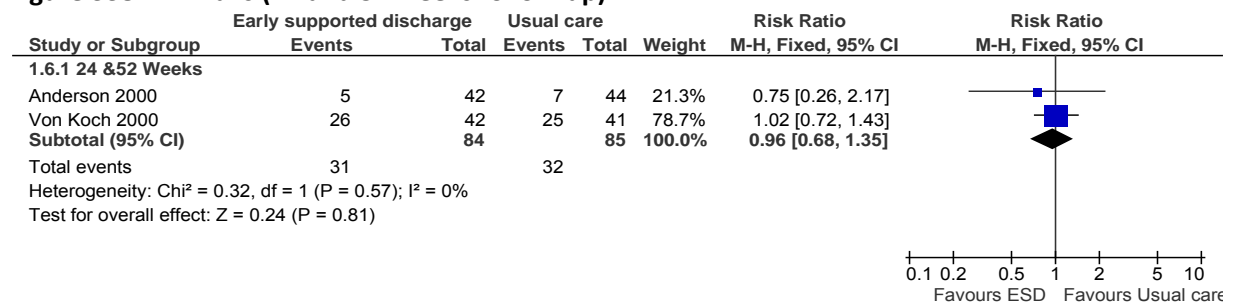


Figure 338: Falls (24 and 52 weeks follow-up)



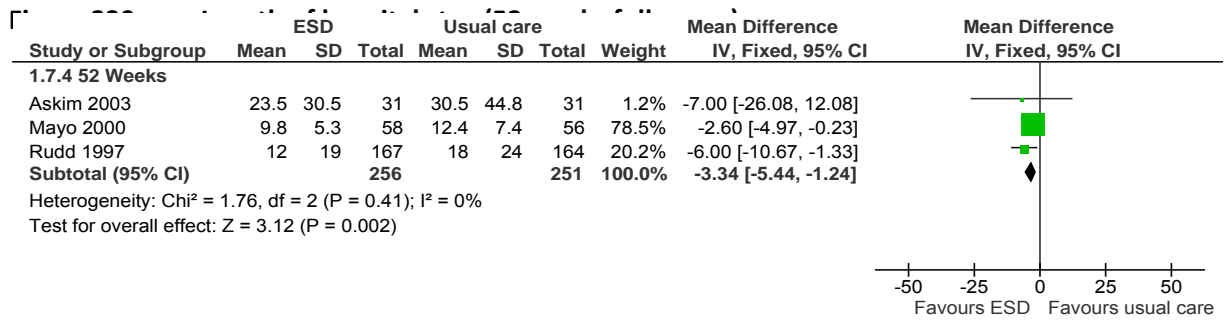


Figure 340: Length of hospital stay (52 weeks follow-up)

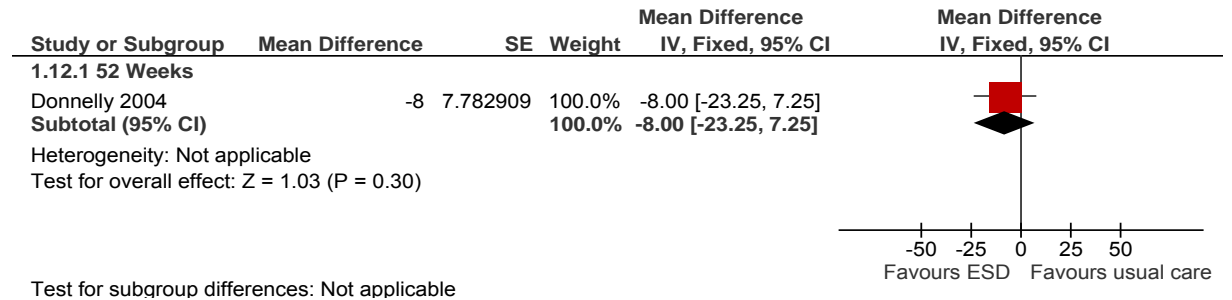


Figure 341: Mortality (12 – 52 weeks follow-up)

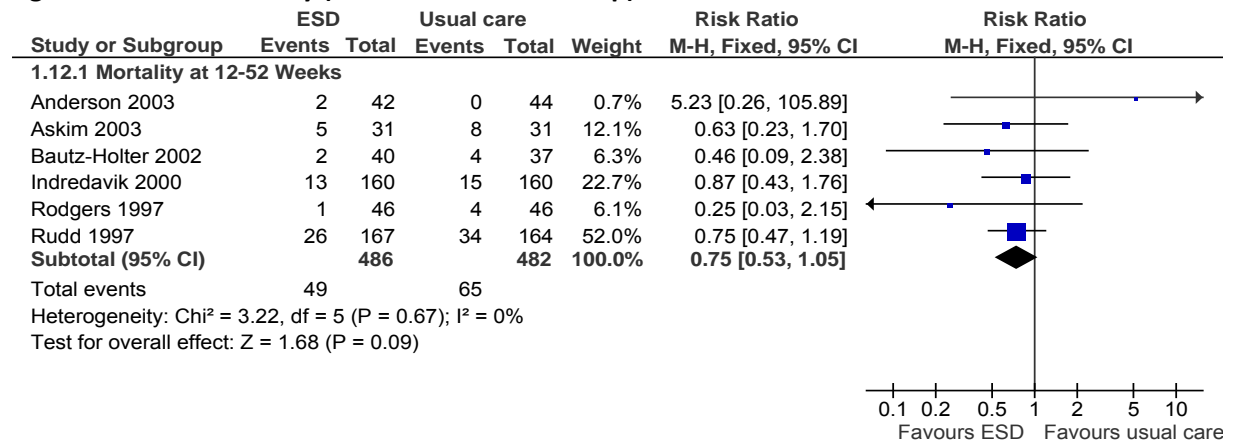
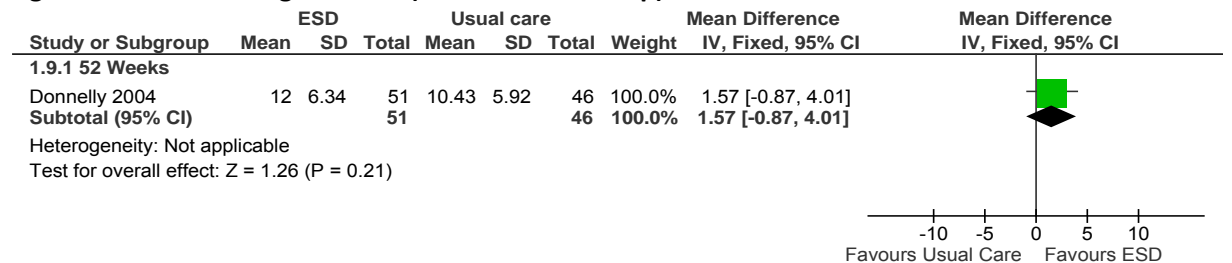


Figure 342: Nottingham ADL (52 weeks follow-up)



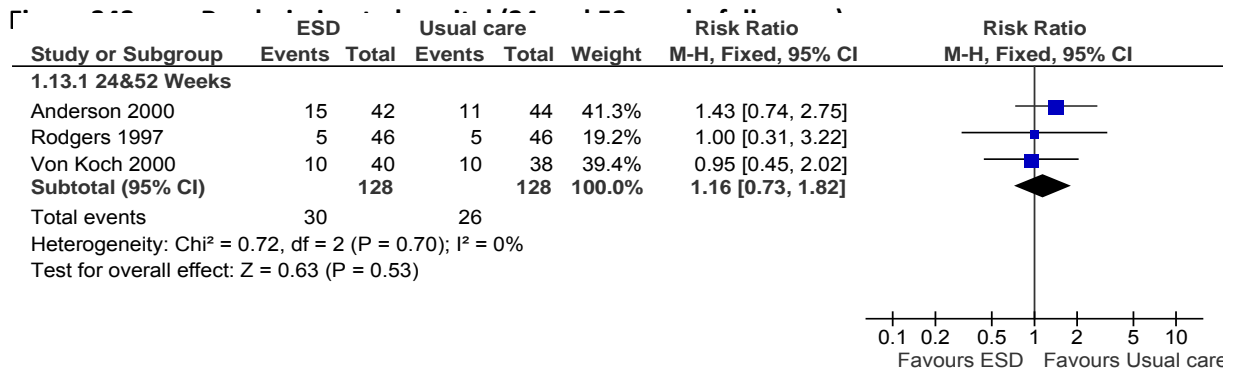


Figure 344: SF-36-Anderson – Physical and social functioning (24 weeks follow-up)

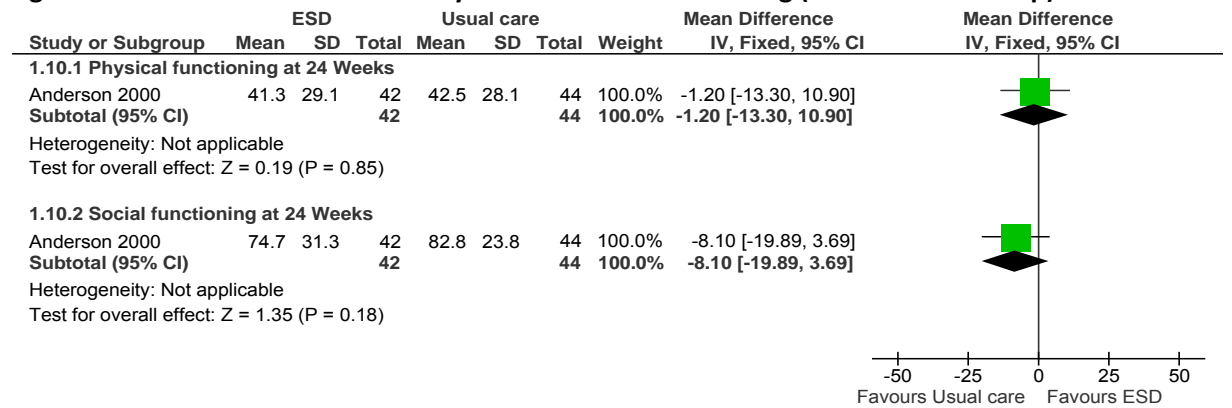


Figure 345: SF-36 – Physical and mental health (12 and 52 weeks follow-up)

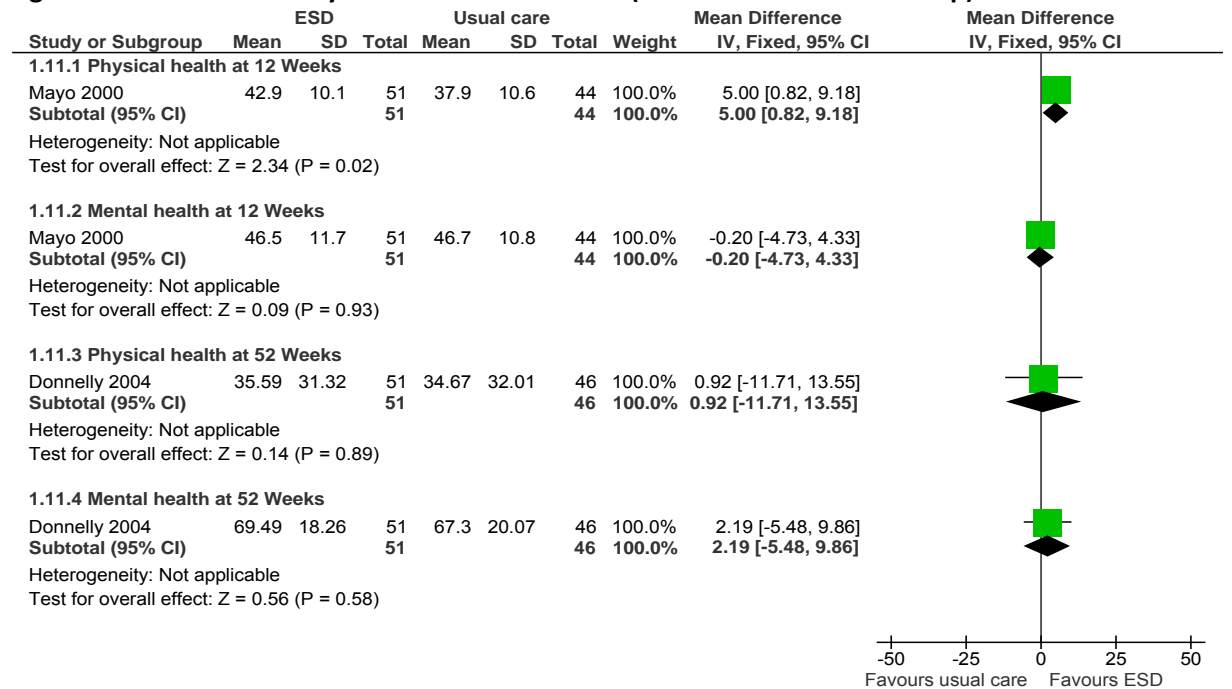


Figure 346: EuroQol (52 weeks follow-up)

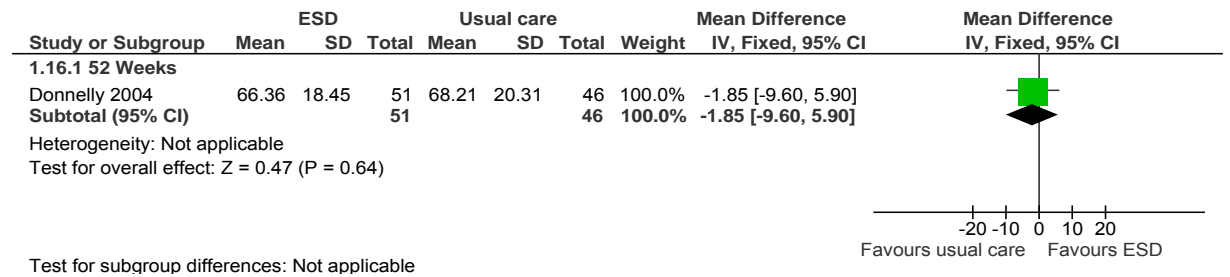


Figure 347: Global Nottingham Health Profile 1 and 2 (52 weeks follow-up)

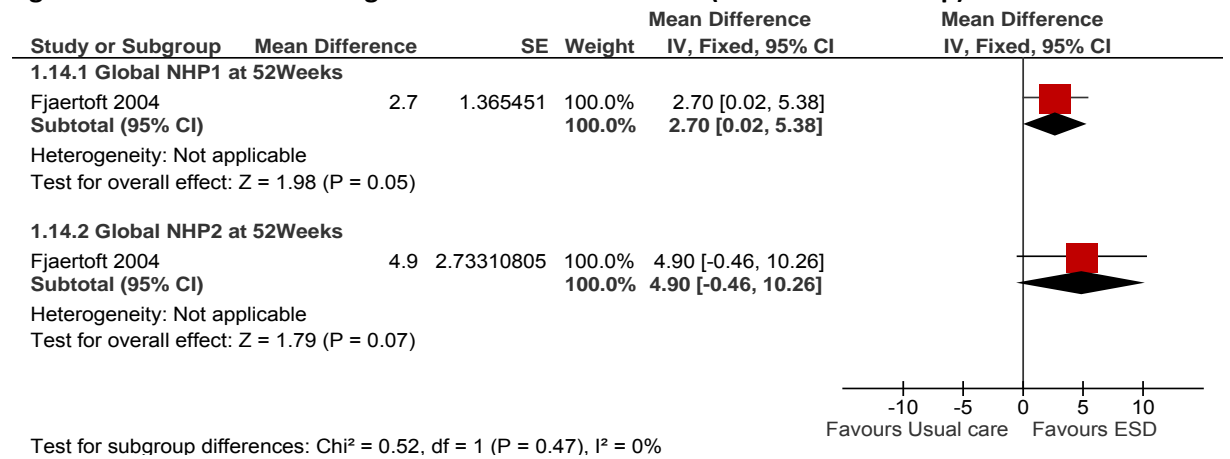


Figure 348: Hospital Anxiety and Depression scale (52 weeks follow-up)

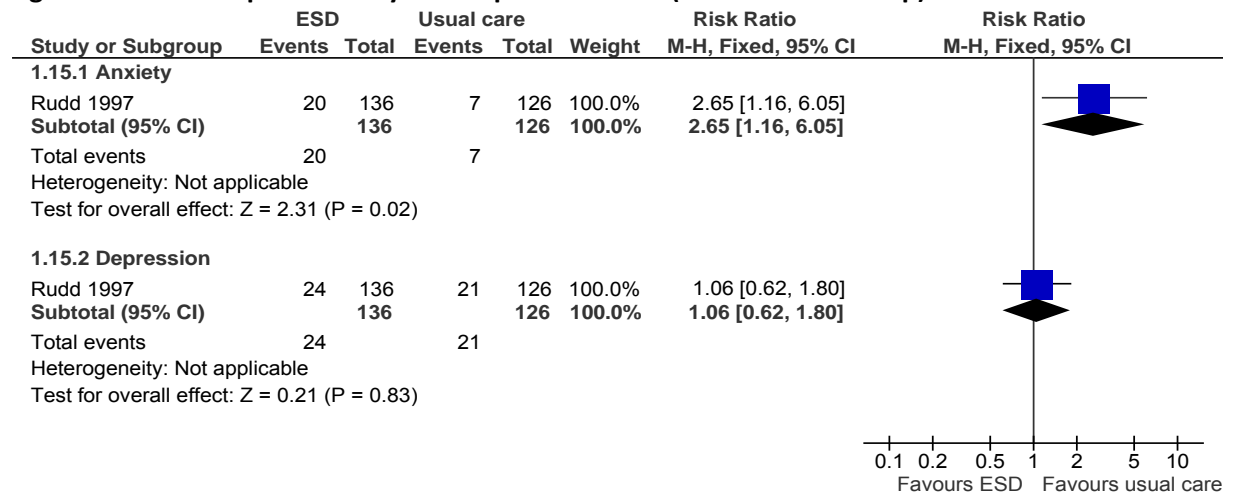


Figure 349: Caregiver Strain Index (6 weeks follow-up)

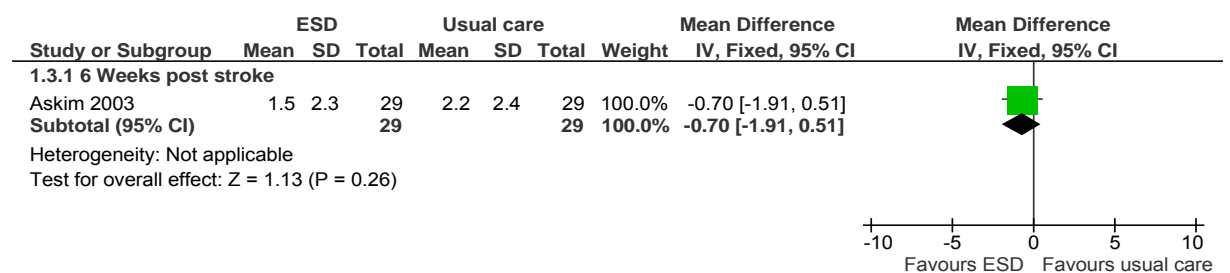
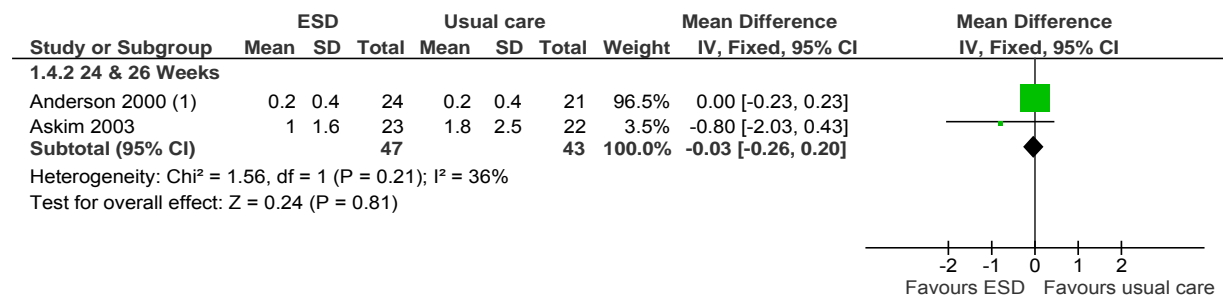
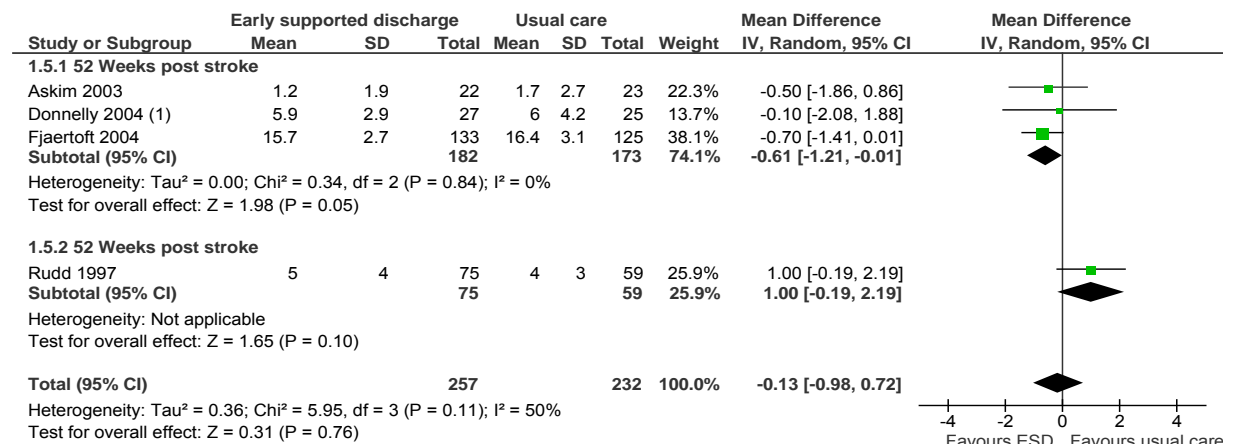


Figure 350: Caregiver Strain Index (24 and 26 weeks follow-up)



(1) Lower scores indicate better outcomes.

Figure 351: Caregiver Strain Index (52 weeks follow-up)



(1) Lower scores indicate better outcomes. Different scales used.

J.21 In people after stroke what is the clinical and cost-effectiveness of intensive rehabilitation versus standard rehabilitation?

J.21.1 Intensive rehabilitation versus standard rehabilitation for stroke rehabilitation

Figure 352: Barthel Index (3 months follow-up)

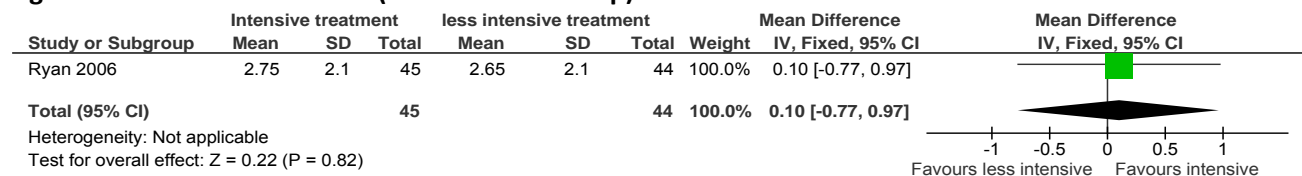


Figure 353: Euroqol VAS (3 months follow-up)

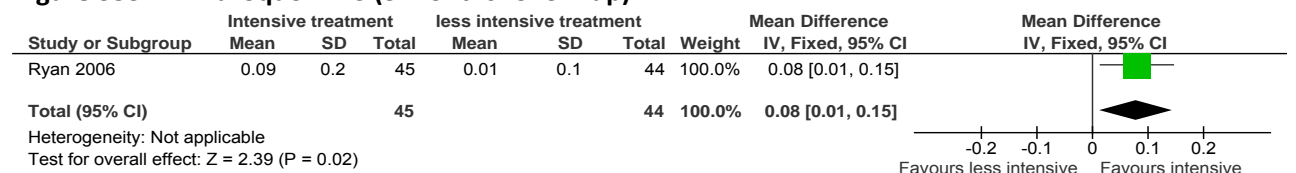


Figure 354: Euroquol 5D (3 months follow-up)

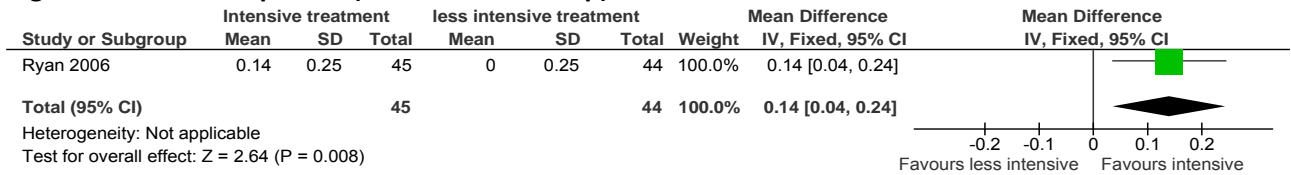


Figure 355: Frenchay activities index (3 months follow-up)

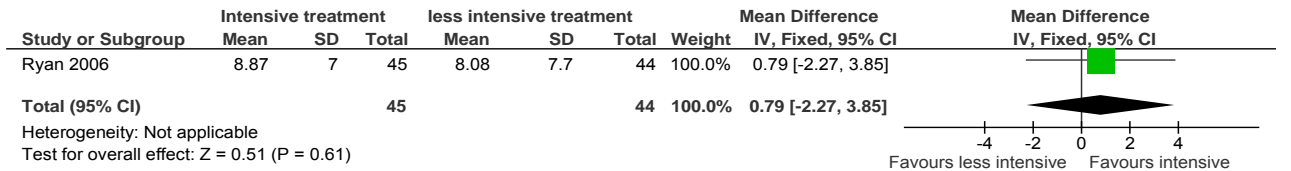
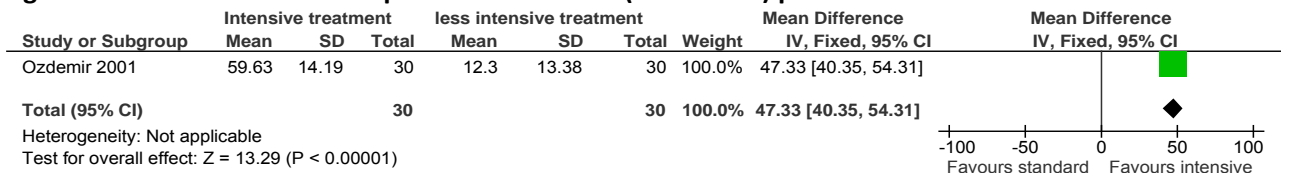


Figure 356: Functional Independence Measure (total score) post treatment effect



J.22 In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?

J.22.1 Intensive speech therapy versus less intensive speech therapy or no therapy

Figure 357: Aachen Aphasie Test (AAT) – Token test (6 month follow-up)

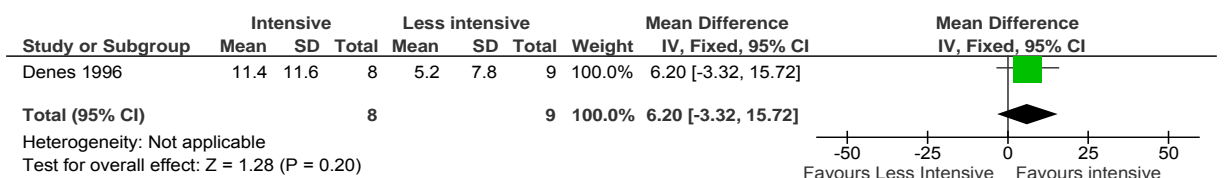


Figure 358: Aachen Aphasie Test (AAT) – Repetition (6 month follow-up)

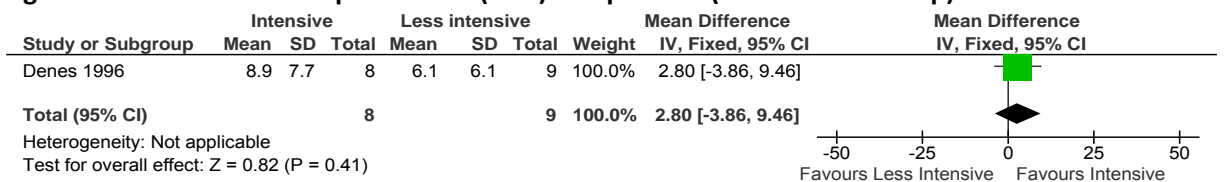
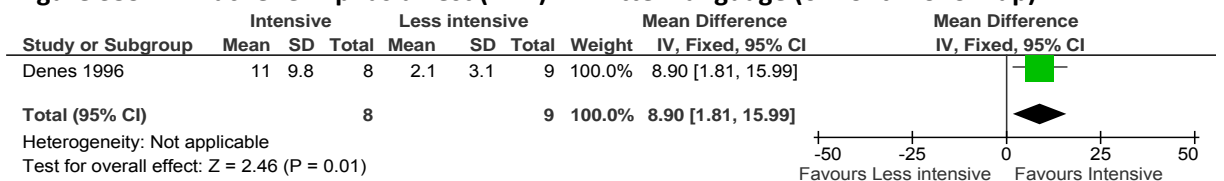


Figure 359: Aachen Aphasie Test (AAT) – Written language (6 month follow up)



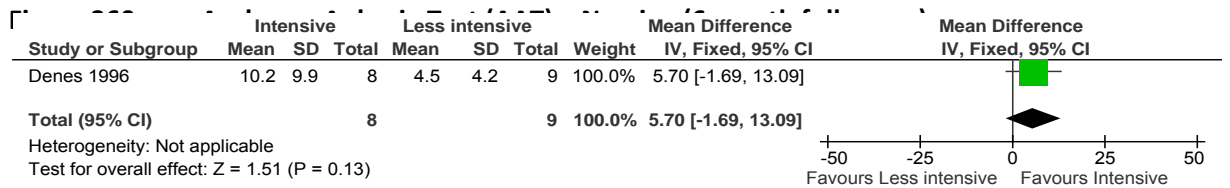


Figure 361: Aachenner Aphasia Test (AAT) – Comprehension (6 month follow-up)

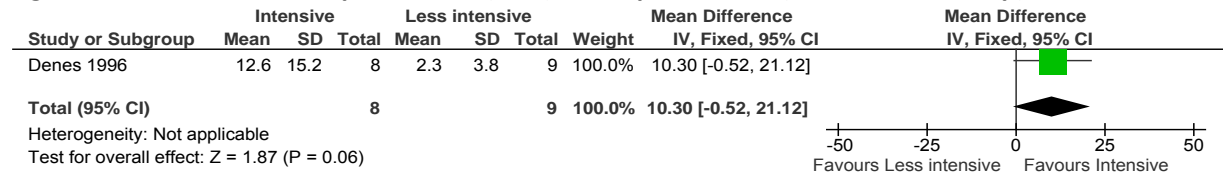


Figure 362: Aachenner Aphasia Test (AAT) – Profile level (6 month follow-up)

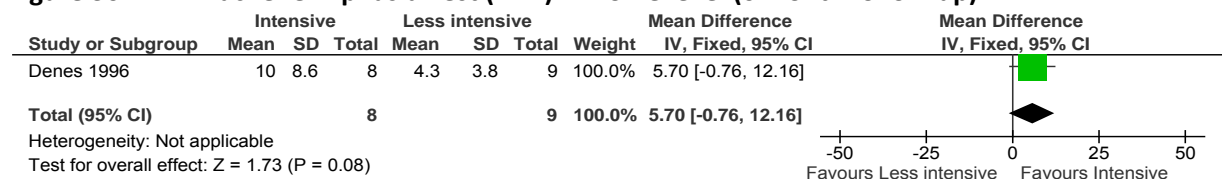


Figure 363: Western Aphasia Battery (8 weeks follow-up)

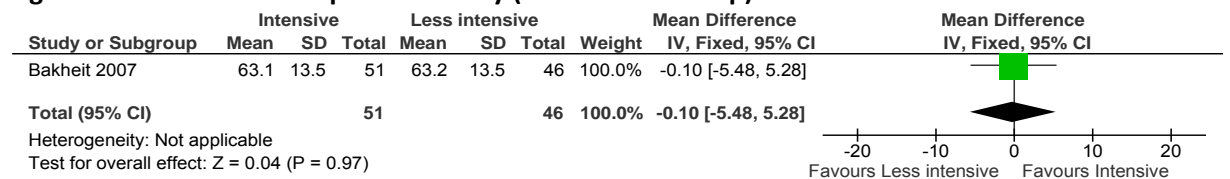


Figure 364: Western Aphasia Battery (12 weeks follow-up)

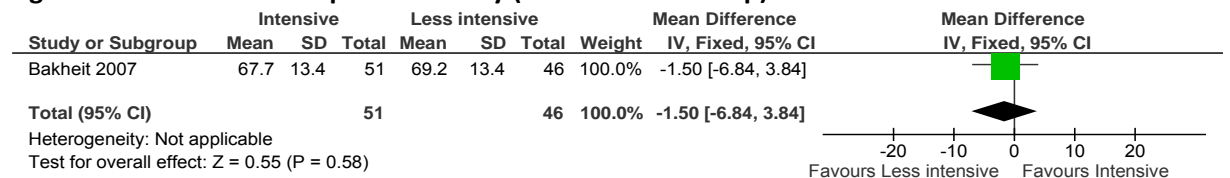
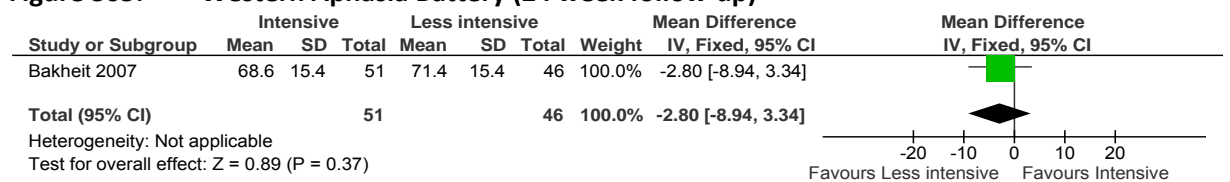


Figure 365: Western Aphasia Battery (24 week follow-up)



J.22.2 Intensive speech therapy versus no treatment

Figure 366: Boston Naming Test (BNT) (2 month follow-up post-treatment)

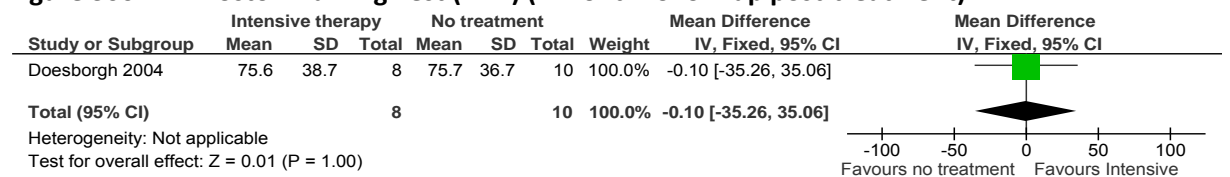


Figure 367: Amsterdam Nijmegen Everyday Language Test, scale A (ANELT-A) change score (26 week follow-up)

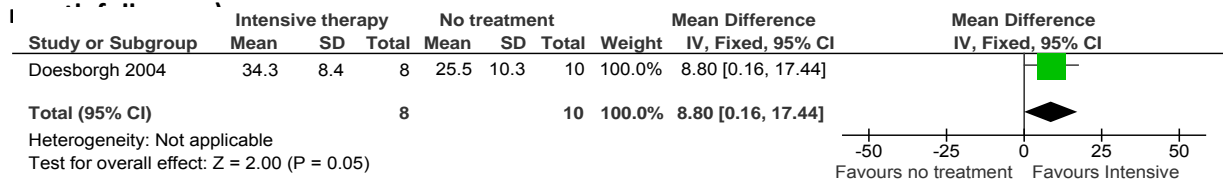


Figure 368: Porch Index of Communicative Ability (PICA) (more intensive versus no treatment) (26 week follow-up)

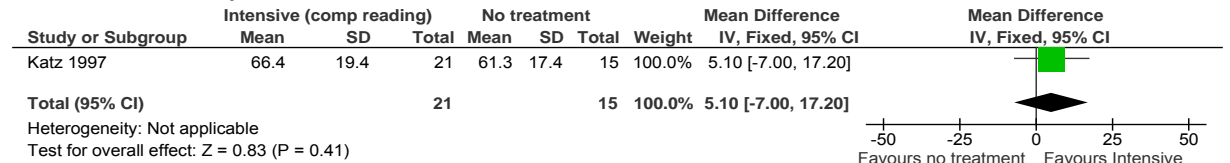


Figure 369: Porch Index of Communicative Ability (PICA) (less intensive versus no treatment) (26 week follow-up)

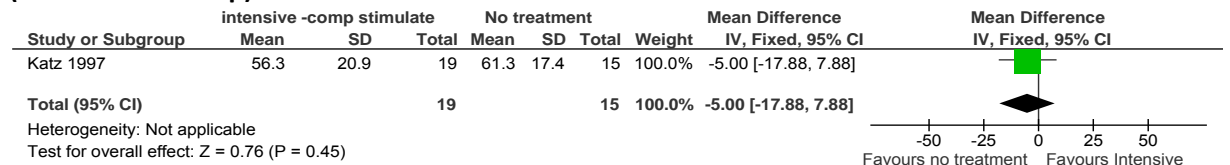


Figure 370: Western Aphasia Battery (more intensive versus no treatment) (26 week follow-up)

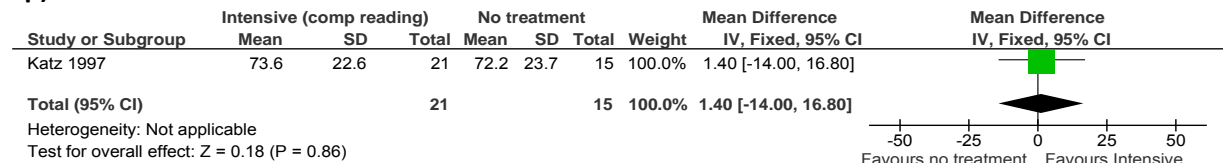


Figure 371: Western Aphasia Battery (less intensive versus no treatment) (26 week follow-up)

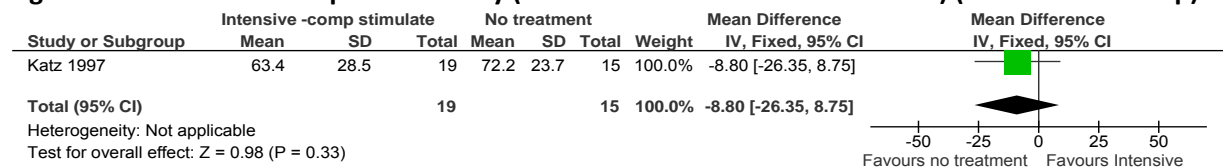


Figure 372: Porch Index of Communicative Ability (PICA) (one month follow-up after lesion onset)

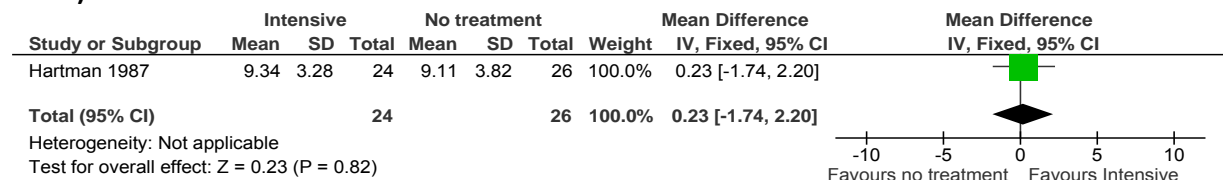
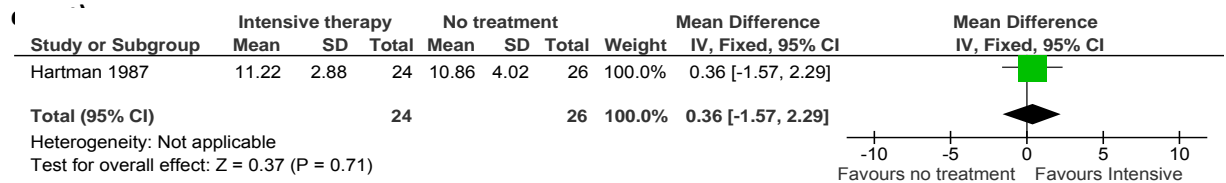


Figure 373: Porch Index of Communicative Ability (PICA) (10 month follow up after lesion)



J.23 In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language/communication abilities and/or psychological wellbeing?

