NICE clinical guideline XX – Critical Illness Rehabilitation

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6.1 Appendix 1 – Scope

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Critical illness: rehabilitation after a period of critical illness

1.1 Short title

Critical illness rehabilitation

2 Background

a) The Department of Health has asked the National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') to develop a short clinical guideline on rehabilitation after a period of critical illness requiring a stay in an ITU, for use in the NHS in England and Wales (see appendix B). This guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

b) The Institute's clinical guidelines support the implementation of National Service Frameworks (NSFs) in those aspects of care for which a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued have the effect of updating the Framework.

c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and

their carers and families, if appropriate) can make informed decisions about their care and treatment.

3 Clinical need for the guideline

a) More than 100,000 people are admitted into critical care units in the UK each year. Many of these people experience significant and persistent problems with physical, non-physical (such as psychological or cognitive) and social functioning after discharge from critical care. This morbidity is frequently unrecognised and, when identified, may not be appropriately assessed or managed.

b) Physical morbidity, consisting of muscle loss and reduction of neuromuscular function, is universal following a period of critical illness. It is estimated that patients who require intensive care will lose 1% of their muscle mass per day of critical illness. Consequently, delayed motor recovery is common after discharge from critical care, particularly in patients who required prolonged mechanical ventilation (for 7 days or longer). Physical recovery is often slow, being measured in months rather than weeks. Some patients may also have difficulty in swallowing as a result of muscle weakness or surgery such as tracheostomy.

c) Non-physical morbidity such as psychological morbidity and cognitive dysfunction are also common after a period of critical illness: it has been reported that 1 in 10 critically ill patients develop severe psychological problems, with attendant problems in relatives/carers. These problems include anxiety, depression and post-traumatic stress disorder (PTSD). There are many reasons for psychological distress following critical illness. These include being unable to recall events accurately, having difficulty in communication, delusional memories, the choice of sedative used in treatment and previous psychological disease. Early recognition

and management of psychological problems may shorten the recovery period.

d) Up to three quarters of critically ill patients also have impairments in cognitive function – particularly memory, attention and problem solving – following critical illness. These impairments are frequently undiagnosed. Although in some cases the cause of the problem (for example, brain trauma) can be easily identified, for the majority of patients the reasons for the impairments are less well understood.

e) Rehabilitation strategies after discharge from critical care may help to improve patient outcomes. Such strategies may also reduce the length of hospital stay after discharge from critical care, minimise hospital readmission rates and decrease the use of primary care resources. Furthermore, these strategies could help patients return to their previous activities sooner. The time taken to return to previous activities depends on the reason for critical care admission and is typically between 9 and12 months after hospital discharge.

f) Currently, rehabilitation strategies after a period of critical illness tend to focus on physical function (patient mobility) and are limited to inpatient settings. However, multidisciplinary rehabilitation strategies, such as intensive care follow-up clinics, are increasingly being established in a number of UK hospitals. These strategies differ in nature, but all aim to support patient recovery in the year following discharge from critical care.

g) There is evidence to suggest that structured, self-directed rehabilitation strategies following critical illness can aid physical recovery and help people cope with the physical and psychological effects associated with critical illness. The composition of these structured, self-directed rehabilitation strategies varies widely. They

may include manuals that provide general advice, techniques to overcome cognitive dysfunctions and various exercise programmes.

h) To deliver individualised rehabilitation it is necessary to have accurate information on the physical and non-physical problems faced by each patient. There are a number of tools that can provide this information, such as the Barthel Index, Hospital Anxiety and Depression scale and the Impact of Event scale.

i) There is currently no evidence-based guideline available in England and Wales that addresses the identification, timing and nature of effective interventions to manage the physical and non-physical morbidity associated with critical illness.

4 The guideline

a) The guideline development process is described in detail in three publications that are available from the NICE website (see ‘Further information’). ‘The guideline development process: an overview for stakeholders, the public and the NHS’ describes how organisations can become involved in the development of a guideline. 'The guide to the short clinical guideline process' and 'The guidelines manual’ provide advice on the technical aspects of guideline development.

b) This document is the scope. It defines exactly what this 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.

c) 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

d) Adults with rehabilitation needs as a result of a period of critical illness that required level 2 and level 3 Critical Care. .

4.1.2 Groups that will not be covered

a) Adults receiving palliative care.

b) Clinical subgroups of patients whose specialist rehabilitation needs are already routinely assessed and delivered as part of their care pathway (for example, patients who received critical care as part of an elective pathway and who did not develop an unanticipated, ongoing critical illness, and in areas where published guidelines already exist such as head injury, myocardial infarction and stroke - see section 4.6.1).

4.2 Healthcare settings

a) Critical Care Areas.

b) General medical and surgical wards, and other inpatient and community settings where rehabilitation strategies may be delivered following a period of critical illness.

4.3 Clinical management

a) Identification and assessment of adult patients who are at risk of physical and non-physical morbidities, such as psychological, and cognitive dysfunction, resulting from, critical illness and treatment in critical care. This will include an evaluation of diagnostic screening and assessment tools that have been developed and/or validated in those who have had a period of critical illness. Where the evidence allows, recommendations will be made on those sub-groups of patients who have a greater potential to benefit (for example,

patients who have undergone significant periods of mechanical ventilation) or who may have specific needs (for example, older people).

b) Optimum timing for assessment and intervention to treat physical and non-physical dysfunction including psychological and cognitive dysfunction associated with critical illness.

c) Rehabilitation strategies to support adults identified as being at risk of physical and non-physical morbidities, including psychological, and cognitive dysfunction, after critical illness. The evidence that will be reviewed relates to rehabilitation strategies delivered to adult patients who have developed physical, psychological and cognitive dysfunction associated with their critical illness. It is also acknowledged that it is important for rehabilitation strategies to be flexible to the individual patient's needs. Where available, evidence on the role of the carer, and interventions aimed at the carer, will be reviewed.[1]

d) The information and support needs of adults who have had a period of critical illness and treatment in critical care.

e) The specific information and support needs of people who care for adults who have been in critical care.

f) The Guideline Development Group will take reasonable steps to identify ineffective interventions and approaches to care. If robust and credible recommendations for re-positioning the intervention for optimal use, or changing the approach to care to make more efficient use of resources, can be made, they will be clearly stated. If the resources released are substantial, consideration will be

[1] The guideline will identify the effective components of rehabilitation strategies. It will not address the service configuration and delivery of the strategies.

given to listing such recommendations in the 'Key priorities for implementation' section of the guideline.

4.4 Key outcome measures

a) Mortality.

b) Morbidity (including physical functional status, psychological impairments and cognitive dysfunction).

c) Readmission to hospital (as a result of physical or non-physical morbidities)

d) Hospital length of stay.

e) Health-related quality of life

4.5 Economic aspects

In line with 'The guidelines manual', developers will take into account both clinical and cost effectiveness. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and costs in the 'reference case' will be from an NHS and Personal Social Services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual'.

4.6 Status

4.6.1 Scope

This is the final draft of the scope.

Related NICE guidance

Anxiety: management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care. NICE clinical guideline CG22 (2004)

Depression: management of depression in primary and secondary care. NICE clinical guideline CG23 (2004)

Critical illness rehabilitation: NICE clinical guideline DRAFT (November 2008)

Dementia: Supporting people with dementia and their carers in health and social care. NICE clinical guideline CG42 (2006)

Head injury: triage, assessment, investigation and early management of head injury in infants, children and adults. NICE clinical guideline CG56 (2007)

MI: secondary prevention: secondary prevention in primary and secondary care for patients following a myocardial infarction. NICE clinical guideline CG48 (2007)

Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition. NICE clinical guideline CG32 (2006)

Anxiety: Management of post-traumatic stress disorder in adults in primary, secondary and community care. NICE clinical guideline CG26 (2005)

Stroke: The diagnosis and acute management of stroke and transient ischaemic attacks. NICE clinical guideline (to be published in July 2008)

Delirium: diagnosis, prevention and management of delirium. NICE clinical guideline (to be published in April 2010).

4.6.2 Guideline

The development of the guideline recommendations will begin in July 2008.

5 Further information

Information on the guideline development process is provided in:

- ‘The guideline development process: an overview for stakeholders, the public and the NHS’
- 'The guide to the short clinical guideline process'
- ‘The guidelines manual’.

These are available as PDF files from the NICE website (www.nice.org.uk/guidelinesmanual). Information on the progress of the guideline will also be available from the website.

Appendix A: Structured clinical questions

Questions on:

- The evaluation of screening and/or assessment tools for identifying adult patients receiving level 2 or 3 Critical Care at risk of physical and non-physical morbidities (including psychological and cognitive dysfunction) following a period of critical illness.

- The identification of the optimal timing for screening and/or assessment for physical and non-physical (psychological and cognitive) dysfunction associated with critical illness.

- The clinical effectiveness and cost-effectiveness of rehabilitation strategies for adult patients who have developed physical and non-physical morbidities (including psychological and cognitive dysfunction) following a period of critical illness requiring level 2 or 3 Critical Care.

- The identification of the optimal timing for rehabilitation strategies to address physical and non-physical morbidities (including psychological and cognitive dysfunction) associated with critical illness.

- The specific information and support needs of carers or families of adult patients who have developed rehabilitation needs following a period of critical illness requiring level 2 and level 3 Critical Care.

Appendix B: Referral from the Department of Health.

The Department of Health asked NICE:

'To prepare a clinical guideline on the rehabilitation of adults after a period of critical illness requiring a stay on ITU.'

6.2 Appendix 2 – Structured clinical questions

Structured Clinical Question 1:

The evaluation of screening and/or assessment tools for identifying adult patients receiving critical care at risk of physical and non-physical morbidity (including psychological and cognitive dysfunction) following a period of critical illness.

Review Question 1:

What are the clinical/test utilities of screening and assessment tools (developed and/or modified for critical care population) in identifying critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive dysfunction associated with their treatment experience and critical illness?

Structured Clinical Question 2:

The identification of the optimal timing for screening and/or assessment for physical and non-physical morbidity (including psychological and cognitive dysfunction) associated with critical illness.

Review Question 2:

When is the optimal time for screening and assessing critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive dysfunction associated with their treatment experience and critical illness?

Structured Clinical Question 3:

The clinical effectiveness and cost-effectiveness of rehabilitation strategies for adult patients who have developed physical and non-physical morbidity (including psychological and cognitive dysfunction) following a period of critical illness requiring critical care.

Review Question 3:

What are the clinical effectiveness and cost-effectiveness of different rehabilitation strategies/programmes for adult patients who have developed physical and non-physical morbidity including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?

Structured Clinical Question 4:

The identification of the optimal timing for rehabilitation strategies to address physical and non-physical morbidity (including psychological and cognitive dysfunction) associated with critical illness.

Review Question 4:

When is the optimal time for adult critical care rehabilitation? This includes:

- *Does early rehabilitation during critical care reduce subsequent risk of adult patients developing physical and non-physical morbidities following a period of critical illness and associated with their treatment experience in critical care?*
- *When is the optimal time for initiating or delivering rehabilitation strategies/programmes to adult patients with physical and non-physical morbidities including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?*

Structured Clinical Question 5:

The specific information and support needs of adult patients and their carers or families who have developed rehabilitation needs during and following a period of critical illness requiring critical care.

Review Question 5:

What information and support needs are viewed as important by adult patients and their carers or family who have developed rehabilitation needs during and following a period of critical illness requiring critical care?

6.3 Appendix 3 – Search strategy

Medline search strategies for Rehab guideline

6.3.1 Scoping searches

Scoping searches were undertaken on the following websites and databases (listed in alphabetical order) in January 2008 to provide information for scope development and project planning. Browsing or simple search strategies were employed.

Guidance/guidelines	Systematic reviews/economic evaluations
• American Association of Critical Care Nurses • Audit Commission • Australian and New Zealand Intensive Care Society • British Association for Emergency Medicine • British Association of Critical Care Nurses • Canadian Association of Critical Care Nurses • Canadian Critical Care Society • Canadian Medical Association Infobase • Department of Health • European Federation of Critical Care Nurses Associations • European Society of Intensive Care Medicine • Guidelines International Network (GIN) • Intensive Care National Audit and Research Centre • Intensive Care Society • Intensive Care Society – Ireland • National Audit Office • National Guideline Clearing House (US) • National Health and Medical Research Council (Australia) • National Institute for Health and Clinical Excellence (NICE) - published & in development • National Institute for Health and Clinical Excellence (NICE) - Topic	• Clinical Evidence • Cochrane Database of Systematic Reviews (CDSR) • Database of Abstracts of Reviews of Effects (DARE) • Health Economic Evaluations Database (HEED) • Health Technology Assessment (HTA) Database • NHS Economic Evaluation Database (NHS EED) • NHS R&D Service Delivery and Organisation (NHS SDO) Programme • National Institute for Health Research (NIHR) Health Technology Assessment Programme • TRIP Database

Selection • National Institute for Innovation and Improvement • National Library for Health (NLH) Guidelines Finder • National Library for Health (NLH) Protocols and Care Pathways Database • National Library for Health (NLH) Specialist Libraries • New Zealand Guidelines Group • Northern Ireland Intensive Care Society • Prodigy • Resuscitation Council • Royal College of Anaesthetists • Royal College of General Practitioners • Royal College of Nursing • Royal College of Physicians • Royal College of Psychiatrists • Royal College of Radiologists • Royal College of Speech and Language Therapists • Royal College of Surgeons • Scottish Intensive Care Society • Scottish Intensive Care Society - EBM site • Scottish Intercollegiate Guidelines Network (SIGN) • Society of Critical Care Medicine • Welsh Intensive Care Society	

389

6.3.2 Main searches

The following sources were searched for the topics presented in the sections below.

- Cochrane Database of Systematic Reviews – CDSR (Wiley)
- Cochrane Central Register of Controlled Trials – CENTRAL (Wiley)
- Database of Abstracts of Reviews of Effects – DARE (Wiley and CRD website)
- Health Technology Assessment Database – HTA (Wiley and CRD website)
- AMED (Dialog)
- CINAHL (Dialog and EBSCO)
- EMBASE (Ovid)
- MEDLINE (Ovid)
- MEDLINE In-Process (Ovid)
- PsycINFO (Ovid)
- Clinicaltrials.gov
- metaRegister of Controlled Trials – mRCT
- UK Clinical Research Network (UKCRN) Portfolio Database

Identification of evidence on screening and/or assessment tools to identify patients at risk of critical care morbidities

The searches were conducted on June 13th 2008. The aim of the searches was to identify evidence to answer the question: 'What are the clinical/test utilities of screening and assessment tools (developed and/or modified for critical care population) in identifying critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive dysfunction associated with their treatment experience and critical illness?' (see also section 2.2 in the main guideline)

The MEDLINE search strategy is presented below. It was translated for use in all of the other databases. Where appropriate, search filters for systematic reviews, randomised controlled trials and observational studies were appended to the search strategies to retrieve high quality papers (See **Systematic reviews, randomised controlled trials and observational studies search filters**).

Database: Ovid MEDLINE(R) <1950 to June Week 1 2008>

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1 exp Critical Care/

2 critical care.tw.

3 Critical Illness/

4 critical$ ill$.tw.

5 exp Intensive Care Units/

6 intensive care.tw.

7 (ICU$ or SICU$ or MICU$ or ITU$).tw.

8 or/1-7

9 exp "Sensitivity and Specificity"/

10 sensitivity.tw.

11 specificity.tw.

12 ((pre-test or pretest) adj probability).tw.

13 post-test probability.tw.

14 predictive value$.tw.

15 likelihood ratio$.tw.

16 roc curv$.tw.

17 "reproducibility of results"/

18 or/9-17

19 efficac$.tw.

20 evaluat$.tw.

21 effectiv$.tw.

22 utilit$.tw.

23 useful$.tw.

24 test$.tw.

25 value$.tw.

26 reliab$.tw.

27 valid$.tw.

28 or/19-27

29 18 or 28

30 Diagnosis/

31 exp Nursing Assessment/

32 ((diag$ or screen$ or assess$) adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

33 or/30-32

34 29 and 33

35 ((physical$ or physiolog$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

36 Walking/

37 (walk or walks or walking).tw.

38 (ambulate$ or ambulation$ or ambulating$).tw.

39 exp Movement Disorders/ or exp Movement/

40 mobility limitation/

41 ((mov$ or mobil$ or motor$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$)).tw.

42 exp Musculoskeletal Physiology/

43 Neuromuscular Diseases/

44 exp neuromuscular manifestations/

45 exp Muscular Diseases/

46 ((musc$ or neuromusc$ or neuro-musc$ or neuro musc$) adj3 (atroph$ or dystroph$ or hypoton$ or weak$ or strength$ or loss$ or dys$ or function$ or dis$ or abilit$ or degenerat$ or difficult$ or limit$ or problem$ or condition$ or debilit$ or impair$ or manifest$ or symptom$ or deteriorat$ or state or states or status)).tw.

47 (myopath$ or neuromyopath$ or neuro-myopath$ or neuro myopath$ or neuropath$ or polyneuropath$ or (peripher$ adj2 nerve$)).tw.

48 Fatigue/

49 (fatigu$ or letharg$ or tired$ or weak$).tw.

50 exp Somatosensory Disorders/

51 (somatosensor$ or hypesthes$ or hypesthaes$ or paresthes$ or paresthaes$ or numb$).tw.

52 locomot$.tw.

53 Communication/

54 exp verbal behavior/

55 (communicat$ or speech or speak$ or talk$ or converse$ or conversing or conversation$ or verbal$).tw.

56 Deglutition/

57 Deglutition Disorders/

58 deglut$.tw.

59 dysphagi$.tw.

60 swallow$.tw.

61 exp Nutrition Physiology/

62 exp "nutritional and metabolic diseases"/

63 nutrition$.tw.

64 malnutrition$.tw.

65 diet$.tw.

66 exp Weight Loss/

67 (weight adj3 (los$ or reduc$)).tw.

68 cachexi$.tw.

69 emaciat$.tw.

70 wasting.tw.

71 or/35-70

72 34 and 71

73 barthel$.tw.

74 katz$.tw.

75 Karnofsky Performance Status/

76 karnofsky$.tw.

77 (activit$ level$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

78 (function$ state$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

79 Exercise Test/

80 walk$ test$.tw.

81 new york heart association.tw.

82 nyha.tw.

83 borg.tw.

84 (oxford$ adj5 musc$ adj5 grad$).tw.

85 shuttle$.tw.

86 (function$ independen$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

87 (short form health survey$ or short form 36 or short-form 36 or shortform 36 or sf 36 or sf-36 or sf36).tw.

88 or/73-87

89 29 and 88

90 72 or 89

91 exp Mental Disorders/

92 exp Neurobehavioral Manifestations/

93 exp Behavioral Symptoms/

94 ((mental$ or psyc$ or neuropsyc$ or neuro-psyc$ or neuro psyc$ or behav$ or neurobehav$ or neuro$ behav$ or neuro-behav$) adj3 (ill$ or dis$ or abilit$ or dys$ or function$ or morbid$ or condition$ or deteriorat$ or problem$ or symptom$ or manifest$ or debilit$ or degenerat$ or state or states or status)).tw.

