National Collaborating Centre for
Mental Health

Document information (v1.0)

Mental health problems in people with learning disabilities

Prevention, assessment and management

NICE Guideline <…>

Methods, evidence and recommendations

7 March 2016

Draft for Consultation

*Commissioned by the National Institute for
Health and Care Excellence*

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Acknowledgments

The GC and the NCCMH would like to thank the following people:

Dr Nuala Livingstone, editor and systematic reviewer at Cochrane Developmental, Psychosocial and Learning Problems Cochrane Review Group

Daniela Gonçalves Bradley, systematic reviewer for Effective Practice and Organisation of Care (EPOC) Cochrane Review Group

Sasha Shepherd, co-ordinating editor at Effective Practice and Organisation of Care (EPOC) Cochrane Review Group

Dr Joanne Wilson, managing editor at Cochrane Developmental, Psychosocial and Learning Problems Cochrane Review Group

1 Preface

This guideline has been developed to advise on the prevention, assessment and management of mental health problems in people with learning disabilities. The guideline recommendations have been developed by a multidisciplinary team of healthcare and education professionals, carers of people with learning disabilities and guideline methodologists after careful consideration of the best available evidence. It is intended that the guideline will be useful to clinicians and service commissioners in providing and planning high-quality mental health care for people with learning disabilities while also emphasising the importance of the experience of care for people with learning disabilities and their carers (see Appendix A for more details on the scope of the guideline).

Although the evidence base is rapidly expanding, there are a number of major gaps. The guideline makes a number of research recommendations specifically to address gaps in the evidence base. In the meantime, it is hoped that the guideline will assist clinicians, and people with learning disabilities and their carers to prevent, identify, assess, and manage mental health problems, by identifying the merits of particular treatment approaches where the evidence from research and clinical experience exists.

1.1 National clinical guidelines

1.1.1 What are clinical guidelines?

Clinical guidelines are ‘systematically developed statements that assist clinicians and service users in making decisions about appropriate treatment for specific conditions’ (Mann, 1996).They are derived from the best available research evidence, using predetermined and systematic methods to identify and evaluate the evidence relating to the specific condition in question. Where evidence is lacking, the guidelines include statements and recommendations based upon the consensus statements developed by the GC.

Clinical guidelines are intended to improve the process and outcomes of healthcare in a number of different ways. They can:

- provide up-to-date evidence-based recommendations for the management of conditions and disorders by healthcare professionals
- be used as the basis to set standards to assess the practice of healthcare professionals
- form the basis for education and training of healthcare professionals
- assist service users and their carers in making informed decisions about their treatment and care
- improve communication between healthcare professionals, service users and their carers
- help identify priority areas for further research.

1.1.2 Uses and limitations of clinical guidelines

Guidelines are not a substitute for professional knowledge and clinical judgement. They can be limited in their usefulness and applicability by a number of different factors: the availability of high-quality research evidence, the quality of the methodology used in the development of the guideline, the generalisability of research findings and the uniqueness of individuals.

Although the quality of research in this field is variable, the methodology used here reflects current international understanding on the appropriate practice for guideline development (AGREE Collaboration, 2003), ensuring the collection and selection of the best research evidence available and the systematic generation of treatment recommendations applicable to the majority of mental health problems in people with learning disabilities. However, there will always be some people and situations where clinical guideline recommendations are not readily applicable. This guideline does not, therefore, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual, in consultation with the person or their carer.

In addition to the clinical evidence, cost-effectiveness information, where available, is taken into account in the generation of statements and recommendations in clinical guidelines. While national guidelines are concerned with clinical and cost effectiveness, issues of affordability and implementation costs are to be determined by the National Health Service (NHS).

In using guidelines, it is important to remember that the absence of empirical evidence for the effectiveness of a particular intervention is not the same as evidence for ineffectiveness. In addition, and of particular relevance in mental health, evidence-based treatments are often delivered within the context of an overall treatment programme including a range of activities, the purpose of which may be to help engage the person and provide an appropriate context for the delivery of specific interventions. It is important to maintain and enhance the service context in which these interventions are delivered, otherwise the specific benefits of effective interventions will be lost. Indeed, the importance of organising care in order to support and encourage a good therapeutic relationship is at times as important as the specific treatments offered.

1.1.3 Why develop national guidelines?

The National Institute for Health and Care Excellence (NICE) was established as a Special Health Authority for England and Wales in 1999, with a remit to provide a single source of authoritative and reliable guidance for service users, professionals and the public. NICE guidance aims to improve standards of care, diminish unacceptable variations in the provision and quality of care across the NHS, and ensure that the health service is person-centred. All guidance is developed in a transparent and collaborative manner, using the best available evidence and involving all relevant stakeholders.