J.23.1 Speech and language therapy versus no speech and language therapy

Figure 374: Functional communication

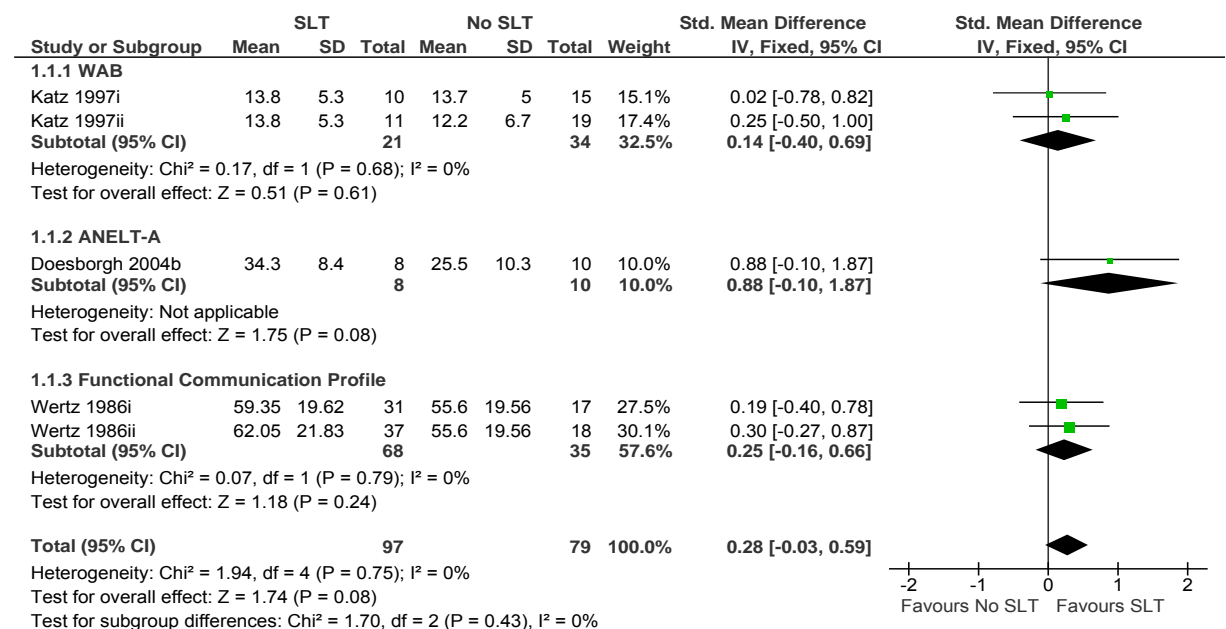


Figure 375: Receptive language: auditory comprehension

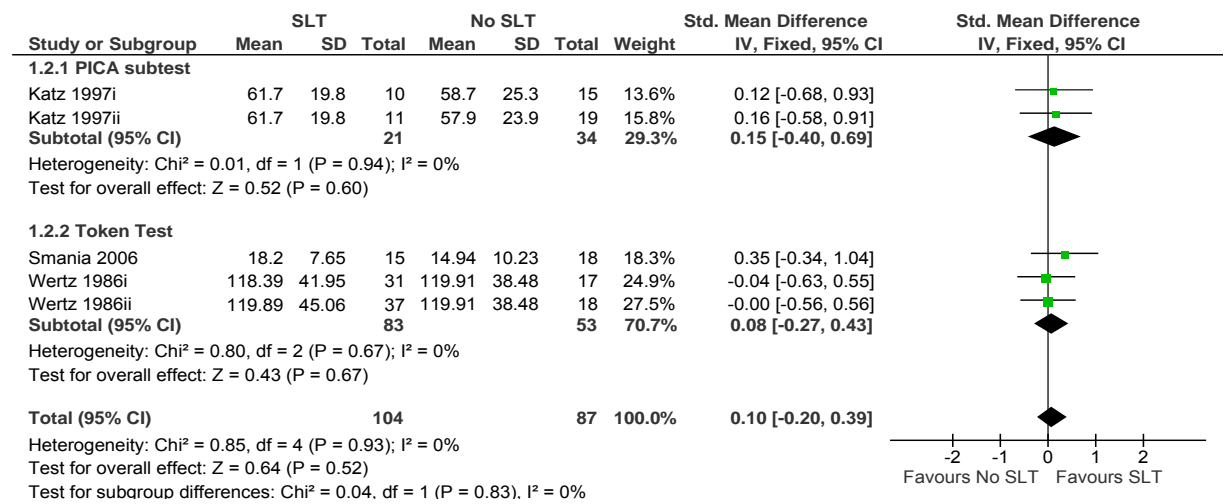


Figure 376: Receptive language: reading comprehension

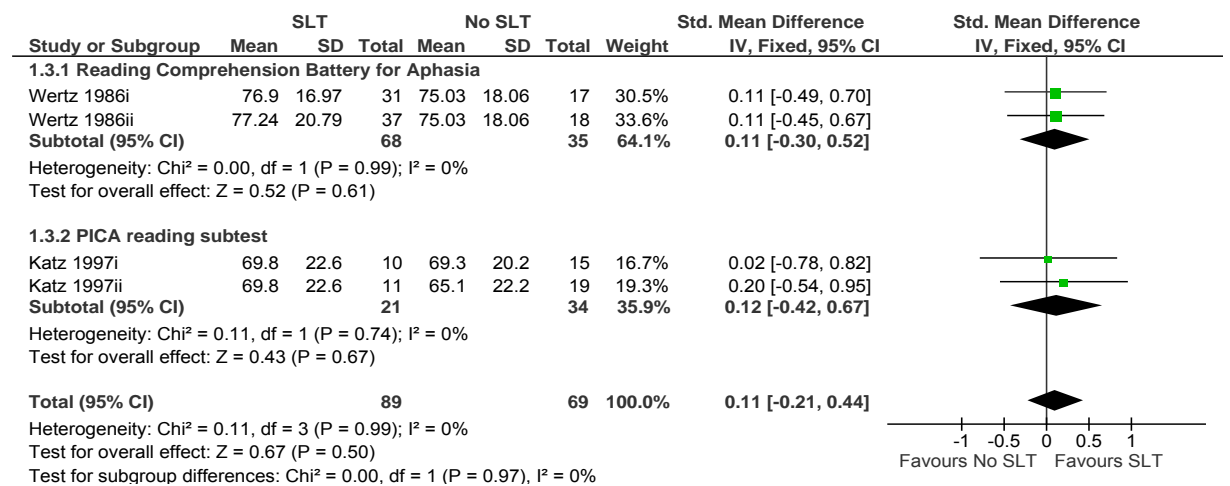


Figure 377: Receptive language: gesture use

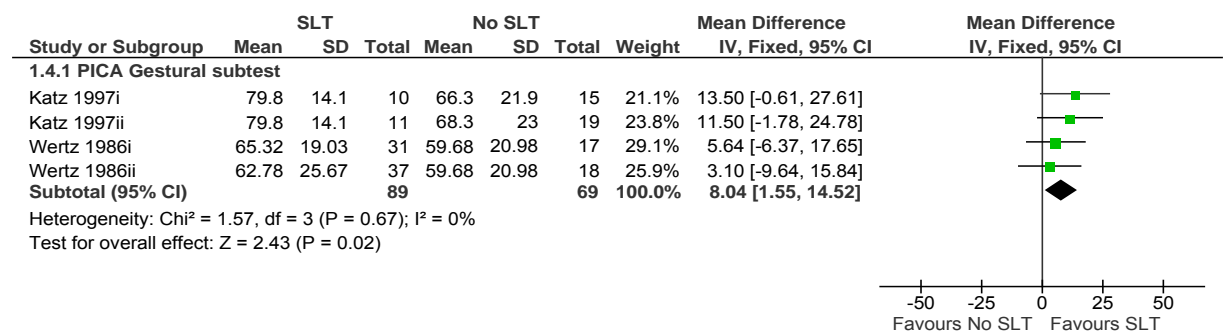


Figure 378: Receptive language: gesture comprehension

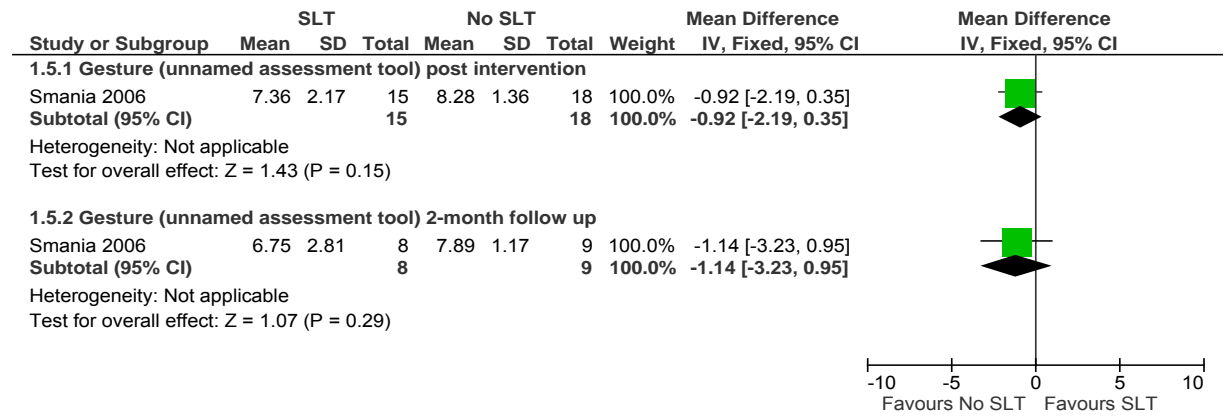


Figure 379: Expressive language: naming

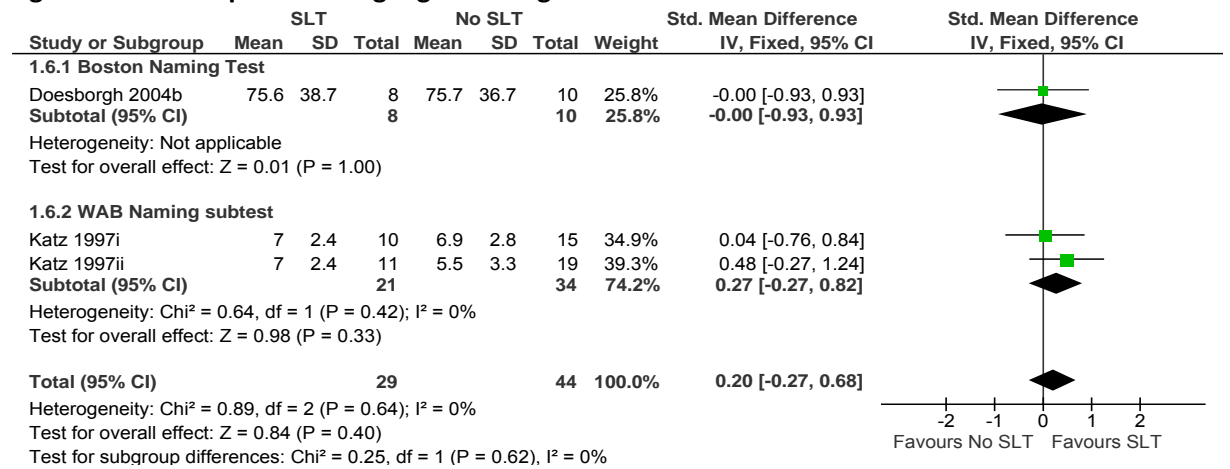


Figure 380: Expressive language: naming (Object and Action Naming Battery)

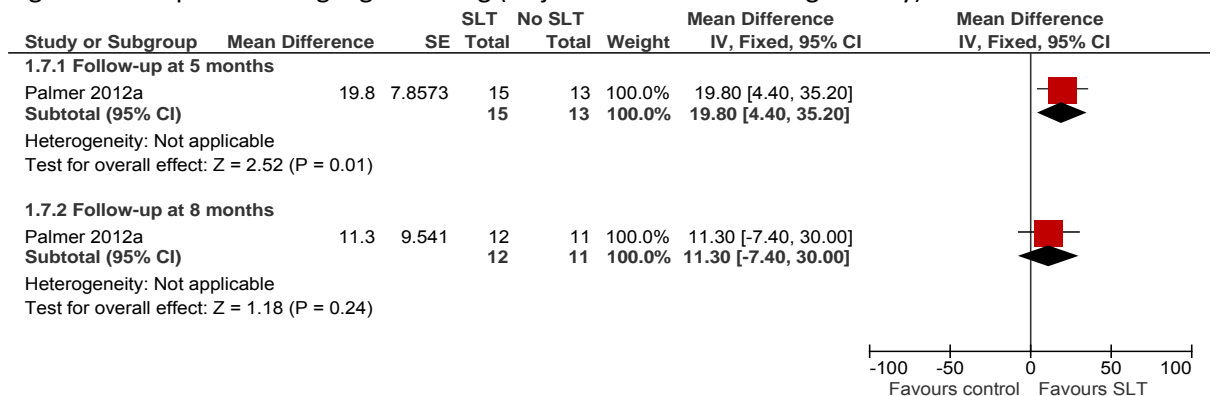


Figure 381: Expressive language: general

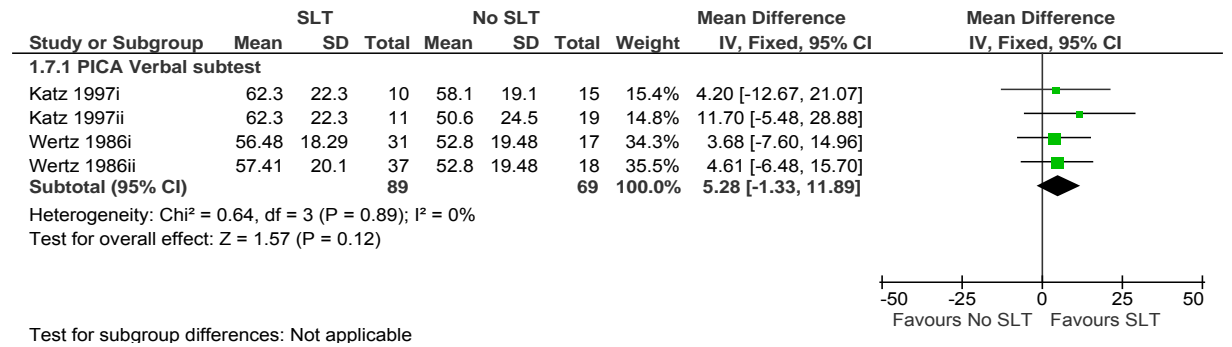


Figure 382: Expressive language: written

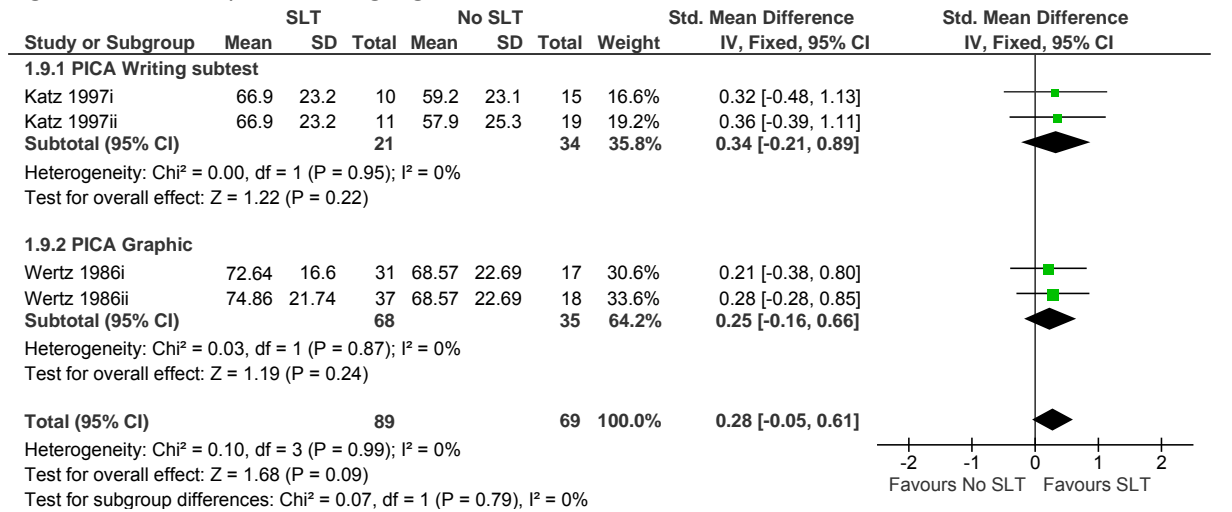


Figure 383: Expressive language: written copying

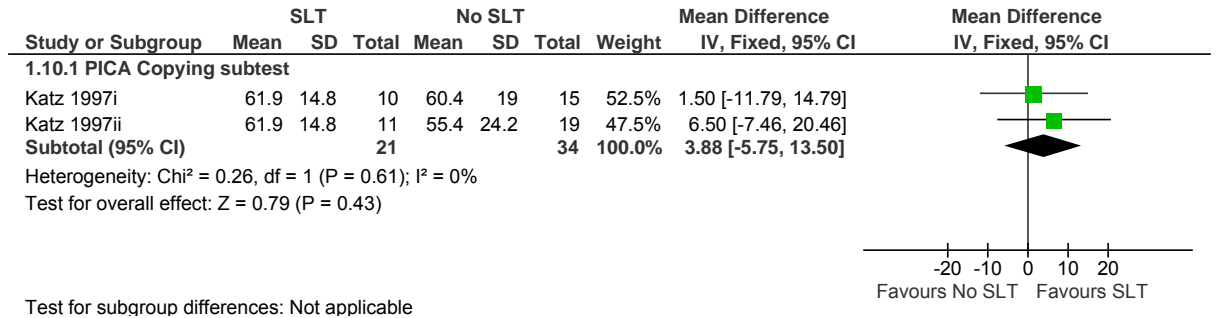


Figure 384: Expressive language: repetition

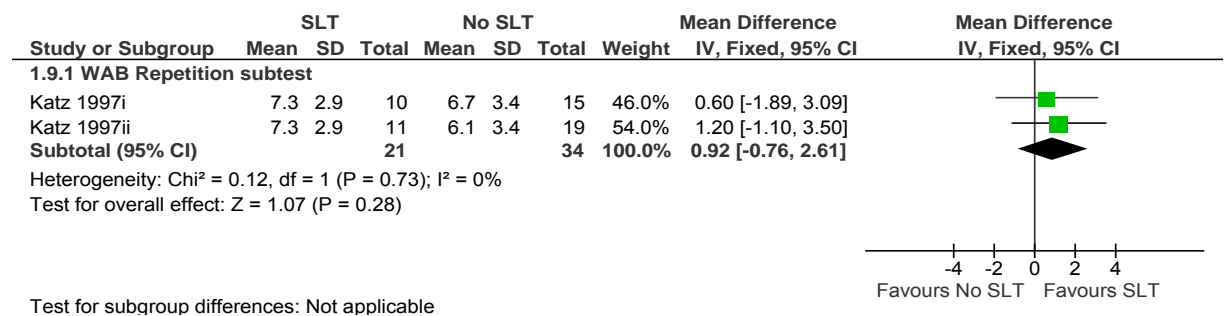


Figure 385: Severity of impairment: post intervention

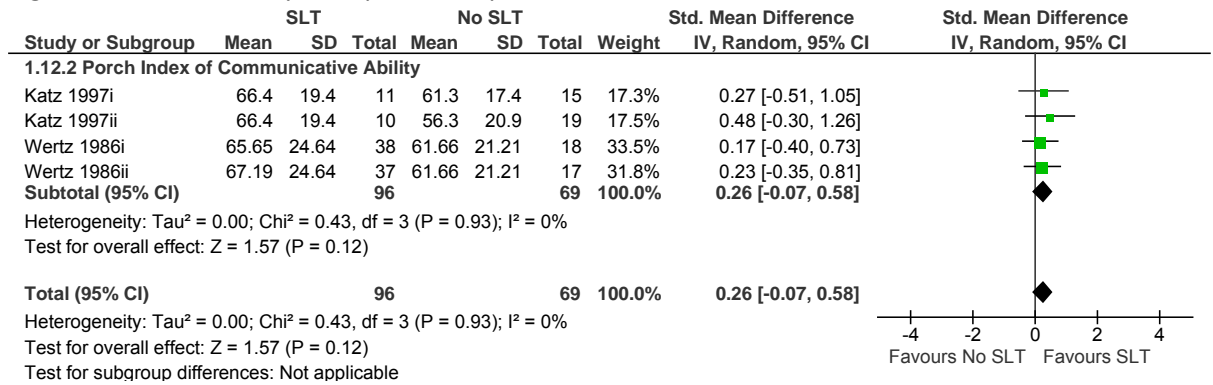


Figure 386: Psychosocial

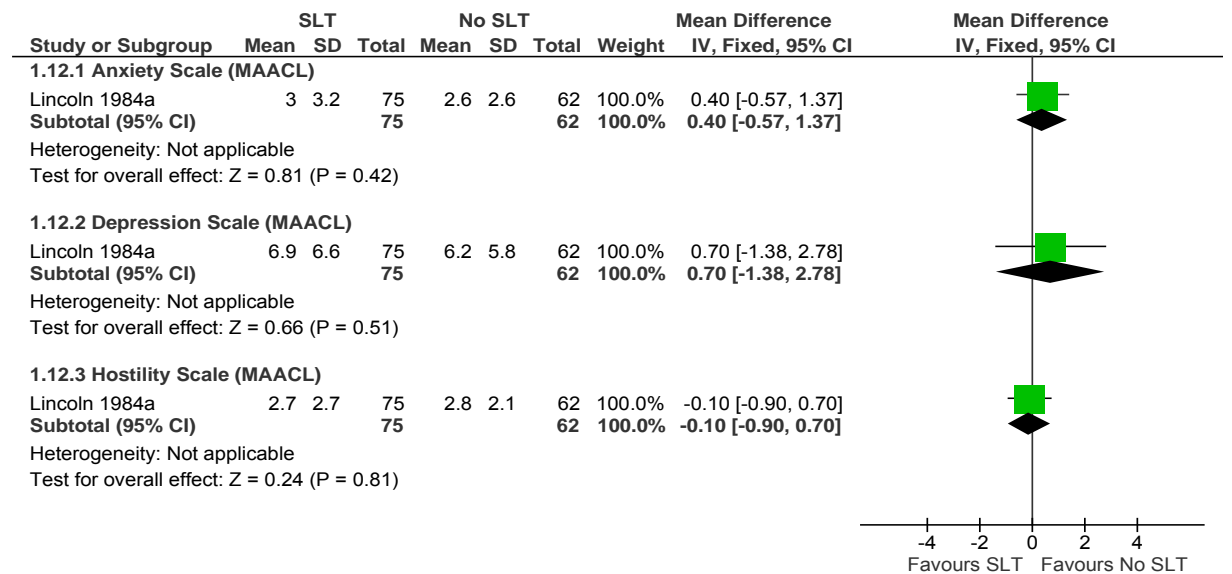


Figure 387: Number of drop-outs (any reason)

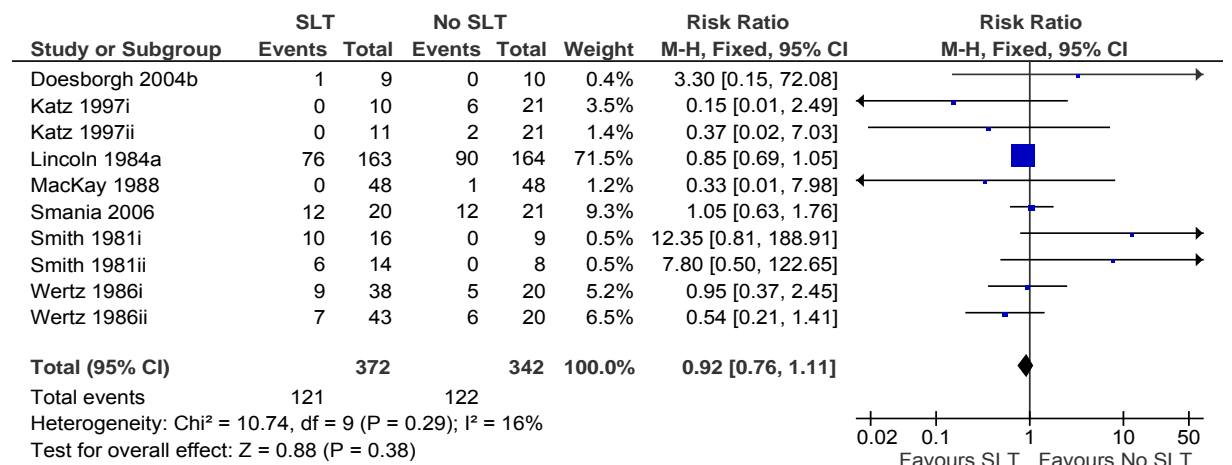
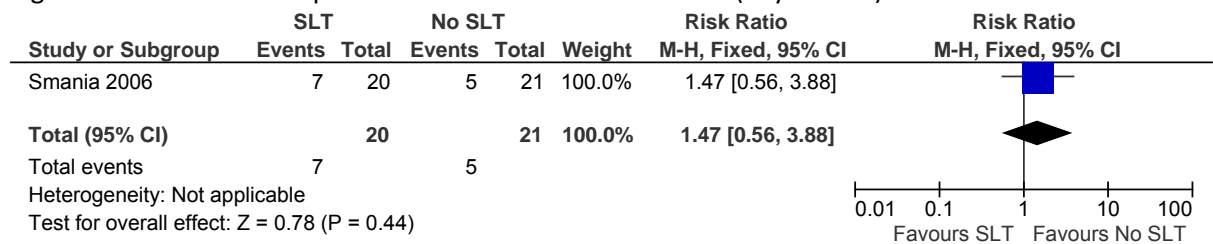


Figure 388: Non-compliance with allocated intervention (any reason)



J.23.2 Speech and language therapy versus placebo (social support and stimulation)

Figure 389: Functional communication

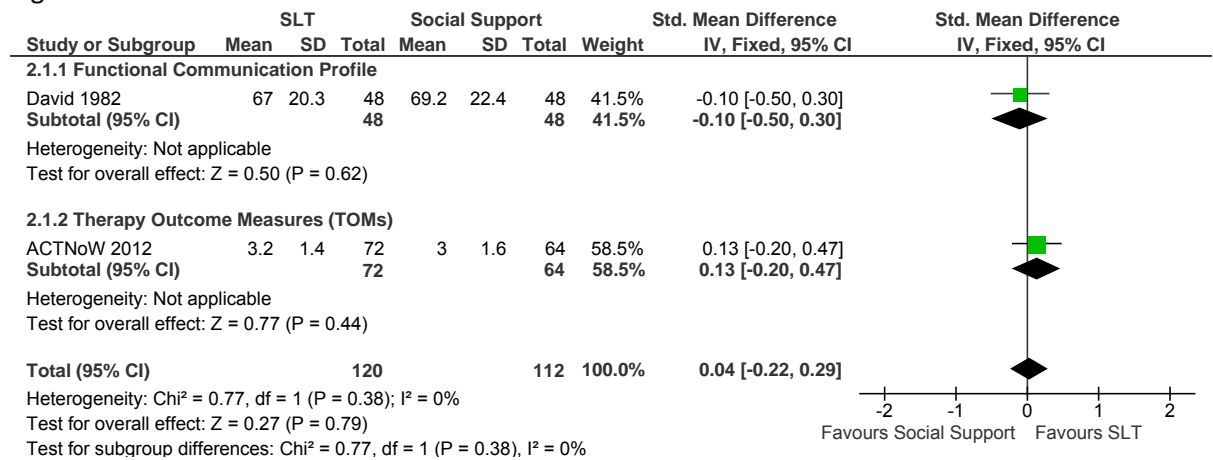


Figure 390: Functional communication: 3 and 6 months follow-up

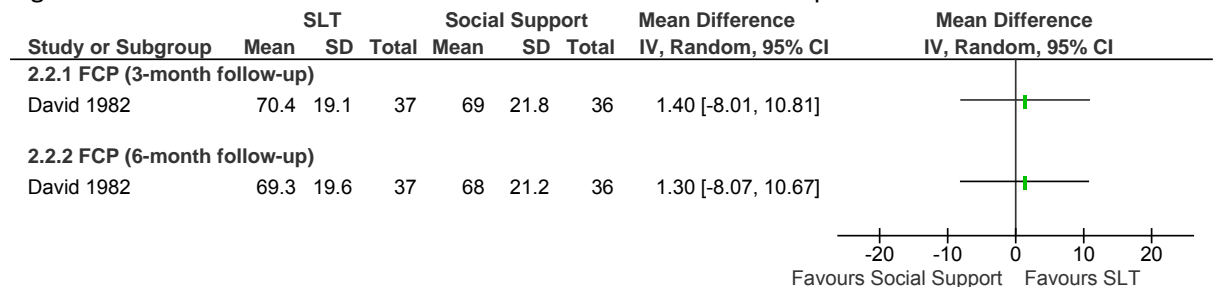


Figure 391: Receptive language: auditory comprehension

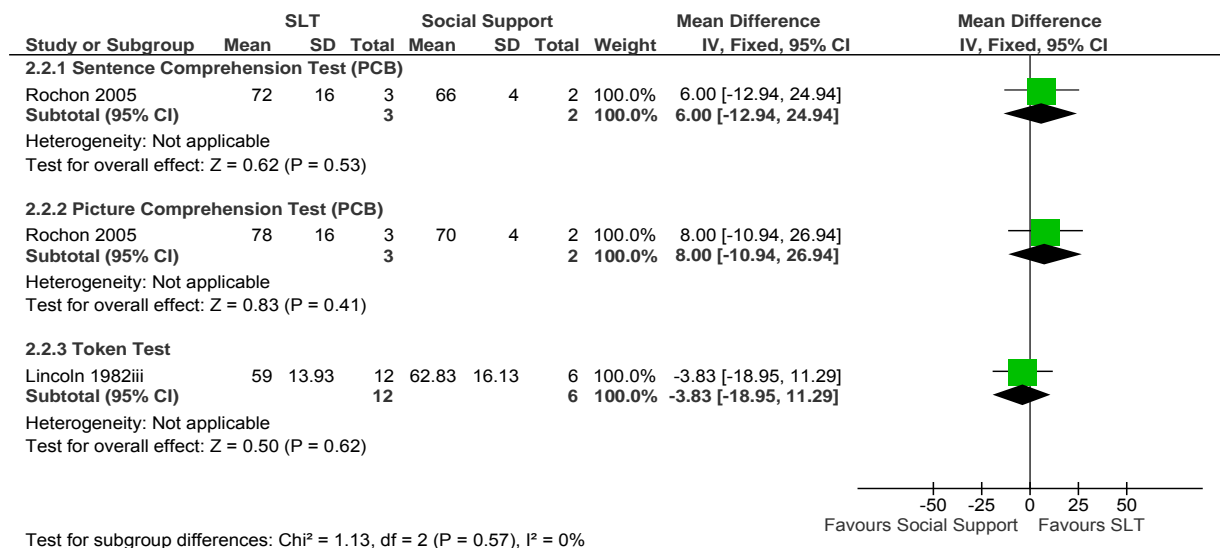


Figure 392: Receptive language: auditory and written comprehension

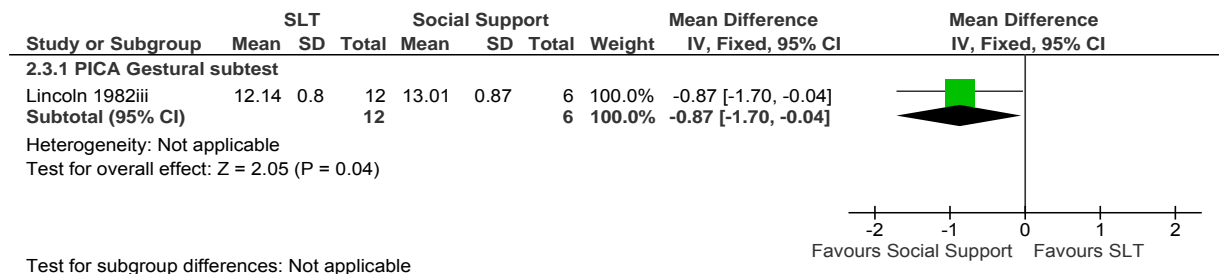


Figure 393: Expressive language: single words

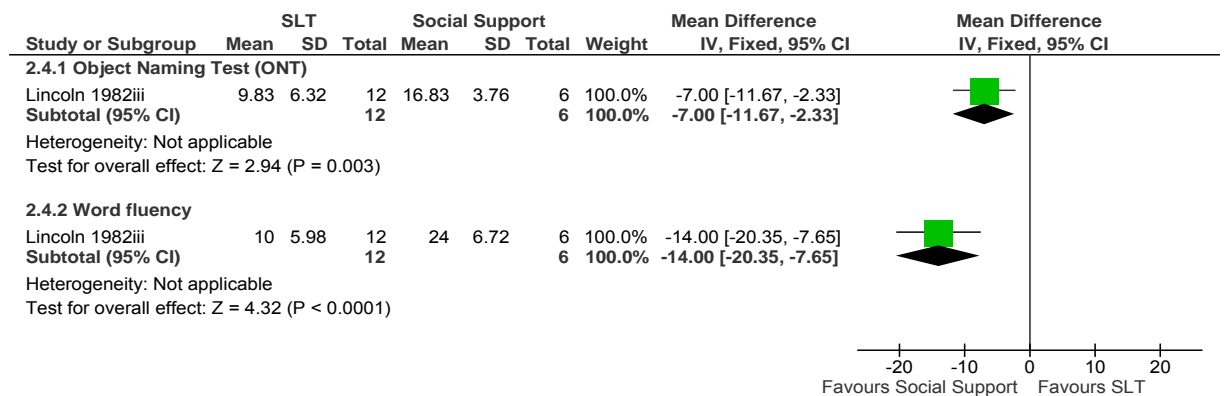


Figure 394: Expressive language: single words 7 and 10 months follow-up (change from baseline)