95 Anxiety/

96 (anxi$ or depress$ or dysthym$ or posttrauma$ or post-trauma$ or post trauma$ or ptsd$ or stress$ or delud$ or delus$ or delir$).tw.

97 or/91-96

98 34 and 97

99 (profile$ adj2 mood$ state$).tw.

100 poms.tw.

101 (depress$ adj2 anx$ adj2 stress$ adj2 scale$).tw.

102 dass.tw.

103 depression scale$.tw.

104 beck$ depress$.tw.

105 bdi.tw.

106 beck$ anx$.tw.

107 bai.tw.

108 (hospital$ anxiet$ adj2 depression scale$).tw.

109 hads.tw.

110 (impact$ adj2 event$ scale$).tw.

111 centre for epidemiological studies depress$.tw.

112 ces-d.tw.

113 cesd.tw.

114 ces d.tw.

115 spielberger$.tw.

116 state trait anxi$.tw.

117 stai.tw.

118 (trauma$ symptom$ adj2 (checklist$ or check-list$ or check list$)).tw.

119 (tsc 33 or tsc-33 or tsc33).tw.

120 ((posttrauma$ or post-trauma$ or post trauma$ or ptsd$) adj5 (scale$ or inventor$)).tw.

121 (14-q or 14 q or 14q).tw.

122 (10-q or 10 q or 10q).tw.

123 ptss.tw.

124 pds.tw.

125 davidson$.tw.

126 trauma$ scale$.tw.

127 (short form health survey$ or short form 36 or short-form 36 or shortform 36 or sf 36 or sf-36 or sf36).tw.

128 or/99-127

129 29 and 128

130 98 or 129

131 Cognition Disorders/

132 exp Neurobehavioral Manifestations/

133 ((neurobehavio$ or neuro-behavio$ or neuro$ behavio$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

134 (confus$ or disorient$).tw.

135 Attention/

136 exp Sleep Disorders/

137 ((cognit$ or social or neurocogn$ or neuro-cogn$ or neuro cogn$ or brain or consciousness or memor$ or executive or attenti$ or inattenti$ or concentrat$ or sleep$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or function$ or dys$ or impair$ or loss$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or process$ or state or states or status)).tw.

138 Problem Solving/

139 (problem-solv$ or problem$ solv$).tw.

140 Hallucinations/

141 hallucinat$.tw.

142 or/131-141

143 34 and 142

144 Trail Making Test/

145 trailmaking test$.tw.

146 trail-making test$.tw.

147 trail$ making test$.tw.

148 card$ sorting test$.tw.

149 wisconsin$.tw.

150 Wechsler Scales/

151 wechsler$.tw.

152 memor$ scale$.tw.

153 Pattern Recognition, Visual/

154 benton$.tw.

155 visual$ retention test$.tw.

156 wcst.tw.

157 mini mental state$ exam$.tw.

158 mini-mental state$ exam$.tw.

159 mmse.tw.

160 paced auditory serial addition test$.tw.

161 pasat$.tw.

162 (cognitive$ test$ adj2 delir$).tw.

163 confus$ assess$ method$.tw.

164 cam icu.tw.

165 cam-icu.tw.

166 intensive care delir$ screen$ checklist$.tw.

167 ICDSC.tw.

168 NEECHAM.tw.

169 delir$ detection score$.tw.

170 cambridge neuro$ test$.tw.

171 cantab.tw.

172 function$ activit$ question$.tw.

173 informant question$.tw.

174 iqcode.tw.

175 dementia rating.tw.

176 (mbdrs or mb-drs or mb drs).tw.

177 or/144-176

178 29 and 177

179 143 or 178

180 90 or 130 or 179

181 8 and 180

Identification of evidence on the optimal timing of screening and/or assessment tools to identify patients at risk critical care morbidities

The searches were conducted on June 13th 2008. The aim of the searches was to identify evidence to answer the question: 'When is the best or optimal time for screening and assessing critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive dysfunction associated with their treatment experience and critical illness?' (see also section X.X.X in the main guideline)

The MEDLINE search strategy is presented below. It was translated for use in all of the other databases. Where appropriate, search filters for systematic reviews, randomised controlled trials and observational studies were appended to the search strategies to retrieve high quality papers (See **Systematic reviews, randomised controlled trials and observational studies search filters**).

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---

1 exp Critical Care/

2 critical care.tw.

3 Critical Illness/

4 critical$ ill$.tw.

5 exp Intensive Care Units/

6 intensive care.tw.

7 (ICU$ or SICU$ or MICU$ or ITU$).tw.

8 or/1-7

9 Time/

10 Time Factors/

11 (time$ or timing$).tw.

12 After-Hours Care/

13 hour$.tw.

14 (night$ or day$ or morning$ or afternoon$ or evening$ or week$).tw.

15 or/9-14

16 Diagnosis/

17 exp Nursing Assessment/

18 ((diag$ or screen$ or assess$) adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

19 or/16-19

20 15 and 19

21 ((physical$ or physiolog$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

22 Walking/

23 (walk or walks or walking).tw.

24 (ambulate$ or ambulation$ or ambulating$).tw.

25 exp Movement Disorders/ or exp Movement/

26 mobility limitation/

27 ((mov$ or mobil$ or motor$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$)).tw.

28 exp Musculoskeletal Physiology/

29 Neuromuscular Diseases/

30 exp neuromuscular manifestations/

31 exp Muscular Diseases/

32 ((musc$ or neuromusc$ or neuro-musc$ or neuro musc$) adj3 (atroph$ or dystroph$ or hypoton$ or weak$ or strength$ or loss$ or dys$ or function$ or dis$ or abilit$ or degenerat$ or difficult$ or limit$ or problem$ or condition$ or debilit$ or impair$ or manifest$ or symptom$ or deteriorat$ or state or states or status)).tw.

33 (myopath$ or neuromyopath$ or neuro-myopath$ or neuro myopath$ or neuropath$ or polyneuropath$ or (peripher$ adj2 nerve$)).tw.

34 Fatigue/

35 (fatigu$ or letharg$ or tired$ or weak$).tw.

36 exp Somatosensory Disorders/

37 (somatosensor$ or hypesthes$ or hypesthaes$ or paresthes$ or paresthaes$ or numb$).tw.

38 locomot$.tw.

39 Communication/

40 exp verbal behavior/

41 (communicat$ or speech or speak$ or talk$ or converse$ or conversing or conversation$ or verbal$).tw.

42 Deglutition/

43 Deglutition Disorders/

44 deglut$.tw.

45 dysphagi$.tw.

46 swallow$.tw.

47 exp Nutrition Physiology/

48 exp "nutritional and metabolic diseases"/

49 nutrition$.tw.

50 malnutrition$.tw.

51 diet$.tw.

52 exp Weight Loss/

53 (weight adj3 (los$ or reduc$)).tw.

54 cachexi$.tw.

55 emaciat$.tw.

56 wasting.tw.

57 or/21-56

58 20 and 57

59 barthel$.tw.

60 katz$.tw.

61 Karnofsky Performance Status/

62 karnofsky$.tw.

63 (activit$ level$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

64 (function$ state$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

65 Exercise Test/

66 walk$ test$.tw.

67 new york heart association.tw.

68 nyha.tw.

69 borg.tw.

70 (oxford$ adj5 musc$ adj5 grad$).tw.

71 shuttle$.tw.

72 (function$ independen$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-

list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

73 (short form health survey$ or short form 36 or short-form 36 or shortform 36 or sf 36 or sf-36 or sf36).tw.

74 or/59-73

75 15 and 74

76 58 or 75

77 exp Mental Disorders/

78 exp Neurobehavioral Manifestations/

79 exp Behavioral Symptoms/

80 ((mental$ or psyc$ or neuropsyc$ or neuro-psyc$ or neuro psyc$ or behav$ or neurobehav$ or neuro$ behav$ or neuro-behav$) adj3 (ill$ or dis$ or abilit$ or dys$ or function$ or morbid$ or condition$ or deteriorat$ or problem$ or symptom$ or manifest$ or debilit$ or degenerat$ or state or states or status)).tw.

81 Anxiety/

82 (anxi$ or depress$ or dysthym$ or posttrauma$ or post-trauma$ or post trauma$ or ptsd$ or stress$ or delud$ or delus$ or delir$).tw.

83 or/77-82

84 20 and 83

85 (profile$ adj2 mood$ state$).tw.

86 poms.tw.

87 (depress$ adj2 anx$ adj2 stress$ adj2 scale$).tw.

88 dass.tw.

89 depression scale$.tw.

90 beck$ depress$.tw.

91 bdi.tw.

92 beck$ anx$.tw.

93 bai.tw.

94 (hospital$ anxiet$ adj2 depression scale$).tw.

95 hads.tw.

96 (impact$ adj2 event$ scale$).tw.

97 centre for epidemiological studies depress$.tw.

98 ces-d.tw.

99 cesd.tw.

100 ces d.tw.

101 spielberger$.tw.

102 state trait anxi$.tw.

103 stai.tw.

104 (trauma$ symptom$ adj2 (checklist$ or check-list$ or check list$)).tw.

105 (tsc 33 or tsc-33 or tsc33).tw.

106 ((posttrauma$ or post-trauma$ or post trauma$ or ptsd$) adj5 (scale$ or inventor$)).tw.

107 (14-q or 14 q or 14q).tw.

108 (10-q or 10 q or 10q).tw.

109 ptss.tw.

110 pds.tw.

111 davidson$.tw.

112 trauma$ scale$.tw.

113 (short form health survey$ or short form 36 or short-form 36 or shortform 36 or sf 36 or sf-36 or sf36).tw.

114 or/85-113

115 15 and 114

116 84 or 115

117 Cognition Disorders/

118 exp Neurobehavioral Manifestations/

119 ((neurobehavio$ or neuro-behavio$ or neuro$ behavio$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

120 (confus$ or disorient$).tw.

121 Attention/

122 exp Sleep Disorders/

123 ((cognit$ or social or neurocogn$ or neuro-cogn$ or neuro cogn$ or brain or consciousness or memor$ or executive or attenti$ or inattenti$ or concentrat$ or sleep$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or function$ or dys$ or impair$ or loss$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or process$ or state or states or status)).tw.

124 Problem Solving/

125 (problem-solv$ or problem$ solv$).tw.

126 Hallucinations/

127 hallucinat$.tw.

128 or/117-127

129 20 and 128

130 Trail Making Test/

131 trailmaking test$.tw.

132 trail-making test$.tw.

133 trail$ making test$.tw.

134 card$ sorting test$.tw.

135 wisconsin$.tw.

136 Wechsler Scales/

137 wechsler$.tw.

138 memor$ scale$.tw.

139 Pattern Recognition, Visual/

140 benton$.tw.

141 visual$ retention test$.tw.

142 wcst.tw.

143 mini mental state$ exam$.tw.

144 mini-mental state$ exam$.tw.

145 mmse.tw.

146 paced auditory serial addition test$.tw.

147 pasat$.tw.

148 (cognitive$ test$ adj2 delir$).tw.

149 confus$ assess$ method$.tw.

150 cam icu.tw.

151 cam-icu.tw.

152 (intensive care delir$ screen$ adj2 (checklist$ or check-list$ or check list$)).tw.

153 ICDSC.tw.

154 NEECHAM.tw.

155 delir$ detection score$.tw.

156 cambridge neuro$ test$.tw.

157 cantab.tw.

158 function$ activit$ question$.tw.

159 informant question$.tw.

160 iqcode.tw.

161 dementia rating.tw.

162 (mbdrs or mb-drs or mb drs).tw.

163 or/130-162

164 15 and 163

165 129 or 164

166 76 or 116 or 165

167 8 and 166

Identification of evidence on rehabilitation strategies for patients with critical care morbidities

These searches were conducted on July 7th 2008. The aim of the searches was to identify evidence to answer the questions: 'What are the clinical effectiveness and cost-effectiveness of different rehabilitation strategies/programmes for adult patients who have developed physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive deficits associated with their treatment experience in Critical Care and critical illness?' (see also section X.X.X in the main guideline) and 'When is the best or optimal time for initiating or delivering rehabilitation strategies/programmes to adult patients with physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive deficits associated with their treatment experience in Critical Care and critical illness?' (see also section X.X.X in the main guideline)

The MEDLINE search strategy is presented below. It was translated for use in all of the other databases. Search filters for systematic reviews, randomised controlled trials and observational studies were appended to the search strategies to retrieve high quality papers (See **Systematic reviews, randomised controlled trials and observational studies search filters**).

Database: Ovid MEDLINE(R) <1950 to June Week 4 2008>

---

1 exp Critical Care/

2 critical care.tw.

3 Critical Illness/

4 critical$ ill$.tw.

5 exp Intensive Care Units/

6 intensive care.tw.

7 (ICU$ or SICU$ or MICU$ or ITU$).tw.

8 or/1-7

9 exp Rehabilitation/

10 Convalescence/

11 convales$.tw.

12 "Recovery of Function"/

13 Rehabilitation Nursing/

14 Rehabilitation Centers/ or Subacute Care/

15 (rehab$ or habilitat$ or recover$).tw.

16 Residential Facilities/

17 Assisted Living Facilities/

18 Halfway Houses/

19 exp Nursing Homes/

20 (extend$ adj2 care$ adj3 (facilit$ or service$ or unit$ or center$ or clinic$ or program$ or residen$ or home$ or hous$)).tw.

21 ((residen$ or intermediate$ or assist$ liv$) adj3 (facilit$ or care$ or service$ or unit$ or center$ or clinic$ or program$ or residen$ or home$ or hous$)).tw.

22 ((halfway or transition$) adj3 (home$ or hous$ or facilit$ or care$ or residen$ or service$ or unit$ or center$ or clinic$ or program$)).tw.

23 (nurs$ adj2 home$).tw.

24 ((acute$ or critical$ or intensive$ or discharg$) adj5 (followup or follow$ up or follow-up)).tw.

25 (postacute$ or postcritical$ or postintensive$ or postdischarg$ or subacute$).tw.

26 (post-acute$ or post-critical$ or post-intensive$ or post-discharg$ or sub-acute$).tw.

27 (post acute$ or post critical$ or post intensive$ or post discharg$ or "sub acute$").tw.

28 ((post or after or discharg$ or follow$) adj3 (ICU$ or SICU$ or MICU$ or ITU$)).tw.

29 ((post or after or follow$ or discharg$) adj3 (acute$ or critical$ or intensive$ or discharg$)).tw.

30 preventive health services/

31 preventive medicine/ or preventive psychiatry/

32 Primary Prevention/

33 prevent$.tw.

34 prophyla$.tw.

35 ((reducti$ or reduci$ or reduce$ or lower$ or decreas$ or minimis$ or minimiz$ or diminish$ or lessen$ or lesser$ or abate$ or abati$ or curtail$ or stop or stops or stopp$) adj3 (illness$ or morbid$ or declin$ or manifest$ or symptom$ or disease$ or disorder$ or dysfunct$ or function$ or impair$ or difficult$ or problem$ or condition$ or debilit$ or degenerat$ or complicat$ or risk$)).tw.

36 ((early or earli$ or immediat$ or initial$ or begin$ or first$ or first-line or first line or first choice or primar$ or preceed$ or original$) adj3 (interven$ or treat$ or therap$ or care or medicine$ or technique$ or strateg$ or activit$ or mobili$)).tw.

37 or/9-36

38 ((physical$ or physiolog$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

39 Walking/

40 (walk or walks or walking).tw.

41 (ambulate$ or ambulation$ or ambulating$).tw.

42 exp Movement Disorders/ or exp Movement/

43 mobility limitation/

44 ((mov$ or mobil$ or motor$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$)).tw.

45 exp Musculoskeletal Physiology/

46 Neuromuscular Diseases/

47 exp neuromuscular manifestations/

48 exp Muscular Diseases/

49 ((musc$ or neuromusc$ or neuro-musc$ or neuro musc$) adj3 (atroph$ or dystroph$ or hypoton$ or weak$ or strength$ or loss$ or dys$ or function$ or dis$ or abilit$ or degenerat$ or difficult$ or limit$

or problem$ or condition$ or debilit$ or impair$ or manifest$ or symptom$ or deteriorat$ or state or states or status)).tw.

50 (myopath$ or neuromyopath$ or neuro-myopath$ or neuro myopath$ or neuropath$ or polyneuropath$ or (peripher$ adj2 nerve$)).tw.

51 Fatigue/

52 (fatigu$ or letharg$ or tired$ or weak$).tw.

53 exp Somatosensory Disorders/

54 (somatosensor$ or hypesthes$ or hypesthaes$ or paresthes$ or paresthaes$ or numb$).tw.

55 locomot$.tw.

56 Communication/

57 exp verbal behavior/

58 (communicat$ or speech or speak$ or talk$ or converse$ or conversing or conversation$ or verbal$).tw.

59 Deglutition/

60 Deglutition Disorders/

61 deglut$.tw.

62 dysphagi$.tw.

63 swallow$.tw.

64 exp Nutrition Physiology/

65 exp "nutritional and metabolic diseases"/

66 nutrition$.tw.

67 malnutrition$.tw.

68 diet$.tw.

69 exp Weight Loss/

70 (weight adj3 (los$ or reduc$)).tw.

71 cachexi$.tw.

72 emaciat$.tw.

73 wasting.tw.

74 or/38-73

75 37 and 74

76 8 and 75

77 Physical Medicine/

78 exp Physical Therapy Modalities/

79 "Physical Therapy (Specialty)"/

80 exp Exercise Movement Techniques/

81 (exerci$ adj3 (rehab$ or habilitat$ or recover$ or therap$ or treat$ or medicine$ or intervention$ or technique$ or strateg$)).tw.

82 ((walk$ or mobil$ or mov$ or motor$ or physi$) adj3 (rehab$ or habilitat$ or recover$ or therap$ or treat$ or medicine$ or intervention$ or technique$ or strateg$)).tw.

83 (physio or physiotherap$).tw.

84 (self-directed adj3 (exerci$ or phys$ or activit$)).tw.

85 (self adj3 directed adj3 (exerci$ or phys$ or activit$)).tw.

86 (self-care adj3 (exerci$ or phys$ or activit$)).tw.

87 (self adj3 care adj3 (exerci$ or phys$ or activit$)).tw.

88 (patient-directed adj3 (exerci$ or phys$ or activit$)).tw.

89 (patient$ adj3 directed adj3 (exerci$ or phys$ or activit$)).tw.

90 (self-manag$ adj3 (exerci$ or phys$ or activit$)).tw.

91 (self adj3 manag$ adj3 (exerci$ or phys$ or activit$)).tw.

92 (self-administ$ adj3 (exerci$ or phys$ or activit$)).tw.