NICE generates guidance in a number of different ways, 3 of which are relevant here. First, national guidance is produced by the Technology Appraisal Committee to give robust advice about a particular treatment, intervention, procedure or other health technology. Second, NICE commissions public health intervention guidance focused on types of activity (interventions) that help to reduce people’s risk of developing a disease or condition, or help to promote or maintain a healthy lifestyle. Third, NICE commissions the production of national clinical guidelines focused upon the overall treatment and management of a specific condition. To enable this latter development, NICE has established 4 National Collaborating Centres in conjunction with a range of professional organisations involved in healthcare.

1.1.4 From national clinical guidelines to local protocols

Once a national guideline has been published and disseminated, local healthcare groups will be expected to produce a plan and identify resources for implementation, along with appropriate timetables. Subsequently, a multidisciplinary group involving commissioners of healthcare, primary care and specialist mental health professionals, service users and carers should undertake the translation of the implementation plan into local protocols, taking into account both the recommendations set out in this guideline and the priorities in the National Service Framework for Mental Health (Department of Health, 1999) and related documentation. The nature and pace of the local plan will reflect local healthcare needs and the nature of existing services; full implementation may take a considerable time, especially where substantial training needs are identified.

1.1.5 Auditing the implementation of clinical guidelines

This guideline identifies key areas of clinical practice and service delivery for local and national audit. Although the generation of audit standards is an important and necessary step in the implementation of this guidance, a more broadly-based implementation strategy will be developed. Nevertheless, it should be noted that the Care Quality Commission in England, and the Healthcare Inspectorate Wales, will monitor the extent to which commissioners and providers of health and social care and Health Authorities have implemented these guidelines.

1.2 The national mental health problems in people with learning disabilities guideline

1.2.1 Who has developed this guideline?

This guideline has been commissioned by NICE and developed within the National Collaborating Centre for Mental Health (NCCMH). The NCCMH is a collaboration of the professional organisations involved in the field of mental health, national service user and carer organisations, a number of academic institutions and NICE. The NCCMH is funded by NICE and is led by a partnership between the Royal College of Psychiatrists and the British Psychological Society's Centre for Outcomes Research and Effectiveness, based at University College London.

The GC was convened by the NCCMH and supported by funding from NICE. The GC included carers of people with learning disabilities, and professionals from speech and language therapy, physiotherapy, paediatric and general practice and the private and voluntary sectors.

Staff from the NCCMH provided leadership and support throughout the process of guideline development, undertaking systematic searches, information retrieval, appraisal and systematic review of the evidence. Members of the GC received training in the process of guideline development from NCCMH staff, and carers received training and support from the NICE Patient and Public Involvement Programme. The NICE Guidelines Technical Adviser provided advice and assistance regarding aspects of the guideline development process.

All GC members made formal declarations of interest at the outset, which were updated at every GC meeting. The GC met a total of 11 times throughout the process of guideline development. The GC was supported by the NCCMH technical team, with additional expert advice from special advisers and focus groups where needed. The group oversaw the production and synthesis of research evidence before presentation. All statements and recommendations in this guideline have been generated and agreed by the whole GC.

1.2.2 For whom is this guideline intended?

This guideline will be relevant for adults, children and young people with learning disabilities and covers the care provided by primary, community, secondary, tertiary and other healthcare professionals who have direct contact with, and make decisions concerning the care of, adults, children and young people with learning disabilities.

The guideline will also be relevant to the work, but will not cover the practice, of those in:

- occupational health services
- social services
- the independent sector.

1.2.3 Specific aims of this guideline

The guideline makes recommendations for the prevention, identification, assessment and management of mental health problems in people with learning disabilities. It aims to:

- improve access and engagement with treatment and services for people with learning disabilities
- evaluate the role of specific physical, psychological, psychosocial and pharmacological interventions (and any combination of the above) in the treatment of mental health problems in people with learning disabilities
- integrate the above to provide best-practice advice on the care of individuals throughout the course of their treatment
- promote the implementation of best clinical practice through the development of recommendations tailored to the requirements of the NHS in England and Wales.

1.2.4 The structure of this guideline

The guideline is divided into chapters, each covering a set of related topics. The first 3 chapters provide a general introduction to guidelines, an introduction to the topic of mental health problems in people with learning disabilities and to the methods used to develop them. Chapter 3 to Chapter 9 provide the evidence that underpins the recommendations about the prevention, assessment and management of mental health problems in people with learning disabilities.