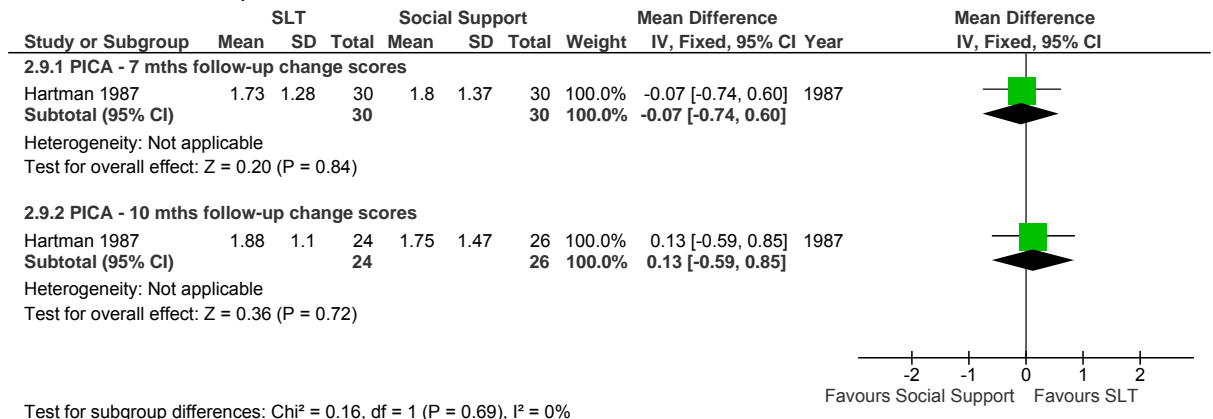


Figure 395: Expressive language: sentences

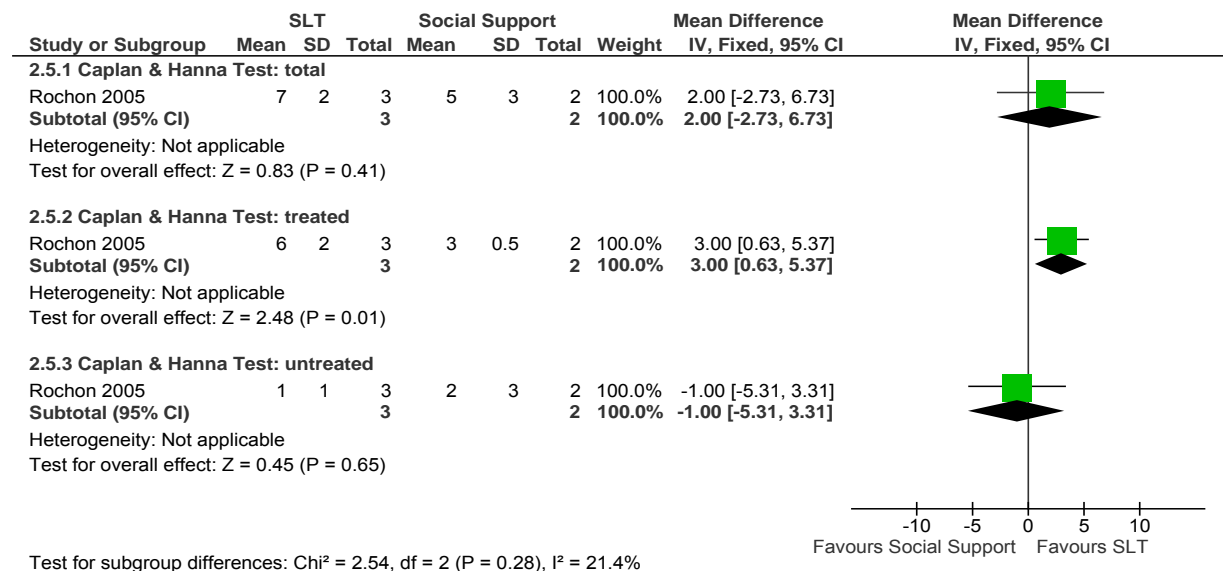


Figure 396: Expressive language: picture description

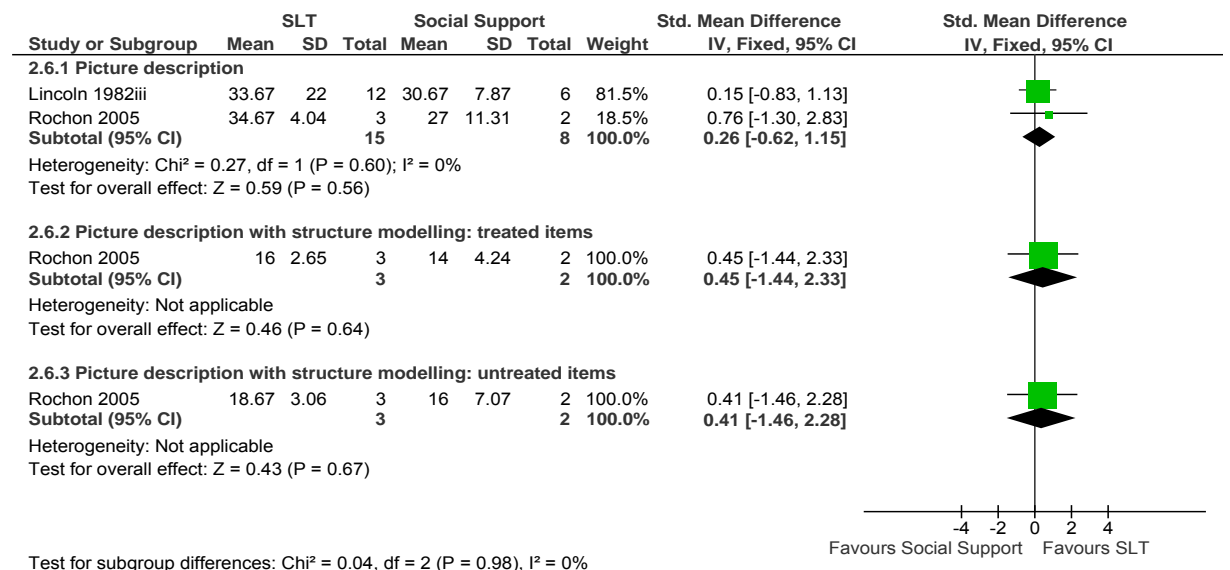


Figure 397: Expressive language: overall spoken

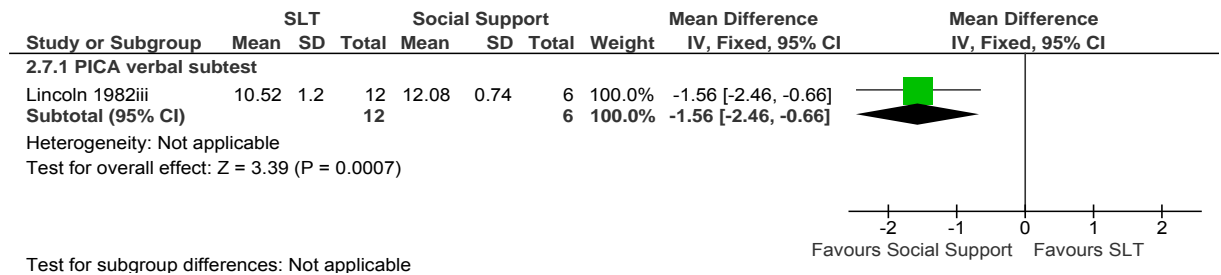


Figure 398: Expressive language: written

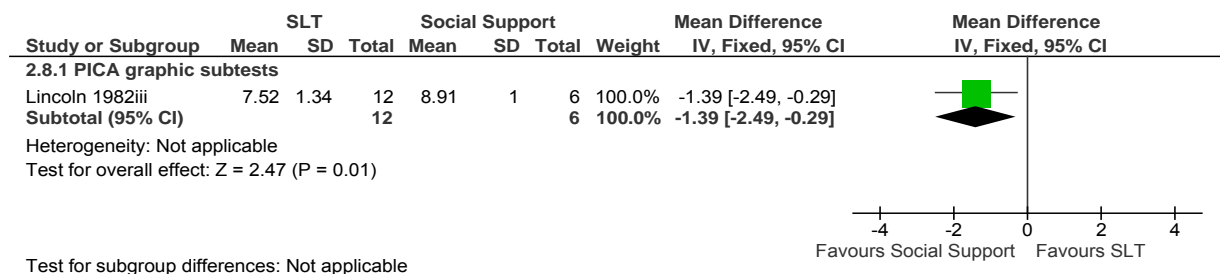


Figure 399: Severity of impairment

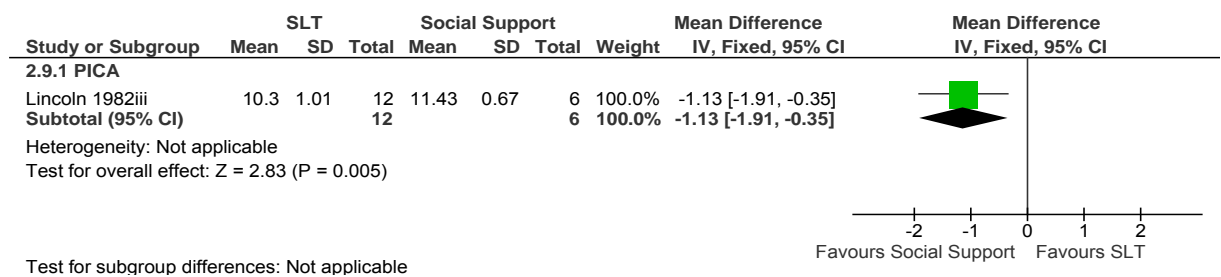


Figure 400: Psychosocial: Communication Outcomes after Stroke scale (COAST)

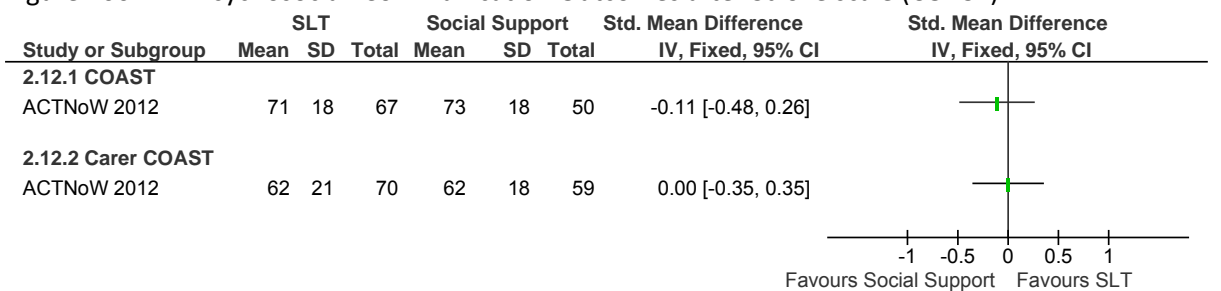


Figure 401: Number of drop-outs (any reason)

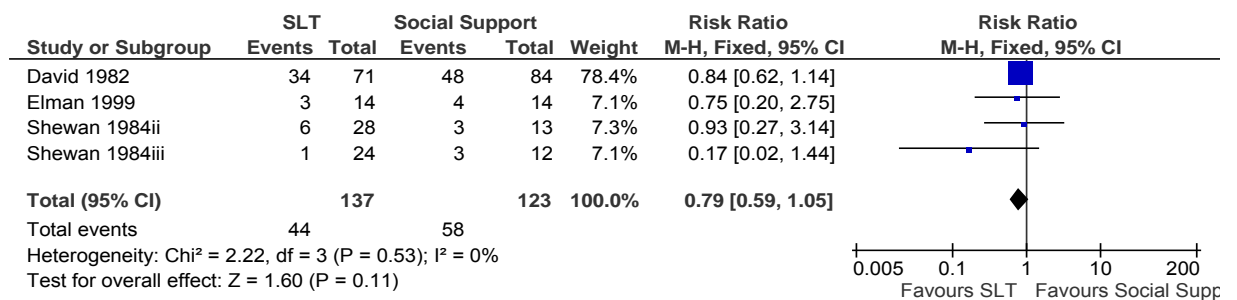
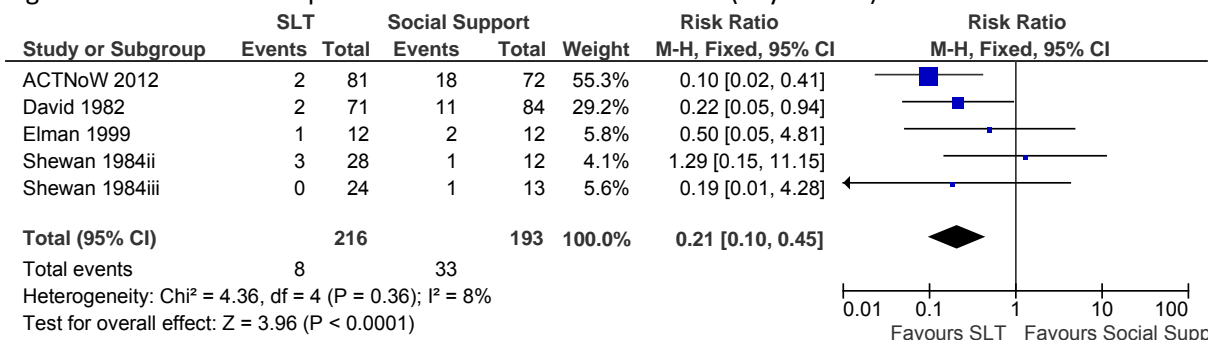


Figure 402: Non-compliance with allocated intervention (any reason)



J.24 In people after stroke, does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome mortality, dependency, requirement for institutional care and length of stay)?

J.24.1 Organised stroke unit care vs general medical ward

Figure 403: Death by the end of scheduled follow up

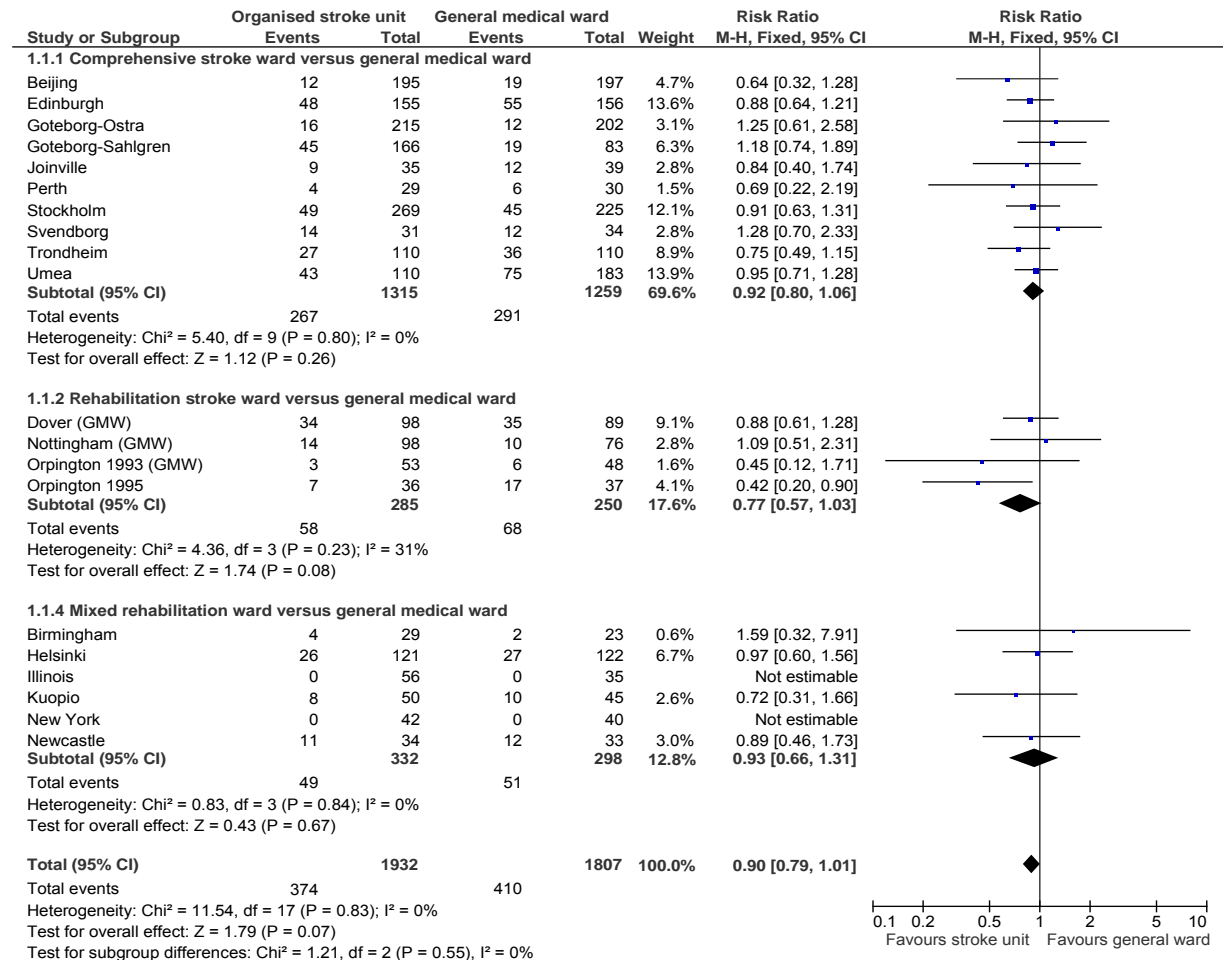


Figure 404: Death or institutional care by the end of scheduled follow up

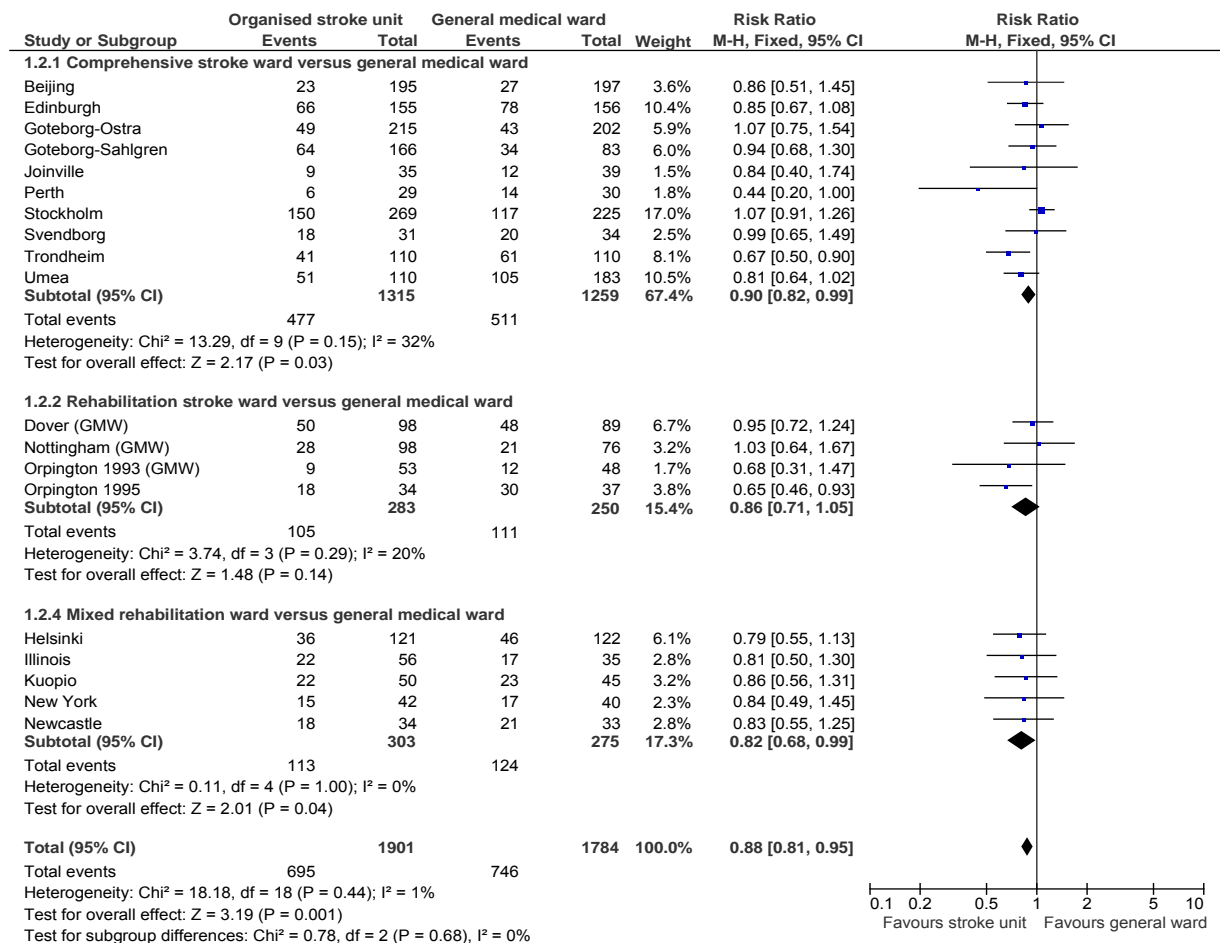


Figure 405: Death or dependency by the end of scheduled follow up

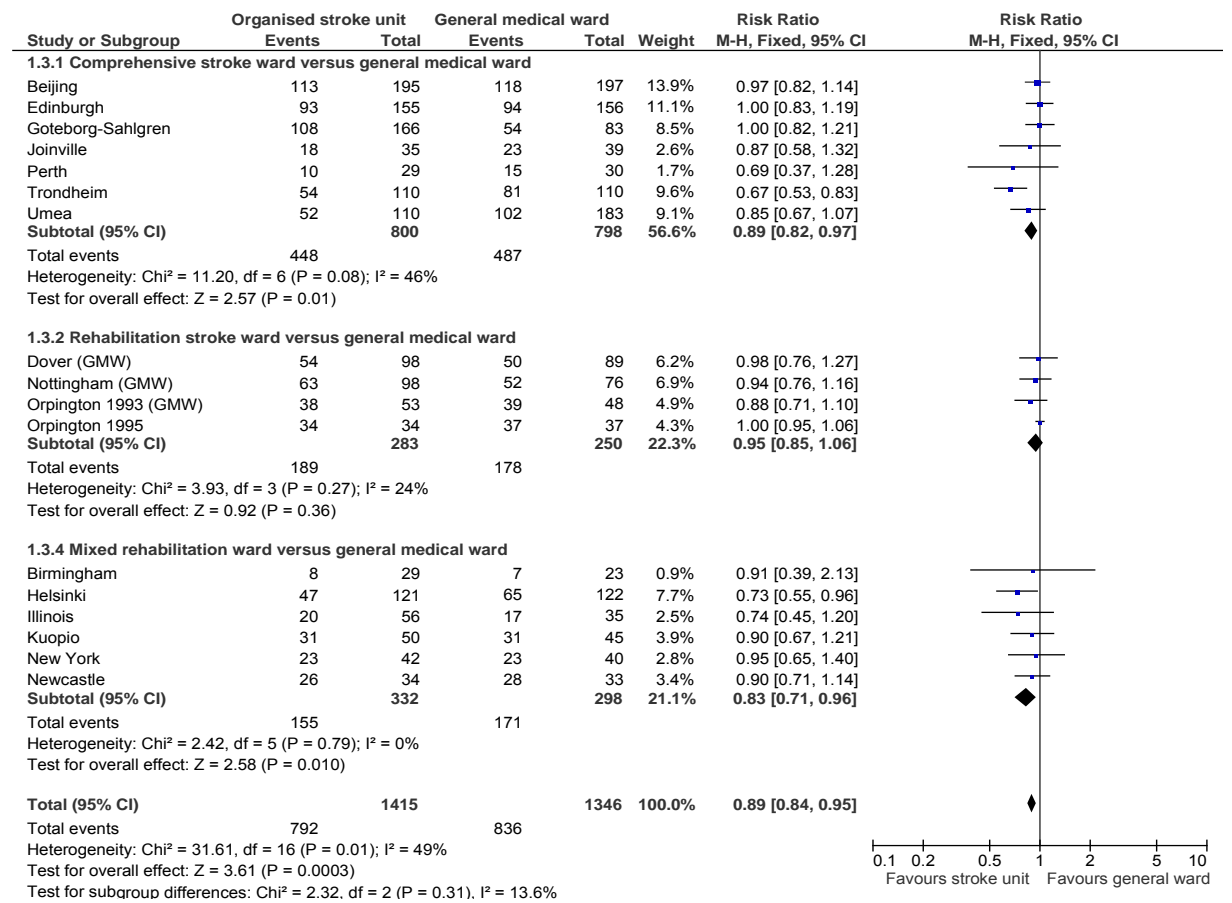


Figure 406: Length of stay (days) in a hospital or institution

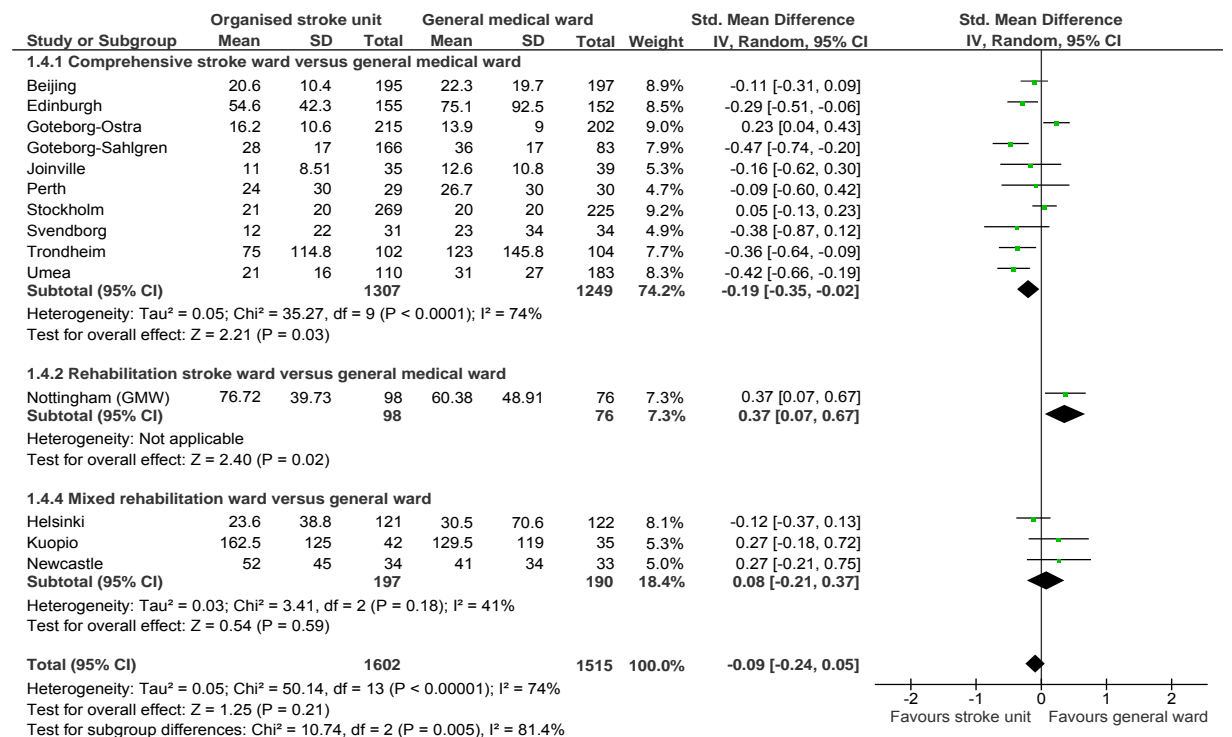


Figure 407: Death at five-year follow up

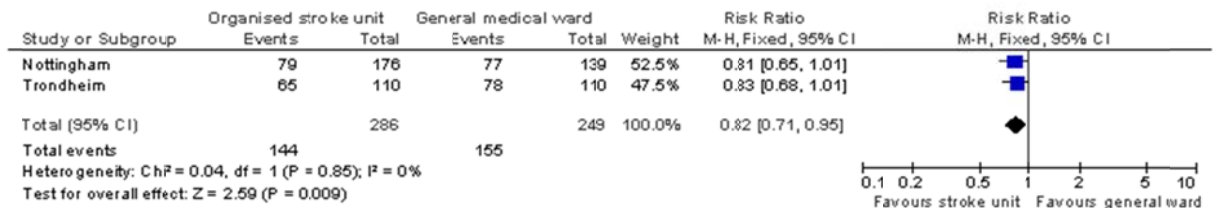


Figure 408: Death or institutional care at five-year follow up

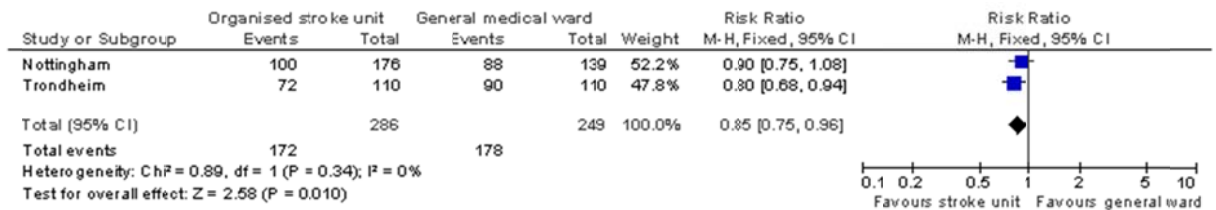


Figure 409: Death or dependency at five-year follow up

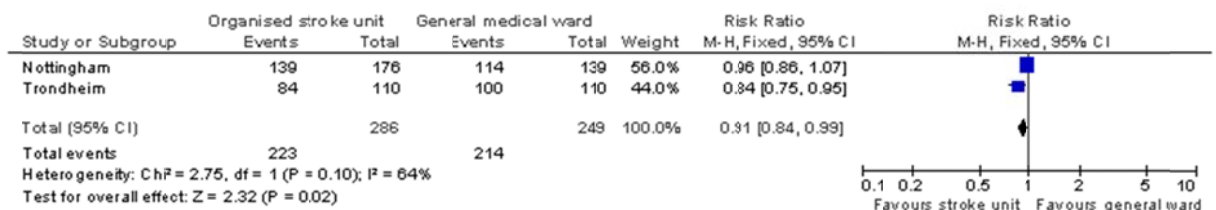


Figure 410: Death at 10-year follow up

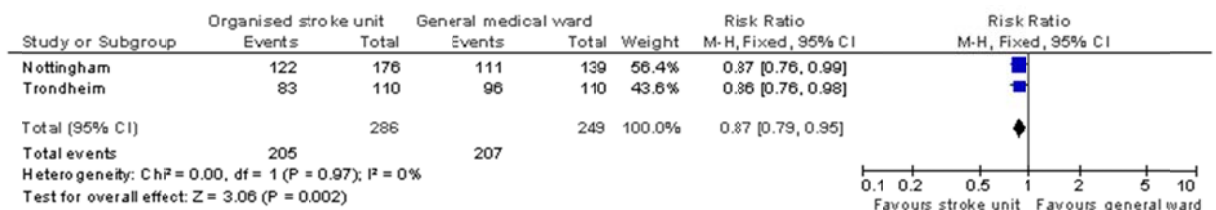


Figure 411: Death or institutional care at 10-year follow up

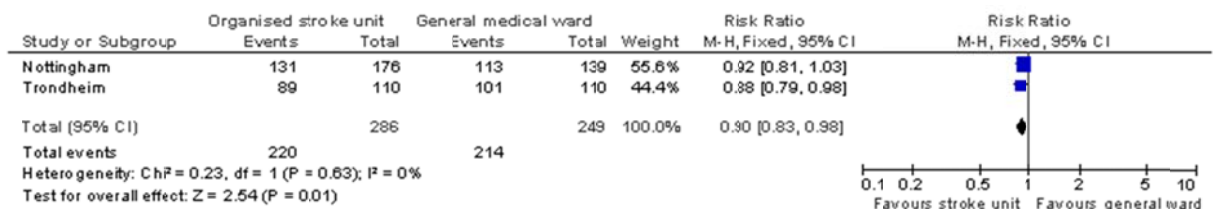
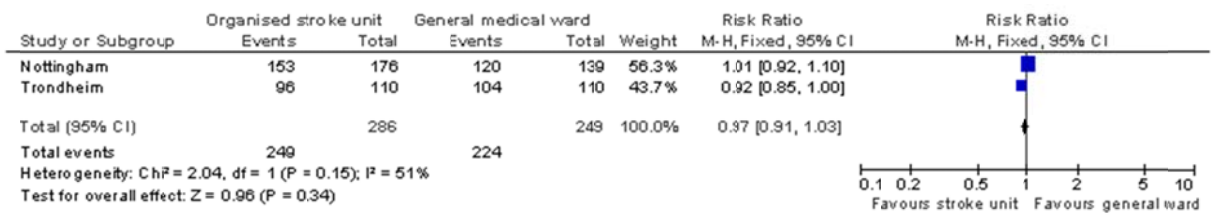


Figure 412: Death or dependency at 10-year follow up



Appendix K: Cost Effectiveness Model

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K.1 Introduction

The GDG identified the comparison of more intensive programmes of rehabilitation for people with stroke with less intensive programmes as a high priority area for economic analysis.

The review question linked to this high priority area was: *“In people after stroke what is the clinical and cost-effectiveness of intensive rehabilitation versus standard rehabilitation?”* The literature review is described in the full guideline. No cost-effectiveness analysis was found which addressed this question.

More intensive rehabilitation may be more costly to deliver than less intensive rehabilitation because it may require additional staff time. However, additional costs may be offset by an improvement in outcomes for the patient (such as independency in activities of daily living), leading to increased QALYs and potentially a reduction in future healthcare and social care costs.

There is no definition of what ‘intense’ and ‘standard’ rehabilitation is in any current UK standard. There is an existing NICE stroke quality standard for on-going rehabilitation²³, which specifies that: “patients with stroke are offered a minimum of 45 minutes of each active therapy that is required, for a minimum of 5 days a week, at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy and are able to tolerate it”. The GDG considered however that actual delivery of rehabilitation is very variable across the country and that often this level of rehabilitation is not achieved. As far as they are aware there is not yet data about what the actual level of provision of rehabilitation is currently across the UK NHS.

No economic analyses were identified in the published literature that evaluated the cost effectiveness of different levels of intensity of rehabilitation. The review of the clinical literature (described in the full guideline) identified limited evidence although what was found generally suggested that more intensive rehabilitation had more favourable outcomes. However, to calculate QALYs a particular measure of quality of life is required known as utility; commonly assessed using the EuroQol 5 dimension (EQ-5D) instrument. Only the Ryan study²⁸ reported utility data and the GDG agreed that an economic analysis should be undertaken based on this study.

It was noted, that over time the expectations have changed and the amount of therapy delivered is now much greater than it was, say, 10 years ago. Thus older studies (like the Ryan study) may describe ‘high’ levels of input which are actually lower than described in the stroke strategy and quality standard^{11,23}.

It was also noted that rehabilitation is a complex intervention, that is, the outcome does not vary linearly with inputs. One possibility is that there is a critical threshold for improvement. For example, if one leg is weak the patient will be unable to walk. The strength may increase linearly for 6 weeks, but only in week 7 will the patient walk. If a functional outcome is used, the patient will appear to plateau for 6 weeks and then may show a significant change in functional status.

The following general principles were adhered to in developing the cost-effectiveness analysis:

- The GDG was consulted during the construction and interpretation of the model.
- Model inputs were based on the systematic review of the clinical literature supplemented with other published data sources where possible.
- When published data was not available expert opinion was used to populate the model.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The model was peer-reviewed by another health economist at the NCGC.

K.2 Methods

K.2.1 Model overview

A cost-utility analysis was undertaken to evaluate the cost-effectiveness of more intensive versus less intensive stroke rehabilitation. Lifetime quality-adjusted life years (QALYs) and costs were estimated from a current UK NHS and personal social services perspective. As is standard practice in economic evaluation, costs and QALYs were discounted to reflect time preference; a rate of 3.5% per annum was used in line with NICE methodological guidance²². The cost effectiveness outcome of the model was cost per QALY gained.

The analysis was based on data from the UK randomised clinical trial (N=89; 75% drop out) reported by Ryan and colleagues, 2006²⁸. This study compared two different intensities of rehabilitation in the community setting: less intensive rehabilitation was three or less face-to-face contacts per week, for 12 weeks maximum; more intensive rehabilitation was six or more face-to-face contacts per week, for 12 weeks maximum. Outcomes were assessed at 12-weeks.

K.2.1.1 Population

The population for the cost-effectiveness analysis was adults and young people 16 or older who have had a stroke and required rehabilitation.

K.2.1.2 Comparators

The comparators in the model were:

- Less intensive multidisciplinary rehabilitation
- More intensive multidisciplinary rehabilitation

Following Ryan et al (2006)²⁸, the intervention was assumed to be delivered at home. Less intensive rehabilitation was three or less face-to-face contacts per week, for 12 weeks maximum. More intensive rehabilitation in the study was six or more face-to-face contacts per week, for 12 weeks maximum.

K.2.2 Approach to modelling

K.2.2.1 Model structure

A life table approach was taken to the analysis. Life tables for England and Wales were adjusted for the increased mortality in people who have had a stroke. This estimated the number of people alive after each 3 month period (each cycle) and this was used to estimate life years for people in the model. It was assumed that mortality is not impacted by the type of rehabilitation received and so life expectancy did not vary by comparator.

A quality of life (utility) value was attributed to people who were alive in the model that depended on the type of rehabilitation received ('more intensive' or 'less intensive'). This resulted in differences in QALYs between patients.

Differences in total costs between the groups were due to differences in the cost of delivering rehabilitation – this cost was incurred in the first 3 month cycle. It was assumed in the base-case analysis that in the post-rehabilitation period costs did not vary between the more intensive and the less intensive rehabilitation groups as data was not identified on which to base a difference.

K.2.2.2 Uncertainty

The model was built probabilistically to take account of the uncertainty around input parameter point estimates. Probability distributions were defined for model input parameters. When the model was run, a value for each input was randomly selected from its respective probability distribution simultaneously; mean costs and mean QALYs were calculated using these values. The model was run repeatedly – 1000 times – and results were summarised. Probability distributions in the analysis were parameterised using error estimates from data sources.

In addition, various sensitivity analyses were undertaken to test the robustness of model assumptions and data sources. In these, one or more inputs were changed and the analysis rerun to evaluate the impact on results.

Threshold sensitivity analyses were also performed to explore different cost and QALY differences.

K.2.3 Model inputs

K.2.3.1 Summary table of model inputs

Model inputs were based on clinical evidence identified in the systematic review undertaken for the guideline, supplemented by additional data sources as required. Model inputs were validated with clinical members of the GDG. A summary of the model inputs used in the base-case (primary) analysis is provided in Table 30 below. More details about sources, calculations and rationale can be found in the sections following this summary table.

Table 30: Summary of base-case model inputs

Input	Data	Source	Probability distribution
Comparators	<ul style="list-style-type: none"> • Less intensive rehabilitation • More intensive rehabilitation 		
Population	People who have had a stroke and need rehabilitation		
Perspective	UK NHS & PSS	NICE reference case ²²	
Time horizon	Lifetime		
Discount rate	Costs: 3.5% Outcomes: 3.5%	NICE reference case ²²	n/a
Cohort settings			
Age on entry to model	77 years	Ryan et al. 2006 ²⁸	Fixed
% female	61%	Ryan et al. 2006 ²⁸	Fixed
Mortality			
Mortality rate	Age dependent	England and Wales 2007-09 life tables ²⁴	Fixed
Mortality rate adjustment for stroke (SMR)	Female: 2.85 (CI: 2.66, 3.05) Male: 2.58 (CI: 2.43, 2.75)	Bronnum-Hansen et al. 2001 ⁸	Lognormal
Quality of life (utility)			
Before rehabilitation	0.54	Ryan et al. 2006 ²⁸	Fixed
Change after less intensive rehabilitation	0 (SE 0.04)	Ryan et al. 2006 ²⁸	Normal
Difference in change with more versus less	0.14 (SE 0.05)	Ryan et al. 2006 ²⁸	Normal

Input	Data	Source	Probability distribution
intensive rehabilitation			
Long term utility assumption	<ul style="list-style-type: none"> Scenario 1: difference is maintained over lifetime Scenario 2: difference disappears over time (3 months, 1 year or 5 years) 	Assumptions	n/a
Costs			
Rehabilitation costs	Less intensive: £634 More intensive: £865	Derived from resource use and unit costs below	n/a
Total number of rehabilitation sessions	Less: 17.9 (SE 1.19) Difference, more – less: 6.5 (SE 1.76)	Ryan et al. 2006 ²⁸	Gamma Normal
Length of rehabilitation session	45 minutes	Assumption based on trial range (30-60minutes) (Personal communication AW Ryan, email January 2011)	Fixed
Personnel delivering rehabilitation	Professional: 75% sessions Assistant: 25% sessions	Assumption	Fixed
Cost per hour home visit: rehabilitation professional(a)	£54	PSSRU 2010: Community; hour cost of home visiting ¹⁰ ; band 6(b); including qualifications	Fixed
Cost per hour home visit: rehabilitation assistant	£27	PSSRU 2010: Clinical support worker nursing (community); per hour spent on home visits ¹⁰ ; band 3(b); including qualifications	Fixed
Post-rehabilitation costs	No difference	Assumption	Fixed

CI = 95% confidence interval; n/a = not applicable; PSSRU = Personal Social Services Research Unit; SMR = standardised mortality ratio; SE = standard error

(a) Physiotherapist, occupational therapist and speech and language therapist

(b) Costs were calculated using PSSRU data and approach but with the salary band stated

K.2.3.2 Initial cohort settings

As the model was developed using outcomes from the Ryan study, initial cohort settings were based on the mean baseline characteristics from this study (N=89)²⁸. The population therefore had an age of 77 years on entry to the model and 61% were female.

K.2.3.3 Mortality

Mortality was incorporated into the model using life-tables for England and Wales adjusted to reflect the increased mortality rates in people who have had a stroke. Standardized mortality ratios (SMR) for all-cause mortality after stroke compared with age/sex adjusted rates for the general population reported by Bronnum-Hansen et al. 2001⁸ were used. These were from a large Danish study of people who had a stroke 1982-1991 (n=4162) with up to 15 years follow-up. For females this was 2.85 (CI: 2.66, 3.05) over the course of the study and for males 2.58 (CI: 2.43, 2.75).