93 (self adj3 administ$ adj3 (exerci$ or phys$ or activit$)).tw.

94 (patient-directed adj3 (breath$ or inhal$ or exhal$)).tw.

95 (patient$ adj3 directed adj3 (breath$ or inhal$ or exhal$)).tw.

96 (self-care adj3 (breath$ or inhal$ or exhal$)).tw.

97 (self adj3 care adj3 (breath$ or inhal$ or exhal$)).tw.

98 (self-directed adj3 (breath$ or inhal$ or exhal$)).tw.

99 (self adj3 directed adj3 (breath$ or inhal$ or exhal$)).tw.

100 (self-manag$ adj3 (breath$ or inhal$ or exhal$)).tw.

101 (self adj3 manag$ adj3 (breath$ or inhal$ or exhal$)).tw.

102 (self-administ$ adj3 (breath$ or inhal$ or exhal$)).tw.

103 (self adj3 administr$ adj3 (breath$ or inhal$ or exhal$)).tw.

104 positioning.tw.

105 (passive$ adj5 (mov$ or motion$)).tw.

106 cpm therap$.tw.

107 (bed$ adj3 (mobil$ or mov$)).tw.

108 ((limb$ or arm$ or leg$) adj3 exerci$).tw.

109 Percussion/

110 percussion$.tw.

111 Vibration/

112 vibration$.tw.

113 kinesiotherap$.tw.

114 ((musc$ or spin$ or osteo$ or ortho$ or chiro$) adj3 (manipulation$ or rehab$ or habilitat$ or recover$ or therap$ or treat$ or medicine$ or intervention$ or technique$ or strateg$)).tw.

115 massag$.tw.

116 (manip$ adj3 (rehab$ or habilitat$ or recover$ or therap$ or treat$ or medicine$ or intervention$ or technique$ or strateg$)).tw

117 (manual$ adj3 (rehab$ or habilitat$ or recover$ or therap$ or treat$ or medicine$ or intervention$ or technique$ or strateg$)).tw.

118 (musc$ adj3 stretch$).tw.

119 (function$ adj3 training$).tw.

120 exp "rehabilitation of speech and language disorders"/

121 ((speech or languag$) adj3 (rehab$ or recover$ or therap$)).tw.

122 or/77-121

123 8 and 122

124 76 or 123

125 exp Mental Disorders/

126 exp Neurobehavioral Manifestations/

127 exp Behavioral Symptoms/

128 ((mental$ or psyc$ or neuropsyc$ or neuro-psyc$ or neuro psyc$ or behav$ or neurobehav$ or neuro$ behav$ or neuro-behav$) adj3 (ill$ or dis$ or abilit$ or dys$ or function$ or morbid$ or condition$ or deteriorat$ or problem$ or symptom$ or manifest$ or debilit$ or degenerat$ or state or states or status)).tw.

129 Anxiety/

130 (anxi$ or depress$ or dysthym$ or posttrauma$ or post-trauma$ or post trauma$ or ptsd$ or stress$ or delud$ or delus$ or delir$).tw.

131 or/125-130

132 37 and 131

133 8 and 132

134 Self-Help Groups/

135 (self-help or self help or support$ group$ or patient$ group$).tw.

136 134 or 135

137 Depression/

138 exp Depressive Disorder/

139 depress$.tw.

140 or/137-139

141 136 and 140

142 8 and 141

143 133 or 142

144 Cognition Disorders/

145 exp Neurobehavioral Manifestations/

146 ((neurobehavio$ or neuro-behavio$ or neuro$ behavio$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

147 (confus$ or disorient$).tw.

148 Attention/

149 exp Sleep Disorders/

150 ((cognit$ or social or neurocogn$ or neuro-cogn$ or neuro cogn$ or brain or consciousness or memor$ or executive or attenti$ or inattenti$ or concentrat$ or sleep$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or function$ or dys$ or impair$ or loss$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or process$ or state or states or status)).tw.

151 Problem Solving/

152 (problem-solv$ or problem$ solv$).tw.

153 Hallucinations/

154 hallucinat$.tw.

155 or/144-154

156 37 and 155

1112 157 8 and 156

1113 158 diar$.tw.

1114 159 8 and 158

1115 160 157 or 159

1116 161 124 or 143 or 160

Systematic reviews, randomised controlled trials and observational studies search filters

Search filters for systematic reviews, randomised controlled trials and observational studies were appended to the search strategies above to retrieve high quality evidence.

The MEDLINE search filters are presented below. They were translated for use in all of the other databases.

Systematic Reviews

1. Meta-Analysis/
2. Meta-Analysis.pt.
3. Meta-Analysis as Topic/
4. Review/
5. Review.pt.
6. exp Review Literature as Topic/
7. (metaanaly$ or metanaly$ or (meta adj2 analy$)).tw.
8. (review$ or overview$).ti.
9. (systematic$ adj4 (review$ or overview$)).tw.
10. ((quantitative$ or qualitative$) adj4 (review$ or overview$)).tw.
11. ((studies or trial$) adj1 (review$ or overview$)).tw.
12. (integrat$ adj2 (research or review$ or literature)).tw.
13. (pool$ adj1 (analy$ or data)).tw.

14. (handsearch$ or (hand adj2 search$)).tw.

15. (manual$ adj2 search$).tw.

16. or/1-15

Randomised Controlled Trials

1 Randomized Controlled Trial/

2 Randomized Controlled Trial.pt.

3 Controlled Clinical Trial/

4 Controlled Clinical Trial.pt.

5 Clinical Trial/

6 Clinical Trial.pt.

7 exp Clinical Trials as Topic/

8 Placebos/

9 Random Allocation/

10 Double-Blind Method/

11 Single-Blind Method/

12 Cross-Over Studies/

13 ((random$ or control$ or clinical$) adj2 (trial$ or stud$)).tw.

14 (random$ adj2 allocat$).tw.

15 placebo$.tw.

16 ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).tw.

17 (crossover$ or (cross adj over$)).tw.

18 or/1-17

Observational studies

1 Epidemiologic Studies/

2 exp Case-Control Studies/

3 exp Cohort Studies/

4 Cross-Sectional Studies/

5 Comparative Study.pt.

6 case control$.tw.

7 case series.tw.

8 (cohort adj (study or studies)).tw.

9 cohort analy$.tw.

10 (follow up adj (study or studies)).tw.

11 (observational adj (study or studies)).tw.

12 longitudinal.tw.

13 prospective.tw.

14 retrospective.tw.

15 cross sectional.tw.

16 or/1-15

Identification of evidence on the information and support needs of patients with critical care morbidity rehabilitation needs and identification of evidence on the information and support needs their carers or families

The searches were conducted on September 4th 2008. The aim of the searches was to identify evidence to answer the question: 'What information and support needs are viewed as important by adult patients and their carers or family who have developed rehabilitation needs during and following a period of critical illness requiring Critical Care?' (see also section X.X.X in the main guideline)

The MEDLINE search strategy is presented below. It was translated for use in all of the other databases.

Database: Ovid MEDLINE(R) <1950 to August Week 4 2008>

---

1 exp Rehabilitation/

2 Convalescence/

3 convales$.tw.

4 "Recovery of Function"/

5 Rehabilitation Nursing/

6 Rehabilitation Centers/ or Subacute Care/

7 (rehab$ or habilitat$ or recover$).tw.

8 Residential Facilities/

9 Assisted Living Facilities/

10 Halfway Houses/

11 exp Nursing Homes/

12 (extend$ adj2 care$ adj3 (facilit$ or service$ or unit$ or center$ or clinic$ or program$ or residen$ or home$ or hous$)).tw.

13 ((residen$ or intermediate$ or assist$ liv$) adj3 (facilit$ or care$ or service$ or unit$ or center$ or clinic$ or program$ or residen$ or home$ or hous$)).tw.

14 ((halfway or transition$) adj3 (home$ or hous$ or facilit$ or care$ or residen$ or service$ or unit$ or center$ or clinic$ or program$)).tw.

15 (nurs$ adj2 home$).tw.

16 ((acute$ or critical$ or intensive$ or discharg$) adj5 (followup or follow$ up or follow-up)).tw.

17 (postacute$ or postcritical$ or postintensive$ or postdischarg$ or subacute$).tw.

18 (post-acute$ or post-critical$ or post-intensive$ or post-discharg$ or sub-acute$).tw.

19 (post acute$ or post critical$ or post intensive$ or post discharg$ or "sub acute$").tw.

20 ((post or after or discharg$ or follow$) adj3 (ICU$ or SICU$ or MICU$ or ITU$)).tw.

21 ((post or after or follow$ or discharg$) adj3 (acute$ or critical$ or intensive$ or discharg$)).tw.

22 or/1-21

23 Patients/px

24 Family/px

25 Spouses/px

26 Caregivers/px

27 exp Consumer Satisfaction/

28 ((patient$ or famil$ or relative$ or carer$ or caregiver$ or care-giver$ or spous$ or husband$ or wife$ or wive$ or partner$) adj5 (experience$ or belief$ or stress$ or emotion$ or anx$ or fear$ or concern$ or uncertain$ or unsure or thought$ or feeling$ or felt$ or view$ or opinion$ or perception$ or perspective$ or attitud$ or satisfact$ or know$ or understand$ or aware$)).ti.

29 or/23-28

30 Patients/

31 Family/

32 Spouses/

33 Caregivers/

34 or/30-33

35 Pamphlets/

36 Needs Assessment/

37 Information Centers/

38 Information Services/

39 health education/

40 Information Dissemination/

41 Counseling/

42 Social Support/

43 Self-Help Groups/

44 Self Care/

45 or/35-44

46 34 and 45

47 ((patient$ or famil$ or relative$ or carer$ or caregiver$ or care-giver$ or spous$ or husband$ or wife$ or wive$ or partner$) adj5 (educat$ or informat$ or communicat$ or pamphlet$ or handout$ or hand-out$ or hand out$ or booklet$ or leaflet$ or support$ or need$ or advice$ or advis$)).ti.

48 ((patient$ or famil$ or relative$ or carer$ or caregiver$ or care-giver$ or spous$ or husband$ or wife$ or wive$ or partner$) adj5 (counsel$ or selfhelp$ or self-help$ or self help$ or selfcar$ or self-car$ or self car$)).ti.

49 47 or 48

50 Patient Education as Topic/

51 patient education handout/

52 consumer health information/

53 critical care family needs inventor$.tw.

54 icu diar$.tw.

55 (intensive care adj3 diar$).tw.

56 patient$ diar$.tw.

57 or/50-56

58 29 or 46 or 49 or 57

59 22 and 58

60 exp Critical Care/

61 critical care.tw.

62 Critical Illness/

63 critical$ ill$.tw.

64 exp Intensive Care Units/

65 intensive care.tw.

66 (ICU$ or SICU$ or MICU$ or ITU$).tw.

67 or/60-66

68 59 and 67

Economic evaluations and quality of life data

Sources

The following sources were searched to identify economic evaluations:

- NHS Economic Evaluation Database – NHS EED (Wiley and CRD website
- Health Economic Evaluations Database – HEED (Wiley)
- Embase (Ovid)
- MEDLINE (Ovid)
- MEDLINE In-Process (Ovid)

Identification of evidence on the cost-effectiveness of screening and/or assessment tools to identify patients at risk of critical care morbidities

The searches were undertaken on June 6th 2008. The MEDLINE search strategy is presented below. It was translated for use in all of the other databases. Filters to retrieve economic evaluations and quality of life papers were appended to the MEDLINE, MEDLINE IN PROCESS and EMBASE searches to identify relevant evidence (See **Appendix X.X.X.X Economic evaluations and quality of life search filters**).

Database: Ovid MEDLINE(R) <1950 to June Week 1 2008>

---

1 exp Critical Care/

2 critical care.tw.

3 Critical Illness/

4 critical$ ill$.tw.

5 exp Intensive Care Units/

6 intensive care.tw.

7 (ICU$ or SICU$ or MICU$ or ITU$).tw.

8 or/1-7

9 Diagnosis/

10 exp Nursing Assessment/

11 ((diag$ or screen$ or assess$) adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

12 or/9-11

13 ((physical$ or physiolog$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

14 Walking/

15 (walk or walks or walking).tw.

16 (ambulate$ or ambulation$ or ambulating$).tw.

17 exp Movement Disorders/ or exp Movement/

18 mobility limitation/

19 ((mov$ or mobil$ or motor$) adj3 (morbid$ or manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or weak$ or strength$ or difficult$ or limit$ or problem$ or condition$ or debilit$)).tw.

20 exp Musculoskeletal Physiology/

21 Neuromuscular Diseases/

22 exp neuromuscular manifestations/

23 exp Muscular Diseases/

24 ((musc$ or neuromusc$ or neuro-musc$ or neuro musc$) adj3 (atroph$ or dystroph$ or hypoton$ or weak$ or strength$ or loss$ or dys$ or function$ or dis$ or abilit$ or degenerat$ or difficult$ or limit$ or problem$ or condition$ or debilit$ or impair$ or manifest$ or symptom$ or deteriorat$ or state or states or status)).tw.

25 (myopath$ or neuromyopath$ or neuro-myopath$ or neuro myopath$ or neuropath$ or polyneuropath$ or (peripher$ adj2 nerve$)).tw.

26 Fatigue/

27 (fatigu$ or letharg$ or tired$ or weak$).tw.

28 exp Somatosensory Disorders/

29 (somatosensor$ or hypesthes$ or hypesthaes$ or paresthes$ or paresthaes$ or numb$).tw.

30 locomot$.tw.

31 Communication/

32 exp verbal behavior/

33 (communicat$ or speech or speak$ or talk$ or converse$ or conversing or conversation$ or verbal$).tw.

34 Deglutition/

35 Deglutition Disorders/

36 deglut$.tw.

37 dysphagi$.tw.

38 swallow$.tw.

39 exp Nutrition Physiology/

40 exp "nutritional and metabolic diseases"/

41 nutrition$.tw.

42 malnutrition$.tw.

43 diet$.tw.

44 exp Weight Loss/

45 (weight adj3 (los$ or reduc$)).tw.

46 cachexi$.tw.

47 emaciat$.tw.

48 wasting.tw.

49 or/13-48

50 12 and 49

51 barthel$.tw.

52 katz$.tw.

53 Karnofsky Performance Status/

54 karnofsky$.tw.

55 (activit$ level$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

56 (function$ state$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

57 Exercise Test/

58 walk$ test$.tw.

59 new york heart association.tw.

60 nyha.tw.

61 borg.tw.

62 (oxford$ adj5 musc$ adj5 grad$).tw.

63 shuttle$.tw.

64 (function$ independen$ adj3 (index$ or indices or instrument$ or scale$ or tool$ or test$ or grad$ or survey$ or checklist$ or check-list$ or check list$ or inventor$ or exam$ or method$ or batter$ or score$ or scoring$ or rate$ or rating$ or question$ or interview$ or measure$)).tw.

65 (short form health survey$ or short form 36 or short-form 36 or shortform 36 or sf 36 or sf-36 or sf36).tw.

66 or/51-65

67 50 or 66

68 exp Mental Disorders/

69 exp Neurobehavioral Manifestations/

70 exp Behavioral Symptoms/

71 ((mental$ or psyc$ or neuropsyc$ or neuro-psyc$ or neuro psyc$ or behav$ or neurobehav$ or neuro$ behav$ or neuro-behav$) adj3 (ill$ or dis$ or abilit$ or dys$ or function$ or morbid$ or condition$ or deteriorat$ or problem$ or symptom$ or manifest$ or debilit$ or degenerat$ or state or states or status)).tw.

72 Anxiety/

73 (anxi$ or depress$ or dysthym$ or posttrauma$ or post-trauma$ or post trauma$ or ptsd$ or stress$ or delud$ or delus$ or delir$).tw.

74 or/68-73

75 12 and 74

76 (profile$ adj2 mood$ state$).tw.

77 poms.tw.

78 (depress$ adj2 anx$ adj2 stress$ adj2 scale$).tw.

79 dass.tw.

80 depression scale$.tw.

81 beck$ depress$.tw.

82 bdi.tw.

83 beck$ anx$.tw.

84 bai.tw.

85 (hospital$ anxiet$ adj2 depression scale$).tw.

86 hads.tw.

87 (impact$ adj2 event$ scale$).tw.

88 centre for epidemiological studies depress$.tw.

89 ces-d.tw.

90 cesd.tw.

91 ces d.tw.

92 spielberger$.tw.

93 state trait anxi$.tw.

94 stai.tw.

95 (trauma$ symptom$ adj2 (checklist$ or check-list$ or check list$)).tw.

96 (tsc 33 or tsc-33 or tsc33).tw.

97 ((posttrauma$ or post-trauma$ or post trauma$ or ptsd$) adj5 (scale$ or inventor$)).tw.

98 (14-q or 14 q or 14q).tw.

99 (10-q or 10 q or 10q).tw.

100 ptss.tw.

101 pds.tw.

102 davidson$.tw.

103 trauma$ scale$.tw.

104 (short form health survey$ or short form 36 or short-form 36 or shortform 36 or sf 36 or sf-36 or sf36).tw.

105 or/76-104

106 75 or 105

107 Cognition Disorders/

108 exp Neurobehavioral Manifestations/

109 ((neurobehavio$ or neuro-behavio$ or neuro$ behavio$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or dys$ or function$ or impair$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or state or states or status)).tw.

110 (confus$ or disorient$).tw.

111 Attention/

112 exp Sleep Disorders/

113 ((cognit$ or social or neurocogn$ or neuro-cogn$ or neuro cogn$ or brain or consciousness or memor$ or executive or attenti$ or inattenti$ or concentrat$ or sleep$) adj3 (manifest$ or symptom$ or dis$ or abilit$ or function$ or dys$ or impair$ or loss$ or problem$ or morbidit$ or debilit$ or degenerat$ or deteriorat$ or process$ or state or states or status)).tw.

114 Problem Solving/

115 (problem-solv$ or problem$ solv$).tw.

116 Hallucinations/

117 hallucinat$.tw.

118 or/107-117

119 12 and 118

120 Trail Making Test/

121 trailmaking test$.tw.

122 trail-making test$.tw.

123 trail$ making test$.tw.

124 card$ sorting test$.tw.

125 wisconsin$.tw.

126 Wechsler Scales/

127 wechsler$.tw.

128 memor$ scale$.tw.

129 Pattern Recognition, Visual/

130 benton$.tw.

131 visual$ retention test$.tw.

132 wcst.tw.

133 mini mental state$ exam$.tw.

134 mini-mental state$ exam$.tw.

135 mmse.tw.

136 paced auditory serial addition test$.tw.

137 pasat$.tw.

138 (cognitive$ test$ adj2 delir$).tw.

139 confus$ assess$ method$.tw.

140 cam icu.tw.

141 cam-icu.tw.

142 intensive care delir$ screen$ checklist$.tw.

143 ICDSC.tw.

144 NEECHAM.tw.

145 delir$ detection score$.tw.

146 cambridge neuro$ test$.tw.

147 cantab.tw.

148 function$ activit$ question$.tw.

149 informant question$.tw.

150 iqcode.tw.

151 dementia rating.tw.

152 (mbdrs or mb-drs or mb drs).tw.

153 or/120-152

154 119 or 153

155 67 or 106 or 154

156 8 and 155

Identification of evidence of the cost-effectiveness of rehabilitation strategies for patients with critical care morbidities

The searches were undertaken on July 7th 2008. The MEDLINE search strategy presented in the section – **Identification of evidence on rehabilitation strategies for patients with critical care morbidity** was used and translated for use in the other databases. Filters to retrieve economic evaluations and quality of life papers were appended to the MEDLINE, MEDLINE IN PROCESS and EMBASE searches to identify relevant evidence (See **Economic evaluations and quality of life search filters**)

Economic evaluations and quality of life search filters

The MEDLINE economic evaluations and quality of life search filters are presented below. They were translated for use in the MEDLINE In-Process and Embase databases.

Economic evaluations

1 Economics/

2 exp "Costs and Cost Analysis"/

3 Economics, Dental/

4 exp Economics, Hospital/

5 exp Economics, Medical/

6 Economics, Nursing/

7 Economics, Pharmaceutical/

8 Budgets/

9 exp Models, Economic/

10 Markov Chains/

11 Monte Carlo Method/

12 Decision Trees/

13 econom$.tw.

14 cba.tw.

15 cea.tw.

16 cua.tw.

17 markov$.tw.

18 (monte adj carlo).tw.

19 (decision adj2 (tree$ or analys$)).tw.

20 (cost or costs or costing$ or costly or costed).tw.

21 (price$ or pricing$).tw.

22 budget$.tw.

23 expenditure$.tw.

24 (value adj2 (money or monetary)).tw.

25 (pharmacoeconomic$ or (pharmaco adj economic$)).tw.

26 or/1-25

Quality of life

1 "Quality of Life"/

2 quality of life.tw.

3 "Value of Life"/

4 Quality-Adjusted Life Years/

5 quality adjusted life.tw.

6 (qaly$ or qald$ or qale$ or qtime$).tw.

7 disability adjusted life.tw.

8 daly$.tw.

9 Health Status Indicators/

10 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).tw.

11 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).tw.

12 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).tw.

13 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).tw.

14 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).tw.

15 (euroqol or euro qol or eq5d or eq 5d).tw.

16 (qol or hql or hqol or hrqol).tw.

17 (hye or hyes).tw.

18 health$ year$ equivalent$.tw.

19 utilit$.tw.

20 (hui or hui1 or hui2 or hui3).tw.

21 disutili$.tw.

22 rosser.tw.

23 quality of wellbeing.tw.

24 quality of well-being.tw.

25 qwb.tw.

26 willingness to pay.tw.

27 standard gamble$.tw.

28 time trade off.tw.

29 time tradeoff.tw.

30 tto.tw.

31 or/1-30

6.4 Appendix 4 – Review protocols and evidence tables

Critical Illness Rehabilitation

Review Protocols

List of Structured Clinical Questions and Review Questions for GDG 1

Structured Clinical Questions	Review Questions
• The evaluation of screening and/or assessment tools for identifying adult patients receiving critical care at risk of physical and non-physical morbidity (including psychological and cognitive dysfunction) following a period of critical illness. • The identification of the optimal timing for screening and/or assessment for physical and non-physical morbidity (including psychological and cognitive dysfunction) associated with critical illness.	***Review Question 1:*** *What are the clinical/test utility of screening and assessment tools (developed and/or modified for critical care population) in identifying critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive impairment associated with their treatment experience and critical illness?* ***Review Question 2:*** *When is the best or optimal time for screening and assessing critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive impairment associated with their treatment experience and critical illness?*

Review Protocol 1

	Details	Additional comments	Status
Review question ID	1	…	…
Review question	What are the clinical/test utility of screening and assessment tools (developed and/or modified for critical care population) in identifying critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive impairment associated with their treatment experience and critical illness?	…	
Objectives	To review the clinical/test utility of different screening and assessment tools designed and/or validated for identifying physical functional impairment and non-physical dysfunctions	The review does not cover service delivery issues.	As per protocol, with exclusion of service delivery issues

	including psychological problems and cognitive impairment following a period of critical illness.		
Language	*English*	…	As per protocol
Study design	*Cross-sectional studies, case-control studies, RCTs, Cohort studies*	…	As per protocol
Status	*Published papers (full papers only)*	…	As per protocol
Population	**Inclusion:** Adults with rehabilitation needs as a result of a period of critical illness that required level 2 and level 3 Critical Care. ***Exclusion:*** • *Adults receiving palliative care.* • *Clinical subgroups of patients whose specialist rehabilitation needs are already routinely assessed and delivered as part of their care pathway (for example, patients who received critical care as part of an elective pathway and who did not develop an unanticipated, ongoing critical illness, and in areas where published guidelines already exist such as head injury, myocardial infarction and stroke.*	…	As per protocol, with exclusion of service delivery issues
Outcomes	• Morbidity [physical functional status including swallowing and communication problems, psychological and cognitive dysfunction • Clinical/Test utility including: ➢ sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios, diagnostic odds ratio and area under the ROC analyses. ➢ test validity such as Face validity, Content validity, Construct validity, Criterion validity; ➢ test reliability such as Internal reliability/consistency, Test-retest reliability, Inter-rater reliability.	*Since the review question is more general about clinical/test utility, not just solely focused on 'diagnostic accuracy' (ie. sensitivity, specificity, PPV, NPV, LHR, DOR and area under the ROC), studies that reported test validity (eg: face validity, content validity, construct validity, criterion validity) and test reliability (eg: internal reliability/consistency, test-retest reliability, inter-rater reliability) are also included.*	As per protocol, with exclusion of service delivery issues
Other criteria for inclusion/ exclusion of	**Inclusion:** Only screening or assessment tools developed/derived or modified and validated within the general critical care population	*Reasons for strict inclusion and exclusion criteria are concern over spectrum bias* and clinical*	As per protocol, with exclusion of service delivery issues

studies	to identify general rehabilitation needs are included for the review. ***Exclusion:*** *Screening or assessment tools only designed or validated for specific critical care populations such as cardiac, stroke or neurological patients to identify patients who need specific rehabilitation such as cardiac rehabilitation, neurological rehabilitation and other organ-specific rehabilitations are excluded.*	*applicability.* **Spectrum bias – heterogeneity of test performance ie. sensitivity and/or specificity of a test varying with different populations tested.* *Example: the sample population chosen is not representative of the population at risk*	
Search strategies	Please see Appendix 6.3	…	As per protocol, with exclusion of service delivery issues
Review strategies	• NICE Diagnostic studies checklist (QUADAS tool) will be used to appraise included studies. • Evidence table and narrative summary will be used to summarise the evidence. • Where possible, a meta-analytic approach will be used to give an overall summary effect.	…	A meta-analysis was not undertaken due to heterogeneity across the included studies.

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	Details	Additional comments	Status
Review question ID	2	…	…
Review question	When is the best or optimal time for screening and assessing critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive dysfunction associated with their treatment experience and critical illness?	…	
Objectives	To review the optimal timing for identifying or assessing general critical care patients with rehabilitation needs.	The review does not cover service delivery issues.	As per protocol, with exclusion of service delivery issues
Language	*English*	…	As per protocol

Study design	*Cross-sectional studies, case-control studies, RCTs, cohort studies.*	…	As per protocol
Status	*Published papers (full papers only)*	…	As per protocol
Population	**Inclusion:** Adults with rehabilitation needs as a result of a period of critical illness that required level 2 and level 3 Critical Care. ***Exclusion:*** • *Adults receiving palliative care.* • *Clinical subgroups of patients whose specialist rehabilitation needs are already routinely assessed and delivered as part of their care pathway (for example, patients who received critical care as part of an elective pathway and who did not develop an unanticipated, ongoing critical illness, and in areas where published guidelines already exist such as head injury, myocardial infarction and stroke.*	…	As per protocol, with exclusion of service delivery issues
Outcomes	• Morbidity (physical functional status including swallowing and communication problems, psychological and cognitive dysfunction). • Clinical/Test utility at different time-points including: ➢ sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios, diagnostic odds ratio and area under the ROC analyses at different time-points. ➢ test validity such as Face validity, Content validity, Construct validity, Criterion validity at different time-points. ➢ test reliability such as Internal reliability/consistency, Test-retest reliability, Inter-rater reliability at different time-points.	…	As per protocol, with exclusion of service delivery issues
Other criteria for inclusion/ exclusion of studies	**Inclusion:** Only screening or assessment tools developed/derived or modified and validated within the general critical care population, and administered at different time-points to identify general rehabilitation needs are included for the review.	*Reasons for strict inclusion criterion were concerns over spectrum bias and clinical applicability.*	As per protocol, with exclusion of service delivery issues

	Exclusion: *Optimal timing of screening or assessment tools only designed or validated for specific critical care populations such as cardiac, stroke or neurological patients to identify patients who need specific rehabilitation such as cardiac rehabilitation, neurological rehabilitation and other organ-specific rehabilitations are excluded.*		
Search strategies	Please see Appendix 6.3	…	As per protocol, with exclusion of service delivery issues
Review strategies	• NICE Diagnostic studies checklist (QUADAS tool) will be used to appraise included studies. • Evidence table and narrative summary will be used to summarise the evidence. • Where possible, a meta-analytic approach will be used to give an overall summary effect.	…	A meta-analysis was not undertaken due to heterogeneity across the included studies.

List of Structured Clinical Questions and Review Questions for GDG2

Structured Clinical Questions	Review Questions
The clinical effectiveness and cost-effectiveness of rehabilitation strategies for adult patients who have developed physical and non-physical morbidities (including psychological and cognitive dysfunction) following a period of critical illness requiring critical care. The identification of the optimal timing for rehabilitation strategies to address physical and non-physical morbidities (including psychological and cognitive dysfunction) associated with critical illness.	*Review Question 3:* *What are the clinical effectiveness and cost-effectiveness of different rehabilitation strategies/programmes for adult patients who have developed physical and non-physical morbidities including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?* *Review Question 4:* *When is the optimal time for adult critical care rehabilitation? This includes:* • *Does early rehabilitation during critical care reduce subsequent risk of adult patients developing physical and non-physical morbidities following a period of critical illness and associated with their treatment experience*

	in critical care? • *When is the optimal time for initiating or delivering rehabilitation strategies/programmes to adult patients with physical and non-physical morbidities including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?*

Review Protocol 2

	Details	Additional comments	Status
Review question ID	3	…	…
Review question	*What are the clinical effectiveness and cost-effectiveness of different rehabilitation strategies/programmes for adult patients who have developed physical and non-physical morbidities including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?*	…	
Objectives	To review the clinical effectiveness of current available rehabilitation strategies/programmes in addressing physical, psychological and cognitive problems of adult patients requiring critical care.	…	As per protocol, with exclusion of service delivery issues
Language	*English*	…	As per protocol
Study design	*RCTs*	*If no RCTs were available, observational studies such as good quality cohort studies with an appropriate control will be considered.*	As per protocol
Status	*Published papers (full papers only)*	…	As per protocol
Population	**Inclusion:** Adults with rehabilitation needs as a result of a period of critical illness that required critical care. ***Exclusion:*** • *Adults receiving palliative care.*	…	As per protocol, with exclusion of service delivery issues

	• *Clinical subgroups of patients whose specialist rehabilitation needs are already routinely assessed and delivered as part of their care pathway (for example, patients who received critical care as part of an elective pathway and who did not develop an unanticipated, ongoing critical illness, and in areas where published guidelines already exist such as head injury, myocardial infarction and stroke).*		
Outcomes	• Mortality • Morbidity (including physical functional status, psychological impairments and cognitive dysfunction). • Readmission to hospital (as a result of physical or non-physical morbidities) • Hospital length of stay • Health-related quality of life	…	As per protocol, with exclusion of service delivery issues
Other criteria for inclusion/ exclusion of studies	**Inclusion:** Only studies on rehabilitation strategies/programmes/packages developed for general critical care adult patients were included. ***Exclusion:*** • *Rehabilitation strategies/programmes/packages for specific critical care patient subgroups such as cardiac, stroke, neurological, burn patients or any organ-specific rehabilitation programmes.* • *Studies on clinical effectiveness of treatment/intervention for psychological and/or cognitive dysfunction that did not cover general critical care populations.* • *Studies that evaluated and compared detailed individual techniques (eg: antidepressants vs. counselling for depression in critical care patients) will be excluded.* • *Studies that focused on the effectiveness of physical or non-physical therapies as part of the critical care management (rather than rehabilitation as longer-term outcome).*	*Reasons for strict inclusion criterion were concerns over generalisability (external validity) and clinical applicability.*	As per protocol, with exclusion of service delivery issues
Search strategies	Please see Appendix 6.3.	…	As per protocol, with exclusion of service delivery issues

Review strategies	*NICE intervention studies checklist will be used to appraise included studies individually and will be summarised by evidence table.* *Modified version of GRADE profiler will be used to summarise and appraise individual outcomes for generating evidence statements.* *Where possible, a meta-analytic approach will be used to give an overall summary effect in conjunction with the modified GRADE profiler.*	…	*A meta-analysis was not undertaken because there was only one study included.*

1607

	Details	Additional comments	Status
Review question ID	4	…	…
Review question	*When is the optimal time for adult critical care rehabilitation? This includes:* • *Does early rehabilitation during critical care reduce subsequent risk of adult patients developing physical and non-physical morbidities following a period of critical illness and associated with their treatment experience in critical care?* • *When is the optimal time for initiating or delivering rehabilitation strategies/programmes to adult patients with physical and non-physical morbidities including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?*	…	
Objectives	To review the optimal timing for initiating and/or delivering rehabilitation strategies/programmes that would be most effective for critical care adult patients at risks of developing physical/non-physical morbidities or adult patients with rehabilitation needs.	…	As per protocol, with exclusion of service delivery issues
Language	*English*	…	As per protocol
Study design	*RCTs*	*If no RCTs were available, observational studies such as good quality cohort studies with an appropriate control will be considered.*	As per protocol
Status	*Published papers (full papers only)*	…	As per protocol

Population	**Inclusion:** Adults with rehabilitation needs as a result of a period of critical illness that required level 2 and level 3 Critical Care. ***Exclusion:*** • *Adults receiving palliative care.* • *Clinical subgroups of patients whose specialist rehabilitation needs are already routinely assessed and delivered as part of their care pathway (for example, patients who received critical care as part of an elective pathway and who did not develop an unanticipated, ongoing critical illness, and in areas where published guidelines already exist such as head injury, myocardial infarction and stroke).*	…	As per protocol, with exclusion of service delivery issues
Outcomes	• Mortality • Morbidity (including physical functional status, psychological impairments and cognitive dysfunction). • Readmission to hospital (as a result of physical or non-physical morbidities) • Hospital length of stay • Health-related quality of life	…	As per protocol, with exclusion of service delivery issues
Other criteria for inclusion/ exclusion of studies	**Inclusion:** • Only studies on early rehabilitation (vs. late rehabilitation or usual care) during general critical care for reducing subsequent risk of adult patients developing physical and non-physical morbidities will be included. • Only studies on optimal timing for initiating/delivering rehabilitation strategies/programmes/packages developed for general critical care adult patients who have developed physical /non-physical morbidities were included. ***Exclusion:*** • *Optimal timing for specialist rehabilitation strategies for specific critical care patient subgroups such as cardiac, stroke, neurological, burn patients or any organ-specific rehabilitation programmes.*	*Reasons for strict inclusion criterion were concerns over generalisability (external validity) and clinical applicability.*	As per protocol, with exclusion of service delivery issues

	• *Studies on optimal timing of treatment/intervention for psychological and/or cognitive dysfunction that did not cover general critical care populations.* • *Studies that evaluated and compared detailed individual techniques (eg: antidepressants vs. counselling for depression in critical care patients) will be excluded.* • *Studies that focused on the effectiveness of physical or non-physical therapies as part of the critical care management (rather than rehabilitation as longer-term outcome).*		
Search strategies	(to be completed by Information Specialist)	…	As per protocol, with exclusion of service delivery issues
Review strategies	*NICE intervention studies checklist will be used to appraise included studies individually and will be summarised by evidence table.* *Modified version of GRADE profiler will be used to summarise and appraise individual outcomes for generating evidence statements.* *Where possible, a meta-analytic approach will be used to give an overall summary effect in conjunction with the modified GRADE profiler.*	…	*A meta-analysis was not undertaken because no study was identified.*

List of Structured Clinical Question and Review Question for GDG3

Structured Clinical Questions	Review Questions
The specific information and support needs of adult patients and their carers or families who have developed rehabilitation needs during and following a period of critical illness requiring critical care.	*Review Question 5:* *What information and support needs are viewed as important by adult patients and their carers or family who have developed rehabilitation needs during and following a period of critical illness requiring critical care?*

Review Protocol 3

	Details	Additional comments	Status
Review question	5	…	…

ID			
Review question	*What information and support needs are viewed as important by adult patients and their carers or family who have developed rehabilitation needs during and following a period of critical illness requiring critical care?*	…	
Objectives	*To review patients and their carers/family members' experiences and views on what they think are important elements of care to support them through the patient's care pathway and patient's recovery.*	…	As per protocol, with exclusion of service delivery issues
Language	*English*	…	As per protocol
Study design	*No restrictions, including qualitative studies & survey questionnaire*	…	As per protocol
Status	*Published papers (full papers only)*	…	As per protocol
Population	**Inclusion:** Adults with rehabilitation needs as a result of a period of critical illness that required critical care. ***Exclusion:*** • *Adults receiving palliative care.* • *Clinical subgroups of patients whose specialist rehabilitation needs are already routinely assessed and delivered as part of their care pathway (for example, patients who received critical care as part of an elective pathway and who did not develop an unanticipated, ongoing critical illness, and in areas where published guidelines already exist such as head injury, myocardial infarction and stroke).*	…	As per protocol, with exclusion of service delivery issues
Outcomes	*N/A*	…	As per protocol, with exclusion of service delivery issues
Other criteria for inclusion/ exclusion of studies	*Inclusion:* *Only studies, including survey questionnaire and qualitative studies that explored themes or views based on patients/carers/families' experiences on what they perceived as important elements of information and support needs were included.*	*Reasons for strict inclusion criterion were concerns over generalisability (external validity) and clinical applicability.* *Non-UK studies excluded:*	As per protocol, with exclusion of service delivery issues

	Exclusion: • *Studies conducted on patients and their carers/family members who have received specific rehabilitation strategies/programmes/packages such as cardiac, stroke, neurological patients.* • *Studies that only summarised number of cases or experiences but did not provide patients/carers' views.* • *Studies with non-UK population.*	*Cultural differences, language used, environment, social structure and other societal factors from other countries may create systematic differences on what patients/carers perceived as important elements compared to UK patients.*	
Search strategies	…	…	As per protocol, with exclusion of service delivery issues
Review strategies	*NICE checklists, such as NICE qualitative studies checklist for qualitative study will be used to appraise included studies.* *Evidence table and narrative summary will be used to summarise the evidence.*	…	N/A

Critical Illness Rehabilitation

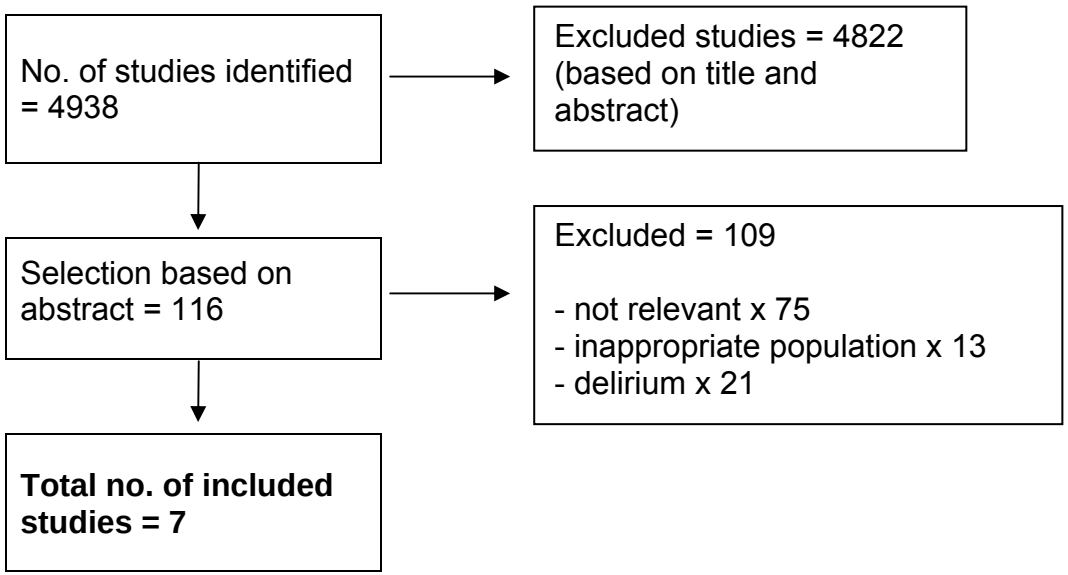
Review Question 1:

What are the clinical/test utility of screening/assessment tools (developed and/or modified for critical care population) in identifying critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive impairment associated with their treatment experience and critical illness?