It was assumed that mortality does not differ with more or less intensive rehabilitation.

K.2.3.4 Quality of life (utility)

Utility values were based on the Ryan et al (2006)²⁸ study that reported EQ-5D scores for people undergoing more intensive rehabilitation (n=35) and less intensive rehabilitation (n=32) using the UK tariff.

Quality of life before rehabilitation for both groups in the model was based on an average of the median values observed in the Ryan study at baseline (0.54). This input was not incorporated into the probabilistic analysis.

Quality of life following rehabilitation was based on the 12 weeks follow-up in the Ryan study. Change from baseline in the less intensive arm was 0 (SE 0.04). So after less intensive rehabilitation in the model quality of life was still 0.54. The difference at 12 weeks with more intensive rehabilitation compared with less intensive was 0.14 (SE 0.05). So after more intensive rehabilitation in the model quality of life was increased to 0.68. Inputs were incorporated into the probabilistic analysis using normal distributions.

As longer term follow-up was not available in the Ryan study but we wished to consider the impact over the whole lifetime, in the model we applied a series of different assumptions regarding what happens to the difference in utility between groups observed at 12 weeks over time:

- Scenario 1: the difference remains the same over the remaining lifetime of the patient (Figure 413)
- Scenario 2: the difference disappears over time (Figure 414)
 - o it was assumed the difference disappears over 3 months, 1 year, or 5 years (analysis 2a, 2b and 2c respectively).

Figure 413: Quality of life (utility) over time – scenario 1, difference maintained

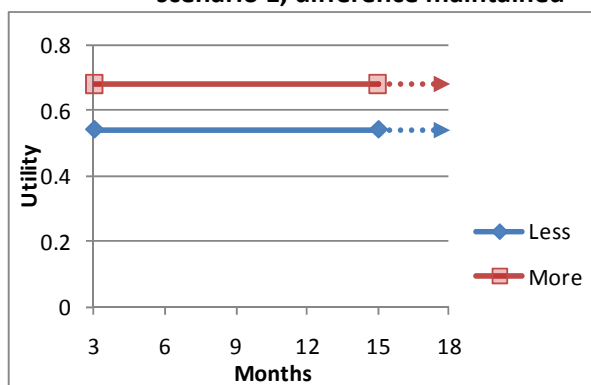
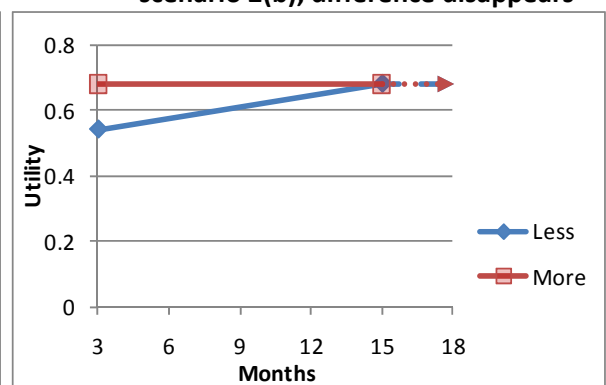


Figure 414: Quality of life (utility) over time – scenario 2(b), difference disappears



The GDG noted that these were the two extremes of what could happen to differences in quality of life over time and that in reality it may be somewhere between the two with the difference diminishing over time but not completely disappearing. However, for analysis purposes these were considered the most useful scenarios to model as they consider the best and worst case scenarios.

The GDG also noted that plausibly both groups' quality of life may improve over time (if functional status independently improves with time) or worsen over time (quality of life decreases with age). However, in the model it is the difference between the groups that drives the results rather than the absolute values and so it was not considered necessary to explicitly model these scenario as they would not impact conclusions.

K.2.3.5 Resource use and cost

Rehabilitation

The cost of the less and more intensive rehabilitation programmes was calculated based on the resource use from the Ryan study supplemented by assumptions where required and relevant UK unit costs^{10,28}. The average total cost per person with less intensive rehabilitation was £634 and with more intensive rehabilitation was £865.

The number of rehabilitation sessions reported was 17.9 (SE 1.19) with less intensive rehabilitation sessions with an additional 6.5 (SE 1.76) with more intensive rehabilitation. The number of rehabilitation sessions with less intensive rehabilitation was incorporated in the probabilistic analysis using a gamma distribution as this is bounded by 0 and so reflects the plausible range. The difference in session with more versus less intensive rehabilitation was incorporated using a normal distribution. Information was provided by AW Ryan (email January 2011) regarding the duration of rehabilitation sessions in the study (between 30 and 60 minutes) and the professionals who delivered the work (physiotherapist, occupational therapist, speech and language therapist, and rehabilitation assistant). Data was not available about the average length of sessions from the study. It was therefore assumed that typically the length of a session would be 45 minutes (midpoint of the range) and that the length of sessions did not vary between groups. Information was not available about the proportions of sessions carried out by different professionals, and so it was assumed that 75% were carried out by rehabilitation professionals and 25% by rehabilitation assistants. These inputs were not incorporated into the probabilistic analysis. Unit costs per hour home visit for a band 6 rehabilitation professional and a band 3 rehabilitation assistant were £54 and £27 respectively – these were calculated using the PSSRU 2010 approach and data adjusted for the salary band indicated as most appropriate by the GDG¹⁰. Costs include qualifications, overheads and travel expenditure. The cost per hour of home visiting takes account of the proportion of time spent on travel and non-contact time. These inputs were not incorporated into the probabilistic analysis.

Post-rehabilitation

In the base-case analysis it was assumed that there was no difference in costs post-rehabilitation as data was not identified on which to base a difference.

K.2.4 Computations

The model was constructed in Microsoft Excel and was evaluated by cohort simulation.

People started in cycle 0 in the alive health state. Patients moved to the dead health state each 3 month cycle as defined by the mortality rate. Life years for the cohort were computed each cycle. To calculate QALYs for each cycle, $Q(t)$, the time spent (i.e. 0.25 years) in the alive state of the model was weighted by a utility value that was dependent on the cycle, the long-term utility assumption being employed and the treatment group. A half-cycle correction was applied. QALYs were then discounted to reflect time preference (discount rate = r). QALYs during the first cycle were not discounted. The total discounted QALYs was the sum of the discounted QALYs per cycle. The total discounted QALYs were the sum of the discounted QALYs per cycle.

Costs per cycle, $C(t)$, were calculated in the same way as QALYs. Rehabilitation costs were applied in cycle 1 only. If a difference in post-rehabilitation costs was being included, this was applied in cycle two and beyond. Costs were discounted to reflect time preference (discount rate = r) in the same way as QALYs.

Discount formula for costs and QALYs:

$$\text{Discounted total} = \frac{\text{Total}}{(1+r)^n}$$

Where:
 r = discount rate per annum
 n = time (years)
 Total = total costs or QALYs

The widely used cost-effectiveness metric is the incremental cost-effectiveness ratio (ICER). This is calculated by dividing the difference in costs associated with two alternatives by the difference in QALYs (formula below). The decision rule then applied is that if the ICER falls below a given cost per QALY threshold the result is considered to be cost effective. If both costs are lower and QALYs are higher the option is said to dominate and an ICER is not calculated.

$$\text{ICER} = \frac{\text{Costs(B)} - \text{Costs(A)}}{\text{QALYs(B)} - \text{QALYs(A)}}$$

Where: Costs/QALYs(X) = total discounted costs/QALYs for option X

- Cost-effective if:
 ICER < Threshold

It is also possible, for a particular cost-effectiveness threshold, to re-express cost-effectiveness results in term of net monetary benefit (NMB). This is calculated by multiplying the total QALYs for a comparator by the threshold cost per QALY value (for example, £20,000) and then subtracting the total costs (formula below). The decision rule then applied is that the comparator with the highest NMB is the most cost-effective option at the specified threshold. That is the option that provides the highest number of QALYs at an acceptable cost. For ease of computation NMB was used to identify the optimal strategy in the probabilistic analysis simulations.

$$\text{Net monetary benefit(X)} = (\text{QALYs(X)} \times D) - \text{Costs(X)}$$

Where: Costs/QALYs(X) = total discounted costs/QALYs for option X; D = threshold

- Cost-effective if:
 highest net monetary benefit

The probabilistic analysis was run for 1000 simulations. Each simulation, total discounted costs and total discounted QALYs were calculated for each diagnosis option. Net benefit was also calculated and the most cost-effective option identified (that is, the one with the highest net benefit), at a threshold of £20,000 per QALY gained. The results of the probabilistic analysis were summarised in terms of mean costs, mean QALYs and mean net benefit for each treatment option, where each was the average of the 1000 simulated estimates. The option with the highest mean net benefit (averaged across the 1000 simulations) was the most cost-effective at the specified threshold. The percentage of simulations where each strategy was the most cost-effective gives an indication of the strength of evidence in favour of that strategy being cost-effective.

K.2.5 Sensitivity analyses

Sensitivity analyses were performed using the probabilistic analysis unless otherwise specified. Below is a description of the sensitivity analyses that were undertaken.

Rehabilitation costs

The length of the rehabilitation sessions for both less and more intensive rehabilitation in the base-case was based on the midpoint of the range used in the study (45 minutes). In sensitivity analysis we varied this input in both groups to the minimum length (30 minutes) and the maximum length (60 minutes) to explore how sensitive results were to this assumption.

Impact of age

In the base-case analysis the cohort had an initial age of 77 years in line with the mean age in the Ryan et al study²⁸. We explored the impact of age in sensitivity analysis running the model for age 40, 50, 60, 70, 80 and 90 year olds. All other inputs were kept constant.

Threshold analyses

The GDG noted that the intensity level in the Ryan study more intensive rehabilitation arm was likely to be lower than that now specified by the stroke rehabilitation quality standard²³. We therefore undertook threshold analyses to provide information help inform GDG decision making.

Costs

An analysis was undertaken to determine the cost difference where intensive rehabilitation was no longer cost-effective (given a £20,000 per QALY gained cost-effectiveness threshold) using the quality of life inputs from the Ryan study as in the basecase analysis.

QALYs

We also undertook a threshold analysis where we varied the difference in the number of rehabilitation sessions between the more and less intensive groups and then calculated what QALY difference would be required for it to be considered cost effective.

The GDG estimated that in current UK practice a level of input in line with the current NICE quality standard²³ would be 45 minutes of each relevant therapy at least 5 days a week as long as they are continuing to benefit from it. Thus over 6 weeks an individual might receive 60 - 90 sessions of input. The GDG recognised that the recent Stroke Sentinel audit highlighted that about a third of patients received less than this while in hospital¹⁹. No data is available for community-based rehabilitation services. The GDG estimated that a typical level of input would be three physiotherapy sessions per week, one occupational therapy session per week, and one speech and language therapy session per week (that is 30 sessions). This would be a difference of 60 sessions total between ideal and typical input. The difference in number of sessions was therefore varied between 6.5 (from the Ryan study²⁸) and 60 (based on the GDG estimate).

We then also calculated the number of months different quality of life (utility) gains would need to be maintained for in order to achieve these QALY gains. The quality of life (utility) gain explored in this analysis was 0.02 to 0.24 (Ryan study reported a 0.14 gain²⁸).

Discount rate for health outcomes

A sensitivity analysis was undertaken to look at the effect of changing the discount rate for outcomes from 3.5% to 1.5%. Costs remained discounted at 3.5%.

Impact of making resource use and costs probabilistic

There is methodological debate as to whether it is necessary and/or appropriate to incorporate inputs based on standard national cost sources or resource use assumptions into a probabilistic analysis. In the base-case analysis we used fixed values for such inputs but we undertook a sensitivity analysis to assess the impact of this decision. Probability distributions were parameterised by assuming that point estimate used represented the mean and that the standard error was 20% of the mean.

Table 31: Sensitivity analysis – probability distributions

Input	Probability distribution applied in sensitivity analysis
Length of rehabilitation session	Gamma
Personnel delivering rehabilitation	Beta
Cost per hour home visit: rehabilitation professional	Gamma
Cost per hour home visit: rehabilitation assistant	Gamma

K.2.6 Interpreting results

NICE’s report ‘Social value judgements: principles for the development of NICE guidance’ sets out the principles that GDGs should consider when judging whether an intervention offers good value for money^{21,22}.

In general, an intervention was considered to be cost effective if either of the following criteria applied:

- a) The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- b) The intervention cost less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

As the analysis is based on a single RCT²⁸ with a selected population and specified intervention it had limited applicability to the overall stroke population and current UK practice. The GDG felt that the Ryan study compares two levels of intensity which are likely to be below that of the current quality standard (even the high intensity arm only received 17 therapy sessions in 60 days, far below the current standard). It was felt that the analysis could help evaluate the likelihood that more intensive rehabilitation was cost-effective and provide useful information to feed into decision making; however, it was also noted that it would not be able to provide definitive conclusions given these limitations.

K.2.7 Validation

The model was developed in consultation with the GDG; model structure, inputs and results were presented to and discussed with the GDG for clinical validation and interpretation.

The model was systematically checked by the health economist undertaking the analysis; this included inputting null and extreme values and checking that results were plausible given inputs. The model was peer reviewed by a second experienced health economist from the NCGC; this included systematic checking of many of the model calculations.

K.3 Results

K.3.1 Base case results

The analysis found that more intensive rehabilitation was cost effective compared to less intensive rehabilitation, based on levels of intervention and outcomes from the Ryan et al. 2006 study²⁸. There was an additional cost associated with more intensive rehabilitation as more rehabilitation sessions were provided; however this was offset by the additional improvement in quality of life. This conclusion was maintained for all long-term utility scenarios. There was low within analysis uncertainty about this conclusion.

Table 32: Base case results – more intensive versus less intensive rehabilitation (probabilistic analysis)

Analysis	Mean cost difference(a) (more - less)	Mean QALY difference (more - less)	Incremental cost effectiveness ratio (ICER)	% simulations 'more intensive' cost-effective (£20K/QALY)
Scenario 1 - difference in utility maintained over time				
Maintained over lifetime	£226	0.70	£324	99%
Scenario 2 - utility difference disappears over time				
Disappears over 3 months	£228	0.03	£6,722	95%
Disappears over 1 year	£228	0.08	£2,751	99%
Disappears over 5 years	£226	0.29	£776	100%

(a) Minor difference are due to results being from different runs of the probabilistic analysis

People entering the model were aged 77 years and the undiscounted life expectancy generated by the model was 5.8 years. To validate the model this was compared against a paper suggested by a GDG member that reported expected life expectancy for 1-week survivors after stroke according to age at stroke onset from another, more recent, Danish cohort (n=392) who had a stroke between 1998-2001⁷. This reported an estimated life expectancy for women of 8.8 years for those aged 70 years at time of stroke and 4.9 years for those aged 80 years. The corresponding figures for men were 7.8 and 4.3 years. This was considered consistent with the life expectancy estimated by the model.

K.3.2 Sensitivity analysis

Rehabilitation costs

The length of the rehabilitation sessions in the base-case was based on the midpoint of the range used in the study (45 minutes). In sensitivity analysis we varied this input to the minimum length (30 minutes) and the maximum length (60 minutes) to explore how sensitive results were to this assumption. This did not impact conclusions.

Table 33: Sensitivity analysis results – varying cost of rehabilitation based on change in session length: (probabilistic analysis)

Analysis	Mean cost difference (more - less)	Mean QALY difference (more - less)	Incremental cost effectiveness ratio (ICER)	% simulations 'more intensive' cost-effective (£20K/QALY)
Session length = 30 mins				

Analysis	Mean cost difference (more - less)	Mean QALY difference (more - less)	Incremental cost effectiveness ratio (ICER)	% simulations 'more intensive' cost-effective (£20K/QALY)
Scenario 1 - difference in utility maintained over time				
Maintained over lifetime	£151	0.70	£216	100%
Scenario 2 - utility difference disappears over time				
Disappears over 3 months	£153	0.03	£4,450	98%
Disappears over 1 year	£151	0.08	£1,840	100%
Disappears over 5 years	£148	0.29	£518	100%
Session length = 60 mins				
Scenario 1 - difference in utility maintained over time				
Maintained over lifetime	£306	0.67	£455	99%
Scenario 2 - utility difference disappears over time				
Disappears over 3 months	£302	0.03	£8,964	92%
Disappears over 1 year	£297	0.08	£3,586	98%
Disappears over 5 years	£304	0.29	£1,051	99%

Impact of age

In the base-case analysis the cohort had an initial age of 77 years in line with the mean age in the Ryan et al study²⁸. We explored the impact of age in sensitivity analysis running the model for age 40, 50, 60, 70, 80 and 90 year olds. All other inputs were kept constant.

Table 34: Sensitivity analysis results – varying cohort initial age (scenario 1 - probabilistic analysis)

Analysis	Mean cost difference (more - less)	Mean QALY difference (more - less)	Incremental cost effectiveness ratio (ICER)	% simulations 'more intensive' cost-effective (£20K/QALY)
Cohort initial age = 50 years	£231	2.11	£109	100%
Cohort initial age = 60 years	£232	1.58	£147	100%
Cohort initial age = 70 years	£231	1.05	£219	100%
Cohort initial age = 80 years	£227	0.56	£409	100%
Cohort initial age = 90 years	£219	0.24	£907	100%

Threshold analysis: costs

An analysis was undertaken to determine the cost difference threshold where intensive rehabilitation was no longer cost-effective (using a £20,000 per QALY gained cost-effectiveness threshold). Under the most conservative long-term utility assumption (where the utility difference observed at the end of rehabilitation had disappeared over 3 months), more intensive rehabilitation would no longer be cost effective if the difference in rehabilitation cost was more than £685 (equivalent to a difference of about 17 sessions, of 45 minutes, with a rehabilitation professional). Under the most favourable utility assumption (where the difference observed at the end of rehabilitation was maintained indefinitely), more intensive rehabilitation remained cost effective until the difference in rehabilitation costs exceeded £13,433 (equivalent to a difference of over 300 sessions with a rehabilitation professional).

Table 35: Threshold analysis results: cost threshold where more intensive rehabilitation is no longer cost effective at £20,000 per QALY gained threshold

Analysis	QALY difference(a)	Cost difference threshold(b)
Scenario 1 - difference in utility maintained over time		
Maintained over lifetime	0.67	£13,433
Scenario 2 - utility difference disappears over time		
Disappears over 3 months	0.03	£685
Disappears over 1 year	0.08	£1,640
Disappears over 5 years	0.29	£5,720

(a) From probabilistic base-case analysis

(b) Calculated using a cost-effectiveness threshold of £20,000 per QALY gained and rearranging the incremental cost effectiveness ratio equation >> Cost difference threshold = £20,000 x QALY difference

Threshold analysis: QALYs

We also undertook a threshold analysis where we varied the difference in the number of rehabilitation sessions between the groups (difference of 6.5 to 60) and then calculated what QALY difference would be required for it to be considered cost-effective. Table 6 shows the resulting cost differences and the lifetime QALY gain that would be required in order for the higher level of intervention to be cost-effective (using on a £20,000 per QALY gained threshold). The lifetime QALY gain required for more intensive rehabilitation to be cost effective ranged from 0.01-0.11 when the difference in number of rehabilitation sessions was varied between 6.5 and 60.

Table 36: Sensitivity analysis results – rehabilitation cost and QALY gain threshold

Difference in number of sessions with more versus less intensive rehabilitation >	6.5(a)	10	20	30	40	50	60
Cost difference (more - less)(b)	£230	£354	£709	£1,063	£1,418	£1,772	£2,126
Lifetime QALY difference required for more intensive rehabilitation to be cost-effective (more - less)(c)	0.01	0.02	0.04	0.05	0.07	0.09	0.11

(a) Base-case analysis inputs

(b) Calculated using base-case assumptions of 45 minute sessions, 75% delivered by rehabilitation professional and 25% by rehabilitation assistant with associated cost per hour of home visits of £39 and £24.

(c) Calculated using a cost-effectiveness threshold of £20,000 per QALY gained and rearranging the incremental cost effectiveness ratio equation >> QALY gain required = Cost ÷ £20,000

We then also calculated the number of months different quality of life (utility) gains would need to be maintained for in order to achieve these QALY gains – see Table 7. With a difference of 60 rehabilitation sessions with more intensive compared to less intensive rehabilitation, it was found that a utility gain of 0.14 would need to be maintained for 9 months in order for more intensive rehabilitation to be cost effective. When utility gain was varied between 0.02 and 0.24, this varied from 5 months to 64 months.

Table 37: Sensitivity analysis results – number of months that quality of life difference must be maintained for intensive rehabilitation to be cost effective under different resource use and quality of life gain scenarios

Difference in number of sessions with more versus less intensive rehabilitation >		6.5(a)	10	20	30	40	50	60
Increase in quality of life (utility) with more	0.02	7	11	21	32	43	53	64
	0.04	3	5	11	16	21	27	32

versus less intensive rehabilitation >	0.06	2	4	7	11	14	18	21
	0.08	2	3	5	8	11	13	16
	0.1	1	2	4	6	9	11	13
	0.12	1	2	4	5	7	9	11
	0.14(a)	1	2	3	5	6	8	9
	0.16	1	1	3	4	5	7	8
	0.18	1	1	2	4	5	6	7
	0.2	1	1	2	3	4	5	6
	0.22	1	1	2	3	4	5	6
	0.24	1	1	2	3	4	4	5

(a) Calculated using QALY gain required for number of sessions difference (table 1) and the quality of life (utility) increase in table >> Number of months utility difference must be maintained = QALY gain required ÷ increase in utility with more versus less intensive rehabilitation x 12

(b) Base-case analysis inputs

Discount rate for health outcomes

A sensitivity analysis was undertaken to look at the effect of changing the discount rate for outcomes from 3.5% to 1.5%. Costs remained discounted at 3.5%. This did not impact conclusions.

Table 38: Sensitivity analysis results - discount rate for health outcomes 1.5% (probabilistic analysis)

Analysis	Mean cost difference (more - less)	Mean QALY difference (more - less)	Incremental cost effectiveness ratio (ICER)	% simulations >12 cost-effective (£20K/QALY)
Scenario 1 - difference in utility maintained over time				
Maintained over lifetime	£229	0.74	£310	100%
Scenario 2 - utility difference disappears over time				
Disappears over 1 year	£225	0.03	£6,523	97%
Disappears over 5 years	£226	0.08	£2,684	99%
Disappears over 10 years	£229	0.29	£784	99%

Making costs probabilistic

This sensitivity analysis essentially did not change any results.

K.4 Discussion

K.4.1 Summary of results

The analysis found that more intensive rehabilitation was cost effective compared to less intensive rehabilitation, based on levels of intervention and outcomes from the Ryan et al. 2006 study²⁸. There was an additional cost associated with more intensive rehabilitation as more rehabilitation sessions were provided; however this was offset by the additional improvement in quality of life. This conclusion was maintained for all long-term utility scenarios. There was low within analysis uncertainty about this conclusion. It was also robust to various one-way sensitivity analyses.

Due to concerns about the generalisability of the Ryan study to current UK practice, threshold analysis was used to explore under what scenarios more intensive rehabilitation would not be cost effective and these are described below.

Keeping the utility gain with more intensive rehabilitation constant we first looked at the cost threshold where more intensive rehabilitation was not cost effective. Under the most conservative long-term utility assumption (where the utility difference observed at the end of rehabilitation disappeared over 3 months), more intensive rehabilitation would no longer be cost effective if the difference in rehabilitation cost was more than £685 (equivalent to a difference of about 17 sessions, of 45 minutes, with a rehabilitation professional). Under the most favourable utility assumption (where the difference observed at the end of rehabilitation was maintained indefinitely), more intensive rehabilitation remained cost effective until the difference in rehabilitation costs exceeded £13,433 (equivalent to a difference of over 300 sessions with a rehabilitation professional).

Secondly, we systematically varied the difference in number of rehabilitation sessions (and thus cost) between more and less intensive rehabilitation and calculated the QALY difference that would be required for each difference to be considered cost-effective. We then calculated how long different utility gains would need to be maintained for in order to achieve these QALY gains. Assuming a difference of 60 sessions between more and less intensive rehabilitation: a utility difference of 0.14 would need to be maintained for 9 months for more intensive to be cost effective; a difference of 0.24 for 5 months; and a difference of 0.02 for 64 months (about 4 years).

K.4.2 Limitations & interpretation

Ryan study generalisability

The key limitations of this analysis are the limitations of the clinical effectiveness data for the comparison of more and less intensive rehabilitation. Only one study (Ryan 2006²⁸) reported utility data that could be used to calculate QALYs and the amount of rehabilitation received in this study compared with the current quality standard, and even current UK practice is very different. In Ryan more intensive rehabilitation was a total of 17 sessions on average per person and less intensive was 11. The GDG estimated that a level of intervention similar to that recommended by the current NICE quality standard²³ would be more like 90 rehabilitation sessions per patient (spread across specialities), and that typical levels of input in the UK would be around 30 sessions.

It was noted that rehabilitation is a complex intervention, that is, the outcome does not vary linearly with inputs. One possibility is that there is a critical threshold for improvement. For example, if one leg is weak the patient will be unable to walk. The strength may increase linearly for 6 weeks, but only in week 7 will the patient walk. If a functional outcome is used, the patient will appear to plateau for 6 weeks and then may show a significant change in functional status. This again makes it difficult to extrapolate from the Ryan study.

Stratification

The GDG noted that younger patients also often have the capacity to participate in more sessions of rehabilitation as this is linked to cardiovascular fitness, frailty and co-morbidity, all of which tend to be worse in older patients. They also often have a greater range of needs (education, work, parenting). Yet often younger patients do not get more rehabilitation. It was not possible to undertake subgroup analysis on this basis in the model as not clinical studies had examined this.

Quality of life assumptions

The Ryan study²⁸ reported EQ5D quality of life data at 3 months but did not have any longer term follow-up and so assumptions were made regarding what happens to the difference in quality of life over time between the groups. However both conservative and more favourable assumptions were explored in the model to test the impact on results.

The analysis does not include any impact on carer quality of life as there was no evidence available. It is plausible that greater functional ability for the person who has had a stroke, may also mean less burden on their carer and this may lead to an improvement in the carer's quality of life as well. If this were the case this would increase the QALY gain with more intensive rehabilitation, making it more cost effective.

Post-rehabilitation costs

In the base-case analysis we assumed no difference in post-rehabilitation costs however greater functional ability could plausibly result in lower dependency and potentially lower social care costs. This would further favour more intensive rehabilitation.

Rehabilitation setting

The Ryan study²⁸ was based on community rehabilitation and so costs in the model are also based on community rehabilitation. The GDG considered that the amount of rehabilitation should be the same whether delivered in the community or in hospital. In addition if rehabilitation was taking place in hospital the intensity of rehabilitation would most likely not change the length of stay but would just impact the amount of input from different professionals whilst in hospital. Therefore in either setting the cost impact would largely be about people's time rather than changes in hospital capacity, overheads or hotel costs and so this was not considered likely to greatly impact the results. It was noted that potentially more intensive rehabilitation during the initial hospitalisation may even reduce hospital stay as patients become more functionally able more quickly.

K.4.3 Comparisons with published studies

No published cost-effectiveness studies were identified that compared more versus less intensive rehabilitation after stroke.

K.4.4 Conclusion = evidence statement

More intensive rehabilitation was found to be cost effective compared to less intensive rehabilitation, based on a modelled analysis using levels of intervention and outcomes from the Ryan et al. 2006 study (24 versus 18 rehabilitation sessions; EQ5D difference 0.14 at 3 months) and a range of long-term utility assumptions. However, these conclusions are limited by concerns regarding applicability of the Ryan study²⁸ to current UK practice. Exploratory threshold analyses found:

- Under the most conservative long-term utility assumption (where the utility difference observed at the end of rehabilitation had disappeared over 3 months), more intensive rehabilitation would

no longer be cost effective if the difference in rehabilitation cost was more than £685 (equivalent to a difference of about 17 sessions, of 45 minutes, with a rehabilitation professional).

- Under the most favourable long-term utility assumption (where the difference observed at the end of rehabilitation was maintained indefinitely), more intensive rehabilitation remained cost effective until the difference in rehabilitation costs exceeded £13,433 (equivalent to a difference of over 300 sessions with a rehabilitation professional).
- Assuming a difference of 60 sessions between more and less intensive rehabilitation: a utility difference of 0.14 would need to be maintained for 9 months for more intensive to be cost effective; a difference of 0.24 for 5 months; and a difference of 0.02 for 64 months (about 4 years).

K.4.5 Implications for future research

This analysis provides evidence to suggest that more intensive rehabilitation may be cost effective. However, it is limited by the generalisability of the study it is based on²⁸ to current UK practice, in particular the low levels of intervention in both arms of the trial, and the lack of follow-up of the impact of different levels of rehabilitation on long-term quality of life for people with stroke. Further research in these areas and associated cost-effectiveness analysis should therefore be undertaken.

Appendix L: Research Recommendations

L.1 Upper Limb Functional Electrical Stimulation (FES)	717
L.2 Intensive rehabilitation after stroke	717
L.3 Psychological therapies	718
L.4 Shoulder pain	718

L.1 Upper Limb Functional Electrical Stimulation (FES)

Research recommendation

What is the clinical and cost effectiveness of ES as an adjunct to rehabilitation to improve hand and arm function in people after stroke, from early rehabilitation through to use in the community?

Why this is important

After stroke an estimated 30–70% of people have reduced or no use of one arm and hand. ES has long been thought to be a possible useful adjunct to rehabilitation to improve arm and hand function. ES is believed to enhance the training effect of active, task-specific and strengthening rehabilitation programmes. However, the evidence to date does not inform clinicians or people with stroke whether ES will be an effective addition to rehabilitation for them. A linked-series of studies are needed to:

1. identify the dose, practice parameters and rehabilitation programme content needed to effect change in hand and arm function with ES;
2. Characterise the clinical profiles of people who will benefit from ES in early, middle, and late stages of the stroke pathway. The primary outcome measure should be the person's assessment of improvement in function. Secondary outcomes should include measures of impairment, function, and quality of life and these should reflect people with low-, middle- and high-functioning upper limbs.

L.2 Intensive rehabilitation after stroke

Research recommendation

In people after stroke what is the clinical and cost effectiveness of intensive rehabilitation (6 hours per day) versus moderate rehabilitation (2 hours per day) on activity, participation and quality of life outcomes?

Why this is important

Rehabilitation aims to maximise activity and participation and minimise distress for people with stroke and their families and carers. The physical and mental capacity to participate in rehabilitation possessed by people with stroke varies widely. Some people who are unwell may not be able to participate at all, whereas others may be able to tolerate 6 hours of therapy a day. The potential long-term cost benefits of even small changes in function may be significant.

Evidence suggests that increasing rehabilitation intensity early after stroke results in improved outcomes but the evidence for this is not robust. Previous studies comparing different levels of intensity have used rehabilitation inputs that are lower than the current recommended levels in the NICE stroke Quality Standard.

Should it be shown that increasing the intensity of rehabilitation in people who are able to participate results in functional and cost benefits, stroke rehabilitation services and funding tariffs should be reviewed.

L.3 Psychological therapies

Research recommendation

Which neuropsychological interventions provide better outcomes for identified subgroups of people with stroke and their families at different stages of the stroke pathway?

Why this is important

There are many well-established studies showing that mood disorders (such as depression and anxiety) occur frequently after stroke and may occur at any point along the rehabilitation pathway, causing distress to people with stroke and their families and carers and adversely affecting outcomes.

Cognitive and communication impairments interact with mood, and often compound difficulties by compromising people's abilities to participate in standard evidence-based psychological therapies. The need for psychological input for people with stroke is well recognised (for example, by the 'National service framework for long-term neurological conditions'). However, the literature does not provide robust evidence about which psychological interventions will be most effective for different subgroups of people.

L.4 Shoulder pain

Research recommendation

Which people with a weak arm after stroke are at risk of developing shoulder pain? What management strategies are effective in the prevention or management of shoulder pain of different aetiologies?

Why this is important

Shoulder pain after stroke is a common problem, with some prevalence estimates as high as 84%. Onset has been reported to occur from 2 weeks to several months after stroke.

Most experts agree that prevention of shoulder pain after stroke is an important goal and should be prioritised as an aim of rehabilitation from the first day after a stroke. However, the means of preventing hemiplegic shoulder pain (HSP) is not universally agreed. This may be due, in part, to the large array of identified causes of HSP.

Because of this, there is little agreement on which treatment is best. Treatments include positioning, upper limb support (including slings and orthotics), strapping of the shoulder, range-of-motion exercises, ultrasound, oral non-steroidal anti-inflammatory medications, electrical stimulation for muscle contraction, electrical stimulation for pain relief (TENS), surgery, intra-articular steroid injection, and intramuscular botulinum toxin injections.

Appendix M: Excluded studies

M.1 In people after stroke what is the clinical and cost effectiveness of memory strategies versus usual care to improve memory?	721
M.2 In people after stroke what is the clinical and cost effectiveness of sustained attention training versus usual care to improve attention?	722
M.3 In people after stroke what is the clinical and cost-effectiveness of repetitive task training versus usual care on improving function and disability?	724
M.4 In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and visual neglect?	726
M.5 In people after stroke what is the clinical and cost effectiveness of all treadmill versus usual care on improving walking?.....	736
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M.8 In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?	748
M.9 In people after stroke what is the clinical and cost effectiveness of constraint-induced therapy versus usual care on improving function and reducing disability?	750
M.10 In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?	755
M.11 What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?	759
M.12 In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing / others) versus usual care?	761
M.13 In people after stroke what is the clinical and cost effectiveness of intensive rehabilitation versus standard rehabilitation?	763
M.14 In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?.....	767
M.15 In people after stroke what is the clinical and cost-effectiveness of Functional Electrical Stimulation for hand function versus usual care?	772
M.16 In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?.....	779
M.17 In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?.....	784
M.18 In people after stroke what is the clinical and cost-effectiveness of ankle/foot orthoses of all types to improve walking function versus usual care?	787
M.19 In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?	791
M.20 In people after stroke what is the clinical and cost-effectiveness of psychological therapies provided to the family (including patients)?.....	799

M.21	In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions / usual care to improve swallowing? (dysphagia).....	804
M.22	What is the clinical and cost-effectiveness of supported information provision versus unsupported information provision on mood and depression in people with stroke?	808
M.23	In people after stroke does cardiorespiratory or resistance training improve outcome (fitness, function, QOL, mood and reduce disability)?	813
M.24	In people after stroke does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?	815
M.25	In people after stroke does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?	816
M.26	In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language/communication abilities and/or psychological wellbeing	816
M.26.1	Excluded studies from top up search.....	819
M.27	How should people with shoulder pain after stroke be managed to reduce pain?	821
M.28	How should people with visual impairments including diplopia be best managed after a stroke?	821

M.1 In people after stroke what is the clinical and cost effectiveness of memory strategies versus usual care to improve memory?

Author	Title	Year	Journal Name	Reason for Exclusion
Toglia J;Cermak SA;	Dynamic assessment and prediction of learning potential in clients with unilateral neglect	2009	American Journal of Occupational Therapy	Not matching our protocol
Nadar MS;McDowd J;	'Show me, don't tell me'; is this a good approach for rehabilitation?	2008		Compared Stroke patients with healthy controls
Thickpenny DK;Barker CS;	Evaluation of a structured group format memory rehabilitation program for adults following brain injury	2007	Journal of Head Trauma Rehabilitation	
Geusgens CA;Winkens I;Van Heugten CM;Jolles J;van den Heuvel WJ;	Occurrence and measurement of transfer in cognitive rehabilitation: A critical review. [Review] [63 refs]	2007		Relevant primary studies included
Majid MJ;Lincoln NB;Weyman N;	Cognitive rehabilitation for memory deficits following stroke. [Review] [21 refs][Update in Cochrane Database Syst Rev. 2007;(3):CD002293; PMID: 17636703]	2000	Cochrane Database of Systematic Reviews	Literature review
Rose FD;Brooks BM;Attree EA;Parslow DM;Leadbetter AG;McNeil JE;Jayawardena S;Greenwood R;Potter J;	A preliminary investigation into the use of virtual environments in memory retraining after vascular brain injury: indications for future strategy?	1999	Disability & Rehabilitation	No relevant outcomes reported
Reinke KS;He Y;Wang C;Alain C;	Perceptual learning modulates sensory evoked response during vowel segregation	2003	Cognitive Brain Research	Assessment of auditory memory training
Sun XF;Xiao GR;Song JL;	Relationship between the cognitive impairment in senile stroke patients and	2004	Chinese Journal of Clinical Rehabilitation	Cohort Study

Author	Title	Year	Journal Name	Reason for Exclusion
	the restoration of activities of daily living			
Winkens I;Van Heugten CM;Wade DT;Habets EJ;Fasotti L;	Efficacy of time pressure management in stroke patients with slowed information processing: a randomized controlled trial	2009	Archives of Physical Medicine & Rehabilitation	Mental Slowness Study
Johnston M;Bonetti D;Joice S;Pollard B;Morrison V;Francis JJ;MacWalter R;	Recovery from disability after stroke as a target for a behavioural intervention: results of a randomized controlled trial	2007	Disability & Rehabilitation	Workbook on general recovery outcomes
Fish J;Manly T;Emslie H;Evans JJ;Wilson BA;	Compensatory strategies for acquired disorders of memory and planning: differential effects of a paging system for patients with brain injury of traumatic versus cerebrovascular aetiology	2008	Journal of Neurology, Neurosurgery & Psychiatry	Less than 50% stroke population
Blanchet S;Belleville S;Noreau L;Fougeyrollas P;	Memory rehabilitation in individuals with vascular cognitive impairment	2010	Canadian Journal of Neurological Sciences	Abstract
Salazar AM;Warden DL;Schwab K;Spector J;Braverman S;Walter J;Cole R;Rosner MM;Martin EM;Ecklund J;Ellenbogen RG;	Cognitive rehabilitation for traumatic brain injury: A randomized trial	2000		

M.2 In people after stroke what is the clinical and cost effectiveness of sustained attention training versus usual care to improve attention?

Author	Title	Year	Journal Name	Reason for Exclusion
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Author	Title	Year	Journal Name	Reason for Exclusion
Akinwuntan AE;Devos H;Verheyden G;Baten G;Kiekens C;Feys H;De Weerd W;	Retraining moderately impaired stroke survivors in driving-related visual attention skills	2010		Not addressing clinical question
Kang EK;Baek MJ;Kim S;Paik NJ;	Non-invasive cortical stimulation improves post-stroke attention decline	2009	Restorative Neurology & Neuroscience	Not all participants in the trial experienced stroke
Robertson IH;Tegner R;Tham K;Lo A;Nimmo-Smith I;	Sustained attention training for unilateral neglect: Theoretical and rehabilitation implications	1995	Journal of Clinical and Experimental Neuropsychology	Not RCT
Petry MC;Crosson B;Gonzalez Rothi LJ;Bauer RM;Schauer CA;	Selective attention and aphasia in adults: preliminary findings	1994	Neuropsychologia	Compared and assessed stroke patients with healthy controls
Lincoln NB;Majid MJ;Weyman N;	Cognitive rehabilitation for attention deficits following stroke. [Review] [15 refs]	2000	Cochrane Database of Systematic Reviews	Not matching our protocol
Lane BA;Tate RL;	Apathy after acquired brain impairment: a systematic review of non-pharmacological interventions	2009	Neuropsychological Rehabilitation	Wrong intervention
Winkens I;Van Heugten CM;Wade DT;Habets EJ;Fasotti L;	Efficacy of time pressure management in stroke patients with slowed information processing: a randomized controlled trial	2009	Archives of Physical Medicine & Rehabilitation	Study not focused on attention alone - mental slowness (mixed concept)
Sturm W;Willmes K;	Efficacy of a reaction on various attentional and cognitive functions in stroke patients	1991	Neuropsychological Rehabilitation	Not RCT

M.3 In people after stroke what is the clinical and cost-effectiveness of repetitive task training versus usual care on improving function and disability?