Review Question 2:

When is the best or optimal time for screening/assessing critical care adult patients at risk of physical functional impairment and non-physical dysfunctions such as psychological problems and cognitive impairment associated with their treatment experience and critical illness?

Volume of Evidence



Evidence Table – Physical (Physical Functional Status)

Title: The Rivermead Mobility Index: a further development of Rivermead Motor Assessment							
Study type	No. of patients	Prevalence/ incidence	Patient characteristics	Type of test	Reference standard	Sensitivity & specificity, PPV & NPV Validity & Reliability	
ID: Author: Collen et al (1991) Study type: cohort Level of evidence: (-)	Total no. of patients = 23 <u>Based on 23 patients:</u> Male = 65% Female = 35% Mean age = 43.5 yrs (range 17-73) Suffered stroke = 9 Suffered head injury = 13 Neurosurgery = 1 <u>Study period:</u> Not reported. <u>Setting:</u> An outpatient clinic at The Rivermead Rehabilitation Centre, Oxford, UK.	All patients had reduced mobility.	Patients attending the outpatient unit with reduced mobility who agreed to take part. <u>Exclusion:</u> Not reported.	<u>The Rivermead Mobility Index (RMI):</u> Further developed from the Rivermead Motor Assessment. The RMI is a measure of disability related to bodily mobility. It demonstrates the patient's ability to move her or his own body. It does not measure the effective use of a wheelchair or the mobility when aided by someone else. There are 15 items with yes (1) or no (0) answer, scores range from 0 to 15. The index test was administered twice by 2 raters separately (neurologist then physiotherapist) when patients visited the outpatient unit (one visit). No follow-ups.	N/A	Inter-rater reliability (Spearman's ρ): Correlations (concurrent validity): RMI vs. Barthel Index	$\rho = 0.94$ ($p < 0.001$) $r = 0.91$ ($p < 0.01$)
<u>Additional comments:</u> Very small sample size. No information on time-point and periods of follow-up, study population were already in rehabilitation programme and did not provide information on critical care/ICU stay. No clear exclusion criteria No reference standard. Only patients with head injury or stroke – issue on generalisability							

1658 **Evidence Table – Non-Physical (PTSD)**

Title: Use of a screening questionnaire for PTSD on a sample of UK ICU patients.							
Study type	No. of patients	Prevalence/ incidence	Patient characteristics	Type of test	Reference standard	Sensitivity & specificity, PPV & NPV Validity & Reliability	
ID: 35 Author: Twigg et al (2008) Study type: Case series cohort Level of evidence: (++)	Total no. of patients = 44 <u>Whiston (n = 39)</u> Male = 86% Age (median) = 56 (18-74) ICU stay (days/median range) = 10.5 (2-32) APACHE II (median) = 16 (3-35) Days of artificial ventilation (median range) = 8 (1-20) <u>Hope (n = 5)</u> Male = 67%% Age (median) = 56 (25-63) ICU stay (days/median range) = 7 (2-11) APACHE II (median) = 14 (10-18) Days of artificial ventilation (median range) = 8 (3-19) *no statistical difference between 2 sites. <u>Study period:</u> Dec 2000 – Feb 2002 <u>Setting:</u> 2 ICUs in 2 UK district hospitals.	Confirmed diagnosis by PDS = 7/44 (16%)	Patients aged 18 or older <u>Exclusion:</u> Patients younger than 18, grasp of English insufficient to complete the questionnaire, ICU stay < 48hrs, history of dementia or learning disabilities, admission due to self-inflicted injury/overdose or unable to give consent in time for time-point 1 data collection.	<u>UK-PTSS-14</u> 14 items Each item rated 1 (never) to 7 (always) Total score ranging from 14 to 98 *<u>*administered at 3 time-points:*</u> 4-14 days, 2 months & 3 months post ICU discharge Self-report questionnaire	Posttraumatic Stress Diagnostic Scale (PDS) *corresponds to DSM-IV diagnostic criteria for PTSD. *only administered at time-point 3.	Internal reliability: 4-14 days 2 mths 3 mths Test-retest reliability: 4-14 days vs. 2 mths 2 mths vs. 3 mths 4-14 days vs. 3 mths Concurrent validity: 3 mths (UK-PTSS-14 vs. PDS) Predictive validity: 4-14 days 2 mths <u>ROC analysis</u> 4-14 days sensitivity = specificity = 2 mths sensitivity = specificity = 3 mths sensitivity = specificity = AUC of 3 time-points: Note: optimal timing for assessment = at 2	 α = 0.89 α = 0.86 α = 0.84 ICC = 0.77 ICC = 0.90 ICC = 0.70 r = 0.86 r = 0.50 (95%CI: 0.24-0.69), p = 0.001 r = 0.85 (95%CI: 0.74-0.92), p < 0.0001 71% (95% CI: 29.3-95.5) 84% (95% CI: 68.0-93.8) 86% (95% CI: 42.2-97.6) 97% (95% CI: 85.8-99.5) 100% (95% CI: 58.9-100.0) 84% (95% CI: 68.0-93.8) Time-point 2 (2 mths) had the highest AUC index = 0.95 (95%CI: 0.84-0.99) *cut-off point = 45

						mths post ICU discharge.	
Additional comments: Limited sample size. Generalisability: patients with dementia and learning disabilities were excluded. Only up to 3 months follow-up (only validated to screen acute PTSD but not validated to predict chronic or delayed onset PTSD).							

1685

Title: Sensitivity and specificity of a screening test to document traumatic experiences & to diagnose PTSD in ARDS patients after intensive care treatment.							
Study type	No. of patients	Prevalence/ incidence	Patient characteristics	Type of test	Reference standard	Sensitivity & specificity, PPV & NPV Validity & Reliability	
ID: 1086 Author: Stoll et al (1999) Study type: Follow-up cohort Level of evidence: (+)	First original cohort (1995) = 80 Total no. of follow-up cohort of patients (1997) = 52 <u>Based on 52 patients:</u> Female = 50% Male = 50% Median age = 36.5 years Median duration of ICU stay = 30 days Median duration of mechanical ventilation = 26.5 days <u>Study period:</u> 1995-1997 <u>Setting:</u> 20-bed multidisciplinary ICU of a university teaching hospital, Munich, Germany.	Of the original cohort of 80 patients in 1995 = 27.5% (22 patients) based on questionnaires on traumatic memories. Of the follow-up cohort confirmed by clinical interview based on DSM-IV (1997) = 13 (25%)	All patients aged > 16 treated for ARDS treated by the hospital Department of Anesthesiology and the trauma centre. <u>Exclusion:</u> Patients with pre-existing neurological or psychiatric diseases (including alcohol and drug abuse), or a history of cerebral trauma, surgery or cardiopulmonary resuscitation were excluded, as were patients who had been discharged from the ICU less than 6 months before the start of the study or those who couldn't complete a questionnaire in German language.	Part A: Assessment of traumatic memories from ICU (4 questions with binary scale: yes/no). <u>Part B: modified German version of the PTSS-10:</u> record presence & intensity of 10 PTSD symptoms using a scale 1 (never) to 7 (always). In this study, item 9 'avoidance of activities' was adapted to 'fears of approaching place of accident'. Self-report questionnaire <u>Follow-up:</u> Original cohort of 80 patients identified in 1995, follow-up 2 years later (52 patients completed study). Note: Test administered 2 years post ICU discharge.	Structured clinical interview with 2 trained psychiatrists to diagnose PTSD according to DSM-IV criteria.	Validation of the PTSS-10 against the reference standard at 2 years follow-up: <u>ROC curve analysis:</u> Optimal threshold value (cut-off point) = 35 Maximal sensitivity/specificity at optimal threshold *(39 patients had no PTSD based on reference standard, PTSS-10 at cut-off point 35 correctly identified 38 patients with no PTSD).* Internal reliability: Test-retest reliability (over the time interval of 2 years: Intraclass correlation coefficient:	 Sensitivity = 77% (95%CI: 54%-100%) Specificity = 97.5% (95%CI: 91%-100%) PPV = 91% (95%CI: 74%-100%) NPV = 93% (95%CI: 85%-100%) α = 0.93 α = 0.89 (F = 9.24, 95%CI: 0.81-0.94)
<u>Additional comments:</u> Due to the 2 years interval period, the researchers verified that the episode of critical illness and the associated period of ICU treatment was the major traumatic event for these patients and they had not experienced other traumas that caused the symptoms (predicting chronic or delayed PTSD). Small sample, only apply to ARDS ICU patients. In German language.							

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1689 **Evidence Table – Non-Physical (Depression and Anxiety)**

Title: Clinical validation of an anxiety and depression screening test for intensive in-hospital rehabilitation.

Study type	No. of patients	Prevalence/ incidence	Patient characteristics	Type of test	Reference standard	Sensitivity & specificity, PPV & NPV Validity & Reliability	
ID: Author: Vedana et al (2001) Study type: Cross-sectional Level of evidence: (+)	Total no. of patients = 102 <u>Based on 102 patients:</u> Male = 66.7% Female = 33.3% Mean age (range) = 61.4 (19-76) Cardiac rehabilitation = 61 Respiratory rehabilitation = 25 Neuro-orthopaedic rehabilitation = 16 <u>Study period:</u> Not stated. <u>Setting:</u> An Intensive Rehabilitation Centre in Italy	Not provided.	Voluntary, self-sufficient & literate patients admitted to the Division of Cardiac, Respiratory and neuro-motor rehabilitation in the Intensive Rehabilitation Centre. <u>Exclusion:</u> Not stated.	<u>Hospital Anxiety & Depression Scales (HADS)</u> *14 items – score rated 0-3 *subscale: depression 7 items *subscale: anxiety 7 items (scores ranging from 0-21) Cut-off point = 9 <u>Schedule A-D: State-Trait Anxiety Inventory (STAI-X1)</u> *20 items – score rated 1-4 (scores ranging from 20-80) Male cut-off point = 49 Female cut-off point = 55 <u>Depression Questionnaire (DQ)</u> *24 items – rated Yes or No (scores ranging from 0-24) Male cut-off point = 8 Female cut-off point = 12 Cut-off point equal to the 90th percentile. All self-report questionnaires. Note: All tests administered first followed by the clinical interview by the psychologist (same day).	Clinical interview by clinical psychologist using an anxiety-depression assessment form based on previous experiences and the DSM-IV (DSM code 300.4)	(psychologist as reference standard) STAI-X1 HADS-A QD HADS-D <u>Analysis of ROC</u> STAI-X1 with 80th percentile cut-off point instead of 90th (psychologist as reference standard) STAI-X1 with 80th percentile cut-off point instead of 90th (HADS-A as reference standard)	 Sensitivity = 52%, Specificity = 99% PPV = 93%, NPV = 86% Sensitivity = 72%, Specificity = 84% PPV = 60%, NPV = 90% Sensitivity = 75%, Specificity = 88% PPV = 60%, NPV = 93% Sensitivity = 80%, Specificity = 84% PPV = 55%, NPV = 95% Sensitivity = 76%, Specificity = 84% PPV = 61%, NPV = 91% AUC = 0.88 (95%CI: 0.80-0.95) Female cut-off point = 48 Sensitivity = 75% Specificity = 91% AUC = 0.85 (95%CI: 0.71-0.99) Male cut-off point = 43 Sensitivity = 78% Specificity = 96% AUC = 0.95 (95%CI: 0.90-1.00)

<u>Additional comments:</u>
No information on time-point and periods of follow-up, study population were already in rehabilitation programme and did not provide information on critical care/ICU stay.
No clear exclusion criteria
Italian rehabilitation setting – issue on generalisability

1690

Title: Psychological assessment of ICU survivors: a comparison between the Hospital Anxiety & Depression scale and the Depression, Anxiety & Stress scale

Study type	No. of patients	Prevalence/ incidence	Patient characteristics	Type of test	Reference standard	Sensitivity & specificity, PPV & NPV Validity & Reliability	
ID: 155 Author: Sukantar at et al (2007) Study type: Follow-up cohort Level of evidence: (+)	Total no. of patients = 51 (51 at 3 months, 45 at 9 months) <u>Based on 51 patients:</u> Female = 56.9% Male = 43.1% Mean age = 57.4±13.6 years (SD) Mean duration of ICU stay = 16.9±17.0 days (range 3-78 days) <u>Study period:</u> Not provided. <u>Setting:</u> UK ICU.	Definite cases by HADS (score: ≥11) <u>3-month:</u> Depression = 12 (24%) Anxiety = 8 (16%) <u>9-month:</u> Depression = 14 (31%) Anxiety = 10 (22%)	Adult patients who survived a severe illness that required more than 3 days of intensive care (including mechanical ventilation). <u>Exclusion:</u> Not stated.	<u>DASS</u> 42 questions (14 for each 3 subscales: depression, anxiety, stress) Scored from (0-3) Range of (0-42 for each parameter) <u>*cut-off points:</u> <u>DASS Depression</u> *Moderate (14-20),Severe (21-27)* *Extremely severe (28-42)* <u>DASS Anxiety</u> *Moderate (10-14),Severe (15-19)* *Extremely severe (20-42)* <u>DASS Stress</u> *Not reported* <u>HADS</u> 14 items – score rated 0-3 Subscale HADS-D: depression 7 items Subscale HADS-A: anxiety 7 items (scores ranging from 0-21) <u>*Cut-off points:</u> *7 or less = non-case* *8 to 10 = doubtful case* *11 or more = definite case* <u>Follow-up:</u> At 3 & 9 months after ICU discharge, where both scale were administered.	HADS	Internal reliability: **DASS** - Anxiety - Depression - Stress **HADS** - Anxiety - Depression Concurrent validity: (Spearman's ρ, all significant at p<0.0001) <u>3 months:</u> DASS Depression/HADS-D DASS Anxiety/HADS-A DASS Depression/HADS-A DASS Anxiety/HADS-D DASS Stress/HADS -D DASS Stress/HADS-A <u>9 months:</u> DASS Depression/HADS-D DASS Anxiety/HADS-A DASS Depression/HADS-A DASS Anxiety/HADS-D DASS Stress/HADS-D DASS Stress/HADS-A Criterion validity: (Bland & Altman plot) DASS Depression/HADS-D DASS Anxiety/HADS-A	3 mths: α = 0.92, 9 mths: α = 0.92 3 mths: α = 0.92, 9 mths: α = 0.93 3 mths: α = 0.94, 9 mths: α = 0.95 3 mths: α = 0.83, 9 mths: α = 0.86 3 mths: α = 0.82, 9 mths: α = 0.86 ρ = 0.734 ρ = 0.666 ρ = 0.908 ρ = 0.921 ρ = 0.693 ρ = 0.711 ρ = 0.781 ρ = 0.767 ρ = 0.851 ρ = 0.948 ρ = 0.719 ρ= 0.740 r = 0.93, p < 0.0001 r = 0.88, p < 0.0001

<u>Additional comments:</u>
Study did not demonstrate that the DASS has significant advantages over the HADS in ICU population.
Small sample
Concurrent validity: the correlation was actually stronger between anxiety on one scale and depression on the other.
DASS has 3 times as many questions as the HADS, and the appropriateness of reference standard used is questionable.

1691

Title: Validity of the Faces Anxiety Scale for the assessment of state anxiety in intensive care patients not receiving mechanical ventilation.

Study type	No. of patients	Prevalence/ incidence	Patient characteristics	Type of test	Reference standard	Sensitivity & specificity, PPV & NPV Validity & Reliability	
ID: 1568 Author: McKinley & Madronio (2008) Study type: cohort Level of evidence: (-)	Total no. of patients = 100 <u>Based on 100 patients:</u> Female = 35% Male = 65% Mean age = 59.8 years (range 17-95) Mean duration of ICU stay = 4.63 days (range 0.7-44.5) <u>Study period:</u> Not reported. <u>Setting:</u> 29-bed multidisciplinary ICUs (general, cardiothoracic, neurological) of a 600-bed metropolitan tertiary referral hospital in Sydney, Australia.	72% of patients had SAI scores at or below the level originally reported as the norm of 42.38 for medical-surgical inpatients.	Patients were eligible to take part in the study if they were aged 18 years or older, conscious and orientated in time and place, able to read and understand English, able to respond verbally to questions about their feelings and emotions and had sufficient corrected vision to see the FAS. <u>Exclusion:</u> Patients were excluded if they currently receiving mechanical ventilation or not able to understand and respond to English language questions and instructions.	The Faces Anxiety Scale (FAS) is a single-item scale with 5 possible responses, ranging from a neutral face to a face showing extreme fear, and is scored form 1 to 5. The scale was on an 11x24cm card and patients were asked to point to the face that how the patient felt that time. Spielberger State Anxiety Inventory (SAI): 20-item, 10 anxiety-present, 10 anxiety-absent, with 4-choice Likert scale from 'not at all' to 'very much' Note: The FAS was administered first followed by the SAI during ICU stay. No follow-up.	SAI	The Faces Anxiety Scale: Criterion validity (Spearman's ρ):	ρ = 0.70 (p < 0.0005)

<u>Additional comments:</u>
Main aim of the study is to decide intervention to reduce anxiety during ICU stay, not to identify rehabilitation needs (no follow-up).
83 patients received sedative and/or opioid therapy in the 24 hours prior to reporting their anxiety, which may have influenced the anxiety ratings.
The appropriateness of reference standard used is questionable.