Author	Title	Year	Journal Name	Reason for Exclusion
French B;Thomas LH;Leathley MJ;Sutton CJ;McAdam J;Forster A;Langhorne P;Price CI;Walker A;Watkins CL;	Repetitive task training for improving functional ability after stroke	2007	Cochrane Database of Systematic Reviews	Relevant primary studies included
Kalra L;Walker MF;	Stroke Rehabilitation in the United Kingdom	2009		Not a RCT
Timmermans A;Lemmens R;Pulles S;Smeets R;Seelen H;	Effectiveness of haptic master supported task-oriented arm training in chronic stroke patients	2012	Neurorehabilitation and Neural Repair	Abstract
Helbok R;	Robot-assisted hand training (AMADEO) compared with conventional physiotherapy techniques in chronic ischemic stroke patients:A pilot study	2010	Neurologie und Rehabilitation	Abstract
Cauraugh JH;Kim SB;	Stroke motor recovery: active neuromuscular stimulation and repetitive practice schedules	2003	Journal of Neurology, Neurosurgery & Psychiatry	wrong intervention (blocked practice vs random practice in active neuromuscular stimulation)
Yen JG;Wang RY;Chen HH;Hong CT;	Effectiveness of modified constraint-induced movement therapy on upper limb function in stroke subjects	2005		wrong intervention - CIMT
de Seze M;Wiert L;Bon-Saint-Come A;Debelleix X;de SM;Joseph PA;Mazaux JM;Barat M;	Rehabilitation of postural disturbances of hemiplegic patients by using trunk control retraining during exploratory exercises	2001		wrong outcomes
Dean	Task-related circuit	2000		N<10 in each arm

Author	Title	Year	Journal Name	Reason for Exclusion
CM;Richards CL;Malouin F;	training improves performance of locomotor tasks in chronic stroke: a randomized, controlled pilot trial			
Dean CM;Shepherd RB;	Task-related training improves performance of seated reaching tasks after stroke. A randomized controlled trial	1997		Not addressing pre-specified outcomes and comparison
Howe TE;Taylor I;Finn P;Jones H;	Lateral weight transference exercises following acute stroke: a preliminary study of clinical effectiveness	2005		non relevant outcomes
Langhammer B;Stanghelle JK;	Bobath or motor relearning programme? A follow-up one and four years post stroke	2003		wrong intervention
van Vliet PM;Lincoln NB;Robinson E;	Comparison of the content of two physiotherapy approaches for stroke	2001		wrong intervention (Bobath based vs Movement Science-based)
McClellan R;Ada L;	A six-week, resource-efficient mobility program after discharge from rehabilitation improves standing in people affected by stroke: placebo-controlled, randomised trial	2004		therapist not present all the time
Salbach NM;Mayo NE;Robichaud-Ekstrand S;Hanley JA;Richards CL;Wood-Dauphinee S;	The effect of a task-oriented walking intervention on improving balance self-efficacy poststroke: a randomized, controlled trial	2005		Included primary analysis which reports the same result
van Vliet PM;Lincoln NB;Foxall A;	Comparison of Bobath based and movement science based treatment for stroke: a randomised controlled trial	2005		Not addressing pre-specified intervention and comparison

Author	Title	Year	Journal Name	Reason for Exclusion
Turton A;Fraser C;	The use of home therapy programmes for improving recovery of upper limb following stroke	1990	British Journal of Occupational Therapy	therapist not present during intervention
Barreca S;Sigouin CS;Lambert C;Ansley B;	Effects of extra training on the ability of stroke survivors to perform an independent sit-to stand: a randomized controlled trial	2004	Journal of Geriatric Physical Therapy	Not addressing pre-specified outcomes
Dean CM;Richards CL;Malouin F;	Task-related circuit training improves performance of locomotor tasks in chronic stroke: a randomized, controlled pilot trial	2000		n<10 in each arm
Feys H;De WW;Verbeke G;Steck GC;Capiou C;Kiekens C;Dejaeger E;Van HG;Vermeersch G;Cras P;	Early and Repetitive Stimulation of the Arm Can Substantially Improve the Long-Term Outcome after Stroke: A 5-Year Follow-up Study of a Randomized Trial	3807 8		sham comparator
Langhammer B;Stanghelle JK;	Bobath or motor relearning programme? A comparison of two different approaches of physiotherapy in stroke rehabilitation: a randomized controlled study	2000		Not addressing pre-specified intervention and comparison

M.4 In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and visual neglect?

Author	Title	Year	Journal Name	Reason for Exclusion
Nelles G;Esser J;Eckstein A;Tiede A;Gerhard H;Diener HC;	Compensatory visual field training for patients with hemianopia after stroke	2001	Neuroscience Letters	Compared stroke patients with healthy controls
Siengsukon C;Boyd LA;	Sleep enhances off-line spatial and	2009	Neurorehabilitation and	Not RCT

Author	Title	Year	Journal/full	Reason for Exclusion
	temporal motor learning after stroke		Neural Repair	
Bowen A;Lincoln NB;	Rehabilitation for spatial neglect improves test performance but not disability	2007		Update of Cochrane. Relevant primary studies included
Lin KC;Cermak SA;	Cognitive perceptual intervention in post-stroke patients with unilateral neglect: An annotated bibliography	1991	Physical and Occupational Therapy in Geriatrics	Literature review
Zeloni G;Farne A;Baccini M;	Viewing less to see better	2002		N<10 patients
Van Heugten C;Dekker J;Deelman BG;Stehmann-Saris JC;Kinebanian A;	Rehabilitation of stroke patients with apraxia: The role of additional cognitive and motor impairments	2000	Disability and Rehabilitation	Assessment study, not RCT of intervention
Hartman-Maer A;Soroaker N;Oman SD;Katz N;	Awareness of disabilities in stroke rehabilitation - A clinical trial	2003	Disability and Rehabilitation	Not our pre-specified population
Weinberg J;Piasetsky E;Diller L;Gordon W;	Treating perceptual organization deficits in nonneglecting RBD stroke patients	1982	Journal of Clinical Neuropsychology	Not addressing the intervention
Wilson B;Cockburn J;Halligan P;	Development of a behavioral test of visuospatial neglect	1987	Archives of Physical Medicine & Rehabilitation	Assessment of patients not RCT of an intervention
Pizzamiglio L;Frasca R;Guariglia C;Incoccia C;Antonucci G;	Effect of optokinetic stimulation in patients with visual neglect	1990	Cortex	Evaluation of patients not intervention RCT
Rose L;Bakal DA;Fung TS;Farn P;Weaver LE;	Tactile extinction and functional status after stroke. A preliminary investigation	1994		Measurement of Assessment Tool/Predictors
Cermak SA;	The Behavioral Inattention Test for unilateral visual neglect: A critical review		Physical & Occupational Therapy in Geriatrics	Evaluation of BIT test not of an intervention
Bartolomeo P;Sieroff E;Decaix C;Chokron S;	Modulating the attentional bias in unilateral neglect: the effects of the	2001	Experimental Brain Research	Comparison study not intervention study

Author	Title	Year	Journamfull	Reason for Exclusion
	strategic set			
Devine JM;Zafonte RD;	Physical Exercise and Cognitive Recovery in Acquired Brain Injury: A Review of the Literature	2009	PM and R	Incorrect intervention.
Rasquin SM;Verhey FR;Lousberg R;Winkens I;Lodder J;	Vascular cognitive disorders: memory, mental speed and cognitive flexibility after stroke	2002	Journal of the Neurological Sciences	Cohort study an evaluation of patients not RCT of intervention
Beis JM;Keller C;Morin N;Bartolomeo P;Bernati T;Chokron S;Leclercq M;Louis DA;Marchal F;Martin Y;Perennou D;Pradat DP;Prairial C;Rode G;Rousseaux M;Samuel C;Sieroff E;Wiat L;Azouvi P;French Collaborative Study Group on Assessment of Unilateral Neglect (G	Right spatial neglect after left hemisphere stroke: qualitative and quantitative study	2004		Evaluation of patients not intervention RCT
Gialanella B;Monguzzi V;Santoro R;Rocchi S;	Functional recovery after hemiplegia in patients with neglect: the rehabilitative role of anosognosia	2005		Examined the effect of Agnosognosia
Gillespie DC;Bowen A;Foster JK;	Memory impairment following right hemisphere stroke: a comparative meta-analytic and narrative review. [Review] [69 refs]	2006	Clinical Neuropsychologist	Meta-analysis of assessment
Geusgens C;van HC;Donkervort M;van den EE;Jolles J;van den HW;	Transfer of training effects in stroke patients with apraxia: an exploratory study	2006	Neuropsychological Rehabilitation	Population not relevant stroke patients with apraxia
Keane S;Turner	Use of fresnel prism	2006	Archives of	N<10 patient observation study

Author	Title	Year	Journal/full	Reason for Exclusion
C;Sherrington C;Beard JR;	glasses to treat stroke patients with hemispatial neglect		Physical Medicine & Rehabilitation	
Bergsma DP;Van der Wildt GJ;	Properties of the regained visual field after visual detection training of hemianopsia patients	2008	Restorative Neurology & Neuroscience	Compared patients with healthy controls
Koch G;Oliveri M;Cheeran B;Ruge D;Lo GE;Salerno S;Torriero S;Marconi B;Mori F;Driver J;Rothwell JC;Caltagirone C;	Hyperexcitability of parietal-motor functional connections in the intact left-hemisphere of patients with neglect	2008	Brain	Assessment study, not RCT of intervention
Barrett BT;	A critical evaluation of the evidence supporting the practice of behavioural vision therapy. [Review] [171 refs]	2009	Ophthalmic & Physiological Optics	Not a systematic review
Dohle C;Pullen J;Nakaten A;Kust J;Rietz C;Karbe H;	Mirror therapy promotes recovery from severe hemiparesis: a randomized controlled trial	2009	Neurorehabilitation & Neural Repair	Wrong population and intervention
Nys GM;Stuart M;Dijkerman HC;	Repetitive exploration towards locations that no longer carry a target in patients with neglect	2010	Journal of Neuropsychology	Compared patients with healthy controls
Antonucci G;Guariglia C;Judica A;Magnotti L;Paolucci S;Pizzamiglio L;Zoccolotti P;	Effectiveness of neglect rehabilitation in a randomized group study	1995	Journal of Clinical & Experimental Neuropsychology: Official Journal of the International Neuropsychological Society	Not addressing our question
Fong KN;Chan MK;Ng PP;Tsang MH;Chow KK;Lau CW;Chan FS;Wong	The effect of voluntary trunk rotation and half-field eye-patching for patients with unilateral neglect in stroke: a randomized	3929 5		Not specified intervention and comparison

Author	Title	Year	Journal/full	Reason for Exclusion
IP;Chan DY;Chan CC;	controlled trial			
Bowen A;Knapp P;Gillespie D;Vail A;	Non-pharmacological interventions for perceptual disorders following stroke and other adult, acquired, non-progressive brain injury	2008	Cochrane Database of Systematic Reviews	Cochrane protocol. Not relevant to clinical question
Bergego C;Azouvi P;Deloche G;Samuel C;Louis-Dreyfus A;Kaschel R;Willmes K;	Rehabilitation of unilateral neglect: A controlled multiple-baseline-across-subjects trial using computerised training procedures	1997	Neuropsychological Rehabilitation	Patient population only n<10
Fish J;Manly T;Emslie H;Evans JJ;Wilson BA;	Compensatory strategies for acquired disorders of memory and planning: differential effects of a paging system for patients with brain injury of traumatic versus cerebrovascular aetiology	3966 1	Journal of Neurology, Neurosurgery and Psychiatry	<50% stroke population
Cherney LR;Halper AS;Papachronis D;	Two approaches to treating unilateral neglect after right hemisphere stroke: a preliminary investigation	2003		population <10
Ferreira HP;Leite Lopes MA;Luiz RR;Cardoso L;Andre C;	Is visual scanning better than mental practice in hemispatial neglect? Results from a pilot study	4060 3		< 10 patients and not addressing clinical/review question
Erez AB;Katz N;Ring H;Soroker N;	Assessment of spatial neglect using computerised feature and conjunction visual search tasks	2009	Neuropsychological Rehabilitation	Compared patients with healthy controls
Rusconi ML;Meinecke C;Sbrissa P;Bernadini B;	Different cognitive trainings in the rehabilitation of visuo-spatial neglect	2002	Europa Medicophysica	Patients allocated to interventions not specified in protocol. No control arm
Beis JM;Andre JM;Barre A;Paysant J;	Mirror images and unilateral spatial neglect	2001	Neuropsychologia	N<10 patients

Author	Title	Year	Journal/full	Reason for Exclusion
Matz K;Brainin M;Teuschl Y;Eckhardt R;Herbst A;Dachenhause n A;	Prevention of post-stroke cognitive decline - a randomized pilot trial testing cognitive training in patients with first lacunar stroke	2008	International Journal of Stroke	Abstract
Skidmore ER;Whyte EM;Holm MB;Becker JT;Butters MA;Dew MA;Munin MC;Lenze EJ;	Cognitive and affective predictors of rehabilitation participation after stroke	2010	Archives of Physical Medicine & Rehabilitation	Assessment of patients not RCT on intervention
Schroder A;Wist ER;Homberg V;	TENS and optokinetic stimulation in neglect therapy after cerebrovascular accident: a randomized controlled study	3969 2	European journal of neurology : the official journal of the European Federation of Neurological Societies	not addressing pre-specified interventions, comparison and outcomes
Kim YK;Seo CH;Park JW;Lee HJ;Shin SH;	Effects of cognitive rehabilitative treatment using computerized program (RehaCom) in stroke patients	2008	Neurorehabilitation and Neural Repair	Abstract
Perdices M;	The Evidence Base of Neuropsychological Rehabilitation in Acquired Brain Impairment (ABI): How Good is the Research? [References]	2006	Brain Impairment	Systematic review including case series studies
Polanowska K;Seniow J;Paprot E;Lesniak M;Czlonkowska A;	Left-hand somatosensory stimulation combined with visual scanning training in rehabilitation for post-stroke hemineglect: a randomised, double-blind study	3996 5	Neuropsychological Rehabilitation	Not addressing clinical question
Hu X;Dou Z;Zhu H;Wan G;Li J;	The single blind procedure research of cognitive rehabilitation interventions on	2003	Chinese Journal of Clinical Rehabilitation	Chinese language paper

Author	Title	Year	Journamfull	Reason for Exclusion
	cognitive deficits in patients with stroke			
Harvey M;Hood B;North A;Robertson IH;	The effects of visuomotor feedback training on the recovery of hemispatial neglect symptoms: assessment of a 2-week and follow-up intervention	2003	Neuropsychologia	Outcomes focused on motor aspects of neglect
Lincoln NB;Whiting SE;Cockburn J;Bhavnani G;	An evaluation of perceptual retraining	1985	International Rehabilitation Medicine	Unclear whether participants had visual neglect
Niemeier JP;Cifu DX;Kishore R;	The lighthouse strategy: Improving the functional status of patients with unilateral neglect after stroke and brain injury using a visual imagery intervention	2001		Not our outcomes
Si HK;Kim DK;Kyung MS;Kwang NC;Jin YY;Sang YS;Heon JP;	A computerized visual perception rehabilitation programme with interactive computer interface using motion tracking technology -- a randomized controlled, single-blinded, pilot clinical trial study	2009		Compared intervention with another intervention, no control arm
Luukkainen MR;Tarkka IM;Pitkanen K;Sivenius J;Hamalainen H;	Rehabilitation of hemispatial neglect: A randomized study using either arm activation or visual scanning training	2009	Restorative Neurology & Neuroscience	Compared one attention intervention versus another attention intervention
Pizzamiglio L;Fasotti L;Jehkonen M;Antonucci G;Magnotti L;Boelen D;Asa S;	The use of optokinetic stimulation in rehabilitation of the hemineglect disorder	2004	Cortex	Not included our pre-specified outcomes
Edmans JA;Webster J;Lincoln NB;	A comparison of two approaches in the treatment of perceptual problems after stroke	2000		Not all participants had visual neglect

Author	Title	Year	Journal/full	Reason for Exclusion
Weinberg J;Diller L;Gordon WA;Gerstman LJ;Lieberman A;Lakin P;Hodges G;Ezrachi O;	Training sensory awareness and spatial organization in people with right brain damage	1979	Archives of Physical Medicine & Rehabilitation	Post hoc subgroup analysis in severe and mild groups, not prespecified in our protocol
Cicerone KD;Dahlberg C;Malec JF;Langenbahn DM;Felicetti T;Kneipp S;Ellmo W;Kalmar K;Giacino JT;Harley JP;Laatsch L;Morse PA;Catanese J;	Evidence-based cognitive rehabilitation: updated review of the literature from 1998 through 2002. [Review] [117 refs]	2005	Archives of Physical Medicine & Rehabilitation	Literature review
Rohling ML;Faust ME;Beverly B;Demakis G;	Effectiveness of cognitive rehabilitation following acquired brain injury: a meta-analytic re-examination of Cicerone et al.'s (2000, 2005) systematic reviews. [Review] [148 refs]	2009	Neuropsychology	Relevant primary studies included
Lin KC;	Right-hemispheric activation approaches to neglect rehabilitation poststroke. [Review] [114 refs]	1996	American Journal of Occupational Therapy	Review; Primary studies included
Ottensbacher KJ;	The results of clinical trials in stroke rehabilitation research		Archives of Neurology	Review; Not addressing clinical questions
Salisbury LG;Baer G;Dennis M;Pitman J;Smith M;	Does treadmill training affect activities of daily living or quality of life after stroke? Results of a phase II randomised controlled trial	2009	International Journal of Stroke	Abstract
Teasell RW;Foley NC;Bhogal SK;Speechley	An evidence-based review of stroke rehabilitation	2003		Literature review

Author	Title	Year	Journamfull	Reason for Exclusion
MR;				
Vahlberg B;Hellstrom K;	Treatment and assessment of neglect after stroke - From a physiotherapy perspective: A systematic review	2008	Advances in Physiotherapy	Relevant primary studies included
Bowen A;Lincoln NB;	Cognitive rehabilitation for spatial neglect following stroke	2007	Cochrane Database of Systematic Reviews	Relevant primary studies included
Luaute J;	Prism adaptation first among equals in alleviating left neglect: A review. [References]	2006	Restorative Neurology and Neuroscience	Review with case studies
Cicerone KD;Dahlberg C;Kalmar K;Langenbahn DM;Malec JF;Bergquist TF;Felicetti T;Giacino JT;Harley JP;Harrington DE;Herzog J;Kneipp S;Laatsch L;Morse PA;	Evidence-based cognitive rehabilitation: recommendations for clinical practice. [Review] [185 refs]	2000	Archives of Physical Medicine & Rehabilitation	Literature review
Luaute J;Halligan P;Rode G;Rossetti Y;Boisson D;	Visuo-spatial neglect: A systematic review of current interventions and their effectiveness	2006	Neuroscience and Biobehavioral Reviews	Systematic review: relevant studies included
Pierce SR;Buxbaum LJ;	Treatments of unilateral neglect: a review. [Review] [159 refs]	2002	Archives of Physical Medicine & Rehabilitation	Literature review
Ogourtsova T;Korner-Bitensky N;Leh SE;Eskes G;Ptito A;	Superior colliculi involvement in poststroke unilateral spatial neglect: A pilot study	2011		Not an RCT
Kerkhoff G;Keller I;Artinger F;Hildebrandt H;Marquardt C;Reinhart S;Ziegler W;	Recovery from auditory and visual neglect after optokinetic stimulation with pursuit eye movements-- transient modulation and enduring	2012	Neuropsychologia	Several studies in one paper - the RCT part focused on auditory neglect

Author	Title	Year	Journal/full	Reason for Exclusion
	treatment effects			
Ianes P;Varalta V;Gandolfi M;Picelli A;Corno M;Di Matteo A;Fiaschi A;Smania N;	Stimulating visual exploration of the neglected space in the early stage of stroke by hemifield eye-patching: a randomized controlled trial in patients with right brain damage	2012	European Journal of Physical and Rehabilitation Medicine	Control group received visual scanning training whereas intervention group received patches only (all had stroke onset < 15 days before inclusion)
Kim YM;Chun MH;Yun GJ;Song YJ;Young HE;	The effect of virtual reality training on unilateral spatial neglect in stroke patients	2011	Annals of rehabilitation medicine	Intervention not in the protocol
Walker MF;Sunderland A;Fletcher-Smith J;Drummond A;Logan P;Edmans JA;Garvey K;Dineen RA;Ince P;Horne J;Fisher RJ;Taylor JL;	The DRESS trial: a feasibility randomized controlled trial of a neuropsychological approach to dressing therapy for stroke inpatients	4112 2		<50% participants had visual neglect and subgroup analysis was not based on neglect
Weinberg J;Diller L;Gordon WA;Gerstman LJ;Lieberman A;Lakin P;Hodges G;Ezrachi O;	Visual scanning training effect on reading-related tasks in acquired right brain damage	1977		Not addressing our pre-specified outcomes
Fortis P;Maravita A;Gallucci M;Ronchi R;Grassi E;Senna I;Olgiati E;Perucca L;Banco E;Posteraro L;Tesio L;Vallar G;	Rehabilitating patients with left spatial neglect by prism exposure during a visuomotor activity	2010	Neuropsychology	not all patients with stroke (1/10 had tumor)

M.5 In people after stroke what is the clinical and cost effectiveness of all treadmill versus usual care on improving walking?

Author	Title	Year	Journal Name	Reason for Exclusion
Limpar P;Macko RF;Sorkin JD;Katzel LI;Hanley DF;	Safety of treadmill aerobic exercise in chronic hemiparetic stroke patients	2004		Abstract
Sullivan KJ;Brown DA;Klassen T;Mulroy S;Ge T;Azen SP;Winstein CJ;	Effects of task-specific locomotor and strength training in adults who were ambulatory after stroke: results of the STEPS randomized clinical trial ... including commentary by Carey JR, and author response by Sullivan KJ, Brown DA, Mulroy S, and Winstein	2007	Physical Therapy	No control group
Kuys S;	Treadmill walking to improve walking and fitness following stroke: a single blinded pilot randomised controlled trial	2007		Unpublished data
Eng JJ;Tang P;	Gait training strategies to optimize walking ability in people with stroke: A synthesis of the evidence	3935 6	Expert Review of Neurotherapeutics	Not addressing our question
Altenburger P;Gill M;Hunter C;Kustudia M;Altenburger B;Schuerman S;	Body weight support treadmill training compared with overhead harness training in chronic stroke patients: a multi case study investigation	2007	Journal of Neurologic Physical Therapy	Abstract
Ada L;Dean CM;Morris ME;	Supported treadmill training	2007	BMC Neurology	Protocol, not RCT

Author	Title	Year	Journal Name	Reason for Exclusion
	to establish walking in non-ambulatory patients early after stroke			
Yagura H;Hatakenaka M;Miyai I;	Does therapeutic facilitation add to locomotor outcome of body weight--supported treadmill training in nonambulatory patients with stroke? A randomized controlled trial	2006	Archives of Physical Medicine & Rehabilitation	Not addressing our question
Macko RF;	Treadmill exercise prescriptions to improve fitness versus ambulatory function after stroke	2006		Unpublished data
Kilbreath SL;	PBWST (Partial body-weight supported treadmill training) and muscle power training after sub-acute stroke	2006		Unpublished data
Du J;Song W;Wang M;	The application of partial body weight support treadmill training in hemiplegia rehabilitation after stroke]	2006		Paper written in Chinese
Reisman DS;Wityk R;Bastian AJ;	Split-belt treadmill walking adaptation in poststroke hemiparesis	2005		Abstract
Kuys SS;Brauer SG;Ada L;Russell TG;	Increasing intensity during treadmill walking does not adversely affect walking pattern or quality in newly-ambulating stroke patients: an experimental	2008		Not RCT

Author	Title	Year	Journal Name	Reason for Exclusion
	study			
Stephenson J;Maitland M;Beckstead J;	Body weight support treadmill training compared with PNF training in persons with chronic stroke	2004	Journal of Neurologic Physical Therapy	Abstract
Baer G;	Treadmill training and sub-acute stroke: a phase II feasibility study	2008		Abstract
Protas E;	Stroke rehabilitation outcomes with supported treadmill ambulation training	2003		Unpublished data
Manning CD;Pomeroy VM;	Effectiveness of treadmill retraining on gait of hemiparetic stroke patients: Systematic review of current evidence	3777 3	Physiotherapy	Systematic review including also case studies - not fitting our protocol
Lennihan L;Wootten ME;Wainwright M;Tenteromano L;McMahon D;Cotier J;	Treadmill with partial body-weight support versus conventional gait training after stroke	2003		Abstract
Sullivan KJ;Knowlton BJ;Dobkin BH;	Step training with body weight support: effect of treadmill speed and practice paradigms on poststroke locomotor recovery	3737 7	Archives of Physical Medicine & Rehabilitation	No control group
Hesse S;Werner C;Bardeleben A;von FS;	Treadmill therapy with partial body weight support and an automated gait trainer for restoration of gait after stroke: a randomized study	2001	Neurorehabilitation and Neural Repair	Abstract
Sullivan KJ;Knowlton	The effect of varying treadmill	2000		Abstract

Author	Title	Year	Journal Name	Reason for Exclusion
BJ;Dobkin BH;	speed to enhance overground walking in patients with chronic stroke			
Smith GV;Forrester LW;Silver KHC;Macko RF;	Effects of treadmill training on translational balance perturbation responses in chronic hemiparetic stroke patients	2000		Sample size <20 participants, not RCT
Hesse S;Konrad M;Uhlenbrock D;	Treadmill walking with partial body weight support versus floor walking in hemiparetic subjects	3625 1	Archives of Physical Medicine & Rehabilitation	Sample size <20 participants
Hesse S;Uhlenbrock D;Sarkodie-Gyan T;	Gait pattern of severely disabled hemiparetic subjects on a new controlled gait trainer as compared to assisted treadmill walking with partial body weight support	3643 4		Sample size under 20 participants (N=14)
Hesse S;Bertelt C;Schaffrin A;Malezic M;Mauritz K;	Restoration of gait in nonambulatory hemiparetic patients by treadmill training with partial body-weight support	1994		Sample size <20 participants
Van Peppen RPS;Kwakkel G;Wood-Dauphinee S;Hendriks HJM;Van der Wees P;Dekker J;	The impact of physical therapy on functional outcomes after stroke: What's the evidence?	3832 2		Systematic Review not addressing our question
Lewek MD;Cruz TH;Moore JL;Roth HR;Dhafer YY;Hornby TG;	Allowing intralimb kinematic variability during locomotor training poststroke improves	4002 6	Physical Therapy	Sample size <20 participants (N=19)

Author	Title	Year	Journal Name	Reason for Exclusion
	kinematic consistency: a subgroup analysis from a randomized clinical trial			
Langhammer B;Lindmark B;Tanghelle JKS;	Motor function, activity and participation one year post stroke: A I follow-up of a randomised controlled trial in persons with stroke	2010		abstract
Ada L;Dean CM;Hall JM;Bampton J;Crompton S;	A treadmill and overground walking program improves walking in individuals residing in the community after stroke: a placebo-controlled randomised trial	2004		Abstract
Ada L;Dean CM;Morris ME;Simpson JM;Katrak P;	Randomized trial of treadmill walking with body weight support to establish walking in subacute stroke: the MOBILISE trial	2010		not relevant outcomes
Statt TC;	Treadmill training in sub-acute stroke: report of an ongoing phase II feasibility study of a complex intervention	2007		Abstract
Ada L;Dean CM;Vargas J;Ennis S;	Mechanically assisted walking with body weight support results in more independent walking than assisted overground walking in non-ambulatory patients early after stroke: a systematic review	2010	Journal of Physiotherapy	study compared 2 interventions: treadmill vs. electromechanical gait trainer

Author	Title	Year	Journal Name	Reason for Exclusion
Ploughman M;McCarthy J;Bosse M;Sullivan HJ;Corbett D;	Does Treadmill Exercise Improve Performance of Cognitive or Upper-Extremity Tasks in People With Chronic Stroke? A Randomized Cross-Over Trial	3975 3		Did not include our prespecified outcomes in the protocol
Langhammer B;Johan;Stanghelle K;	Outdoors or indoors walking, what is more beneficial? A comparison of exercise methods in a randomized trial	2010		abstract
Moore JL;Roth EJ;Killian C;Hornby TG;	Locomotor training improves daily stepping activity and gait efficiency in individuals poststroke who have reached a 'plateau' in recovery	4017 9		Intervention/control group do not match our protocol
Globas C;Becker C;Cerny J;Lam JM;Lindemann U;Forrester LW;Macko RF;Luft AR;	Elderly chronic stroke survivors benefit from aerobic treadmill exercise: A randomized, controlled trial	2011		conference abstract
Saccavini M;Zaccaria B;Franceschini M;Maestrini E;Agosti M;Mammi P;	Treadmill walking with bodyweight support in stroke patients during acute phase: a randomized controlled trial	2009	Cerebrovascular Diseases	Abstract
Eich HJ;Parchmann H;Hesse S;Mach H;Werner C;	Aerobic treadmill training plus physiotherapy improves walking ability in subacute stroke patients: a randomized controlled study	2004	Neurologie und Rehabilitation	
Lam T;Luttmann K;Houldin A;Chan C;	Treadmill-based locomotor training with leg weights to	4005 7	Journal of Neurologic Physical Therapy	Sample size <20 participants, not RCT

Author	Title	Year	Journal Name	Reason for Exclusion
	enhance functional ambulation in people with chronic stroke: a pilot study			
Jayaram G;Stinear JW;	The effects of transcranial stimulation on paretic lower limb motor excitability during walking	40026	Journal of Clinical Neurophysiology	Sample size <20 participants
Baer G;Dennis M;Pitman J;Salisbury LG;Smith M;	Does treadmill training improve walking after stroke - the long term follow-up from a phase II randomised controlled trial	2009	International Journal of Stroke	Abstract
Ada L;Dean CM;Lindley R;Lloyd G;	Improving community ambulation after stroke: the AMBULATE Trial	2009	BMC Neurology	Protocol of a RCT (not results)
Tilson JK;Settle SM;Sullivan KJ;	Application of evidence-based practice strategies: current trends in walking recovery interventions poststroke. [Review] [62 refs]	39569		Narrative review
Lau WK;Mak MKY;	The effects of speed-dependent treadmill training on gait and balance performance in patients with sub-acute stroke	2010	Hong Kong Physiotherapy Journal	Abstract
Srivastava A;Gupta A;Taly AB;Kumar S;Murali T;	Role of body weight supported treadmill training in retraining gait after stroke: randomized controlled study	2008	International Journal of Stroke	Not RCT
Lau KWK;Mak MKY;	Speed-dependent treadmill training is effective to improve gait and balance	2011		Not comparing treadmill to usual care (with or without body weight support)

Author	Title	Year	Journal Name	Reason for Exclusion
	performance in patients with sub-acute stroke			
Teixeira da CF;Lim PA;Qureshy H;Henson H;Monga T;Protas EJ;	A comparison of regular rehabilitation and regular rehabilitation with supported treadmill ambulation training for acute stroke patients	3695 1	Journal of Rehabilitation Research & Development	Sample size <20 participants
Scheidtmann K;Brunner H;Müller M;Weinandy-Trapp M;Wulf DaK;	Treadmill training in early poststroke patients - do timing and walking ability matter?	1999		Paper written in German
Eich HJ;Parchmann H;Hesse S;Mach H;Werner C;	Aerobic treadmill training plus physiotherapy improves walking ability in subacute stroke patients. A randomized controlled study	2004	Neurologie und Rehabilitation	Not appropriate control group
Zielke DR;	The effect of partial body weight supported treadmill training on gait rehabilitation in early acute stroke patients: preliminary data	2003	Journal of Neurologic Physical Therapy	Abstract
Yang YR;Chen IH;Liao KK;Huang CC;Wang RY;	Cortical reorganization induced by body weight-supported treadmill training in patients with hemiparesis of different stroke durations	2010	Archives of Physical Medicine & Rehabilitation	Sample size <20 participants
Macko RF;Ivey FM;Forrester LW;Hanley D;Sorkin JD;Katzel LI;Silver KH;Goldberg AP;	Treadmill exercise rehabilitation improves ambulatory function and cardiovascular fitness in patients with chronic	3862 6		not addressing the comparisons specified in the protocol

Author	Title	Year	Journal Name	Reason for Exclusion
	stroke: a randomized, controlled trial			
Dean CM;Ada L;Bampton J;Morris ME;Katrak PH;Potts S;	Treadmill walking with body weight support in subacute non-ambulatory stroke improves walking capacity more than overground walking: a randomised trial	2010	Journal of Physiotherapy	Results are presented only for a subgroup of participants
Pohl M;Werner C;Holzgraefe M;Kroczeck G;Mehrholtz J;Wingendorf I;Hoolig G;Koch R;Hesse S;	Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (DEutsche GAngtrainerStudie, DEGAS)	3908 3		Not addressing the intervention specified in the protocol
National Coordinating Centre for Health Technology Assessment;	A systematic review of repetitive functional task practice with modelling of resource use, costs and effectiveness	2008	Health Technology Assessment	HTA
Ada L;Dean CM;Lindley R;Vargas J;	Improving walking after stroke: The ambulate trial	2012	Neurorehabilitation and Neural Repair	Abstract

M.6 In people after stroke who can walk, what is the clinical and cost effectiveness of treadmill plus body support versus treadmill only on improving walking?

Author	Title	Year	Study Type	Reason for Exclusion
Van NM;Gerrits K;Janssen T;De HA;	Robot-assisted treadmill training during rehabilitation of	2011		Abstract

Author	Title	Year	Study Type	Reason for Exclusion
	stroke patients			
Van NM;Gerrits K;Janssen T;De HA;	RCT evaluating the effectiveness of robot-assisted treadmill training in restoring walking ability of stroke patients	2012		Abstract
Combs SA;Tucker L;Harmeyer A;Ertel T;Colburn D;Parameswaran AK;	Body weight-supported treadmill training vs. over-ground walking training for persons with chronic stroke: A randomized controlled trial	2012		Abstract

M.7 In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?

Author	Title	Year	Journamfull	Reason for Exclusion
Lee MJ;Kilbreath SL;Singh MF;Zeman B;Davis GM;	Effect of progressive resistance training on muscle performance after chronic stroke	4017 9	Medicine & Science in Sports & Exercise	No relevant outcomes
Scianni A;Teixeira-Salmela LF;Ada L;	Effect of strengthening exercise in addition to task-specific gait training after stroke: A randomised trial	2010	International Journal of Stroke	Study protocol (no results)
Ferrarello F;Baccini M;Rinaldi LA;Cavallini MC;Mossello E;Masotti G;Marchionni N;Di Bari M;	Efficacy of physiotherapy interventions late after stroke: a meta-analysis	4057 5	Journal of Neurology, Neurosurgery & Psychiatry	Not addressing clinical question
Dean CM;Richards CL;Malouin F;	Task-related circuit training improves performance of locomotor tasks	3661 7	Archives of Physical Medicine & Rehabilitation	N<20

Author	Title	Year	Journamfull	Reason for Exclusion
	in chronic stroke: a randomized, controlled pilot trial			
Inaba M;Edberg E;Montgomery J;Gillis MK;	Effectiveness of functional training, active exercise, and resistive exercise for patients with hemiplegia	2666 5	Physical Therapy	Authors did not specify the assessment tool of activities of daily living
Pang MY;Harris JE;Eng JJ;	A community-based upper-extremity group exercise program improves motor function and performance of functional activities in chronic stroke: a randomized controlled trial	3871 8	Archives of Physical Medicine & Rehabilitation	arm exercise versus leg exercise; no usual care group
Sims J;Galea M;Taylor N;Dodd K;Jespersen S;Joubert L;Joubert J;	Regenerate: assessing the feasibility of a strength-training program to enhance the physical and mental health of chronic post stroke patients with depression	3981 4	International Journal of Geriatric Psychiatry	Paper did not address specified population and outcomes
Bale M;Strand LI;	Does functional strength training of the leg in subacute stroke improve physical performance? A pilot randomized controlled trial	3972 2		Population <20
Lexell J;Flansbjerg UB;Brogardh C;	What are the long-term benefits of progressive resistance training in chronic stroke? A 4-year follow-up	2012	Neurorehabilitation and Neural Repair	Abstract
Galvin R;Cusack T;Stokes E;	A randomised controlled trial evaluating family mediated exercise	2008	BMC Neurol	Study protocol used as background information for full study reference Galvin et al. 2011

Author	Title	Year	Journamfull	Reason for Exclusion
	(FAME) therapy following stroke			
Bonetti D;Johnston M;	Perceived control predicting the recovery of individual-specific walking behaviours following stroke: testing psychological models and constructs	2008	British Journal of Health Psychology	wrong design, intervention
de B;Burlot S;Gleizes S;Roques CF;Marque P;	A randomized controlled trial to compare isokinetic and conventional muscular strengthening in poststroke patients	2005		abstract only
Harris JE;Eng JJ;	Strength training improves upper-limb function in individuals with stroke: a meta-analysis	40179	Stroke	relevant studies ordered separately
Woldag H;Renner C;Hummelsheim H;	Isotonic and isometric contractions exert the same amount of corticomotor system excitability in healthy subjects and patients after stroke	39479		not a RCT, N<20
Riolo L;Fisher K;	Is there evidence that strength training could help improve muscle function and other outcomes without reinforcing abnormal movement patterns or increasing reflex activity in a man who has had a stroke?	37865		wrong design, search description
Weiss A;Suzuki	High intensity	3670		N<20

Author	Title	Year	Journamfull	Reason for Exclusion
T;Bean J;Fielding RA;	strength training improves strength and functional performance after stroke	8		
Ada L;Dorsch S;Canning CG;	Strengthening interventions increase strength and improve activity after stroke: a systematic review	2006		relevant RCTs ordered separately
Morris SL;Dodd KJ;Morris ME;	Outcomes of progressive resistance strength training following stroke: a systematic review. [Review] [50 refs]	3801 8		relevant studies ordered
Engardt M;Knutsson E;Jonsson M;Sternhag M;	Dynamic muscle strength training in stroke patients: effects on knee extension torque, electromyographic activity, and motor function	3482 0	Archives of Physical Medicine & Rehabilitation	wrong outcome
Pak S;Patten C;	Strengthening to promote functional recovery poststroke: an evidence-based review	3956 9		relevant studies ordered separately

M.8 In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?

Author	Title	Year	Journamfull	Reason for Exclusion
Mehrholz J;Pohl M;	Electromechanical -assisted gait training after stroke: a systematic review comparing end-effector and exoskeleton devices	2012		Review article

Author	Title	Year	Journal/full	Reason for Exclusion
Mehrholz J;Werner C;Kugler J;Pohl M;	Electromechanical -assisted training for walking after stroke	2007	Cochrane Database of Systematic Reviews	Relevant primary studies included
Fasoli SE;Krebs HI;Stein J;Frontera WR;Hughes R;Hogan N;	Robotic therapy for chronic motor impairments after stroke: Follow-up results	38169	Archives of Physical Medicine & Rehabilitation	upper limb intervention not gait training
Morone G;Bragoni M;Iosa M;De AD;Venturiero V;Coiro P;Pratesi L;Paolucci S;	Who may benefit from robotic-assisted gait training? A randomized clinical trial in patients with subacute stroke	40787	Neurorehabilitation and Neural Repair	Background information for a later follow-up publication of the same trial
Hesse S;Tomelleri C;Bardeleben A;Werner C;Waldner A;	Robot-assisted practice of gait and stair climbing in nonambulatory stroke patients	2012	Journal of rehabilitation research and development	Not an RCT
Dickstein R;Yoeli Y;Holtzman A;Faust A;Markoviz E;	Weight bearing on the affected lower limb in residents of a geriatric rehabilitation hospital	2010		Not RCT
Ferraro M;Palazzolo JJ;Krol J;Krebs HI;Hogan N;Volpe BT;	Robot-aided sensorimotor arm training improves outcome in patients with chronic stroke	37964		Not RCT
Hesse S;Uhlenbrock D;Bardeleben A;von FS;Werner C;	A mechanized gait trainer for restoration of gait after stroke	2000	Neurorehabilitation and Neural Repair	only abstract
Lum PS;Burgar CG;Shor PC;Majmundar M;Van der Loos M;	Robot-assisted movement training compared with conventional therapy techniques for the rehabilitation of upper-limb motor function after stroke	37438	Archives of Physical Medicine & Rehabilitation	robot-assisted upper limb intervention so outcomes for upper limbs, not lower limbs
Prange GB;Jannink MJ;Groothuis-	Systematic review of the effect of robot-aided	38777		relevant studies ordered separately

Author	Title	Year	Journamfull	Reason for Exclusion
Oudshoorn CG;Hermens HJ;ljzerman MJ;	therapy on recovery of the hemiparetic arm after stroke			
Peurala SH;Titianova EB;Mateev P;Pitkanen K;Sivenius J;Tarkka IM;	Gait characteristics after gait-oriented rehabilitation in chronic stroke	2005		Not RCT
Masiero S;Celia A;Rosati G;Armani M;	Robotic-assisted rehabilitation of the upper limb after acute stroke	39114		wrong intervention and outcomes, all for upper limbs
Mayr A;Saltuari L;Quirbach E;	Impact of Lokomat training on gait rehabilitation: a prospective randomized controlled trial in stroke patients	2008	Neurorehabilitation & Neural Repair	only asbtract
Faran S;van KS;Eickhoff C;Mahoney R;Mauritz KH;	An active and repetitive robot assisted training improves functional motor recovery of the arm in sub-acute stroke patients	2008		abstract
Lim PA;Henson H;Cunha I;Qureshy H;Monga T;Protas EJ;	Body weight-supported gait training in stroke patients	2000	American Journal of Physical Medicine and Rehabilitation	abstract only

M.9 In people after stroke what is the clinical and cost effectiveness of constraint-induced therapy versus usual care on improving function and reducing disability?

Author	Title	Year	Journamfull	Reason for Exclusion
Liepert J;	Evidence-based therapies for upper extremity dysfunction	2010	Current Opinion in Neurology	Not RCT
Corbetta D;Sirtori V;Moja L;Gatti R;	Constraint-induced movement therapy in stroke patients:	2010	European journal of physical & rehabilitation medicine	Cochrane review: relevant studies included

Author	Title	Year	Journamfull	Reason for Exclusion
	systematic review and meta-analysis			
Tang Z;Zeng W;Liao W;Luo X;	Constraint-induced movement therapy for upper extremities in adult stroke patients: A meta-analysis of randomized controlled trials	2010	International Journal of Stroke	Abstract
Wang YC;Lehman LA;Sindhu BS;Davenport RD;Rymer WZ;	Cerebrovascular Diseases. Conference: 19th European Stroke Conference Barcelona Spain	2010	Cerebrovascular Diseases	Conference abstract
Hammer A;Lindmark B;yagura	Is forced use of the paretic upper limb beneficial? A randomized pilot study during subacute post-stroke recovery1	2009		Not our prespecified outcomes
Lima RC;Teixeira-Salmela L;Michaelsen SM;	Effects of trunk restraint in addition to home-based modified constraint-induced movement therapy after stroke: a randomized controlled trial	2012	International Journal of Stroke	Protocol
Peurala SH;Kantanen MP;Sjogren T;Paltamaa J;Karhula M;Heinonen A;	Effectiveness of constraint-induced movement therapy on activity and participation after stroke: a systematic review and meta-analysis of randomized controlled trials	2012		Primary studies included in our review
Nijland R;Kwakkel G;Bakers J;van Wegen E;	Constraint-induced movement therapy for the upper paretic limb in acute or	2011	International Journal of Stroke	Primary studies addressing our protocol included in the review

Author	Title	Year	Journal	Reason for Exclusion
	sub-acute stroke: a systematic review			
Wang Q;Zhao JL;Zhu QX;Li J;Meng PP;	Comparison of conventional therapy, intensive therapy and modified constraint-induced movement therapy to improve upper extremity function after stroke	2011		Not addressing review question
McCall M;McEwen S;Colantonio A;Streiner D;Dawson DR;	Modified constraint-induced movement therapy for elderly clients with subacute stroke	2011	American Journal of Occupational Therapy	Population <10
Tariah HA;Almaly A;Sbeih Z;Al-Oraibi S;Bernhardt J;Rowe V;	Constraint induced movement therapy for stroke survivors in Jordan: a home-based model... ...includes commentaries by Bernhardt J and Rowe V	2010	International Journal of Therapy & Rehabilitation	sample size <20 patients
Chen H;Dromerick AW;Edwards DF;	Very early constraint-induced movement therapy (VECTORS): Effects of timing or dose on upper extremity function	2011		Abstract: Poster presentation
Shi YX;Tian JH;Yang KH;Zhao Y;	Modified constraint-induced movement therapy versus traditional rehabilitation in patients with upper-extremity dysfunction after	2011	Archives of Physical Medicine & Rehabilitation	The protocol of this review did not match our protocol

Author	Title	Year	Journamfull	Reason for Exclusion
	stroke: a systematic review and meta-analysis			
Lin K;Wu C;Liu J;Chen Y;Hsu C;	Constraint-induced therapy versus dose-matched control intervention to improve motor ability, basic/extended daily functions, and quality of life in stroke	39845	Neurorehabilitation and Neural Repair	control group also had hand restraint mitt
Michaelsen SM;Dannenbaum R;Levin MF;	Task-specific training with trunk restraint on arm recovery in stroke: randomized control trial	38718		wrong kind of intervention: Trunk restraint
Michaelsen SM;Levin MF;	Short-term effects of practice with trunk restraint on reaching movements in patients with chronic stroke: a controlled trial	38200		intervention only 1 day
Lin KC;Wu CY;Liu JS;	A randomized controlled trial of constraint-induced movement therapy after stroke	2008	Acta Neurochirurgica - Supplement	control group had restraint mitt also
Treger I;Aidinof L;Lehrer H;Kalichman L;	Modified constraint-induced movement therapy improved upper limb function in subacute poststroke patients: a small-scale clinical trial	2012		<10 participants in each arm
Pedlow K;Lennon S;Wheatley-Smith L;Morris D;Caldwell S;Wilson C;	Constraint induced movement therapy (CIMT) for patients post acquired brain injury:	2012	Neurorehabilitation and Neural Repair	Abstract

Author	Title	Year	Journal/full	Reason for Exclusion
	Quantitative results from a clinical feasibility randomised controlled trial (RCT)			
Kim DG;Cho YW;Hong JH;Song JC;Chung HA;Bai DS;Lee CH;Jang SH;	Effect of constraint-induced movement therapy with modified opposition restriction orthosis in chronic hemiparetic patients with stroke	2008	Neurorehabilitation	N<20
Azab M;Al-Jarrah M;Nazzal M;Maayah M;Sammour MA;Jamous M;	Effectiveness of constraint-induced movement therapy (CIMT) as home-based therapy on Barthel Index in patients with chronic stroke	2009		results in unuseable format
Wolf SL;Blanton S;Baer H;Breshears J;Butler AJ;	Repetitive task practice: a critical review of constraint-induced movement therapy in stroke	3756 1	Neurologist	relevant RCT ordered separately
Page SJ;Sisto S;Johnston MV;Levine P;	Modified constraint-induced therapy after subacute stroke: a preliminary study	3750 0	Neurorehabilitation Neural Repair	N<20
Brogardh C;Vestling M;Sjolund BH;	Shortened constraint-induced movement therapy in subacute stroke - no effect of using a restraint: a randomized controlled study with independent observers	2009		non relevant outcomes

Author	Title	Year	Journamfull	Reason for Exclusion
Brogardh C;Flansbjerg UB;Lexell J;	What is the long-term benefit of constraint-induced movement therapy? A four-year follow-up	2009		N<20
Bourbonnais D;Bilodeau S;Lepage Y;Beaudoin N;Gravel D;Forget R;	Effect of force-feedback treatments in patients with chronic motor deficits after a stroke	2002		wrong intervention: force-feedback treatment

M.10 In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?

Author	Title	Year	Journamfull	Reason for Exclusion
Smania N;Aglioti SM;Girardi F;Tinazzi M;Fiaschi A;Cosentino A;Corato E;	Rehabilitation of limb apraxia improves daily life activities in patients with stroke	3906 3		Not addressing clinical/review question
MacKay S;Holmes DW;Gersumky AT;	Methods to assess aphasic stroke patients	3226 4	Geriatric Nursing	Not addressing clinical/review question
Bowen A;Hesketh A;Patchick E;Young A;Davies L;Vail A;Long A;Watkins C;Wilkinson M;Pearl G;Ralph ML;Tyrrell P;on behalf of the ACT NoW investigators;	Clinical effectiveness, cost effectiveness and service users' perceptions of early, intensively resourced communication therapy following a stroke, a randomised controlled trial (The ACT NoW Study).	2011		Not addressing pre-specifeid intervention/outcomes
Lyon JG;Cariski D;Keisler L;Rosenbek J;Levine R;Kumpula J;Ryff C;Coyne S;Blanc	Communication partners: Enhancing participation in life and communication	1997	Aphasiology	Not addressing relevant intervention/outcomes

Author	Title	Year	Journal/full	Reason for Exclusion
M;	for adults with aphasia in natural settings			
Meinzer M; Djundja D; Barthel G; Elbert T; Rockstroh B;	Long-term stability of improved language functions in chronic aphasia after constraint-induced aphasia therapy	3853 4		not randomised controlled trial or systematic review
Marshall RC; Wertz RT; Weiss DG; Aten JL; Brookshire RH; Garcia-Bunuel L; Holland AL; Kurtzke JF; LaPointe LL; Milianti FJ;	Home treatment for aphasic patients by trained nonprofessionals	3272 1	Journal of Speech & Hearing Disorders	subset of patients in Wertz 1986 ID 880 so would be double counting to include again
Poock K; Huber W; Willmes K;	Outcome of intensive language treatment in aphasia	1989	Journal of Speech and Hearing Disorders	not randomised study
MacKenzie C;	Four weeks of intensive aphasia treatment and four weeks of no treatment	1991	Aphasiology	Not RCT
Oelschlaeger ML;	Participation of a conversation partner in the word searches of a person with aphasia	3619 2	American Journal of Speech-Language Pathology	not a comparison of more vs. less speech therapy
David R; Enderby P; Bainton D;	Treatment of acquired aphasia: speech therapists and volunteers compared	3025 6	Journal of Neurology, Neurosurgery & Psychiatry	not more vs. less intensive therapy
Bhogal SK; Teasell R; Speechley M;	Intensity of aphasia therapy, impact on recovery	2003		systematic review but included studies not comparing more vs. less intensive therapy
Meinzer M; Elbert T; Wienbruch C; Djundja D; Barthel G; Rockstroh B;	Intensive language training enhances brain plasticity in chronic aphasia	2004	Bmc Biology	not a comparison of more vs. less intensive therapy
Kagan A; Winckel	A Set of	3832		development of rating scales not

Author	Title	Year	Journamfull	Reason for Exclusion
J;Black S;Duchan JF;Simmons-Mackie N;Square P;	Observational Measures for Rating Support and Participation in Conversation between Adults with Aphasia and Their Conversation Partners	2		intensive vs. less intensive therapy
Brindley P;Copeland M;Demain C;Martyn PRU;	A comparison of the speech of ten chronic Broca's aphasics following intensive and non-intensive periods of therapy	1989	Aphasiology	not RCT
Hinckley JJ;Carr TH;	Comparing the outcomes of intensive and non-intensive context-based aphasia treatment	3865 7	Aphasiology	not random allocation
Meinzer M;Streiftau S;Rockstroh B;	Intensive language training in the rehabilitation of chronic aphasia: efficient training by laypersons	3932 6	Journal of the International Neuropsychological Society	not intensive vs. less intensive therapy
Archibald LMD;Orange JB;Jamieson DJ;	Implementation of computer-based language therapy in aphasia	2009	Therapeutic Advances in Neurological Disorders	not comparative study
Whurr R;Lorch MP;Nye C;	A meta-analysis of studies carried out between 1946 and 1988 concerned with the efficacy of speech and language therapy treatment for aphasic patients	1992	European Journal of Disorders of Communication	not SR; included studies not all RCTs; control condition not stated; number of patients not stated; ES only
van der Gaag A;Brooks R;	Economic aspects of a therapy and support service for people with long-term stroke and aphasia (Brief	2008		not RCT or SR

Author	Title	Year	Journal/full	Reason for Exclusion
	record)			
Sellars C;Hughes T;Langhorne P;	Speech and language therapy for dysarthria due to non-progressive brain damage. [Review] [40 refs][Update of Cochrane Database Syst Rev. 2002;(4):CD002088; PMID: 12519567]	2005	Cochrane Database of Systematic Reviews (3):CD002088, 2005	dysarthria not aphasia; review but no RCTs found to include
Basso A;	How intensive/prolonged should an intensive/prolonged treatment be?	2005	Aphasiology	narrative review not SR
Mark VW;Taub E;	Constraint-induced movement therapy for chronic stroke hemiparesis and other disabilities. [Review] [104 refs]	2004	Restorative Neurology & Neuroscience	wrong intervention: CIMT not speech therapy
Barthel G;Meinzer M;Djundja D;Rockstroh B;	Intensive language therapy in chronic aphasia: Which aspects contribute most?	2008	Aphasiology	not RCT ; compares MOAT vs CIAT
Cherney LR;Patterson JP;Raymer A;Frymark T;Schooling T;	Evidence-based systematic review: effects of intensity of treatment and constraint-induced language therapy for individuals with stroke-induced aphasia. [Review] [41 refs]	3972 2	Journal of Speech Language & Hearing Research	relevant studies ordered separately
Pulvermuller F;Neininger B;Elbert T;Mohr B;Rockstroh B;Koebbel P;Taub E;	Constraint-induced therapy of chronic aphasia after stroke	3707 3		comparing conventional therapy to constraint-induced therapy

M.11 What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?

Author	Title	Year	Journamfull	Reason for Exclusion
Kelly H;Brady MC;Enderby P;	Speech and language therapy for aphasia following stroke. [Review] [123 refs][Update of Cochrane Database Syst Rev. 2000;(2):CD000425; PMID: 10796360]	2010	Cochrane Database of Systematic Reviews	Did not match our protocol
Dembowski JS;	Available studies fail to disambiguate contributions of language modality constraint and treatment intensity to effects of constraint-induced language therapy	39965	Evidence-Based Communication Assessment and Intervention	Not matching our pre-specified population, intervention and comparison
Shewan CM;Kertesz A;	Effects of speech and language treatment on recovery from aphasia	1984	Brain and Language	Not a RCT
Croteau C;Le DG;Morin C;	The influence of aphasia severity on how both members of a couple participate in an interview situation	39630	Aphasiology	Descriptive study not RCT/SR
Hustad KC;Gearhart KJ;	Listener attitudes toward individuals with cerebral palsy who use speech supplementation strategies	2004		not a comparison of listener advice vs. other intervention
Genereux S;Julien M;Larfeuil	Using communication plans to facilitate	38322	Aphasiology	not listener advice

Author	Title	Year	Journamfull	Reason for Exclusion
C;Lavoie V;Soucy O;Le DG;	interactions with communication-impaired persons residing in long-term care institutions			
Croteau C;Vychytil A;Larfeuil C;Le DG;	'Speaking for' behaviours in spouses of people with aphasia: A descriptive study of six couples in an interview situation	38078	Aphasiology	descriptive study of "speaking for"
Purdy M;Hindenlang J;	Educating and training caregivers of persons with aphasia	38412	Aphasiology	not comparative study
Croteau C;Le DG;	Overprotection, 'speaking for', and conversational participation: A study of couples with aphasia	38749	Aphasiology	Descriptive study not RCT/SR
Oetting JB;Pruitt SL;Roy VP;	Community-based caregiver training: a rationale and model for early interventionists who work with low-income families	38961		not post-stroke aphasia
Bouchard-Lamothe D;Bourassa S;Laflamme B;Garcia LJ;Gailey G;Stiell K;	Perceptions of three groups of interlocutors of the effects of aphasia on communication: An exploratory study	1999	Aphasiology	qualitative study, not about information to carers
Draper B;Bowring G;Thompson C;Van HJ;Conroy P;Thompson J;	Stress in caregivers of aphasic stroke patients: a randomized controlled trial	39114		Intervention not listener advice but psychological support/coping skills for carer stress
Allard ER;Williams DF;	Listeners' perceptions of speech and language disorders	2008	Journal of Communication Disorders	descriptive ratings of speech samples not RCT
Turner S;Whitworth A;	Conversational partner training	38869	Aphasiology	Review of conversational partner training but no data

Author	Title	Year	Journamfull	Reason for Exclusion
	programmes in aphasia: A review of key themes and participants' roles			
Cunningham R;Ward C;	Evaluation of a training programme to facilitate conversation between people with aphasia and their partners	2003	Aphasiology	4 cases pre to post intervention not RCT
Croteau C;Le DG;Baril G;	Development of a procedure to evaluate the contributions of persons with aphasia and their spouses in an interview situation	3929 5	Aphasiology	descriptive study not RCT/SR
van der Gaag A;Smith L;Davis S;Moss B;Cornelius V;Laing S;Mowles C;	Therapy and support services for people with long-term stroke and aphasia and their relatives: A six-month follow-up study	3850 4		Not RCT; not only listener advice
Maher LM;Kendall D;Swearingin JA;Rodriguez A;Leon SA;Pingel K;Holland A;Rothi LJ;	A pilot study of use-dependent learning in the context of Constraint Induced Language Therapy	3902 2	Journal of the International Neuropsychological Society	Not RCT
Rayner H;Marshall J;	Training volunteers as conversation partners for people with aphasia	3771 2	International Journal of Language & Communication Disorders	Not RCT

M.12 In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing / others) versus usual care?

Author	Title	Year	Journamfull	Reason for Exclusion
Jongbloed L;Morgan D;	An investigation of involvement in	3335 9	American journal of	Not addressing clinical/review question. Not on intensity of occupational therapy

Author	Title	Year	Journal full	Reason for Exclusion
	leisure activities after a stroke		occupational therapy : official publication of the American Occupational Therapy Association	
Turton A;Fraser C;	The use of home therapy programmes for improving recovery of upper limb following stroke	1990	British Journal of Occupational Therapy	Not on intensity of occupational therapy
Sackley CM;Atkinson JC;Walker MF;	Occupational therapy in nursing and residential care settings: A description of a randomised controlled trial intervention	3804 7	British Journal of Occupational Therapy	Description of intervention development not comparison of intervention vs. control groups
Logan PA;Gladman JR;Drummond AE;Radford KA;TOTAL Study Group;	A study of interventions and related outcomes in a randomized controlled trial of occupational therapy and leisure therapy for community stroke patients	3774 2		Not looking at more versus less. Occupational therapy versus Leisure
Sackley CM;Burton CR;Herron-Marx S;Lett K;Mant J;Roalfe AK;Sharp LJ;Sheehan B;Stant KE;Walker MF;Watkins CL;Wheatley K;Williams J;Yao GL;Feltham MG;	A cluster randomised controlled trial of an occupational therapy intervention for residents with stroke living in UK care homes (OTCH): study protocol	2012	BMC Neurology	Study protocol
Walker MF;Leonardi-Bee J;Bath P;Langhorne P;Dewey M;Corr S;Drummond A;Gilbertson L;Gladman JR;Jongbloed	Individual patient data meta-analysis of randomized controlled trials of community occupational therapy for stroke patients	3823 1		relevant papers ordered separately

Author	Title	Year	Journamfull	Reason for Exclusion
L;Logan P;Parker C;				
Walker MF;Drummond AER;Lincoln NB;	Evaluation of dressing practice for stroke patients after discharge from hospital: a crossover design study	3509 6		n<20 in each group
Drummond A;Walker M;	Generalisation of the effects of leisure rehabilitation for stroke patients	3524 7	British Journal of Occupational Therapy	intervention not on activities of daily living
Legg L;Drummond A;Leonardi-Bee J;Gladman JR;Corr S;Donkervoort M;Edmans J;Gilbertson L;Jongbloed L;Logan P;Sackley C;Walker M;Langhorne P;	Occupational therapy for patients with problems in personal activities of daily living after stroke: systematic review of randomised trials. [Review] [13 refs]	3938 9		Review. Primary studies included

M.13 In people after stroke what is the clinical and cost effectiveness of intensive rehabilitation versus standard rehabilitation?

Author	Title	Year	Journamfull	Reason for Exclusion
Zhu XL;Poon WS;Chan CC;Chan SS;	Does intensive rehabilitation improve the functional outcome of patients with traumatic brain injury (TBI)? A randomized controlled trial	3923 4		Not our population
Kwakkel G;	Impact of intensity of practice after stroke: issues for consideration. [Review] [58 refs]	3891 3	Disability & Rehabilitation	Review - debate paper
Outermans JC;Peppen	Effects of a high-intensity task-	4048 3		Does not address any of the outcomes in the protocol

Author	Title	Year	Journal/full	Reason for Exclusion
RPv;Wittink H;Takken T;Kwakkel G;	oriented training on gait performance early after stroke: a pilot study			
Rodgers H;Mackintosh J;Price C;Wood R;McNamee P;Fearon T;Marritt A;Curless R;	Does an early increased-intensity interdisciplinary upper limb therapy programme following acute stroke improve outcome?	2003		Movement specific rehabilitation
Kwakkel G;Wagenaar RC;Koelman TW;Lankhorst GJ;Koetsier JC;	Effects of intensity of rehabilitation after stroke. A research synthesis	3564 3		Systematic review which includes studies on people with acute stroke (i.e. < 2wks post stroke)
Combs SA;Kelly SP;Barton R;lvaska M;Nowak K;	Effects of an intensive, task-specific rehabilitation program for individuals with chronic stroke: a case series	2010	Disability & Rehabilitation	case series with n<20
Langhammer B;Stanghelle JK;Lindmark B;	Exercise and health-related quality of life during the first year following acute stroke. A randomized controlled trial	3947 9		Focused on exercise and training and not multidisciplinary
Aziz NA;Leonardi-Bee J;Phillips M;Gladman JR;Legg L;Walker MF;	Therapy-based rehabilitation services for patients living at home more than one year after stroke	2008	Cochrane Database of Systematic Reviews	Cochrane collaboration. Primary studies sourced
Di Lauro;Pellegrino L;Savastano G;Ferraro C;Fusco M;Balzarano F;Franco MM;Biancardi LG;Grasso A;	A randomized trial on the efficacy of intensive rehabilitation in the acute phase of ischemic stroke	3789 5	Journal of Neurology	Not the representation of the population being addressed
Shiel A;Burn	The effects of	3716		Population with acquired brain injury

Author	Title	Year	Journal/full	Reason for Exclusion
JP;Henry D;Clark J;Wilson BA;Burnett ME;McLellan DL;	increased rehabilitation therapy after brain injury: results of a prospective controlled trial	5		(not due to stroke)
Outpatient Service Trialists;	Therapy-based rehabilitation services for stroke patients at home	2003	Cochrane Database of Systematic Reviews	Cochrane collaboration. Primary studies included
Langhammer B;Lindmark B;Stanghelle JK;	Stroke patients and long-term training: Is it worthwhile? A randomized comparison of two different training strategies after rehabilitation	3923 4		Strength training after rehabilitation
Kwakkel G;Wagenaar RC;Twisk JW;Lankhorst GJ;Koetsier JC;	Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial	3635 8		Movement specific rehabilitation
Blackerby WF;	Intensity of rehabilitation and length of stay	1990		Not a randomised control trial. Study on brain injury
Kirk-Sanchez N;Eide-Corazon N;Rodriguez M;	Relationship between intensity of physical and occupational therapy intervention in an inpatient rehabilitation program and mobility at discharge in patients with cerebrovascular accident	3792 6	Journal of Geriatric Physical Therapy	Review on cerebrovascular accident
Ouellette MM;LeBrasseur NK;Bean JF;Phillips E;Stein J;Frontera WR;Fielding RA;	High-intensity resistance training improves muscle strength, self-reported function, and disability in long-term stroke survivors	3813 9		Resistance training not intensive rehabilitation

Author	Title	Year	Journamfull	Reason for Exclusion
Mulders AHM;de Witte LP;Diederiks JPM;	Evaluation of a rehabilitation after-care programme for stroke patients	1989	Journal of Rehabilitation Sciences	Experimental study. Not addressing recommended outcomes and not randomised
Sheikh K;Meade TW;Brennan PJ;Goldenberg E;Smith DS;	Intensive rehabilitation after stroke: service implications	1981		Not an RCT. Medical record data used.
Slade A;Tennant A;Chamberlain MA;	A randomised controlled trial to determine the effect of intensity of therapy upon length of stay in a neurological rehabilitation setting	2002	Journal of rehabilitation medicine : official journal of the UEMS European Board of Physical and Rehabilitation Medicine	Mixed population. Stroke <50%
Wang DS;Lu YY;Xie RM;Yao JR;	Effect of different intensities of rehabilitation therapy on the prognosis of patients with stroke	2004	Chinese Journal of Clinical Rehabilitation	Study not in English language
Xiao W;Wang J;Luo Z;Xie R;	The economic health evaluation to the early intensive rehabilitation on patients with stroke	2003	Chinese Journal of Clinical Rehabilitation	Study not in English language
Hellweg S;Johannes S;	Physiotherapy after traumatic brain injury: a systematic review of the literature. [Review] [21 refs]	3956 9		Literature eview on traumatic brain injury
Lincoln NB;Parry RH;Vass CD;	Randomized, controlled trial to evaluate increased intensity of physiotherapy treatment of arm function after stroke	1999	Stroke; a journal of cerebral circulation	Movement specific rehabilitation
Sivenius J;Pyorala K;Heinonen OP;Salonen JT;Riekkinen P;	The significance of intensity of rehabilitation of stroke--a controlled trial	3135 2		Not multidisciplinary
Green J;Forster	Physiotherapy for	3727		not multidisciplinary and not addressing

Author	Title	Year	Journamfull	Reason for Exclusion
A;Bogle S;Young J;	patients with mobility problems more than 1 year after stroke: a randomised controlled trial	5		relevant outcomes
Wade DT;Collen FM;Robb GF;Warlow CP;	Physiotherapy intervention late after stroke and mobility	1992		not multidisciplinary and not addressing relevant outcomes
Kwakkel G;Kollen BJ;Wagenaar RC;	Long term effects of intensity of upper and lower limb training after stroke: a randomised trial	2002		Movement specific rehabilitation

M.14 In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?

Author	Title	Year	Journamfull	Reason for Exclusion
Ytterberg C;Thorsen AM;Liljedahl M;Holmqvist LW;von KL;	Changes in perceived health between one and five years after stroke: a randomized controlled trial of early supported discharge with continued rehabilitation at home versus conventional rehabilitation	4037 4	Journal of the Neurological Sciences	Not included our outcomes
Thorsen AM;Holmqvist LW;de Pedro-Cuesta J;von KL;	A randomized controlled trial of early supported discharge and continued rehabilitation at home after stroke: five-year follow-up of patient outcome	3838 4		5 year follow-up
Rudd AG;	Correction: Randomised controlled trial	1998	British Medical Journal	Correction of previous paper

Author	Title	Year	Journamfull	Reason for Exclusion
	to evaluate early discharge scheme for patients with stroke (British Medical Journal (1997) 25 October (1039-1044))			
Shepperd S;Doll H;Broad J;Gladman J;Iliffe S;Langhorne P;Richards S;Martin F;Harris R;	Early discharge hospital at home. [Review] [77 refs][Update of Cochrane Database Syst Rev. 2005;(3):CD000356; PMID: 16034853]	2009	Cochrane Database of Systematic Reviews	Primary studies included
Labarere J;Belle L;Fourny M;Genes N;Lablanche JM;Blanchard D;Cambou JP;Danchin N;Unite de Soins Intensifs Coronaires;	Outcomes of myocardial infarction in hospitals with percutaneous coronary intervention facilities	3921 6	Archives of Internal Medicine	Myocardial Infarction in hospitals
Askim T;Morkved S;Indredavik B;	Does an extended stroke unit service with early supported discharge have any effect on balance or walking speed?	2006		Not looking at relevant outcomes
Grasel E;Biehler J;Schmidt R;Schupp W;	Intensification of the transition between inpatient neurological rehabilitation and home care of stroke patients. Controlled clinical trial with follow-up assessment six months after discharge	3862 6		Personality traits of clients with Parkinson's disease
Vermeer F;Bosl I;Meyer J;Bar F;Charbonnier	Saruplase is a safe and effective	3637 3	Journal of Thrombosis & Thrombolysis	Review on thrombolytic agent

Author	Title	Year	Journamfull	Reason for Exclusion
B;Windeler J;Barth H;	thrombolytic agent; observations in 1,698 patients: results of the PASS study. Practical Applications of Saruplase Study			
Widen HL;von KL;Kostulas V;Holm M;Widsell G;Tegler H;Johansson K;Almazan J;de Pedro-Cuesta J;	A randomized controlled trial of rehabilitation at home after stroke in southwest Stockholm	3585 5		6-month follow-up of the same study was used instead
Wade DT;Langton-Hewer R;Skilbeck CE;Bainton D;Burns-Cox C;	Controlled trial of a home-care service for acute stroke patients	3108 7		Study on home service not on early supported discharge
Winkel A;Ekdahl C;Gard G;	Early discharge to therapy-based rehabilitation at home in patients with stroke: a systematic review	3960 0		primary studies included
Stead LG;Vaidyanathan L;	Evidence-based emergency medicine/systematic review abstract. Role of early supported discharge in acute stroke patients	3920 3	Annals of Emergency Medicine	Review abstract on role of early supported discharge
Rousseaux M;Daveluy W;Kozlowski R;	Value and efficacy of early supported discharge from stroke units. [Review] [34 refs]	3990 4	Annals of Physical & Rehabilitation Medicine	Review of included studies
Thorsen AM;Widen HL;von KL;	Early supported discharge and continued rehabilitation at home after stroke: 5-year follow-up of resource use	3889 9	Journal of Stroke & Cerebrovascular Diseases	Exploring resource cost

Author	Title	Year	Journamfull	Reason for Exclusion
Larsen T;Olsen TS;Sorensen J;	Early home-supported discharge of stroke patients: a health technology assessment	2006		Health Tech. Assessment
Fjaertoft H;Indredavik B;Magnussen J;Johnsen R;	Early supported discharge for stroke patients improves clinical outcome. Does it also reduce use of health services and costs? One-year follow-up of a randomized controlled trial	2005	Cerebrovascular Diseases	Health Economics
Ronning OM;Guldvog B;	Outcome of subacute stroke rehabilitation: a randomized controlled trial	35886		Study on outcome of subacute stroke not on early supported discharge.
Suwanwela NC;Phanthumchinda K;Limtongkul S;Suvanprakorn P;	Comparison of short (3-day) hospitalization followed by home care treatment and conventional (10-day) hospitalization for acute ischemic stroke	2002		Not addressing relevant outcomes
Langhorne P;Taylor G;Murray G;Dennis M;Anderson C;Bautz-Holter E;Dey P;Indredavik B;Mayo N;Power M;Rodgers H;Ronning OM;Rudd A;Suwanwela N;Widen-Holmqvist L;Wolfe C;	Early supported discharge services for stroke patients: a meta-analysis of individual patients' data	38388		Not looking at relevant outcome. Study on cost and resources
Weir RP;	Rehabilitation of cerebrovascular disorder	1999		Health Economics

Author	Title	Year	Journamfull	Reason for Exclusion
	(stroke): early discharge and support: a critical appraisal of the literature			
Anderson C;Ni MC;Brown PM;Carter K;	Stroke rehabilitation services to accelerate hospital discharge and provide home-based care: an overview and cost analysis	2002		study on cost effectiveness
Caro JJ;Huybrechts KF;	Stroke treatment economic model (STEM): predicting long-term costs from functional status	1999		Economic model on stroke
Early Supported Discharge Trialists;	Services for reducing duration of hospital care for acute stroke patients	2005	Cochrane Database of Systematic Reviews	Cochrane review: relevant primary studies included
Askim T;Morkved S;Engen A;Roos K;Aas T;Indredavik B;	Effects of a community-based intensive motor training program combined with early supported discharge after treatment in a comprehensive stroke unit: a randomized, controlled trial	2010		5 year follow-up of a community based service
Chaiyawat P;Kulkantrakorn K;	Effectiveness of home rehabilitation program for ischemic stroke upon disability and quality of life: a randomized controlled trial	2012	Clinical neurology and neurosurgery	Control group not usual care (early home rehabilitation vs. home rehabilitation)
Bai Y;Hu Y;Wu Y;Zhu Y;He Q;Jiang C;Sun	A prospective, randomized, single-blinded	2012		Acute stroke participants (<2 wks post stroke)

Author	Title	Year	Journamfull	Reason for Exclusion
L;Fan W;	trial on the effect of early rehabilitation on daily activities and motor function of patients with hemorrhagic stroke			

M.15 In people after stroke what is the clinical and cost-effectiveness of Functional Electrical Stimulation for hand function versus usual care?