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Evidence Table – Non-Physical (Cognitive Dysfunction)

Title: Reliability of nurses' neurological assessments in the cardiothoracic surgical intensive care unit.

Study type	No. of patients	Prevalence	Patient characteristics	Type of test	Reference standard	Sensitivity & specificity PPV & NPV	
ID: 927 Author: Beauchamp et al (2001) Study type: Prospective, 3-part quasi-experimental design Level of evidence: (-)	Total no. of rating sessions: Rancho scale = 75 by different raters NICE scale = 117 by different raters Total number of patients involved unknown. Patients' characteristics not reported. <u>Study period:</u> Not reported. <u>Setting:</u> 18-bed cardiothoracic surgery ICU at the hospital of the University of Pennsylvania, a 720-bed facility, USA.	Not reported.	Inclusion and exclusion criteria not reported.	Neuro-cognitive assessment tools to document the level of consciousness and the level of cognitive function of patients (carried out by critical care nurses through observation). <u>Rancho scale:</u> A non-verbal 8 levels scale ranging from 1 (unresponsive) to 8 (orientated). <u>Neurologic Intensive Care Evaluation (NICE) – derived from the Rancho scale:</u> A non-verbal 9 levels scale ranging from 0 (absent brainstem reflexes) to 8 (orientated). The Rancho scale was administered then followed by the NICE scale within 1 hour interval. Patients were still in ICU. No follow-up.	N/A	<u>Rancho scale:</u> Interrater reliability: <u>Neurologic Intensive Care Evaluation (NICE):</u> Interrater reliability:	ρ = 0.91 ρ = 0.94

<u>Additional comments:</u>
Lack of information on study population and no information on inclusion and exclusion criteria.
Only covered cardiothoracic surgical ICU.
No measures on validity.
No reference standard.

Measures of Physical Functional Status (for reference)
Instruments currently used widely in rehabilitation or physiotherapy

Tools	Description	Description	Description
Functional Independence Measure (FIM) (UK version) *and/or* Functional Assessment Measure (FAM) (UK FIM+FAM)	The Functional Independence Measure (FIM) scale assesses physical and cognitive disability. This scale focuses on the burden of care, that is, the level of disability indicating the burden of caring for patients. The UK version was developed in 1999.	It was designed to assess areas of dysfunction in activities which commonly occur in individuals with any progressive, reversible or fixed neurologic, musculoskeletal and other disorders. It is widely used in rehabilitation community. However, one limitation relative to using the FIM is that it is not diagnosis specific. **The FAM was developed as an adjunct to the FIM to specifically address the major functional areas that are relatively less emphasized in the FIM, including cognitive, behavioral, communication and community functioning measures. The FAM consists of 12 items. These items do not stand alone, but are intended to be added to the 18 items of the FIM. The total 30 item scale combination is referred to as the FIM+FAM. The time required to administer the FIM+FAM is approximately 35 minutes.*	Items are scored on the level of assistance required for an individual to perform activities of daily living. The scale includes 18 items, of which 13 items are physical domains based on the Barthel Index and 5 items are cognition items. Each item is scored from 1 to 7 based on level of independence, where 1 represents total dependence and 7 indicates complete independence. The scale can be administered by a physician, nurse, therapist or layperson. Possible scores range from 18 to 126, with higher scores indicating more independence. Alternatively, 13 physical items could be scored separately from 5 cognitive items. FIM physical items: • Eating • Grooming • Bathing/showering • Dressing upper body • Dressing lower body • Toileting • Bladder management • Bowel management • Transfers: bed/chair/wheelchair • Transfers: toilet • Transfers: bathtub/shower • Locomotion: walking/wheelchair • Locomotion: stairs FIM cognitive items: • Expression • Comprehension • Social interaction • Problem solving • Memory FAM items: • Swallowing • Transfers: car • Reading • Writing • Speech intelligibility • Emotional status • Adjustment to limitations • Use of leisure time • Orientation • Concentration • Safety awareness • Community mobility

Tools	Description	Description	Description
Barthel index	Developed in 1965 to compare physical functional status before and after an intervention, and to indicate potential nursing requirements for long-term hospitalised patients.	Based on long-term hospitalised patients especially those with musculoskeletal or neuromuscular disorders, has been subsequently widely used within trauma and general critical care. It was designed for in-hospital patients only.	The index is completed by a therapist or other observer and is a rating scale that takes approximately 30 seconds to complete. It comprises nine dimensions: • feeding • mobility from bed to chair • personal toilet • getting on/off the toilet • bathing • walking on level surface • going up/down stairs • dressing • continence The scoring system ranges from zero (totally dependent) to100 (fully independent).
The Rivermead Mobility Index *and* The Modified Rivermead Mobility Index	It was developed in 1991 specifically for patients who had suffered a head injury or stroke at the Rivermead Rehabilitation Centre in Oxford England.	Widely used in other areas involved physiotherapy such as , neurosurgery, multiple sclerosis, physical disability, etc.	The Rivermead Mobility Index is a measure of disability related to bodily mobility. It demonstrates the patient's ability to move her or his own body. It does not measure the effective use of a wheelchair or the mobility when aided by someone else. There are 15 items with yes (1) or no (0) answer, scores range from 0 to 15. The item include: • Turning over in bed • Lying to sitting • Sitting balance • Sitting to standing • Standing unsupported • Transfer • Walking inside with an aid if needed • Stairs • Walking outside (even ground) • Walking inside with no aid • Picking off floor • Walking outside (uneven ground) • Bathing • Up and down 4 steps • Running In its new modified form, the scoring was adapted from a two-point to a six-point scale. The number of test items was reduced from fifteen to eight items in order to measure mobility-related items that physiotherapists consider being essential for demonstrating treatment effects in patients following a stroke.

Tools	Description	Description	Description
Katz's ADL index	Developed in1963 to describe the functional status of elderly patients for clinical purposes.	Based on the observation of a large number of elderly patients with fractured hips, has been subsequently used for patients with rheumatoid arthritis, stroke and within general critical care.	The index was developed for completion by an observer. The index ranks individuals according to their performance of six functions: • bathing • dressing • toileting • transferring • continence • feeding expressed as a grade from A (independent) to G (dependent) in each of the six functions.
Karnofsky index	Originally developed as a measure of overall health status in lung cancer patients.	Has been subsequently used for patients with cardiac surgery, liver transplant, acute lung injury and within general critical care.	The scores were assigned by a clinician rather than the patient. The Karnofsky Index emphasises physical performance and dependency with scores range from 0 (dead) to 100 (normal).
Walk test	There are 1-, 6- and 12-minute walk tests, during which the patient is asked to cover as much ground as possible in the allotted time. The test is used principally with patients suffering COPD.	Widely used in physiotherapy.	Following the walk, patients are asked to assess their level of dyspnoea on a visual analogue scale which ranges from 'extremely short of breath' (0) to 'no shortness of breath' (10).123 <u>For example:</u> The 6-minute walk test measures the maximal distance passed walking within 6-minute period. The lowest limiting value to be reached by a healthy person is published as 400 m.

Review Question 3:

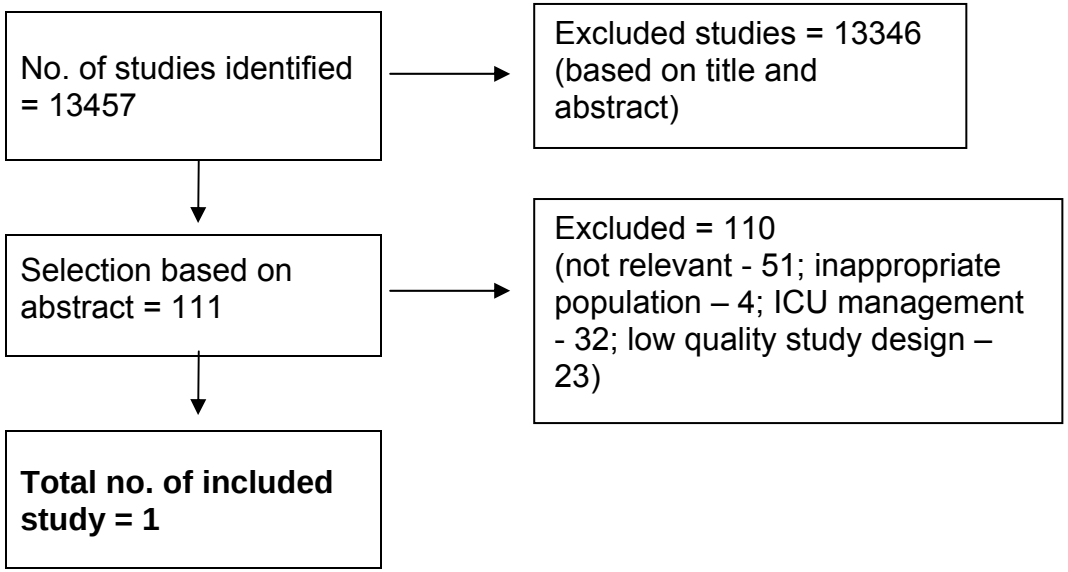
What are the clinical effectiveness and cost-effectiveness of different rehabilitation strategies/programmes for adult patients who have developed physical and non-physical morbidities including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?

Review Question 4:

When is the optimal time for adult critical care rehabilitation? This includes:

- *Does early rehabilitation during critical care reduce subsequent risk of adult patients developing physical and non-physical morbidities following a period of critical illness and associated with their treatment experience in critical care?*
- *When is the optimal time for initiating or delivering rehabilitation strategies/programmes to adult patients with physical and non-physical morbidities including psychological problems and cognitive deficits following a period of critical illness and associated with their treatment experience in critical care?*

Volume of Evidence



Evidence Table

Title: Rehabilitation after critical illness: a randomised, controlled trial.

Level of Evidence	Patient Population/ Characteristics	Selection/Inclusion criteria	Intervention	Comparison	Follow-up	Outcome	Effect Size
ID: 1899 Level of evidence: (++) Study type: RCT Authors: Jones et al (2003)	Total no. of patients: Baseline = 126 (I = 69, C = 57) At 8 wks = 114 (I = 63, C = 51) At 6 mths = 102 (I = 58, C = 44) Lost to follow-up at 6 mths = 19% Baseline characteristics: *Mean age* I = 57 (SD: 17); C = 59 (SD:16) *Male/female* I = 54%/46%; C = 58%/42% *Mean SF-36 score* I = 55 (SD:17); C = 55 (SD: 16) *Mean APACHE II score* I = 17 (SD: 5); C = 16 (SD: 5) *Mean HADS-A score* I = 8 (SD: 5); C = 8 (SD: 4) *Mean HADS-D score* I = 6 (SD: 4); C = 6 (SD: 6) *Mean STAI score* I = 42 (SD: 12); C = 42 (SD: 9) **no significant differences between I group & C group.* Recruited 1 wk post ICU discharge (in general wards) Setting: 3 UK hospitals – Whiston, MRI, Royal Berkshire. All 3 hospitals already had established follow-up clinics.	Inclusion: Adult patients in ICU & ventilated Exclusion: • stayed in ICU < 48hrs • Suffering burn injury • Unable to follow the manual or had language difficulties • Neurosurgical patients • Had pre-exiting psychotic illness • Those discharged for terminal acre and unlikely to survive the 6-mths follow-up	A 6-wk self-help rehabilitation manual Plus 'usual care'. **6-wk self-help rehabilitation manual included:* • *93 pages of text, diagrams & supporting illustrations* • *Advice on psychological, psychosocial, physical problems.* • *A self-directed exercise programme* • *3 weekly telephone calls to reinforce the use of the manual* • *Patients kept a diary.* • *With a close relative or friend of their choosing present.*	'Usual care' *Defined as: routine ICU follow-up included 3 telephone follow-ups at home; ICU follow-up clinic appointments at 8 wks and 6 mths.*	8 wks & 6 mths post ICU discharge	**Physical function** (SF-36) at 3 time-points interaction **Depression** (HADS-D) – cut-off > 11 (at 8 wks) (at 6 mths) **Subgroup analysis (those had received antidepressant – at 8 wks)* **Anxiety** (HADS-A) – cut-off > 11 (at 6 mths) **Subgroup analysis (those not on Benzodiazepines)* **PTSD-related symptoms** (IES) (at 8 wks) **Subgroup analysis (those not on Benzodiazepines)* Norbeck **Social Support** questionnaire	*F* = 3.7, df = 4, p = 0.006 I = 8 (12%), C = 13 (25%), Fisher's exact = 3.1, p = 0.066 I = 10%, C = 12% (not sig.) *F* = 10.47, df = 1, p = 0.004 I = 19 (32.7%), C = 15 (34%), p = not sig. *F* = 0.14, df = 1, p = 0.71 *F* = 5.24, df = 1, p = 0.026 *F* = 6.32, df = 1, p = 0.014 No significant differences.

Additional comments:
45% of patients at 1 site were prescribed benzodiazepines post-ICU discharge, compared with 6% and 0% at the other 2 sites. 48% of patients at 1 site were prescribed benzodiazepines post-ICU discharge, compared with 13% and 25% at the other 2 sites.
Lack of true baseline data for physical function (retrospectively assessed post ICU discharge).

GRADE profiles

Quality Assessment							Summary of findings				
							No. of patients		Effect		Quality
No. of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention[1]	Control[2]	Relative (95%CI)	Absolute	
Physical function[3] *(at 3 time-points: baseline, 8 weeks, 6 months after ICU discharge)*											
1	RCT	No	No	No	Yes[7]	None	58	44	ANOVA (at 3 time-points interaction) *F* = 3.7, p = 0.006		Moderate
Physical function[3] *(at 8 weeks after ICU discharge)*											
1	RCT	No	No	No	Yes[7]	None	63	51	Univariate ANOVA (at 8 weeks) *F* = 12.19, p < 0.0001		Moderate
Physical function[3] *(at 6 months after ICU discharge)*											
1	RCT	No	No	No	Yes[7]	None	58	44	Univariate ANOVA (at 6 months) *F* = 14.4, p < 0.0001		Moderate
Depression[4] *(at 8 weeks after ICU discharge)*											
1	RCT	No	No	No	Yes[7]	None	8/63 (12%)	13/51 (25%)	0.4981 (0.2239, 1.1082)	13%	Moderate
Depression[4] *(at 6 months after ICU discharge)*											
1	RCT	No	No	No	Yes[7]	None	6/58 (10%)	5/44 (12%)	0.9103 (0.2696, 2.7908)	2%	Moderate
Anxiety[5] *(at 6 months after ICU discharge)*											
1	RCT	No	No	No	Yes[7]	None	19/58 (32%)	15/44 (34%)	0.9609 (0.5532, 1.6689)	2%	Moderate
PTSD-related symptoms[6] *(at 8 weeks after ICU discharge)*											
1	RCT	No	No	No	Yes[7]	None	63	51	1-way ANOVA (at 8 weeks) *F* = 5.24, p = 0.026		Moderate

[1] Intervention: 6-wk self-help rehabilitation manual
[2] Control: Usual care defined as: routine ICU follow-up included 3 telephone follow-ups at home; ICU follow-up clinic appointments at 8 wks and 6 mths.
[3] Physical function was measured by SF-36 physical function score.
[4] Depression was measured by HADS-D, with cut-off > 11 as cases.
[5] Anxiety was measured by HADS-A, with cut-off > 11 as cases.
[6] PTSD-related symptoms were measured by IES.
[7] Lack power, total number of event less than 300.

(Indirect/supporting evidence)

Title: Effects of physical training on functional status in patients with prolonged mechanical ventilation.

Level of Evidence	Patient Population/ Characteristics	Selection/Inclusion criteria	Intervention	Comparison	Follow-up	Outcome	Effect Size
ID: Level of evidence: (+) Study type: RCT Authors: Chiang et al (2006)	Total no. of patients: Baseline total = 39 I = 17, C = 15 Lost to follow-up = 7 (I group died = 3) (C group died = 4) Baseline characteristics (based on 32 patients): *Median age* I = 75 (IQR: 63.0-80.3) C = 79 (IQR: 72.5-82.8) *Male/Female* I = 71%/29% C = 80%/20% **no significant differences between I group & C group* Study period: Between Jan and Aug 2003. Setting: The respiratory care centre (a post intensive care umit) in a general hospital in Taiwan.	Inclusion: Patients who required mechanical ventilation for more than 14 days, to be medically stable, mentally alert, to have acceptable hemodynamic stability (defined as a lack of hypotension or a need for only low-dose pressors). Exclusion: Patients with comorbid medical conditions (eg: neurological diseases) or who were under any sedative paralytic agents that would interfere with strength measurements and limb exercises.	Early rehabilitation defined as supervised training sessions conducted by physical therapist 5 times per week for 6 weeks. Training sessions included bedside strengthening exercises for the upper and lower extremities (ROM exercises) and functional activity retraining. Plus 'usual care'.	'Usual care' *Defined as: standard therapy for the underlying disease and possible complications, nutritional support. And patient care, which included proper positioning and assistance with activities of daily living. The promotion of physical mobilization was usually encouraged verbally but not routinely performed by the nursing or medical staff.*	3 weeks & 6 weeks after recruitment and initiation of the 6-week programme.	Median (IQR) Baseline BI FIM 3-week BI FIM 6-week BI FIM Effect sizes (Cohen's d) BI (3-week) BI (6-week) FIM (6-week)	 I =5.0 (0.0-10.0), C = 0.0 (0.0-5.0) p > 0.05 I =34.0 (30.3-38.3), C = 33.0 (24.3-37.0) p > 0.05 I =20.0 (15.0-31.3), C = 0.0 (0.0-8.8) p < 0.05 I =45.0 (40.0-53.5), C = 28.0 (22.0-35.8) p < 0.05 I =35.0 (20.0-55.0), C = 0.0 (0.0-8.8) p < 0.05 I =49.0 (45.0-66.3), C = 26.0 (19.5-35.5) p < 0.05 d = 1.03 (95%CI: 0.27-1.74) d = 2.02 (95%CI: 1.12-2.81) d = 1.93 (95%CI not reported)
Additional comments: Only applied to patients who were receiving long periods of mechanical ventilation and who were medically stable. Very small study sample. A study in Taiwan, question on generalisability.							