Author	Title	Year	Journamfull	Reason for Exclusion
de Kroon JR;ljzerman MJ;Chae J;Lankhorst GJ;Zilvold G;	Relation between stimulation characteristics and clinical outcome in studies using electrical stimulation to improve motor control of the upper extremity in stroke	3841 2		Relevant primary studies included
Pomeroy VM;King L;Pollock A;Baily-Hallam A;Langhorne P;	Electrostimulation for promoting recovery of movement or functional ability after stroke	2006	Cochrane Database of Systematic Reviews	Relevant primary studies included
de Kroon JR;van der Lee JH;ljzerman MJ;Lankhorst G;	Therapeutic electrical stimulation to improve motor control and functional abilities of the upper extremity after stroke: a systematic review	3740 8		Relevant primary studies included
Chae J;Yu D;	A critical review of neuromuscular electrical stimulation for treatment of motor dysfunction in hemiplegia	2000		Review: Relevant primary studies included

Author	Title	Year	Journal/full	Reason for Exclusion
Kraft GH;Fitts SS;Hammond MC;	Techniques to improve function of the arm and hand in chronic hemiplegia	3366 4		Not addressing pre-specified intervention
Wilkinson I;Strike P;Burridge J;Taylor P;	Feasibility of combining physiotherapy and electrical stimulation to improve gait in patients less than 6 months post stroke	2011	International Journal of Stroke	Abstract
Sabut SK;Sikdar C;Kumar R;Mahadevappa M;	Functional electrical stimulation of dorsiflexor muscle: effects on dorsiflexor strength, plantarflexor spasticity, and motor recovery in stroke patients	2011	Neurorehabilitation	Not RCT
Tarkka IM;Pitkanen K;Popovic DB;Vanninen R;Kononen M;	Functional electrical therapy for hemiparesis alleviates disability and enhances neuroplasticity	2011	Tohoku journal of experimental medicine	Not addressing review question
Ring H;Rosenthal N;	Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation	3835 3		Not relevant trial design
Celnik P;Hummel F;Harris-Love M;Wolk R;Cohen LG;	Somatosensory stimulation enhances the effects of training functional hand tasks in patients with chronic stroke	3938 7	Archives of Physical Medicine & Rehabilitation	not motor stimulation - only paraesthesia
Bello AI;Rockson BE;Olaogun MO;	The effects of electromyographic-triggered neuromuscular electrical muscle	2009	African Journal of Medicine & Medical Sciences	not randomised

Author	Title	Year	Journal/full	Reason for Exclusion
	stimulation on the functional hand recovery among stroke survivors			
Klaiput A; Kitisomprayoonkul W;	Increased pinch strength in acute and subacute stroke patients after simultaneous median and ulnar sensory stimulation	3993 4	Neurorehabilitation & Neural Repair	Not addressing pre-specified intervention
Alon G;	Defining and measuring residual deficits of the upper extremity following stroke: a new perspective	2009		Protocol
Hummelsheim H; Amberger S; Mauritz KH;	The influence of EMG-initiated electrical muscle stimulation on motor recovery of the centrally paretic hand	1996		not a RCT
Malaysian Health Technology Assessment Unit;	Electrical stimulation in Stroke (Structured abstract)	2006		Health Technology assessment for shoulder subluxation and pain
Berner YN; Lif KO; Spokoiny V; Finkeltov B;	The effect of electric stimulation treatment on the functional rehabilitation of acute geriatric patients with stroke--a preliminary study	2004	Archives of Gerontology & Geriatrics	Not RCT
Cauraugh JH; Kim SB;	Stroke motor recovery: active neuromuscular stimulation and repetitive practice schedules	3792 6	Journal of Neurology, Neurosurgery & Psychiatry	Wrong intervention: repetitive practice schedules
Celnik P; Hummel F; Harris-Love M; Cohen LG;	Motor learning in chronic stroke patients can be enhanced by peripheral nerve stimulation (PNS)	3868 7	Neurorehabilitation & Neural Repair	Abstract only

Author	Title	Year	Journal full	Reason for Exclusion
Binder-Macleod SA;Lee SCK;	Assessment of the efficacy of functional electrical stimulation in patients with hemiplegia	1997		Clinical review
Jiang ZH;Yin SY;Bi N;He X;Qu F;	Early application of percutaneous neuromuscular electric stimulation in interfering motor function of limbs and difference in temperature of axilla of patients with ischemic stroke	2006	Neural Regeneration Research	Not addressing pre-specified intervention
Conforto AB;Kaelin-Lang A;Cohen LG;	Increase in hand muscle strength of stroke patients after somatosensory stimulation	3725 7	Annals of Neurology	Effect of median nerve stimulation on pinch strength
Celnik P;Paik NJ;Vandermeeren Y;Dimyan M;Cohen LG;	Effects of combined peripheral nerve stimulation and brain polarization on performance of a motor sequence task after chronic stroke	3993 4		peripheral nerve stimulation with anodal direct current stimulation
Hara Y;	Neurorehabilitation with new functional electrical stimulation for hemiparetic upper extremity in stroke patients. [Review] [36 refs]	3947 9	Journal of Nippon Medical School = Nihon Ika Daigaku Zasshi	Review on neuro-rehabilitation
Santos M;Zahner LH;McKiernan BJ;Mahnken JD;Quaney B;	Neuromuscular electrical stimulation improves severe hand dysfunction for individuals with chronic stroke: a pilot study	3905 2	Journal of Neurologic Physical Therapy	Not addressing pre-specified intervention
Conforto	Effects of	3914	Journal of	somatosensory stimulation on motor

Author	Title	Year	Journal/full	Reason for Exclusion
AB;Cohen LG;dos Santos RL;Scaff M;Marie SK;	somatosensory stimulation on motor function in chronic cortico-subcortical strokes	2	Neurology	function
Francisco G;Chae J;Chawla H;Kirshblum S;Zorowitz R;Lewis G;Pang S;	Electromyogram-triggered neuromuscular stimulation for improving the arm function of acute stroke survivors: a randomized pilot study	35916	Archives of Physical Medicine & Rehabilitation	Neuromuscular stimulation for improving the arm function of acute stroke survivors
Kwakkel G;Meskers CG;van Wegen EE;Lankhorst GJ;Geurts AC;van Kuijk AA;Lindeman E;Visser-Meily A;de VE;Arendzen JH;	Impact of early applied upper limb stimulation: the EXPLICIT-stroke programme design	2008	BMC Neurology	Not addressing clinical/review question
Daly JJ;Zimbelman J;Roenigk KL;McCabe JP;Rogers JM;Butler K;Burdall R;Holcomb JP;Marsolais EB;Ruff RL;	Recovery of coordinated gait: randomized controlled stroke trial of functional electrical stimulation (FES) versus no FES, with weight-supported treadmill and over-ground training	2011	Neurorehabilitation and Neural Repair	Not addressing clinical question: FES not for upper limb
Sheffler LR;Chae J;	Neuromuscular electrical stimulation in neurorehabilitation	39203		Narrative review on neurorehabilitation
Bolton DA;Cauraugh JH;Hausenblas HA;	Electromyogram-triggered neuromuscular stimulation and stroke motor recovery of arm/hand functions: a meta-analysis	22004	Journal of the Neurological Sciences	meta-analysis: recovery of arm/hand functions. Primary studies added
Wang RY;Yang	Effects of	3734		Not addressing clinical/review question

Author	Title	Year	Journal/full	Reason for Exclusion
YR;Tsai MW;Wang WT;Chan RC;	functional electric stimulation on upper limb motor function and shoulder range of motion in hemiplegic patients	7		
Alon G;Ring H;	Gait and hand function enhancement following training with a multi-segment hybrid-orthosis stimulation system in stroke patients	2003	Journal of Stroke & Cerebrovascular Diseases	Not RCT
Eldercamp C;	To determine whether functional electrical stimulation has the potential to be used as a treatment for somatosensory loss in the upper limb post stroke	3938 5	Disability & Rehabilitation	Not RCT
Daly JJ;Hogan N;Perepezko EM;Krebs HI;Rogers JM;Goyal KS;Dohring ME;Fredrickson E;Nethery J;Ruff RL;	Response to upper-limb robotics and functional neuromuscular stimulation following stroke	3865 7	Journal of Rehabilitation Research & Development	Robotics and motor learning
Bowman BR;Baker LL;Waters RL;	Positional feedback and electrical stimulation: an automated treatment for the hemiplegic wrist	1979	Archives of Physical Medicine & Rehabilitation	Positional feed back stimulation training for wrist extension
Bhatt E;Nagpal A;Greer KH;Grunewald TK;Steele JL;Wiemiller JW;Lewis SM;Carey JR;	Effect of finger tracking combined with electrical stimulation on brain reorganization and hand function in subjects with stroke	2007	Experimental Brain Research	finger tracking combined with electrical stimulation

Author	Title	Year	Journamfull	Reason for Exclusion
Aoyagi Y;Tsubahara A;	Therapeutic orthosis and electrical stimulation for upper extremity hemiplegia after stroke: a review of effectiveness based on evidence. [Review] [55 refs]	2004		Systematic review including orthosis and electrical stimulation
Chae J;Sheffler L;Knutson J;	Neuromuscular electrical stimulation for motor restoration in hemiplegia	3969 2		Narrative review on NMES for upper and lower limb
O'Dell MW;Dunning K;McBride K;	Functional ambulation: Standard treatment versus electrical stimulation therapy (fastest) trial: Early data	2012	Neurorehabilitation and Neural Repair	Abstract
Potenza A;Faraoni B;Nesi B;Giachi R;Taviani A;	Foot drop in cerebral stroke: A comparison between the use of functional electrical stimulation and conventional physiotherapy	2012	Gait and Posture	Abstract
Knutson JS;Harley MY;Hisel TZ;Hogan SD;Maloney MM;Chae J;	Contralaterally controlled functional electrical stimulation for upper extremity hemiplegia: an early-phase randomized clinical trial in subacute stroke patients	2012	Neurorehabilitation and Neural Repair	No usual care control group
Khan R;Kurupath R;	Theta burst stimulation (TBS) and functional electrical stimulation (FES) in post-stroke motor rehabilitation: A randomised	2012	Neurorehabilitation and Neural Repair	Abstract

Author	Title	Year	Journamfull	Reason for Exclusion
	control trial			

M.16 In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?

Author	Title	Year	Journamfull	Reason for Exclusion
Gottlieb DD;Miesner N;	Innovative concepts in hemianopsia and complex visual loss -- low vision rehabilitation for our older population	38169	Topics in Geriatric Rehabilitation	Not addressing clinical question/ not RCT
Pollock A;Hazelton C;Henderson CA;Angilley J;Dhillon B;Langhorne P;Livingstone K;Munro FA;Orr H;Rowe FJ;Shahani U;	Interventions for visual field defects in patients with stroke	2011	Cochrane Database of Systematic Reviews	Primary studies addressing our protocol included in the review
Pollock A;Hazelton C;	Stroke and visual problems: A comprehensive set of Cochrane reviews to investigate effective interventions	2011	International Journal of Stroke	Abstract
Falke P;Abela BM;Krakau CE;Lilja B;Lindgarde F;Maly P;Stavenow L;	High frequency of asymptomatic visual field defects in subjects with transient ischaemic attacks or minor strokes	33390	J Intern Med	Not RCT
Kalra L;Perez I;Gupta S;Wittink M;	The influence of visual neglect on stroke rehabilitation	35612		not addressing clinical/review question
Pollock A;Hazelton C;Henderson CA;Angilley J;Dhillon B;Langhorne P;Livingstone	Interventions for disorders of eye movement in patients with stroke	2011	Cochrane Database of Systematic Reviews	Not addressing review question

Author	Title	Year	Journamfull	Reason for Exclusion
K;Munro FA;Orr H;Rowe FJ;Shahani U;				
Zeloni G;Farne A;Baccini M;	Viewing less to see better	37469		Not addressing clinical question
Zihl J;	Eye movement patterns in hemianopic dyslexia	34912	Brain	Not RCT
Keller I;Lefin-Rank G;	Improvement of visual search after audiovisual exploration training in hemianopic patients	2010	Neurorehabilitation and Neural Repair	Comparison group was not the usual care (as specified in the protocol)
Weinberg J;Diller L;Gordon WA;Gerstman LJ;Lieberman A;Lakin P;Hodges G;Ezrachi O;	Visual scanning training effect on reading-related tasks in acquired right brain damage	28430		Post hoc subgroup analysis in severe and mild groups, not prespecified in our protocol
Bonan I;Yelnik A;Colle F;Guichard JP;Vicaut E;Eisenfisz M;	Effectiveness of a balance rehabilitation programme with visual cue deprivation after stroke: a randomized controlled trial	2002		Abstract
Hofferberth B;	Results of saccadic eye movement training in stroke patients	1998		Not in English language
Perez L;Wittink M;Kalra L;	Visuospatial dysfunction and stroke rehabilitation	1997	Cerebrovascular Diseases	Abstract
Os van DES;	Visual scanning training in stroke patients	1991		Not available in British library
Gbadamosi J;Zangemeister WH;	Visual imagery in hemianopic patients	37165	Journal of Cognitive Neuroscience	Review: Discussion on visual imagery
Hofferberth B;	Training of saccadic eye movements in patients with unilateral stroke	1996		Abstract
Riggs RV;Andrews	Visual deficit interventions in	2007	American Journal of	Did not address specified interventions

Author	Title	Year	Journal	Reason for Exclusion
K;Roberts P;Gilewski M;	adult stroke and brain injury: A systematic review		Physical Medicine and Rehabilitation	
Pambakian ALM;Wooding DS;Patel N;Morland AB;Kennard C;Mannan SK;	Scanning the visual world: a study of patients with homonymous hemianopia	3686 1	Journal of Neurology, Neurosurgery and Psychiatry	population does not include stroke patients
Bailey MJ;Riddoch MJ;Crome P;	Treatment of visual neglect in elderly patients with stroke: a single-subject series using either a scanning and cueing strategy or a left-limb activation strategy	2002	Physical Therapy	Treating visual neglect: not addressing clinical question
Pizzamiglio L;Fasotti L;Jehkonen M;Antonucci G;Magnotti L;Boelen D;Asa S;	The use of optokinetic stimulation in rehabilitation of the hemineglect disorder	3813 9	Cortex	Rehabilitation of the hemineglect disorder. Non-stroke patients
Schofield TM;Leff AP;	Rehabilitation of hemianopia	3984 5	Current Opinion in Neurology	Narrative review on rehabilitation of hemianopia
Fanthome Y;Lincoln NB;	Eye movements in patients with visual neglect following right hemisphere stroke	3500 4		Prism therapy
Lane AR;Smith DT;Ellison A;Schenk T;	Visual exploration training is no better than attention training for treating hemianopia	4033 0	Brain	visual exploration training versus attention training
Cassidy TP;Bruce DW;Lewis S;Gray CS;	The association of visual field deficits and visuo-spatial neglect in acute right-hemisphere stroke patients	1999	Age & Ageing	study on visual neglect. Not addressing clinical question
Sabel BA;Kasten E;	Restoration of vision in persons with brain injury	3686 1		Narrative review on restoration of vision in persons with brain injury
Weinberg J;Diller L;Gordon	Training sensory awareness and	2916 0	Archives of Physical	Post hoc subgroup analysis in severe and mild groups, not prespecified in our

Author	Title	Year	Journamfull	Reason for Exclusion
WA;Gerstman LJ;Lieberman A;Lakin P;Hodges G;Ezrachi O;	spatial organization in people with right brain damage		Medicine & Rehabilitation	protocol
Taylor L;Poland F;Harrison P;Stephenson R;	A quasi-experimental feasibility study to determine the effect of a systematic treatment programme on the scores of the Nottingham Adjustment Scale of individuals with visual field deficits following stroke	4054 4		Not RCT
Pollock A;Hazelton C;Henderson CA;Angilley J;Dhillon B;Langhorne P;Livingstone K;Munro FA;Orr H;Rowe FJ;Shahani U;	Interventions for disorders of eye movement in patients with stroke	2010	Cochrane Database of Systematic Reviews	Protocol for a review
Kerkhoff G;Munssinger U;Haaf E;Eberle-strauss G;Stogerer E;	Rehabilitation of homonymous scotomata in patients with postgeniculate damage of the visual system: Saccadic compensation training	1992	Restorative Neurology and Neuroscience	Not RCT
Kerkhoff G;Müller-Hilfinger U;Eberle-strauss G;Stögerer E;	Rehabilitation of hemianopic alexia in patients with postgeniculate visual field disorders	1992		Not RCT
Mannan SK;Pambakian AL;Kennard C;	Compensatory strategies following visual search training in patients with homonymous hemianopia: an eye movement study	4048 3	J Neurol	Not RCT

Author	Title	Year	Journal full	Reason for Exclusion
Roth T; Sokolov AN; Messias A; Roth P; Weller M; Trauzettel-Klosinski S;	Comparing explorative saccade and flicker training in hemianopia: a randomized controlled study	39840		Not specified intervention and comparison
Julkunen L; Tenovu O; Jaaskelainen S; Hamalainen H;	Rehabilitation of chronic post-stroke visual field defect with computer-assisted training: a clinical and neurophysiological study	2003	Restorative Neurology and Neuroscience	Not RCT
Simola JM; Kojo IV;	Eye movements during directed visual search: The effects of background versus target-distractor confusability	2003	Journal of Vision	Abstract
Lotery AJ; Wiggam MI; Jackson AJ; Refson K; Fullerton KJ; Gilmore DH; Beringer TR;	Correctable visual impairment in stroke rehabilitation patients	36647		Correcting reduced visual acuity
Pambakian ALM; Currie J; Kennard C;	Rehabilitation strategies for patients with homonymous visual field defects	2005	Journal of Neuro-Ophthalmology	Narrative review on homonymous visual field defects
Hofferberth B;	Results from training saccadic eye movements in stroke patients	1995		Not in English language
Gray CS; French JM; Bates D; Cartlidge NE; Venables GS; James OF;	Recovery of visual fields in acute stroke: homonymous hemianopia associated with adverse prognosis	32813		Not relevant intervention: spontaneous recovery of visual field loss
Pambakian ALM; Mannan SK; Hodgson TL; Kennard C;	Saccadic visual search training: A treatment for patients with homonymous hemianopia	2004	Journal of Neurology, Neurosurgery and Psychiatry	population does not include stroke patients

Author	Title	Year	Journamfull	Reason for Exclusion
Jones SA;Shinton RA;	Improving outcome in stroke patients with visual problems	3902 2	Age Ageing	Literature review on improving visual problems in stroke
Reinhard J;Schreiber A;Schiefer U;Kasten E;Sabel BA;Kenkel S;Vonthein R;Trauzettel-Klosinski S;	Does visual restitution training change absolute homonymous visual field defects? A fundus controlled study	3835 3	British Journal of Ophthalmology	Not RCT
Kerkhoff G;Munssinger U;Meier EK;	Neurovisual rehabilitation in cerebral blindness	3445 5	Archives of Neurology	Not RCT/ Not addressing clinical question
Zihl J;	Visual scanning behavior in patients with homonymous hemianopia	3475 9	Neuropsychologia	Not RCT
Keller I;Lefin-Rank G;Losch J;Kerkhoff G;	Combination of pursuit eye movement training with prism adaptation and arm movements in neglect therapy: A pilot study	2009	Neurorehabilitation and Neural Repair	Not RCT
Jamara RJ;Van de V;Peli E;	Scanning eye movements in homonymous hemianopia documented by scanning laser ophthalmoscope retinal perimetry	3780 3	Optometry and Vision Science	Case series: on benefits scanning laser ophthalmoscopy

M.17 In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?

Author	Title	Year	Journamfull	Reason for Exclusion
Tyson SF;Kent RM;	The effect of upper limb orthotics after stroke: A systematic review	2011	Neurorehabilitation	Primary study addressing our protocol included in the review
Lannin NA;Herbert RD;	Is hand splinting effective for	2003		Not matching our protocol

Author	Title	Year	Journal/full	Reason for Exclusion
	adults following stroke? A systematic review and methodologic critique of published research			
Lai JM;Francisco GE;Willis FB;	Dynamic splinting after treatment with botulinum toxin type-A: a randomized controlled pilot study	1984 5	Advances in Therapy	Outcomes in the study do not match with our prespecified in the protocol
Rose V;Shah S;	A comparative study on the immediate effects of hand orthoses on reduction of hypertonus	1987	Australian Occupational Therapy Journal	Inappropriate intervention
B ³ rge E;Kupper D;Finckh A;Ryerson S;Schnider A;Leemann B;	Neutral functional realignment orthosis prevents hand pain in patients with subacute stroke: a randomized trial	2008		Outcomes in the study do not match with our prespecified outcomes in our protocol
Poole JL;Whitney SL;Hangeland N;Baker C;	The effectiveness of inflatable pressure splints on motor function in stroke patients	1990	Occupational Therapy Journal of Research	Motor function was not measured in degrees as it was specified in our protocol
Foongchomcheay A;Adal L;Canning CG;	Use of devices to prevent subluxation of the shoulder after stroke	2005	Physiotherapy Research International	Preventing shoulder subluxation after stroke
Hanger HC;Whitwood P;Brown G;Ball MC;Harper J;Cox R;Sainsbury R;	A randomized controlled trial of strapping to prevent post-stroke shoulder pain	1973 9		Study on shoulder strapping to reduce pain
Poole JL;Whitney SL;	Inflatable pressure splints (Airsplints) as adjunct treatment for individuals with strokes	1992	Physical and Occupational Therapy in Geriatrics	Discussion on Airsplints
Hijmans JM;Postema K;Geertzen JH;	Elbow orthoses: a review of literature (Structured abstract)	2004	Prosthetics and Orthotics International	Literature review

Author	Title	Year	Journamfull	Reason for Exclusion
Kent RM;Robertson AJ;Tennant A;	Optimising botulinum toxin (BTX-A) treatment of upper limb spasticity in stroke using orthotics and physiotherapy: a randomized controlled trial	2006	Neurorehabilitation and Neural Repair	Abstract
Robertson AJ;Kent RM;Tennant A;	A randomized controlled trial of orthotics and physiotherapy among those treated with botulinum toxin (BtxA) for upper limb spasticity in stroke	2008		Conference Abstract
Gracies JM;Marosszeky JE;Renton R;Sandanam J;Gandevia SC;Burke D;	Short-term effects of dynamic lycra splints on upper limb in hemiplegic patients	3686 1	Archives of Physical Medicine & Rehabilitation	Not RCT
Liao WW;Wu Cy;Hsieh YW;Lin Kc;Chang WY;	Effects of robot-assisted upper limb rehabilitation on daily function and real-world arm activity in patients with chronic stroke: a randomized controlled trial	2012		Intervention not specified in the protocol
Hartwig M;Gelbrich G;Griewing B;	Functional orthosis in shoulder joint subluxation after ischaemic brain stroke to avoid post-hemiplegic shoulder-hand syndrome: a randomized clinical trial	2012		Shoulder orthosis not included in protocol

M.18 In people after stroke what is the clinical and cost-effectiveness of ankle/foot orthoses of all types to improve walking function versus usual care?

Author	Title	Year	Journamfull	Reason for Exclusion
Pomeroy VM;Rowe P;Baron JC;Clark A;Sealy R;Ugbolue UC;Kerr A;SWIFT C;	The SWIFT Cast trial protocol: a randomized controlled evaluation of the efficacy of an ankle-foot cast on walking recovery early after stroke and the neural-biomechanical correlates of response	2012	International Journal of Stroke	Protocol: not an experimental study
Mehrholz J;	The influence of a functional orthosis on walking and standing in patients with hemiparesis	2001	Zeitschrift fur Physiotherapeuten	Not in English language
Mills K;Blanch P;Chapman AR;McPoil TG;Vicenzino B;	Foot orthoses and gait: a systematic review and meta-analysis of literature pertaining to potential mechanisms	40340		Not matching our protocol
Leung J;Moseley A;	Impact of ankle-foot orthoses on gait and leg muscle activity in adults with hemiplegia: systematic literature review	2003	Physiotherapy	Ankle foot orthosis on gait and muscle activity: relevant studies included
Baricich A;Carda S;Bertoni M;Maderna L;Cisari C;	A single-blinded, randomized pilot study of botulinum toxin type A combined with non-pharmacological treatment for spastic foot	2008		Botulinum toxin A on spatic foot
Ada L;Foongchomchey A;Canning C;	Supportive devices for preventing and	2005	Cochrane Database of Systematic	Systematic Review not addressing the clinical question

Author	Title	Year	Journal/full	Reason for Exclusion
	treating subluxation of the shoulder after stroke. [Review] [46 refs]		Reviews	
Hausdorff JM; Ring H;	Effects of a new radio frequency-controlled neuroprosthesis on gait symmetry and rhythmicity in patients with chronic hemiparesis	2008	American Journal of Physical Medicine and Rehabilitation	Not RCT
Beckerman H; Becher J; Lankhorst GJ; Verbeek ALM; Vogelaar TW;	The efficacy of thermocoagulation of the tibial nerve and a polypropylene ankle-foot orthosis on spasticity of the leg in stroke patients: Results of a randomized clinical trial	1996		Thermocoagulation vs polypropylene ankle foot orthosis: on spasticity
Botte MJ; Waters RL; Keenan MA; Jordan C; Garland DE;	Approaches to senior care. Orthopaedic management of the stroke patient. Part II: Treating deformities of the upper and lower extremities	1988	Orthopaedic Review	Orthopaedic management of stroke
Sheffler LR; Hennessey MT; Naples GG; Chae J;	Peroneal nerve stimulation versus an ankle foot orthosis for correction of footdrop in stroke: impact on functional ambulation	2006	Neurorehabilitation and Neural Repair	Efficacy of a transcutaneous peroneal nerve stimulating device
Park S; Lee S; Chun M;	The effects of plastic ankle-foot orthosis on stroke patients	2006		Abstract
He J; Zhang T; Zhu Y;	Effects on abnormal gait pattern in hemiparetic	2003		Not in English language

Author	Title	Year	Journamfull	Reason for Exclusion
	patients using ankle foot orthoses			
Darlington DM;Harmanos L;Tolerico S;Grant-Beuttler M;Day A;	The effects of a plantarflexion assist orthosis on the gait of an individual with hemiplegia	2003	Journal of Neurologic Physical Therapy	Abstract
Hesse S;Werner C;Matthias K;Stephen K;Bertheanu M;	Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity	1999		Not RCT
Perriman DM;Coutts F;	Electro-goniometric measurement of ankle/foot movement in hemiplegic gait: the effect of the air-stirrup ankle brace and the multifit ankle foot orthosis	1997	Physiotherapy	Abstract on electro-goniometric measurement
Mueller K;Cornwall M;McPoil T;Mueller D;Barnwell J;	Effect of a tone-inhibiting dynamic ankle-foot orthosis on the foot-loading pattern of a hemiplegic adult: a preliminary study	1992	Journal of Prosthetics and Orthotics	Not RCT
Paik NJ;Lee JM;Kim CW;	Effect of ankle foot orthosis on hemiplegic gait	1997		Not in English language
Bohannon RW;	Gait after stroke	2001	Orthopaedic Physical Therapy Clinics of North America	Narrative review
De PF;	Aids and orthoses in patients with stroke consequences.	38808	Clinical & Experimental Hypertension (New York)	Literature review

Author	Title	Year	Journamfull	Reason for Exclusion
	[Review] [6 refs]			
Lai JM;Jones M;Willis B;	Efficacy of dynamic splinting on plantarflexion tone and contracture seen in patients with cerebrovascular accident and traumatic brain injury: a controlled crossover study	2007		Poster presentation
Farina S;Migliorini C;Gandolfi M;Bertolasi L;Casarotto M;Manganotti P;Fiaschi A;Smania N;	Combined effects of botulinum toxin and casting treatments on lower limb spasticity after stroke	3953 9	Functional Neurology	Evaluating the combined effect of cast worn at night and botulinum toxin
Kluding PM;Santos M;	Effects of ankle joint mobilizations in adults poststroke: a pilot study	3950 8	Archives of Physical Medicine & Rehabilitation	Pilot study on ankle mobilization
Simons CD;van Asseldonk EH;van der Kooij H;Geurts AC;Buurke JH;	Ankle-foot orthoses in stroke: effects on functional balance, weight-bearing asymmetry and the contribution of each lower limb to balance control	4011 8	Clinical Biomechanics	Effect of AFO on balance, static and dynamic weight bearing asymmetry of the paretic and non-paretic lower limbs
Lin RS;Ounpuu S;Oppedisano MJ;Kamienski K;	Evaluation of the pressure relief ankle foot orthosis in individuals with hemiparesis using three-dimensional gait analysis	3999 5	Journal of Prosthetics and Orthotics	Not RCT. No comparison
Chen CC;Hong WH;Wang CM;Chen CK;Wu KP;Kang CF;Tang SF;	Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthoses in	4051 3		Comparing anterior ankle foot orthoses (AFO) to posterior AFO

Author	Title	Year	Journamfull	Reason for Exclusion
	stroke patients with hemiplegic gait			
Dogan A;Mengulluoglu M;Ozgirgin N;	Evaluation of the effect of ankle-foot orthosis use on balance and mobility in hemiparetic stroke patients	4075 6	Disability & Rehabilitation	Not RCT
Whelan JK;	Effect of orthotics: on upper extremity function of the adult hemiplegic patient	1964	American Journal of Occupational Therapy	Literature review
Maguire C;Sieben JM;Erzer F;Goepfert B;Frank M;Ferber G;Jehn M;Schmidt-Trucksass A;de Bie RA;	How to improve walking, balance and social participation following stroke: a comparison of the long term effects of two walking aids--canes and an orthosis TheraTogs--on the recovery of gait following acute stroke. A study protocol for a multi-centre, sin	2012	BMC Neurology	Abstract
Carda S;Invernizzi M;Cognolato G;Piccoli E;Baricich A;Cisari C;	Efficacy of a hip flexion assist orthosis in adults with hemiparesis after stroke	2012	Physical Therapy	Orthosis is for ankle or foot

M.19 In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?

Author	Title	Year	Journamfull	Reason for Exclusion
Drummond A;Legg L;	Occupational therapy after stroke: a right not a privilege?	3950 7	Therapy	Not a RCT
Legg LA;Drummond AE;Langhorne P;	Occupational therapy for patients with	2006	Cochrane Database of Systematic	Not matching our protocol

Author	Title	Year	Journal/full	Reason for Exclusion
	problems in activities of daily living after stroke		Reviews	
van Velzen JM;van Bennekom CA;Edelaar MJ;Sluiter JK;Frings-Dresen MH;	Prognostic factors of return to work after acquired brain injury: a systematic review	3993 4		not matching our protocol
van Velzen JM;van Bennekom CA;Edelaar MJ;Sluiter JK;Frings-Dresen MH;	How many people return to work after acquired brain injury?: a systematic review	3996 5		Not matching our protocol
Temkin NR;Corrigan JD;Dikmen SS;Machamer J;	Social functioning after traumatic brain injury	4011 8	Journal of Head Trauma Rehabilitation	Not matching our protocol.
Fadyl JK;McPherson KM;	Approaches to vocational rehabilitation after traumatic brain injury: a review of the evidence	3993 4	Journal of Head Trauma Rehabilitation	Not a RCT
Drake AI;Gray N;Yoder S;Pramuka M;Llewellyn M;	Factors predicting return to work following mild traumatic brain injury: a discriminant analysis	3680 0	Journal of Head Trauma Rehabilitation	Not a RCT
Hinckley JJ;	Vocational and social outcomes of adults with chronic aphasia	3756 1	Journal of Communication Disorders	Not a RCT
Anderson TP;Baldrige M;Ettinger MG;	Quality of care for completed stroke without rehabilitation: evaluation by assessing patient outcomes	1979	Archives of Physical Medicine & Rehabilitation	Retrospective assessment
Isaki E;Turkstra L;	Communication abilities and work re-entry following traumatic brain injury	3664 7		Not addressing clinical question; no stroke patients
Braverman SE;Spector	A multidisciplinary	1999		Not RCT; not specified outcomes

Author	Title	Year	Journamfull	Reason for Exclusion
J;Warden DL;Wilson BC;Ellis TE;Bamdad MJ;Salazar AM;	TBI inpatient rehabilitation programme for active duty service members as part of a randomized clinical trial			
Cifu DX;Keyser-Marcus L;Lopez E;Wehman P;Kreutzer JS;Englander J;High W;	Acute predictors of successful return to work 1 year after traumatic brain injury: a multicenter analysis	3546 2	Archives of Physical Medicine & Rehabilitation	Not specified intervention and outcomes; not stroke patients
Saeki S;Ogata H;Okubo T;Takahashi K;Hoshuyama T;	Return to work after stroke. A follow-up study	3475 9		Retrospective cohort
Wehman P;Sherron P;Kregel J;Kreutzer J;Tran S;Cifu D;	Return to work for persons following severe traumatic brain injury. Supported employment outcomes after five years	3430 4		Not RCT
Wehman P;Kregel J;Sherron P;Nguyen S;Kreutzer J;Fry R;Zasler N;	Critical factors associated with the successful supported employment placement of patients with severe traumatic brain injury	3397 0		Not relevant to clinical question
Johansson U;Bernspang B;	Predicting return to work after brain injury using occupational therapy assessments	3709 2	Disability & Rehabilitation	Not RCT
Howard G;Till JS;Toole JF;Matthews C;Truscott BL;	Factors influencing return to work following cerebral infarction	3105 8		Prospective cohort
Wehman P;Targett P;West M;Kregel J;	Productive work and employment for persons with traumatic brain injury: what have we learned after	3841 2	Journal of Head Trauma Rehabilitation	Not a systematic review

Author	Title	Year	Journal full	Reason for Exclusion
	20 years?			
Bruckner FE;Randle AP;	Return to work after severe head injuries	1972	Rheumatology & Physical Medicine	Not relevant to clinical question
Brooks N;McKinlay W;Symington C;Beattie A;Campsie L;	Return to work within the first seven years of severe head injury	1987		Not addressing clinical question
Schonberger M;Humle F;Teasdale TW;	The development of the therapeutic working alliance, patients' awareness and their compliance during the process of brain injury rehabilitation	38808		Not addressing clinical question/ not specified outcomes
Hannerz H;Pedersen BH;Poulsen OM;Humle F;Andersen LL;	Study protocol to a nationwide prospective cohort study on return to gainful occupation after stroke in Denmark 1996 - 2006	2010	BMC Public Health	Study protocol
McNamee S;Walker W;Cifu DX;Wehman PH;	Minimizing the effect of TBI-related physical sequelae on vocational return	2009	Journal of Rehabilitation Research & Development	Review on minimising the effect of TBI
Klonoff PS;Talley MC;Dawson LK;Myles SM;Watt LM;Gehrels JA;Henderson SW;	The relationship of cognitive retraining to neurological patients' work and school status	39356		Not addressing clinical question
Hofgren C;Bjorkdahl A;Esbjornsson E;Sunnerhagen KS;	Recovery after stroke: cognition, ADL function and return to work	39114		Not addressing clinical question
McCrimmon S;Oddy M;	Return to work following moderate-to-severe traumatic brain injury	38961		Not addressing clinical question/not RCT
McLeod A;Wills A;Etherington J;	Employment retention after moderate-severe	38108	Occupational & Environmental Medicine	Not specified population and outcomes; retrospective cohort

Author	Title	Year	Journal/full	Reason for Exclusion
	traumatic brain injury (TBI) in the British Army 1989-98			
Rizzo VM;	Social work support services for stroke patients: interventions and outcomes	2006	Social Work in Health Care	Not addressing clinical question
Hammond FM;Grattan KD;Sasser H;Corrigan JD;Rosenthal M;Bushnik T;Shull W;	Five years after traumatic brain injury: a study of individual outcomes and predictors of change in function	2004	Neurorehabilitation	Not specified population and outcomes; not RCT
Machamer J;Temkin N;Fraser R;Doctor JN;Dikmen S;	Stability of employment after traumatic brain injury	38657	Journal of the International Neuropsychological Society	Not addressing specified intervention and outcomes; stroke population not defined
Inzaghi MG;De TA;Sozzi M;	The effects of traumatic brain injury on patients and their families. A follow-up study	38687	Europa Medicophysica	Not addressing clinical question
Vestling M;Ramel E;Iwarsson S;	Quality of life after stroke: well-being, life satisfaction, and subjective aspects of work	38504	Scandinavian Journal of Occupational Therapy	Not RCT
Kempers E;	Preparing the young stroke survivor for return to work	34394		Not RCT
Adams RA;Sherer M;Struchen MA;Nick TG;	Post-acute brain injury rehabilitation for patients with stroke	2004		Not addressing clinical question
Nair A;Turner-Stokes L;Tyerman A;	Vocational rehabilitation for acquired brain injury in adults	2008	Cochrane Database of Systematic Reviews	Cochrane protocol
Wood RL;Rutterford NA;	Demographic and cognitive predictors of long-term psychosocial outcome	38838	Journal of the International Neuropsychological Society	Not addressing specified intervention and outcomes; wrong population

Author	Title	Year	Journamfull	Reason for Exclusion
	following traumatic brain injury			
Coetzer BR;Hayes NM;Du Toit PL;	Long-term employment outcomes in a rural area following traumatic brain injury	3746 9	Australian Journal of Rural Health	Not specified intervention, population and outcomes
Lundqvist A;Grundstrom K;Samuelsson K;Ronnberg J;	Computerized training of working memory in a group of patients suffering from acquired brain injury	2010		Not addressing clinical question
Benedictus MR;Spikman JM;van der Naalt J;	Cognitive and behavioral impairment in traumatic brain injury related to outcome and return to work	2010	Archives of Physical Medicine & Rehabilitation	Not addressing outcomes
Alcott D;	Limiting the damage and return to work	2009	Medico-Legal Journal	Presentation
Toivanen S;	Job control and the risk of incident stroke in the working population in Sweden	3947 9	Scandinavian Journal of Work, Environment & Health	Not addressing clinical question
Glozier N;Hackett ML;Parag V;Anderson CS;Auckland Regional Community Stroke (ARCOS) Study Group;	The influence of psychiatric morbidity on return to paid work after stroke in younger adults: the Auckland Regional Community Stroke (ARCOS) Study, 2002 to 2003	3956 9		Prospective cohort
Dawson DR;Schwartz ML;Winocur G;Stuss DT;	Return to productivity following traumatic brain injury: cognitive, psychological, physical, spiritual, and environmental	3914 1	Disability & Rehabilitation	Not relevant to clinical question

Author	Title	Year	Journal/full	Reason for Exclusion
	correlates			
Walker WC;Marwitz JH;Kreutzer JS;Hart T;Novack TA;	Occupational categories and return to work after traumatic brain injury: a multicenter study	3905 2	Archives of Physical Medicine & Rehabilitation	Not addressing clinical question
Testa JA;Malec JF;Moessner AM;Brown AW;	Outcome after traumatic brain injury: effects of aging on recovery	3859 6	Archives of Physical Medicine & Rehabilitation	Not RCT
Teasdale TW;Engberg AW;	Subjective well-being and quality of life following traumatic brain injury in adults: a long-term population-based follow-up	3865 7		Not addressing/relevant to clinical question
Teasdale TW;Engberg AW;	Psychosocial consequences of stroke: a long-term population-based follow-up	3865 7		Not addressing/relevant to clinical question
Naito Y;Ando H;Yamaguchi M;	Assessment of traumatic brain injury patients by WAIS-R, P300, and performance on oddball task	2005	Kobe Journal of Medical Sciences	Not addressing clinical question
Doctor JN;Castro J;Temkin NR;Fraser RT;Machamer JE;Dikmen SS;	Workers' risk of unemployment after traumatic brain injury: a normed comparison	3862 6	Journal of the International Neuropsychological Society	Not specified intervention; stroke population not defined
Fraser R;Machamer J;Temkin N;Dikmen S;Doctor J;	Return to work in traumatic brain injury (TBI): a perspective on capacity for job complexity	3905 2	Journal of Vocational Rehabilitation	Not addressing clinical question; not specified population and outcomes
Wozniak MA;Kittner SJ;	Return to work after ischemic stroke: a methodological review	3743 8		Literature review
Fabiano RJ;Crewe N;	Variables associated with employment following severe traumatic brain injury	3494 3	Rehabilitation Psychology	Cross-sectional survey/population not relevant

Author	Title	Year	Journal/full	Reason for Exclusion
Possl J;Jurgensmeyer S;Karlbauer F;Wenz C;Goldenberg G;	Stability of employment after brain injury: a 7-year follow-up study	3689 2		Not addressing clinical question
Kolakowsky-Hayner SA;Kreutzer JS;	Return to work after brain injury: a self-directed approach	2001	Neurorehabilitation	Literature review; not addressing specified intervention
West MD;	Aspects of the workplace and return to work for persons with brain injury in supported employment	3479 0		Not addressing clinical question
Saeki S;Ogata H;Okubo T;Takahashi K;Hoshuyama T;	Factors influencing return to work after stroke in Japan	3418 2		Not specified outcomes; retrospective cohort
Black-Schaffer RM;Osberg JS;	Return to work after stroke: development of a predictive model	1990	Archives of Physical Medicine & Rehabilitation	Follow up study
Bjorkdahl A;	The return to work after a neuropsychological programme and prognostic factors for success	2010		Not addressing outcomes; follow up study
Wolfenden B;Grace M;	Returning to work after stroke: A review	3996 5		Not systematic review
Schonberger M;Humle F;Zeeman P;Teasdale TW;	Working alliance and patient compliance in brain injury rehabilitation and their relation to psychosocial outcome	3886 9	Neuropsychological Rehabilitation	Not addressing clinical question
McMahon R;Crowe DS;	Return to work factors following a stroke	1998		Not a systematic review
Fugl-Meyer AR;	Post-stroke hemiplegia - occupational status	1980	Scandinavian Journal of Rehabilitation Medicine	Not a review
Schulz CH;Wasserman J;Ostwald SK;	Recruitment and retention of stroke survivors: the CARES	3889 9	Physical & Occupational Therapy in Geriatrics	Not addressing clinical question

Author	Title	Year	Journamfull	Reason for Exclusion
	experience			
Niemeier JP;DeGrace SM;Farrar LF;Ketchum JS;Berman AJ;Young JA;	Effectiveness of a comprehensive, manualized intervention for improving productivity and employability following brain injury	40513	Journal of Vocational Rehabilitation	Not RCT; small proportion of stroke patients
Hart T;Dijkers M;Whyte J;Braden C;Trott CT;Fraser R;	Vocational interventions and supports following job placement for persons with traumatic brain injury	40330	Journal of Vocational Rehabilitation	Observation study; stroke not mentioned
Franulic A;Carbonell CG;Pinto P;Sepulveda I;	Psychosocial adjustment and employment outcome 2, 5 and 10 years after TBI	38018		Not RCT

M.20 In people after stroke what is the clinical and cost-effectiveness of psychological therapies provided to the family (including patients)?