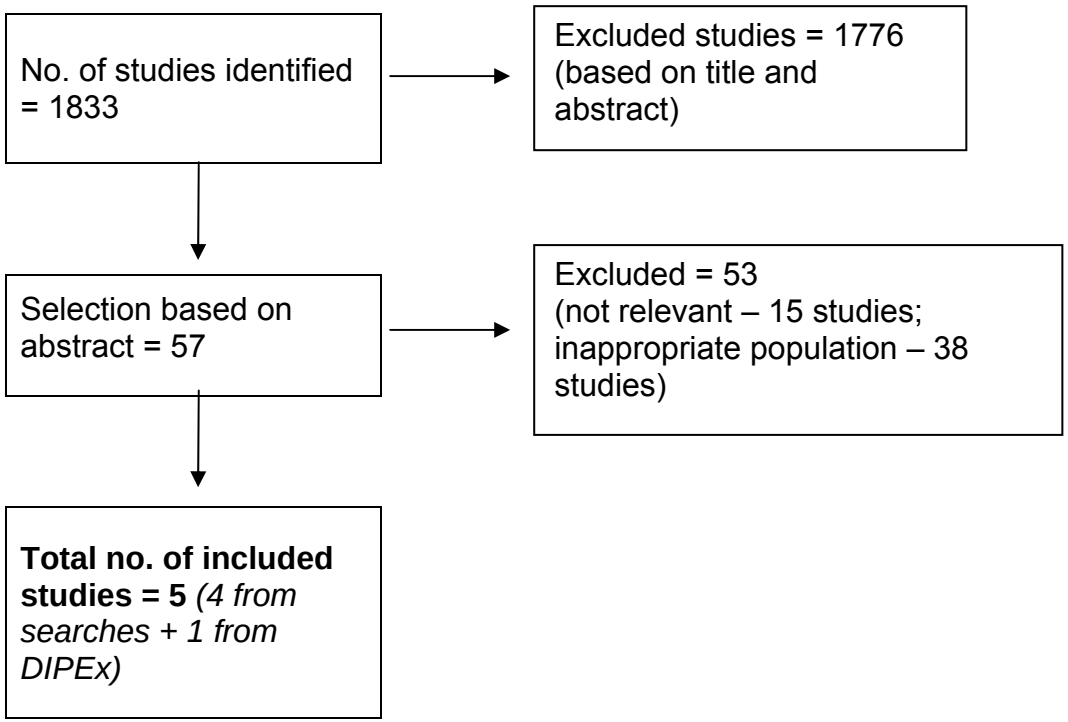
Title: Effectiveness of early exercise in critically ill patients.

Level of Evidence	Patient Population/ Characteristics	Selection/Inclusion criteria	Intervention	Comparison	Follow-up	Outcome	Effect Size
ID: 5206 Level of evidence: (-) Study type: RCT Authors: Galle et al (2007)	Total no. of patients: I = 31, C = 28 Lost to follow-up = none Baseline characteristics: Not provided. Only stated: no differences in gender, age height, weight were observed. Setting: A hospital (including ICU) in Belgium.	Inclusion: Stable patients, ventilatory supported for at least 5 days and who had an expected stay of at least another week on the ICU. Exclusion: Patients with physiological disability and physical or neuropsychiatric instability were excluded.	Early exercise defined as active or passive cycling sessions for 20 mins per day using a bedside ergometer. Plus 'usual care'	'Usual care' *(routine medical treatment and daily sessions of chest physiotherapy and functional rehabilitation)*	Not clear. Data presented at 2 time-points: ICU discharge and hospital discharge	ICU LOS (median, IQR) Hospital LOS (median, IQR) 6-min walking test (median, IQR) *(at hospital discharge, unit of distance not stated)* SF-36 physical function score (median, IQR) *(at hospital discharge)*	I = 22 (15-29), C = 21 (15.5-32) p = 0.67 I = 35 (26-43), C = 32 (27-43) p = 0.47 I = 238 (123-335), C = 154.5 (27-249) p = 0.12 I = 21 (18-23), C = 15 (14-21) p = 0.024
Additional comments: Lack information on study population and setting. Method of randomisation not clear. Concealment of allocation not clear. Blinding processes not clear. Length of follow-up not clear.							

Review Question 5:

What information and support needs are viewed as important by adult patients and their carers or family who have developed rehabilitation needs during or following a period of critical illness requiring Critical Care?

Volume of Evidence



1774 **Evidence table**

Title: Database of Individual Patient Experiences (DIPEx) (intensive care module).				
Study Type	Research parameters	Population & sample selection	Outcomes	Additional Comments
ID: N/A Grading (++) Database of Individual Patient Experiences (DIPEx) Critical care patient experiences (intensive care module).	Methodology: Each of the DIPEx modules is collected and analysed by an experienced and trained researcher who specialises in qualitative study. Purposive sampling method was adopted for the study. The interviews take place throughout the UK, mainly in respondents' homes. Interview tapes were fully transcribed and returned to the respondent for review. A list of categories were drawn up for analysis, but as the analysis progress additional categories were added. During analysis, two member of the DIPEx team looked at the NUDIST N6 reports and together they make sure that important points have been included in the topic summaries.	Total no. of patients & family/carers) = 78 (patients = 40; families/carers = 38) All potential participants would be sent an information pack.	**Admitted to & during Critical Care** ***Theme 1:*** ***Making sense of what happened - information at different stages of illness and recovery:*** (From both patients and families/carers): • Basic information on the illness, the treatments and what had happened • Information on weakness and muscle loss • Information on likely hospital length of stay and recovery • Involvement of family/carers in sharing the information Summary: – Fear, isolation and a loss of control were common feelings among people who were ill or injured in intensive care. – For many, making a good recovery also included making sense of what had happened during their stay in intensive care. – Many of those who were sedated remembered little leading up to sedation and, when they came round, their memories were often hazy or confused. Once they were more aware, some people wanted to ask questions and find out as much as possible. – People also wanted information at different stages of illness and recovery and on different topics. – Most people wanted to find out basic information about what had happened to them, what was wrong with them, how long they'd been in hospital and when they would recover (with the involvement of family or carers). – Many people said that, although they were told about their illness when they were in intensive care, they hadn't been able to remember what was said to them at the time. They stressed the importance of having information repeated to them again and again. – Many people had wondered why they were so weak and had been told, often by physiotherapists, about the muscle loss they'd had after being critically ill and immobile in ICU. – Some said they trusted the expertise of doctors and nurses and asked few questions about their illness and treatments. Others had wanted as much information as possible in order to regain a sense of control.	This qualitative study uses standard qualitative methodology, using the constant comparative method, to present a thematic analysis of patients' experiences of care. The sample size, and sampling strategy, allowed for full exploration of the range of experiences encountered by patients following discharge from critical care areas. Sources of funding: N/A

			– Most families/carers were shocked, frightened and upset when they first saw the patient with bruises, swelling and connected to various machines. Information on patient's illness and treatments would reduce the anxiety of families/carers. (From patients): • To have all the above information repeated again and again Summary: – Many people said that, although they were told about their illness when they were in intensive care, they hadn't been able to remember what was said to them at the time. They stressed the importance of having information repeated to them again and again. (From families/carers): • Information on equipment that attached to the patient. • Detailed information on the possibility that patient might improve as well as deteriorate during different stages of the treatment. • The initiation of ICU diaries. Summary: – To explain the possibility that patient might deteriorate as well as getting better due to any unforeseen problems. – Give detailed info on patient condition to equip family/carer feelings of the extreme highs and lows when patients continually improve and deteriorate. – ICU doctors have to strike a balance between giving information to relatives without raising their hopes at a time when the patient's survival is uncertain and could go either way. Often, doctors are on the side of caution rather than optimism. – Information about the equipment the ill person would be attached to – Given more information about hallucinations earlier as this would have alleviated their anxiety. – To continually providing information on patient's condition or improvement during different stages of the treatment. – Many relatives said writing down dates and brief notes about the illness or treatments had helped them keep a record of this important information, which they'd never have remembered at a later stage. – Writing notes also helped her to deal with her own feelings.	

Discharge from Critical Care & Ward-based care

Theme 1:
Information & discussion on what happened in ICU & related ICU syndrome:

(From both patients and families/carers):

- Information and reassurance regarding dreams and hallucination
- The use of ICU diaries
- Lack of communication between nurses working different shifts in the ward

Summary:

- Many said that, although they couldn't do anything about the days, weeks or months they'd lost, knowing as much as they could help explain where the time had gone and restored some sense of control.
- Making sense of dreams and hallucinations also mattered to some, particularly finding out what had been real or hallucination caused by the illness or treatments they'd received in intensive care. For most people making sense of what happened was a gradual, fragmented process rather than one occasion or stretch of time when they 'pieced it all together'.
- Relatives, health professionals during and after their hospital stay, as well as ICU diaries all contributed to what one man called fixing 'the jigsaw' of his life.
- Many relatives and close friends said the diary they'd kept had been useful for many different reasons: it had helped them answer questions and fill in gaps when the patient had wanted to make sense of what had happened; it had helped them and the patient see just how much the ill person had improved since the illness or accident and this had been encouraging; it had been useful when visiting doctors after the patient had been discharged from hospital, helping them to answer questions about the date of admission, the illness and treatments; it had been very useful later if there'd been insurance claims to deal with or concerns and complaints about the heath care.
- Some people felt there was a lack of communication between nurses on the ward working different shifts

Theme 2:
Information on patient's care pathway

(From both patients and families/carers):

Summary:
- Not all patients or their family/carers were aware of or understand the patient's care pathway and the process from one care setting to another.
- Others noted that their relatives would have liked more information about what to expect on the ward.

Theme 3:
Setting goals for physical recovery

(From patients):

Summary:
- Goal-setting was the key rehabilitation in helping patients to regain strength, mobility and confidence with informed expectation.
- Many people stressed the importance of setting themselves realistic goals while they were recovering because it gave them a sense of achievement when they succeeded.

Hospital discharge
Theme 1:
Information & discussion on discharge plan prior to discharge:

(From both patients and families/carers):
- Information on who decided the discharge and on what basis
- Information on the trajectory projection of the recovery
- Basic information on diet, exercise and drug treatment if applicable
- To be given the ICU diaries at hospital discharge, if not been given at ICU discharge.

Summary:
- Many people said they had been uncertain about how strong they'd need to be before they'd be allowed home and when that would be.
- Several said they had asked doctors, nurses and physiotherapists when they'd be allowed home, and didn't know who would decide and on what basis.
- Most people said they were completely unprepared for how long it took to recover. Some of them wished they'd been told more about this when they were discharged.
- Some people had been given information about recovery before they were

discharged from hospital, particularly on diet, exercise and drug management.

(From families/carers):

- Information on patient rehab needs and services before hospital discharge.
- All the above information to be shared with family/carers
- Information for family/carers on what to expect when a person returns home after being critically ill in ICU

Summary:

- Some relatives said they would have liked more information on what to expect when a person returns home after being critically ill in ICU.
- Most people who had been given diaries of their ICU stay, either when leaving the hospital or at a follow-up appointment, said they learnt a lot more about their stay after reading these, including information about the illness, treatments, changes and improvements, family reactions and visitors.
- Information on patient rehab needs and services before hospital discharge.

Recovering at home

Theme 1:

Information on physical recovery and impact on daily living

(From both patients and families/carers):

Summary:

- Most people said they were completely unprepared for the time it took to regain strength and mobility when they left intensive care and general ward.
- Due to many patients have little or no memory of their critical care experiences, this can affect their false expectations of recovery time.
- Many people still suffered unexpected weakness, tiredness and immobility after discharge back to home. This has big impact on their normal daily activities such as washing, walking, cooking and cleaning, and many found climbing up and down the stairs impossible.
- Some said the visit had given them a better understanding of their illness because the doctor had gone through their notes and talked them through everything that had happened in intensive care.
- Many were surprised at the length of time it had taken the ill person to recover and get back to normal, including resuming work. Some had taken a year, others two years.

			– Most said the ill person had been completely unprepared for the time it took to regain strength and mobility when they left ICU. ***Theme 2:*** ***Information on & discussion of emotional aspects of recovery:*** (From both patients and families/carers): • Discussion on any non-physical morbidity • Information on referrals or support group available • Acknowledgement that everyone is unique and can experience any range of emotions at different times Summary: – Everyone is unique and can experience any range of emotions at different times. A few found discussing nightmares with medical staff, either before they were discharged or at a follow-up appointment, reassuring because they learnt how common it was for people who'd been in intensive care to have nightmares. – Some people said they would have liked to talk to someone outside the family about their experiences of intensive care. – For patients who suffered non-physical morbidity such as depression, some patients found in-depth counselling or attending a support group more beneficial than treatment from anti-depressants. – Some people wanted to discuss what they'd remembered of their hospital experience, their dreams and hallucinations, physical and emotional recovery, any concerns, and to gain reassurance. – The ill person also experienced moods swings and feelings of frustration, anxiety and depression while recovering, especially when recovery seemed to be taking a long time or there'd been a setback.	

1781

Title: A qualitative study of the experiences of patients following transfer from intensive care.				
Study Type	Research parameters	Population & sample selection	Outcomes	Additional comments
ID: 1342 Grading (++) Strahan et al (2005)	<u>Setting:</u> A tertiary referral hospital in Northern Ireland – The Royal Hospitals Trust, Belfast. <u>Methodology:</u> A Husserlian phenomenological approach was adopted (descriptions about situations from persons who experience them in the manner in which they are experienced). Sampling method: purposive sampling. Open interview style was adopted and 4 questions were used to draw out subjects' own experiences in their own words. Data was analysed and meaning units were identified from 91 significant statements. The meanings identified were then grouped into clusters of themes that were subsequently sorted into 3 main categories. Interviews were performed on the wards 3-5 days following transfer from ICU. The interview was conducted at the bedside	Total no. of patients = 10 Male = 7 Female = 3 Mean ICU LOS = 5.2 days Age range = 18-77 <u>Inclusion/exclusion:</u> Patients who had been in intensive care for longer than 3 days, 18 years old or older, and physically and mentally capable of participating in the study as deemed by the consultant in charge were invited.	**<u>Discharge from Critical Care & Ward-based care</u>** ***Theme 1:*** ***Reassurance on physical response*** Information and reassurance on physical response related to how the patients talked about their physical experiences in the immediate post transfer period from ICU. It included 3 minor categories which were: • *Sleep* – tiredness, sleep difficulties, sleep disorders, weakness, exhaustion, flashback, hallucinations and nightmares. • *Digestion* – feelings of sickness, nausea, lack of appetite, bowel complications. • *Mobility* – lack of mobility, the aid of physiotherapists. ***Theme 2:*** ***Reassurance on emotional response & family involvement*** This major theme described the emotional experiences of patients following transfer from ICU. It included 3 sub-themes which were: • *Positive feelings* – progression towards physical recovery, gaining knowledge of the illness and information regarding treatment equipped patients with a feeling of control. • *Negative feelings* – encompasses feelings of anxiety, loneliness, depression and exhaustion. • *Family* – the importance of family presence and the strain on family due to patients' illness. ***Theme 3:*** ***Provision of information & care management*** Concerns were expressed regarding the transfer process from ICU, information giving and care management on the ward. • *Need for information* – the importance of information about patients' own critical illness, explanation on recovery, a lack of continuity caused by inadequate communication between ICU staff and those in the general wards led to unnecessary stress. • *Care management* – attitude, attention and organisation were important aspects of care management, demanded a high quality of individualised care.	The qualitative approach and research design adopted were well explained and justified with focused aims and objectives. A positive feature of this study is reflexivity: researcher's background, position, perspective were described and examined in order to ensure the effect the interviewer had on the data generation process was fully explored . The sampling method is correct. The sample of this study was small but this is appropriate in terms of the methodology used. No follow-up interviews were conducted. The interviews typically lasted 15 to 35 minutes, which is a limited amount of time given the in depth nature of the interview design. Clear inclusion and exclusion criteria. Limited information on consent procedure and ethical considerations.

	and varied in length from 15 to 35 min.		**Summary of implications for nursing practice:** • Opportunity should be offered to discuss memories and nightmares, both real and hallucinatory. • Patients should be encouraged to re-adopt their 'normal' sleep pattern. • Nursing interventions should aim at maximising patient control and help towards reducing anxiety levels. • The need for patient information, explanation and reassurance is real. • The position of a follow-up nurse to co-ordinate care for patients after discharge from ICU would be beneficial.	Source of Funding: Not reported.

1805

Title: Leaving the intensive care unit: a phenomenological study of the patients' experience				
Study Type	Research parameters	Population & sample selection	Outcomes	Additional comments
ID: 488 Grading (+) McKinney et al (2002) .	Setting: Single hospital in Northern Ireland. Methodology: Phenomenology based on the interpretative Heideggerian approach was used. This approach is based on an existential perspective, which considers that an understanding of the person cannot occur in isolation from the persons' world. Thus, it does not advocate 'bracketing' or remaining objective. Sampling method: purposive sampling. Open-ended interview method was adopted in this study. Data was analysed by using the hermeneutic analysis approach. Interviews were performed on the wards approx. 48-hour following transfer from ICU. Interviews typically lasted for approximately 20 min.	Total no. of patients = 6 Age range = 42-75 ICU LOS range = 4-10 days Inclusion/exclusion: Individuals who could not speak, who were confused and/or deemed by the researcher as too unwell to be reviewed.	**Discharge from Critical Care & Ward-based care** ***Theme 1:*** ***Information & reassurance on well-being*** • *Physical* – minor to moderate pain, sleeping difficulties, weakness, limited mobility/physical frailty and loss of appetite. • *Psychological* – feeling of psychological distress, feeling depressed as not progressing physically as well as they perceived they should be. ***Theme 2:*** ***Briefing or information on differences between ICU and the ward*** • *Differences in the physical environment* – not as intense. • *Differences in staffing levels* – acknowledge that they missed the close attention that they received in ICU, and commented how difficult it was to adjust from a one-to-one care in ICU to the ward circumstances. • *Differences in monitoring levels* – less monitoring in the ward and also less staff available. **Author's recommendations based on study findings:** • An education programme could be developed for ward nurses outlining the psychological as well as physical needs of post critical care patients. • This study has highlighted that the critical care experience transcends the boundaries of the ICU. Thus, there is a need to promote continuity of care. The development of Critical Care Outreach Services may prove beneficial.	The qualitative approach and research design adopted were well explained and justified with focused aims and objectives. Clear inclusion and exclusion criteria Clear information on consent procedure and ethical considerations. The sampling method is correct. The sample of this study is small but appropriate in terms of the methodology used. No follow-up interviews were conducted. The interviews typically lasting 20 minutes, which is a limited amount of time given the in depth nature of the interview design. While the researcher did attempt to remain true to the patients' experiences, it was acknowledged by the researcher that the need to identify themes dictated what unit of discourse would be included or excluded. Source of funding: not reported

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Title: Meeting patient and relatives' information needs upon transfer from an intensive care unit: the development & evaluation of an information booklet.				
Study Type	Research parameters	Population & sample selection	Outcomes	Additional comments
ID: 350 Grading (+) Paul et al (2004) .	Setting: Intensive care unit in Dundee. Methodology: Phase 1: identifying info needs Interview guide adapted from McIver's (1993) guidelines was used. A semi-structured interview format was used to encourage patients and relatives to offer their experiences and specific information needs. A convenience sample of 7 patients & 2 relatives was identified, interviews were performed in the ICU prior to transfer in the ward. Interviews typically lasted for approximately 15 min. A thematic content analysis was used to analyse data. Phase 2: evaluation of the information provided As in phase 1.	Phase 1: Total no. of patients = 7 (5 male, 2 female) Age range = 28-75 Admission type = 6 emergency, 1 elective Total no. of relatives = 2 Phase 2: Total no. of patients = 7 (4 male, 3 female) Age range = 22-83 Admission type = all emergency Total no. of relatives = 11 Inclusion/exclusion: Not reported.	**Discharge from Critical Care (transfer to ward)** ***Themes:*** • Uncertain expectations about the ward and the future • Concerns and worries • Ongoing physical effects • Effects on relatives • Anxieties and fears • Lack of confidence in themselves and others • Questions and communication issues • Memory loss • Relatives were more aware than patients of what the transfer from ICU involved ***Elements of the information provided in the booklet based on the findings:*** 1) Preparing to leave ICU • Informs of patient and family of usual practice when preparing to transfer patient to a general ward. 2) Transfer to the ward • Discusses details of transfer 3) Settling into the ward • Prepares patient for new environment 4) Recovering from illness • Explores common post-ICU problems and ways of dealing with them 5) Preparing to go home • Discuss support services and rehabilitation 6) Further help • Details on sources of further help 7) Diary pages • Blank pages for patient to record progress, feelings and questions The majority of the responses regarding the information booklet were very positive. • All patients and relatives felt that the 24-48 hour period prior to transfer was the most appropriate time to receive the information.	The qualitative approach and research design adopted were not well explained. No clear inclusion and exclusion criteria No clear information on consent procedure and ethical considerations. Source of funding: not reported

1810

Title: The use of patient diaries in an intensive care unit.

Study Type	Research parameters	Population & sample selection	Outcomes	Additional comments
ID: 2397 Grading (+) Combe (2005) .	Setting: Intensive care unit in Suffolk between Jan 2001 to Dec 2001. Methodology: Patients were seen weekly when transferred to the ward by the follow-up sister and then in clinic, 2, 6 and 12 months post-discharge home. Structured interviews took place in a discussion room near the ICU with the consultant intensivist, follow-up sister and a physiotherapist. Family members were also invited to attend. The appointments were 45 min for the first one and 30 min for the second and the third. All relatives were encouraged to have photographs included in the diary, but no pressure was placed on them to agree. How the diary was used: The diary began with a brief summary of events leading up to admission to the unit. Thereafter, anyone who had been involved in the care of the patient was invited to write in the diary. Nursing staff were encouraged to write once a day, giving factual information about the patient's condition, events of the day and any changes in treatment. Relatives were encouraged to contribute to the dairy. The dairies were collated and bound and given to the patient at their first follow-up clinic appointment.	Total no. of patients = 35 (22 male, 13 female) Age range = 24-82 ICU LOS range = > 4 days Inclusion/exclusion: Dairies were offered to patients who were likely to be in the unit for more than 3-4 days. On day 3, the patient and family would be assessed as to whether they would benefit from a diary. It was felt that particular benefit would be gained by ventilated/sedated patients. Patients under the age 0f 18 and those with head injuries were excluded from the study. Patients with senile dementia, gross visual impairment and where English was not the first language were also excluded.	**Discharge from Critical Care & Ward-based care (the use of ICU diaries)** ***Theme 1:*** Patients found then photographs helpful in showing what they actually looked like while in ICU and just how ill they were. This has appeared useful for them when setting goals for recovery. ***Theme 2:*** The diaries appeared to be helpful in resolving what did and did not happen and thereby allowed different perception to be grounded in the facts of the stay. ***Theme 3:*** The diaries seemed to open up communication channels between patients and their families. ***Theme 4:*** With the dairies, the patients felt able to move on from the experience and thus help re-orientate more easily to normal life. ***Theme 5:*** For some patients, the diaries acted as a debriefing tool containing the facts of their stay, which addressed, could be put aside before getting back to normal.	The qualitative approach and research design adopted were not very well explained. Clear inclusion and exclusion criteria No information on the sampling method. Source of funding: not reported

6.5 Appendix 5 – Health economic evidence tables

This section provides evidence tables that summarise the data provided in the published economic evaluations identified for the purpose of this guideline.

Published economic evaluations were quality assessed using methods as described in the current 'Guidelines methods manual'.

Data extraction table for included study – rehabilitation interventions

Primary Source	Whiston rehab report (2001) Randomised Control Trial of rehabilitation following critical Illness support for patients and their relatives. *July 2001.* Reviewed alongside the publication of the clinical trial this economic evaluation was based on – Jones et al (2003) Rehabilitation after critical illness: a randomised, controlled trial. Critical Care Medicine Vol. 31, No. 10
Author	Centre for Health Planning and Management – Keele University
Date	2001
Type of economic evaluation	Cost utility analysis based on a randomised controlled trial (RCT)
Currency used	GBP (£)
Year to which costs apply	2000
Perspective used	The analysis was from a NHS and PSS perspective. The authors stated that a broad perspective considering health service costs from both the secondary and primary care perspective was taken. Indirect or patient costs were not considered.
Timeframe	6 months. The overall time frame is unclear. The RCT was conducted over a 2 year period with final follow-up carried out at 6 months post discharge. Outcome data was collected on the pre-morbid state, 2 months and 6 months post discharge. The authors state that resources were only costed from the end of the inpatient stay (intervention itself and post discharge costs) because prior to the intervention, no cost will be affected by the intervention itself.
Comparators	The intervention was a patient information booklet given to patients following a stay in an intensive care unit. The booklet was given to the intervention group following a 20 minute discussion with a dedicated nurse. The control group were discharged from hospital following the standard hospital protocol with no additional information being given to the patient. Both groups received a follow up telephone call at weeks 2, 4 and 6. Jones et al (2003) report that control patients also received usual care consisting of dedicated ICU follow-up clinic visits at 8 weeks and 3 months. Therefore, standard care in this evaluation was routine follow up and ICU rehabilitation clinic.
Source(s) of effectiveness data	This economic evaluation was conducted alongside a RCT (Jones et al. 2003) and all effectiveness data were collected within this trial. EQ-5D and SF-36 data were collected.
Source(s) of resource use data	As for effectiveness data, resource use data were collected from patients in the clinical trial. Social and other local authority services data were obtained directly for each patient from the appropriate social services department and information elicited directly from patients at outpatient follow-up was supplemented by hospital records.
Source(s) of unit cost data	NHS reference costs were used for all outpatient costs and readmission ward costs. All primary and community care contacts were taken from the PSSRU (2000) including GP time, practice nurse time and community nurse time (taking into account whether the visit occurred at the practice or the patient's home). Individual unit costs were not presented.
Modelling approach used	Trial based evaluation – no model was used
Summary of effectiveness results	EQ-5D data were collected at the pre-morbid state as well as at 2 months and 6 months post discharge - at 6 months the intervention group sustained a slightly lower fall in health loss or benefit (0.77 to 0.68) from the pre-morbid state (compared with a fall from 0.71 to 0.60 in the control group) although the difference is extremely small at 0.02 between the two groups. There is no significant difference in EQ-5D scores between the groups at pre-morbid stage or 6 months follow-up. No statistics on this significance were reported. Overall quality adjusted life years (QALYs) were reported for the intervention and control groups at 6 months. QALYs for each of the groups were as follows: Intervention – 20.54, Control – 15.65.

<table>
<tr><td>Summary of cost results</td><td>Costs (£) - the table below outlines the total costs for the intervention and control groups. It is unclear why intervention costs are attributed to the control group. The differences in costs were not significant. No statistics on this significance were reported.
<table>
<tr><th></th><th>Intervention</th><th>Control</th></tr>
<tr><td>Total GP cost</td><td>172.19</td><td>120.32</td></tr>
<tr><td>Total nurse cost</td><td>113.32</td><td>118.88</td></tr>
<tr><td>Total physiotherapy cost</td><td>22.18</td><td>38.27</td></tr>
<tr><td>Social service cost</td><td>0.63</td><td>0.00</td></tr>
<tr><td>Total primary cost</td><td>308.32</td><td>277.46</td></tr>
<tr><td>Outpatient cost</td><td>205.43</td><td>193.38</td></tr>
<tr><td>Total inpatient cost</td><td>430.03</td><td>453.08</td></tr>
<tr><td>Intervention cost</td><td>14.00</td><td>4.50</td></tr>
<tr><td>Secondary cost</td><td>649.47</td><td>650.96</td></tr>
<tr><td>Total cost</td><td>957.79</td><td>928.42</td></tr>
</table></td></tr>
<tr><td>Summary of cost-effectiveness results</td><td>The overall cost effectiveness results showed that by switching from no booklet to providing a patient information booklet costs £939.61 per QALY gained (£1204.52 in 2007 prices if inflation is accounted for[1]).</td></tr>
<tr><td>Sensitivity analysis</td><td>No sensitivity analysis was carried out, this is likely to reflect the type of evaluation this was, in that it was based on data from a clinical trial and no assumptions were made.</td></tr>
<tr><td>Main conclusions</td><td>The results show that the intervention is relatively low cost and there is little difference in either the costs or QALYs gained with the intervention or control group. The majority of costs associated with the intervention are associated with the time spent by staff administering the booklet. The authors state that given the small cost per QALY gained by the intervention, purchasers of health care may deem this an acceptable threshold when considering introducing this patient information booklet, however, this will depend upon other competition for health care funds.</td></tr>
</table>

1. An inflation factor of 1.28 was applied to update this cost from Curtis (2007). Unit costs of health and social care. PSSRU. University of Kent.

6.6 Appendix 6 – NICE Checklists

NICE Methodology checklist: randomised controlled trials

Study identification *Include author, title, reference, year of publication*					
Guideline topic:		**Review question no:**			
Checklist completed by:					
SECTION 1: INTERNAL VALIDITY					
In a well-conducted RCT:		***Circle one option for each question:***			
A. Selection bias (systematic differences between the comparison groups)					
A1	An appropriate method of randomisation was used to allocate participants to treatment groups (which would balance any confounding factors equally across groups)	Yes	No	Unclear	N/A
A2	There was adequate concealment of allocation (such that investigators, clinicians and participants cannot influence enrolment or treatment allocation)	Yes	No	Unclear	N/A
A3	The groups were comparable at baseline, including all major confounders/prognostic factors	Yes	No	Unclear	N/A

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	Unclear/unknown risk	High risk of bias			
Likely direction of effect:					
B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)					
B1	The comparison groups received the same care apart from the intervention(s) studied	Yes	No	Unclear	N/A
B2	Patients receiving care were kept 'blind' to treatment allocation	Yes	No	Unclear	N/A
B3	Individuals administering care were kept 'blind' to treatment allocation	Yes	No	Unclear	N/A
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	Unclear/unknown risk	High risk of bias			
Likely direction of effect:					
C. Attrition bias (systematic differences between the comparison groups with respect to participants lost)					
C1	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	Yes	No	Unclear	N/A
C2	How many patients did not complete treatment in each group?				
	The groups were comparable for treatment completion (that is, no important/systematic differences between groups in terms of those who did not complete treatment)	Yes	No	Unclear	N/A
C3	For how many patients in each group were no outcome data available?				
	The groups were comparable with respect to the availability of outcome data (that is, no important/systematic differences between groups in terms of those for whom outcome data were not available)	Yes	No	Unclear	N/A

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		Unclear/unknown risk		High risk of bias	
Likely direction of effect:					
D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)					
D1	The study had an appropriate length of follow-up	Yes	No	Unclear	N/A
D2	The study employed a precise definition of outcome	Yes	No	Unclear	N/A
D3	A valid and reliable method was used to determine the outcome	Yes	No	Unclear	N/A
D4	Investigators were kept 'blind' to patients' exposure to the intervention	Yes	No	Unclear	N/A
D5	Investigators were kept 'blind' to other important confounding/prognostic factors	Yes	No	Unclear	N/A
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		Unclear/unknown risk		High risk of bias	
Likely direction of effect:					

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SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias? *Code ++, + or –*	

1825

NICE Methodology checklist: the QUADAS tool for diagnostic test accuracy studies

Study identification *Including author, title, reference, year of publication*					
Guideline topic:				**Review question no:**	
Checklist completed by:					
SECTION 1: QUALITY APPRAISAL					
		Circle one option for each question:			
1.1	Was the spectrum of patients representative of the patients who will receive the test in practice?	Yes	No	Unclear	N/A
1.2	Were selection criteria clearly described?	Yes	No	Unclear	N/A
1.3	Was the reference standard likely to classify the target condition correctly?	Yes	No	Unclear	N/A
1.4	Was the period between the reference standard and the index test short enough to be reasonably sure that the target condition did not change between the two tests?	Yes	No	Unclear	N/A
1.5	Did the whole sample or a random selection of the sample receive verification using a reference standard?	Yes	No	Unclear	N/A
1.6	Did the patients receive the same reference standard regardless of the index test result?	Yes	No	Unclear	N/A
1.7	Was the reference standard independent of the index test (that is, the index test did not form part of the reference standard)?	Yes	No	Unclear	N/A
1.8	Was the execution of the index test described in sufficient detail to permit replication of the test?	Yes	No	Unclear	N/A
1.9	Was the execution of the reference standard described in sufficient detail to permit its replication?	Yes	No	Unclear	N/A
1.10	Were the index test results interpreted without knowledge of the results of the reference standard?	Yes	No	Unclear	N/A
1.11	Were the reference standard results interpreted without knowledge of the results of the index test?	Yes	No	Unclear	N/A
1.12	Were the same clinical data available when the test results were interpreted as would be available when the test is used in practice?	Yes	No	Unclear	N/A
1.13	Were uninterpretable/intermediate test results reported?	Yes	No	Unclear	N/A
1.14	Were withdrawals from the study explained?	Yes	No	Unclear	N/A

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias? *Code ++, + or –*	

NICE Methodology checklist: qualitative studies

	Study identification *Include author, title, reference, year of publication*	
	Guidance topic:	**Key research question/aim:**
	Checklist completed by:	

Section 1: theoretical approach		
1. Is a qualitative approach appropriate? *For example,* • Does the research question seek to understand processes or structures, or illuminate subjective experiences or meanings? • Could a quantitative approach better have addressed the research question(s)?	☐ Appropriate ☐ Inappropriate ☐ Unclear	Comments:
2. Is the study clear in what it seeks to do? *For example,* • Is the purpose of the study discussed – aims/objectives/research question(s)? • Is the theoretical approach adequately discussed in relation to the literature? • Are underpinning values/assumptions/theory discussed?	☐ Clear ☐ Unclear	Comments:

Section 2: study design		
3. How defensible/rigorous is the research design/methodology? *For example,* • Is the design appropriate to the research question? • Is a rationale given for using a qualitative approach? • Are there clear accounts of the rationale/justification for the sampling, data collection and data analysis techniques used? • Is the selection of cases/sampling strategy theoretically justified?	☐ Definitely ☐ Not definitely ☐ Not at all	Comments:

Section 3: data collection

4. How well was the data collection carried out? *For example,* • Are the data collection methods clearly described? • Were the appropriate data collected to address the research question? • Was the data collection and record keeping systematic?	☐ Appropriate ☐ Inappropriate ☐ Not sure/ inadequately reported	Comments:

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Section 4: validity		
5. Is the role of the researcher clearly described? *For example,* • Has the relationship between the researcher and the participants been adequately considered? • Does the paper describe how the research was explained and presented to	☐ Clear ☐ Unclear ☐ Not described	Comments:

the participants?		

6. Is the context clearly described? *For example,* • Are the characteristics of the participants and settings clearly defined? • Were observations made in a sufficient variety of circumstances? • Was context bias considered?	☐ Clear ☐ Unclear ☐ Not sure	Comments:
7. Were the	☐ Reliable	Comments:

methods reliable? *For example,* • Were data collected by more than one method? • Is there justification for triangulation, or for not triangulating? • Do the methods investigate what they claim to?	☐ Unreliable ☐ Not sure	

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Section 5: analysis		
8. Is the data analysis sufficiently rigorous? *For example,* • Is the procedure explicit – that is, is it clear how the data were analysed to arrive at the results? • How systematic is the analysis; is the procedure reliable/dependable? • Is it clear how the themes and concepts were derived from the data?	☐ Rigorous ☐ Not rigorous ☐ Not sure/not reported	Comments:
9. Are the data 'rich'? *For example,* • How well are the contexts of the	☐ Rich ☐ Poor ☐	Comments:

data described? • Has the diversity of perspective and content been explored? • How well has the detail and depth been demonstrated? • Are responses compared and contrasted across groups/sites?	Not sure/not reported	

10. Is the analysis reliable? *For example,* • Did more than one researcher theme and code transcripts/data? • If so, how were differences resolved? • Did participants feed back on the transcripts/data if possible and relevant? • Were negative/discrepant results addressed or ignored?	☐ Reliable ☐ Unreliable ☐ Not sure/not reported	Comments:
11. Are the findings convincing? *For example,* • Are the findings clearly presented? • Are the findings	☐ Convincing ☐ Not convincing	Comments:

internally coherent? • Are extracts from the original data included? • Are the data appropriately referenced? • Is the reporting clear and coherent?	☐ N ot su re	

12. Are the findings relevant to the aims of the study?	☐ Relevant ☐ Irrelevant ☐ Partially relevant	Comments:
13. Are the conclusions adequate? *For example,* • How clear are the links between data, interpretation and conclusions? • Are the conclusions plausible and coherent? • Have alternative	☐ Adequate ☐ Inadequate ☐ Not sure	Comments:

explanations been explored and discounted? • Does this study enhance understanding of the research subject? • Are the implications of the research clearly defined? • Is there adequate discussion of any limitations encountered?		

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Section 6: ethics		
14. How clear and coherent is the reporting of ethics? *For example,* • Have ethical issues been taken into consideration? • Are they adequately discussed; for example, do they address consent and anonymity? • Have the consequences of the research	☐ Appropriate ☐ Inappropriate ☐ Not sure/not reported	Comments:

been considered; for example, raising expectations, changing behaviour? • Was the study approved by an ethics committee?		

Section 7: overall assessment

15. As far as can be judged from the paper, how well was the study conducted? (see guidanc	☐ + + ☐ + ☐ –	Comments:

e **no** **tes** **)**		

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