Author	Title	Year	Journamfull	Reason for Exclusion
Mant J;Winner S;Roche J;Wade DT;	Family support for stroke: one year follow up of a randomised controlled trial	2005	Journal of Neurology, Neurosurgery & Psychiatry	Not a comparison group
Banks P;Pearson C;	Parallel lives: Younger stroke survivors and their partners coping with crisis	2004	Sexual and Relationship Therapy	Not addressing review/clinical question
Bakas T;Austin JK;Buelow JM;Habermann B;Li Y;McLennon SM;	Preliminary Efficacy of a Stroke Caregiver Intervention Program for Reducing Depressive Symptoms	2010		Abstract
Anderson R;	The contribution of informal care to the management of	1988	International Disability Studies	Correspondence

Author	Title	Year	Journamfull	Reason for Exclusion
	stroke			
Wilz G;Barskova T;	Evaluation of a cognitive behavioral group intervention program for spouses of stroke patients	2007	Behaviour Research & Therapy	Not RCT
Watkins CL;French B;	Psychological Intervention Poststroke. Ready for Action?	2009		Review
Visser-Meily A;Post M;van de Port I;van Heugten C;van den Bos T;	Psychosocial functioning of spouses in the chronic phase after stroke: improvement or deterioration between 1 and 3 years after stroke?	2008	Patient Education & Counseling	Not RCT. Not addressing clinical/review question
van der Gaag A;Smith L;Davis S;Moss B;Cornelius V;Laing S;Mowles C;	Therapy and support services for people with long-term stroke and aphasia and their relatives: A six-month follow-up study	2005		Not RCT
van den Heuvel ET;de Witte LP;Nooyen-Haazen I;Sanderman R;Meyboom-de Jong B;	Short-term effects of a group support program and an individual support program for caregivers of stroke patients	2000	Patient Education & Counseling	Not RCT. Not specified interventions
Bao X;Wang G;Liu X;	Depression and corresponding psychological intervention after stroke	2001	Chinese Mental Health Journal	Not in English Language
Schulz R;Martire LM;Klinger JN;	Evidence-based caregiver interventions in geriatric psychiatry	2005	Psychiatric Clinics of North America	Summary of reviews
Dennis M;O'Rourke S;Slattery J;Staniforth T;Warlow C;	Evaluation of a stroke family care worker: Results of a randomised controlled trial	1997	British Medical Journal	Not addressing our prespecified interervention
Legg Lynn	Non-	2010	Cochrane	Not addressing clinical/review question

Author	Title	Year	Journal/full	Reason for Exclusion
A;Langhorne P;Tierney J;Stott David J;Weir C;Smith Lorraine N;	pharmacological interventions for caregivers of stroke survivors		Database of Systematic Reviews	
Larson J;Franzen-Dahlin A;Billing E;Arbin M;Murray V;Wredling R;	The impact of a nurse-led support and education programme for spouses of stroke patients: a randomized controlled trial	2005	Journal of Clinical Nursing	Not on psychological therapies
Kalra L;Evans A;Perez I;Melbourn A;Patel A;Knapp M;Donaldson N;	Training carers of stroke patients: randomised controlled trial	2004	BMJ (Clinical research ed)	Not addressing clinical/review question. Not specified intervention
Hackett Maree L;Anderson Craig S;House A;Halteh C;	Interventions for preventing depression after stroke	2008	Cochrane Database of Systematic Reviews	Not addressing clinical/review question
Franzen-Dahlin A;Larson J;Murray V;Wredling R;Billing E;	A randomized controlled trial evaluating the effect of a support and education programme for spouses of people affected by stroke	2008		Not specified interventions and outcomes
Forster A;Young J;Green J;Patterson C;Wanklyn P;Smith J;Murray J;Wild H;Bogle S;Lowson K;	Structured re-assessment system at 6 months after a disabling stroke: A randomised controlled trial with resource use and cost study	2009		Not addressing specified interventions
Dennis M;O'Rourke S;Lewis S;Sharpe M;Warlow C;	A quantitative study of the emotional outcome of people caring for stroke survivors	1998		Follow-up on primary study
Bjorkdahl A;Nilsson AL;Sunnerhagen KS;	Can rehabilitation in the home setting reduce the burden of care for the next-of-kin of stroke victims?	2007		Not RCT. Not addressing specified interventions
Tsouna-Hadjis E;Vemmos	First-stroke recovery process:	2000		Not specified interventions and outcomes

Author	Title	Year	Journamfull	Reason for Exclusion
KN;Zakopoulos N;Stamatelopoulos S;	The role of family social support			
Schure LM;van den Heuvel ETP;Stewart RE;Sanderman R;de Witte LP;Meyboom-de Jong B;	Beyond stroke: description and evaluation of an effective intervention to support family caregivers of stroke patients	2006	Patient Education & Counseling	Not addressing clinical question and specified outcomes
Hackett ML;Anderson CS;House A;Xia J;	Interventions for treating depression after stroke	2008		Not addressing clinical/review question
Bakas T;Farran CJ;Austin JK;Given BA;Johnson EA;Williams LS;	Stroke caregiver outcomes from the Telephone Assessment and Skill-Building Kit (TASK)	2009		Not addressing clinical question
Evans RL;Matlock AL;Bishop DS;Stranahan S;Pederson C;	Family intervention after stroke: Does counseling or education help?	1988		Not addressing specified outcomes
Brereton L;Carroll C;Barnston S;	Interventions for adult family carers of people who have had a stroke: a systematic review	2007		Not addressing specified interventions and outcomes
Towle D;Lincoln NB;Mayfield LM;	Evaluation of social work on depression after stroke	32629		Not addressing review/clinical question. Not aimed at family
Goldberg G;Segal ME;Berk SN;Schall RR;Gershkoff AM;	Stroke transition after inpatient rehabilitation	1997		Not addressing specified outcomes
Watkins CL;Auton MF;Deans CF;Dickinson HA;Jack CIA;Lightbody CE;Sutton CJ;van den Broek MD;Leathley MJ;	Motivational interviewing early after acute stroke: a randomized, controlled trial	2007		Intervention not aimed at the family. Not addressing specified outcomes
Bhagal SK;Teasell RW;Foley	Community reintegration after stroke	2003		Not addressing clinical/review question

Author	Title	Year	Journamfull	Reason for Exclusion
NC;Speechley MR;				
Forster A;Young J;	Specialist nurse support for patients with stroke in the community: a randomised controlled trial	1996	British Medical Journal	Not addressing our prespecified intervention
Ch'ng AM;French D;McLean N;	Coping with the challenges of recovery from stroke: Long term perspectives of stroke support group members	2008	Journal of Health Psychology	Not RCT. Not addressing review/clinical question. Not specified interventions
Mant J;Carter J;Wade DT;Winner S;	Family support for stroke: a randomised controlled trial	2000		Not addressing our prespecified intervention
Lee J;Yoo MS;Jung D;	Caregiving appraisal of family caregivers for older stroke patients in Korea	2010	International Nursing Review	Not RCT. Not addressing review/clinical question
Knapp P;Hewison J;	The protective effects of social support against mood disorder after stroke	1998	Psychology, Health and Medicine	Not RCT; Not addressing clinical/review question
Hull S;Hartigan N;Kneebone I;	Is bingo a psychological intervention? Developing a support group for stroke survivors and carers	2007	Clinical Psychology Forum	Not RCT. Not addressing clinical/review question
Groom MJ;Lilley SA;Francis VM;Lincoln NB;	An analysis of the intervention provided by a stroke family support organizer service	2003	International Journal of Therapy and Rehabilitation	Not specified intervention. Study on patients with no data for the family
Friedman EH;Grant JS;	Re: Telephone intervention with family caregivers of stroke survivors after rehabilitation	2003		Editorial comments
Evans RL;Bishop DS;Matlock AL;Pederson C;	Impact of family intervention after stroke	1988		Abstract
Eldred C;Sykes C;	Psychosocial	2008	British Journal	Not addressing specified interventions

Author	Title	Year	Journal full	Reason for Exclusion
	interventions for carers of survivors of stroke: a systematic review of interventions based on psychological principles and theoretical frameworks		of Health Psychology	
Lincoln NB; Flannaghan T;	Cognitive behavioral psychotherapy for depression following stroke: a randomized controlled trial	2003		Intervention not aimed at family/carers
Hanks RA; Rapport LJ; Wertheimer J; Koviak C;	Randomized controlled trial of peer mentoring for individuals with traumatic brain injury and their significant others	2012		Population not fitting protocol - traumatic brain injury
Alexopoulos GS; Wilkins VM; Marino P; Kanellopoulos D; Reding M; Sirey JA; Raue PJ; Ghosh S; O'Dell MW; Kiosses DN;	Ecosystem focused therapy in poststroke depression: A preliminary study	2012	International Journal of Geriatric Psychiatry	No outcome data for family members reported

M.21 In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions / usual care to improve swallowing? (dysphagia)

Author	Title	Year	Journal full	Reason for Exclusion
Goulding R; Bakheit AM;	Evaluation of the benefits of monitoring fluid thickness in the dietary management of dysphagic stroke patients	36617		Not addressing specified outcomes
Ashford J; McCabe D; Wheeler-	Evidence-based systematic review:	2009	Journal of Rehabilitation Research &	Not RCTs

Author	Title	Year	Journamfull	Reason for Exclusion
Hegland K;Frymark T;Mullen R;Musson N;Schooling T;Hammond CS;	Oropharyngeal dysphagia behavioral treatments. Part III--impact of dysphagia treatments on populations with neurological disorders		Development	
Jayasekeran V;Singh S;Tyrrell P;Michou E;Jefferson S;Mistry S;Gamble E;Rothwell J;Thompson D;Hamdy S;	Adjunctive functional pharyngeal electrical stimulation reverses swallowing disability after brain lesions	4029 9	Gastroenterology	Not addressing specified interventions
Luker JA;Wall K;Bernhardt J;Edwards I;Grimmer-Somers K;	Measuring the quality of dysphagia management practices following stroke: a systematic review	4051 3	International Journal of Stroke	Assessing quality of dysphagia management
Langdon PC;Lee AH;Binns CW;	High incidence of respiratory infections in 'nil by mouth' tube-fed acute ischemic stroke patients	2009		Not RCT
Dziewas R;Warnecke T;Hamacher C;Oelenberg S;Teismann I;Kraemer C;Ritter M;Ringelstein EB;Schaebitz WR;	Do nasogastric tubes worsen dysphagia in patients with acute stroke?	2008	BMC Neurology	Not RCT
Foley N;Teasell R;Salter K;Kruger E;Martino R;	Dysphagia treatment post stroke: a systematic review of randomised controlled trials (Structured abstract)	2008		Not addressing specified interventions and outcomes
Koretz RL;Avenell	Does enteral nutrition affect	3911 4	American Journal of	Not addressing specified interventions

Author	Title	Year	Journamfull	Reason for Exclusion
A;Lipman TO;Braunschweig CL;Milne AC;	clinical outcome? A systematic review of the randomized trials. [Review] [207 refs]		Gastroenterology	
Kedlaya D;Brandstater ME	Swallowing, nutrition, and hydration during acute stroke care	2002		Narrative review on managing and evaluating dysphagia
Finestone HM;Foley NC;Woodbury MG;Greene-Finestone L;	Quantifying fluid intake in dysphagic stroke patients: a preliminary comparison of oral and nonoral strategies	37226		Not RCT
Goulding R;	A study to evaluate the benefits of monitoring fluid thickness in the dietary management of dysphagic stroke patients	2001		Not specified outcomes/ not addressing clinical question
Buchholz DW;Neumann S;	Comments on Selected Recent Dysphagia Literature	1999	Dysphagia	Comments on dysphagia articles
Gomes AR;Lustosa Suzana AS;Matos D;Andriolo RgB;Waisberg DR;Waisberg J;	Percutaneous endoscopic gastrostomy versus nasogastric tube feeding for adults with swallowing disturbances	2010	Cochrane Database of Systematic Reviews	Not addressing clinical/review question
Gariballa SE;Parker SG;Taub N;Castleden CM;	A randomized, controlled, single-blind trial of nutritional supplementation after acute stroke	1998	Journal of Parenteral and Enteral Nutrition	Patients do not have difficulty with swallowing
Karagiannis MJ;Chivers L;Karagiannis TC;	Effects of oral intake of water in patients with oropharyngeal dysphagia	2011	BMC Geriatrics	Not stroke population
Baeten C;Hoefnagels J;	Feeding via nasogastric tube or percutaneous endoscopic	1992	Scand J Gastroenterol Suppl	Not addressing specified interventions

Author	Title	Year	Journal	Reason for Exclusion
	gastrostomy. A comparison			
Groher ME;	Bolus management and aspiration pneumonia in patients with pseudobulbar dysphagia	1897	Dysphagia	Not stroke patients
Clarke J;Cranswick G;Dennis MS;Flaig R;al e;	Effect of timing and method of enteral tube feeding for dysphagic stroke patients (FOOD): a multicentre randomised controlled trial	2006	The Lancet	Not addressing specified interventions
Hamidon BB;Abdullah SA;Zawawi MF;Sukumar N;Aminuddin A;Raymond AA;	A prospective comparison of percutaneous endoscopic gastrostomy and nasogastric tube feeding in patients with acute dysphagic stroke	3877 7	Medical Journal of Malaysia	Not addressing specified interventions
Norton B;Homer-Ward M;Donnelly MT;Long RG;Holmes GKT;	A randomised prospective comparison of percutaneous endoscopic gastrostomy and nasogastric tube feeding after acute dysphagic stroke: BMJ	3507 0	British Medical Journal	Not addressing specified interventions
Rosenbek JC;Roeker EB;Wood JL;Robbins J;	Thermal application reduces the duration of stage transition in dysphagia after stroke	1996	Dysphagia	Not specified interventions
WHELAN K;	Inadequate fluid intakes in dysphagic acute stroke	3716 5		Not addressing specified interventions and outcomes
Crary MA;Mann GDC;Groher ME;Helseth E;	Functional Benefits of Dysphagia Therapy Using Adjunctive sEMG	3820 0	Dysphagia	Not RCT. Not addressing specified interventions

Author	Title	Year	Journamfull	Reason for Exclusion
	Biofeedback			
Logemann JA;Kahrilas PJ;Kobara M;Vakil NB;	The benefit of head rotation on pharyngoesophageal dysphagia	3278 2		Not RCT
Shanahan TK;Logemann JA;Rademaker AW;Pauloski BR;Kahrilas PJ;	Chin-down posture effect on aspiration in dysphagic patients	3415 1		Not RCT
Royal College of Speech and Language Therapists;	RCSLT Resource Manual for Commissioning and Planning Service for SLCN: Dysphagia	2009		Narrative review
Davies S;	Dysphagia in acute strokes	1999	Nursing Standard	Clinical review

M.22 What is the clinical and cost-effectiveness of supported information provision versus unsupported information provision on mood and depression in people with stroke?

Author	Title	Year	Journamfull	Reason for Exclusion
Eames S;Hoffman T;Worrall L;Read S;Wong A;	Randomised controlled trial of a postdischarge education and support package for clients with stroke and their carers... Occupational Therapy Australia, 24th National Conference and Exhibition, 29 June - 1 July 2011	4069 6	Australian Occupational Therapy Journal	Abstract: oral presentation
Legg LA;Quinn TJ;Mahmood F;Weir CJ;Tierney J;Stott DJ;Smith LN;Langhorne P;	Nonpharmacological interventions for caregivers of stroke survivors	2012		Not addressing review question
Hafsteinsdottir TB;Vergunst M;Lindeman E;Schuurmans M;	Educational needs of patients with a stroke and their caregivers: a systematic review of the literature	2011	Patient Education and Counseling	Not addressing review question and included observational studies

Author	Title	Year	Journal	Reason for Exclusion
Johnson J;Pearson V;	The effects of a structured education course on stroke survivors living in the community... including commentary by Phipps M	2000	Rehabilitation Nursing	Not RCT
Desrosiers J;Noreau L;Rochette A;Carbonneau H;Fontaine L;Viscogliosi C;Bravo G;	A home leisure education program may reduce depression after a stroke	2007		Abstract
Yvonne Chan YF;Nagurka R;Richardson LD;Zaets SB;Brimacombe MB;Levine SR;	Effectiveness of stroke education in the emergency department waiting room	2010	Journal of Stroke & Cerebrovascular Diseases	Not specified outcomes
Rodgers H;Bond S;Curless R;	Inadequacies in the provision of information to stroke patients and their families	2001	Age & Ageing	Review on current practice
Rochette A;Korner-Bitensky N;Bishop D;Teasell R;White C;Bravo G;Cote R;Lachaine J;Green T;Lebrun LH;Lanthier S;Kapral M;Wood-Dauphinee S;	Study protocol of the YOU CALL--WE CALL TRIAL: impact of a multimodal support intervention after a 'mild' stroke	2010	BMC Neurology	Not pre-specified interventions
Maasland E;Koudstaal PJ;Habbema JDF;Dippel DWJ;	Effects of an individualized multimedia computer program for health education in patients with a recent minor stroke or transient ischemic attack - a randomized controlled trial	2007		Not specified outcomes
Lowe D;Leathley	An assessment of	2005		Abstract

Author	Title	Year	Journamfull	Reason for Exclusion
MJ;Sharma AK;	the utility of an individualised information booklet in patients after stroke: the CAREFILE project			
Eames S;Hoffmann T;Worrall L;Read S;	Stroke patients' and carers' perception of barriers to accessing stroke information	2010		Not addressing clinical question
Joubert J;Joubert L;Reid C;Barton D;Cumming T;Mitchell P;House M;Heng R;Meadows G;Walterfang M;Pantelis C;Ames D;Davis S;	The positive effect of integrated care on depressive symptoms in stroke survivors	2008	Cerebrovascular Diseases	Not addressing clinical/review question
Lecouturier J;Murtagh MJ;Thomson RG;Ford GA;White M;Eccles M;Rodgers H;	Response to symptoms of stroke in the UK: a systematic review	2010		Not addressing clinical/review question
Brereton L;Carroll C;Barnston S;	Interventions for adult family carers of people who have had a stroke: a systematic review	2007		Not specified intervention/outcomes
Smith J;Forster A;House A;Knapp P;Wright J;Young J;	Information provision for stroke patients and their caregivers	2008		Did not address clinical/review question
Evans RL;Matlock AL;Bishop DS;Stranahan S;Pederson C;	Family intervention after stroke: Does counseling or education help?	1988		Not specified outcomes
Lowe D;Leathley M;Sharma A;	Patient education following stroke: The CareFile Project	2002	Cerebrovascular Diseases	Abstract
Brereton L;Carroll C;Barnston S;	Interventions for adult family carers of people who have had a	2007		Not specified intervention and outcomes

Author	Title	Year	Journal/full	Reason for Exclusion
	stroke: a systematic review			
Green T;Haley E;Eliasziw M;	Patient education in stroke prevention	2006		Abstract
Mant J;Carter J;Wade DT;Winner S;	The impact of an information pack on patients with stroke and their carers: a randomized controlled trial	1998		Not specified comparison/intervention
Oupra R;Griffiths R;Pryor J;Mott S;	Effectiveness of Supportive Educative Learning programme on the level of strain experienced by caregivers of stroke patients in Thailand	2010	Health & Social Care in the Community	Not RCT and aimed at caregivers
Smith J;Forster A;Young J;	Cochrane review: information provision for stroke patients and their caregivers (Brief record)	2009		Primary studies included
Banet GA;Felchlia MA;	The potential utility of a shared medical record in a 'first-time' stroke population	1997	Journal of Vascular Nursing	Not specified outcomes/intervention
Frank G;Johnston M;Morrison V;Pollard B;MacWalter R;	Perceived control and recovery from functional limitations: Preliminary evaluation of a workbook-based intervention for discharged stroke patients	2000	British Journal of Health Psychology	Not specified comparison/intervention
Ellis G;Mant J;Langhorne P;Dennis M;Winner S;	Stroke liaison workers for stroke patients and carers: an individual patient data meta-analysis	2010	Cochrane Database of Systematic Reviews	Not addressing specified intervention/comparison
Downes B;Rooney V;Roper-Hall	The effectiveness of counselling stroke survivors	1993		Abstract

Author	Title	Year	Journamfull	Reason for Exclusion
A;Oyebode J;Main A;Mayer P;	and their carers in the community			
Lomer M;McLellen DL;	Informing hospital patients and their relatives about stroke	1987		Not addressing specified outcomes
Pain HSB;McLellan DL;	The use of individualised booklets after a stroke	1990		Not addressing specified outcomes
Larson J;Franzen-Dahlin A;Billing E;Arbin M;Murray V;Wredling R;	The impact of a nurse-led support and education programme for spouses of stroke patients: a randomized controlled trial	2005	Journal of Clinical Nursing	Not specified intervention
Evans RL;Matlock AL;Bishop DS;Stranahan S;Pederson C;	Family intervention after stroke: Does counseling or education help?	1988		Not specified outcomes. Aimed at caregiver
Chumbler NR;Quigley P;Li X;Morey M;Rose D;Sanford J;Griffiths P;Hoenig H;	Effects of telerehabilitation on physical function and disability for stroke patients: A randomized, controlled trial	2012		Outcomes not in protocol
Goldfinger JZ;Kronish IM;Fei K;Graciani A;Rosenfeld P;Lorig K;Horowitz CR;	Peer education for secondary stroke prevention in inner-city minorities: Design and methods of the prevent recurrence of all inner-city strokes through education randomized controlled trial	2012	Contemporar y clinical trials	Preliminary report reporting only on baseline characterists

M.23 In people after stroke does cardiorespiratory or resistance training improve outcome (fitness, function, QOL, mood and reduce disability)?

Author	Title	Year	Journamfull	Reason for Exclusion
Yang YR;Wang RY;Lin KH;Chu MY;Chan RC;	Task-oriented progressive resistance strength training improves muscle strength and functional performance in individuals with stroke	3899 1		Not addressing pre-specified intervention. Intervention included mixed training
Richards CL;Malouin F;Wood-Dauphinee S;Williams JI;Bouchard JP;Brunet D;	Task-specific physical therapy for optimization of gait recovery in acute stroke patients	3412 1		Not addressing pre-specified intervention. Intervention included mixed training
Duncan P;Richards L;Wallace D;Stoker-Yates J;Pohl P;Luchies C;Ogle A;Studenski S;	A randomized, controlled pilot study of a home-based exercise program for individuals with mild and moderate stroke	3606 9		Not addressing pre-specified intervention. Intervention included mixed training
Teixeira-Salmela LF;Olney SJ;Nadeau S;Brouwer B;	Muscle strengthening and physical conditioning to reduce impairment and disability in chronic stroke survivors	3643 4		Not addressing pre-specified intervention. Intervention included mixed training
Duncan P;Studenski S;Richards L;Gollub S;Lai SM;Reker D;Perera S;Yates J;Koch V;Rigler S;Johnson D;	Randomized clinical trial of therapeutic exercise in subacute stroke	3786 5		Not addressing pre-specified intervention. Intervention included mixed training
Richards CL;Malouin F;Bravo G;Dumas F;Wood-Dauphinee S;	The role of technology in task-oriented training in persons with	3832 2	Neurorehabilitation and Neural Repair	Not addressing pre-specified intervention. Intervention included mixed training

Author	Title	Year	Journal/full	Reason for Exclusion
	subacute stroke: a randomized controlled trial			
Langhammer B;Lindmark B;Stanghelle JK;	Stroke patients and long-term training: Is it worthwhile? A randomized comparison of two different training strategies after rehabilitation	3923 4		Outcomes previously reported in the completed review on strength training
Mead GE;Greig CA;Cunningham I;Lewis SJ;Dinan S;Saunders DH;Fitzsimons C;Young A;	Stroke: a randomized trial of exercise or relaxation	3923 4	Journal of the American Geriatrics Society	Not addressing pre-specified intervention. Intervention included mixed training
Donaldson C;Tallis R;Miller S;Sunderland A;Lemon R;Pomeroy V;	Effects of conventional physical therapy and functional strength training on upper limb motor recovery after stroke: a randomized phase II study	3993 4	Neurorehabilitation and Neural Repair	Outcomes previously reported in the completed guideline review on strength training
James JEP;	Closed kinetic chain training to enhance muscle power, control and retrain dynamic balance under task specific conditions improves functional walking ability in chronic stroke survivors	2002		Not addressing pre-specified intervention. Intervention included mixed training
Gjellesvik TI;Brurok B;Hoff J;Torhaug T;Helgerud J;	Effect of high aerobic intensity interval treadmill walking in people with chronic stroke: A pilot study with one year follow-up	2012		Not an RCT and <10 participants
Hassett LM;Moseley AM;Whiteside B;Barry S;Jones	Circuit class therapy can provide a fitness training stimulus	2012	Journal of Physiotherapy	Incorrect population - traumatic brain injury

Author	Title	Year	Journamfull	Reason for Exclusion
T;	for adults with severe traumatic brain injury: A randomised trial within an observational study			
Kondo R;	Effects of dynamic-intensive exercise for gait ability in chronic stroke patients: A randomized controlled trial	2012		Abstract

M.24 In people after stroke does organised rehabilitation care (comprehensive or rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?

Author	Title	Year	Journamfull	Reason for Exclusion
Govan L;Langhorne P;Weir CJ;	Does the prevention of complications explain the survival benefit of organized inpatient (stroke unit) care?: further analysis of a systematic review	2007		Narrative review
Zhu HF;Newcommon NN;Cooper ME;Green TL;Seal B;Klein G;Weir NU;Coutts SB;Watson T;Barber PA;Demchuk AM;Hill MD;Calgary Stroke Program;	Impact of a stroke unit on length of hospital stay and in-hospital case fatality	2009		Not RCT
Cavallini A;Micieli G;Marcheselli S;Quaglini S;	Role of monitoring in management of acute ischemic stroke patients	3792 6		Not addressing pre-specified intervention. Intervention included acute stroke ward
Dey P;Woodman	Early assessment	3853	Age Ageing	Not addressing pre-specified intervention.

Author	Title	Year	Journamfull	Reason for Exclusion
M;Gibbs A;Steele R;Stocks SJ;Wagstaff S;Khanna V;Chaudhuri MD;	by a mobile stroke team: a randomised controlled trial	4		Intervention included acute stroke ward
Ronning OM;Guldvog B;	Stroke unit versus general medical wards, II: neurological deficits and activities of daily living: a quasi-randomized controlled trial	3585 5		Not addressing pre-specified intervention
Vemmos K;Takis K;Madelos D;Synetos A;Volotaiou V;Tzavellas H;	Stroke unit treatment versus general medical wards: long term survival	2001	Cerebrovascular Diseases	Not addressing pre-specified intervention

M.25 In people after stroke does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?

Author	Title	Year	Journamfull	Reason for Exclusion
Borg J;Wissel J;Ward A;Kullander K;Schupp W;Satkunam L;Walsh M;Wright N;	Goal setting pertaining to lower limb function in post-stroke spasticity (PSS) patients: The BOTOX economic spasticity trial (BEST)	2011		Poster presentation pertaining to lower limb function

M.26 In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language/communication abilities and/or psychological wellbeing

QID	Author	Reason for Exclusion
Aphasia	Bakheit AM, Shaw S, Barrett L, Wood J, Carrington S, Griffiths S et al. A prospective, randomized, parallel	Not addressing pre-specified comparison.

QID	Author	Reason for Exclusion
	group, controlled study of the effect of intensity of speech and language therapy on early recovery from poststroke aphasia. <i>Clinical Rehabilitation</i> . 2007; 21(10):885-894	
Aphasia	Cherney, LR, Babbitt, EM, Cole, R, van Huuren, S, Hurwitz, R, and Ngampatipatpong, M. Computer treatment for aphasia: efficacy and treatment intensity (Poster presentation). ACRM-ASNR Joint Educational Conference, 2006	Not addressing pre-specified comparison
Aphasia	Crerar MA, Ellis AW, Dean EC. Remediation of sentence processing deficits in aphasia using a computer-based microworld. <i>Brain and Language</i> 1996;52:229-75.	Not addressing pre-specified comparison
Aphasia	De Jong-Hagelstein M, Van de Sandt-Koenderman WME, Prins ND, Dippel DW, Koudstaal PJ, Visch-Brink EG. Efficacy of early cognitive-linguistic treatment and communicative treatment in aphasia after stroke: a randomised controlled trial (RATS-2). <i>Journal of Neurology, Neurosurgery and Psychiatry</i> 2011;82(4):399-404.	Not addressing pre-specified comparison
Aphasia	Denes G, Perazzolo C, Piani A, Piccione F. Intensive versus regular speech therapy in global aphasia: A controlled study. <i>Aphasiology</i> . 1996; 10(4):385-394	Not addressing pre-specified comparison
Aphasia	Di Carlo LM. Language recovery in aphasia: effect of systematic filmed programmed instruction. <i>Archives of Physical Medicine and Rehabilitation</i> . 1980; 61(1):41-44	Not addressing pre-specified comparison
Aphasia	Doesborgh SJ, van de Sandt-Koenderman MW, Dippel DW, van HF, Koudstaal PJ, Visch-Brink EG. Effects of semantic treatment on verbal communication and linguistic processing in aphasia after stroke: a randomized controlled trial. <i>Stroke; a Journal of Cerebral Circulation</i> . 2004; 35(1):141-146	Not addressing pre-specified comparison
Aphasia	Drummond SS, Rentschler GJ. The efficacy of gestural cueing in dysphasic word-retrieval responses. <i>Journal of Communication Disorders</i> 1981;14(4):287-98.	Not addressing pre-specified comparison
Aphasia	Godecke E, Hird K, Lalor E, Rai T, Phillips MR. Very early poststroke aphasia therapy: a pilot randomized controlled efficacy trial. <i>International</i>	Not addressing pre-specified comparison

QID	Author	Reason for Exclusion
	Journal of Stroke 2011. [DOI:]	
Aphasia	Hinckley JJ, Patterson JP, Carr TH. Differential effects of context and skill-based treatment approaches: preliminary findings. <i>Aphasiology</i> . 2001; 15(5):463-476	Not addressing pre-specified comparison
Aphasia	Leal, MJ, Farrajota, L, Fonseca, J, Santos, ME, Guerriero, M, and Ferro, JM. The influence of speech therapy on the evolution of stroke aphasia (unpublished report). Lisbon, Portugal: Language Research Laboratory, 1994	Not addressing pre-specified intervention
Aphasia	Lincoln NB, Pickersgill MJ. The effectiveness of programmed instruction with operant training in the language rehabilitation of severely aphasic patients. <i>Behavioural Psychotherapy</i> . 1984; 12:237-248	Not addressing pre-specified intervention
Aphasia	Liu Y, Zhang L. The TCM-combined treatment for aphasia due to cerebrovascular disorders. <i>Journal of Traditional Chinese Medicine</i> 2006;26(1):19-21.	Not addressing pre-specified intervention
Aphasia	Lyon JG, Cariski D, Keisler L, Rosenbek J, Levine R, Kumpula J et al. Communication partners: Enhancing participation in life and communication for adults with aphasia in natural settings. <i>Aphasiology</i> . 1997; 11(7):693-708	Suitable summary data were not reported
Aphasia	Mackay S, Holmes DW, Gersumky AT. Methods to assess aphasic stroke patients. <i>Geriatric Nursing</i> 1988;May/June:177-9.	Suitable summary data were not reported
Aphasia	Meikle M, Wechsler E, Tupper A, Benenson M, Butler J, Mulhall D et al. Comparative trial of volunteer and professional treatments of dysphasia after stroke. <i>British Medical Journal</i> . 1979; 2(6182):87-89	Not addressing pre-specified intervention
Aphasia	Meinzer M, Streiftau S, Rockstroh B. Intensive language training in the rehabilitation of chronic aphasia: efficient training by laypersons. <i>Journal of the International Neuropsychological Society</i> . 2007; 13(5):846-853	Not addressing pre-specified intervention
Aphasia	Prins RS, Schoonen R, Vermeulen J. Efficacy of two different types of speech therapy for aphasic stroke patients. <i>Applied Psycholinguistics</i> . 1989; 10(1):85-123	Not addressing pre-specified intervention

QID	Author	Reason for Exclusion
Aphasia	Pulvermuller F, Neininger B, Elbert T, Mohr B, Rockstroh B, Koebbel P et al. Constraint-induced therapy of chronic aphasia after stroke. <i>Stroke</i> . 2001; 32(7):1621-1626	Not addressing pre-specified comparison
Aphasia	Smith DS, Goldenberg E, Ashburn A, Kinsella G, Sheikh K, Brennan PJ, et al. Remedial therapy after stroke: a randomised controlled trial. <i>BMJ</i> 1981;282:517-20.	Suitable summary data were not reported
Aphasia	van Steenbrugge WJ, Prins RS. Word finding difficulties and efficacy of systematic language therapy in aphasic patients. <i>Logopedie En Foniatrie</i> . 1981; 53:622-637	Not addressing pre-specified comparison
Aphasia	Wertz RT, Collins MJ, Weiss D, Kurtzke JF, Friden T, Brookshire RH et al. Veterans Administration cooperative study on aphasia: a comparison of individual and group treatment. <i>Journal of Speech and Hearing Research</i> . 1981; 24(4):580-594	Not addressing pre-specified comparison
Aphasia	Wu X. Analysis of the effect of 'two-step method' on aphasia in patients with acute cerebrovascular disease. <i>Chinese Journal of Clinical Rehabilitation</i> . 2004; 8(22):4422-4423	Suitable summary data were not reported.
Aphasia	Yao J, Xue Y, Li F. Clinical application research on collective language strengthened training in rehabilitation nursing of cerebral apoplexy patients with aphasia. <i>Chinese Nursing Research</i> 2005;19(3B):482-4.	Chinese language outcomes
Aphasia	Zhang H-M. Clinical treatment of apoplectic aphemia with multi-needle puncture of scalp-points in combination with visual-listening-speech training. <i>Acupuncture Research</i> 2007;32(3):190-4.	Not addressing pre-specified comparison and Chinese language outcomes
Aphasia	Zhao H, Ying B, Shen C. Clinical study on the effect of combined therapy of medicine acupuncture and speech training on aphasia from ischemic apoplexy. <i>Henan Traditional Chinese Medicine</i> 2000;20(5):31-2.	Not addressing pre-specified comparison and Chinese language outcomes

M.26.1 Excluded studies from top up search

Aphasia	Borenstein P, Linell S, Wahrborg P. An innovative therapeutic program for aphasia patients and their relatives. <i>Scandinavian Journal of Rehabilitation Medicine</i> . (Borenstein, Linell,	Not addressing review question
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	Wahrborg) Department of Neurology, Lundby Hospital, Goteborg Sweden. 1987; 19(2):51-56	
Aphasia	Brady MC, Kelly H, Enderby P. Aphasia rehabilitation - A Cochrane systematic review of the evidence for Speech and Language Therapy (SLT) compared with no SLT. International Journal of Stroke. 2011; 6:7	Abstract of the systematic review already included
Aphasia	Cherney LR, Patterson JP, Raymer AM. Intensity of aphasia therapy: evidence and efficacy. Current Neurology and Neuroscience Reports. 2011; 11(6):560-569	Not pre-specified study design and not addressing review question
Aphasia	David RM, Enderby P, Bainton D. Progress report on an evaluation of speech therapy for aphasia. British Journal of Disorders of Communication. (David, Enderby, Bainton) Avon Stroke Res. Unit, Bristol United Kingdom. 1979; 14(2):85-88	A report. Main study included in review
Aphasia	Hesketh A, Long A, Patchick E, Lee J, Bowen A. The reliability of rating conversation as a measure of functional communication following stroke. Aphasiology. (Hesketh, Patchick, Bowen) The University of Manchester, Manchester, United Kingdom. (Long, Lee) University of Leeds, Leeds, United Kingdom. 2008; 22(9):970-984	Not addressing review question
Aphasia	Hesketh A, Long A, Bowen A. Agreement on outcome: Speaker, carer, and therapist perspectives on functional communication after stroke. Aphasiology. 2011; 25(3):291-308	Not RCT. Not addressing review question
Aphasia	Kagan A, Winckel J, Black S, Duchan JF, Simmons-Mackie N, Square P. A Set of Observational Measures for Rating Support and Participation in Conversation between Adults with Aphasia and Their Conversation Partners. Topics in Stroke Rehabilitation. 2004; 11(1):67-83	Not addressing review question
Aphasia	Laska AC, Kahan T, Hellblom A, Murray V, Von Arbin M. A randomized controlled trial on very early speech and language therapy in patients with acute stroke and aphasia. Cerebrovascular Diseases. 2010; 29(Suppl 2):63	Abstract
Aphasia	Laska AC, Kahan T, Hellblom A, Murray V, von Arbin M. A randomized controlled trial on very early speech and language therapy in acute stroke	Not addressing pre-specified population (acute stroke)

	patients with aphasia. Cerebrovascular Diseases 2012, 1(1):66-74.	
Aphasia	McVicker S, Parr S, Pound C, Duchan J. The Communication Partner Scheme: A project to develop long-term, low-cost access to conversation for people living with aphasia. Aphasiology. (McVicker, Parr, Pound, Duchan) Connect - The Communication Disability Network, London, United Kingdom. 2009; 23(1):52-71	Not addressing pre-specified intervention and comparison
Aphasia	Simmons-Mackie N, Kagan A. Communication strategies used by 'good' versus 'poor' speaking partners of individuals with aphasia. Aphasiology. (Simmons-Mackie) Dept. Spec. Educ. Commun. Sci. D., Southeastern Louisiana University, Hammond, LA, United States. (Kagan) Pat Arato Aphasia Centre, Toronto, Ont., Canada. (Simmons-Mackie) 59020, Highway 433, Slidell, LA 70460, United States. 1999; 13(9-11):807-820	Not addressing review question. Not RCT

M.27 How should people with shoulder pain after stroke be managed to reduce pain?

Author	Title	Year	Journamfull	Reason for Exclusion
Lee JA;Park S;Hwang PW;Lim SM;Kook S;Choi KI;Kang KS;	Acupuncture for shoulder pain after stroke: A systematic review	2012	Journal of alternative and complement ary medicine	Shoulder pain covered by Delphi consensus statements

M.28 How should people with visual impairments including diplopia be best managed after a stroke?

Author	Title	Year	Journamfull	Reason for Exclusion
Greenwald BD;Kapoor N;Singh AD;	Visual impairments in the first year after traumatic brain injury	2012		Review - but not a systematic review

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- 3 New Zealand clinical guidelines for stroke management. New Zealand Guidelines Group, 2010 Available from: <http://www.stroke.org.nz/resources/NZClinicalGuidelinesStrokeManagement2010ActiveContents.pdf>
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- 5 Anderson C, Rubenach S, Mhurchu CN, Clark M, Spencer C, Winsor A. Home or hospital for stroke rehabilitation? results of a randomized controlled trial : I: health outcomes at 6 months. *Stroke*. 2000; 31(5):1024-1031
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- 7 Boysen G, Marott JL, Gronbaek M, Hassanpour H, Truelsen T. Long-term survival after stroke: 30 years of follow-up in a cohort, the Copenhagen City Heart Study. *Neuroepidemiology*. 2009; 33(3):254-260
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- 13 Fagerberg B, Claesson L, Gosman-Hedstrom G, Blomstrand C. Effect of acute stroke unit care integrated with care continuum versus conventional treatment: A randomized 1-year study of elderly patients: the Goteborg 70+ Stroke Study. *Stroke*. 2000; 31(11):2578-2584
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