Each evidence chapter begins with a general introduction to the topic that sets the recommendations in context. Depending on the nature of the evidence, narrative reviews or meta-analyses were conducted, and the structure of the chapters varies accordingly. Where appropriate, details about current practice, the evidence base and any research limitations are provided. Where meta-analyses were conducted, information is given about both the interventions included and the studies considered for review. Clinical summaries are then used to summarise the evidence presented. Finally, recommendations related to each topic are presented at the end of each chapter. Full details about the included studies can be found in Appendices J, K, L and M. Where meta-analyses were conducted, the data are presented using forest plots in Appendix O (see Table 1 for details).

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2 Introduction

Learning disabilities are common and many people with learning disabilities have considerable, and often multiple, mental health problems. Additionally, their health needs are often overlooked, or misattributed to their learning disabilities, resulting in unnecessary suffering which could be alleviated by access to the right care and support. Achieving equality in health and social care, and education, does not permit the assumption that one size fits all because reasonable adjustments, as outlined in the Equality Act 2010 (UK Parliament, 2010), are necessary to accommodate individuals' disabilities.

While all NICE guidelines are relevant for people with learning disabilities, this guideline has been produced to highlight reasonable adjustments so that people with learning disabilities who have mental health problems receive equality of care and support. This guideline considers:

- anticipatory care aimed at prevention of mental health problems;
- care, support, and recovery for persons with learning disabilities who have mental health problems; and
- associated support for family and paid carers.

People with learning disabilities deserve to be equally valued and respected. This value and respect will build an inclusive society enriched by diversity, benefitting all citizens.

People with learning disabilities are people first. Sometimes, additional considerations and terms, or 'labels', can be helpful as a means to access appropriate care and support, and that is why the introduction to this guideline now starts by describing the terms that are used within it.

2.1 Definitions and terminology

2.1.1 Learning disabilities

The Department of Health, in their report Valuing people: a new strategy for learning disability for the 21st century (Department of Health, 2001), uses the term 'learning disabilities' when the following 3 core criteria are present:

- a significantly reduced ability to understand new or complex information, to learn new skills (impaired intelligence), with
- a reduced ability to cope independently (impaired social functioning)
- which started before adulthood, with a lasting effect on development.

People have learning disabilities from birth, or develop them during infancy or childhood. They affect the person's development and are long-lasting. A person with learning disabilities needs additional support with learning while at school, and often with daily activities all through their life. Because it can be more difficult to understand, learn and remember new things, they might have needs related to communication, being aware of risks and managing everyday tasks, and need support to live independently. There are many causes of learning disabilities and the cause is often unknown.

Some definitions of learning disabilities also require the person to have an IQ of less than 70, such as The International Classification of Diseases (ICD-10) Classification of Mental and Behavioural Disorders (World Health Organization, 2010). IQs are measured by intelligence tests, which allow a person's scores to be compared with the range of scores achieved by large numbers of people on the same test. However, it must be remembered that an IQ score does not give any information about a person's social, medical, educational and personal needs, nor what help and support the person might need.

Each child inherits a vast amount of genetic information from both parents which is not shared with other children with learning disabilities and, as they grow up, their environment and experiences shape their development, interests, fears, hopes, ambitions and characteristics. So even when a person has a clear genetic cause for their learning disabilities, such as Down’s syndrome, they are unique from all other people with Down’s syndrome. While being individually unique, people with learning disabilities also share some characteristics with most other people with learning disabilities, such as needing additional support when at school, and reasonable adjustments to ensure that their health and social care is equal to people who do not have a learning disability.

2.1.2 Mental health problems

Throughout this guideline, we use the term ‘mental health problems’, and intend it to be synonymous with terms such as mental health needs, mental ill-health, mental health conditions, or mental disorders. The World Health Organisation defines mental disorders as ‘a broad range of problems, with different symptoms, [...] generally characterized by some combination of abnormal thoughts, emotions, behaviour and relationships with others.’

This guideline addresses, for people with learning disabilities, the mental disorders included in the ICD-10 (World Health Organization, 2010): common mental disorders (depression, and anxiety disorders), psychoses (schizophrenia, and bipolar disorder), dementias, eating disorders, alcohol and substance misuse, attachment disorders, and sexually inappropriate behaviour, and also other neuro-developmental conditions (autism, and attention deficit hyperactivity disorders [ADHD] and any associated mental health problems).

Problem behaviours (challenging behaviour, aggressive behaviour, destructive behaviour, and/or self-injurious behaviour) are not addressed in this guideline, as they are the focus of a dedicated NICE guideline on challenging behaviour and learning disabilities (NICE, 2015).

2.1.3 Carers

NICE defines a carer as a person who provides support to a partner, family member, friend, or neighbour who is ill, struggling or has a disability. This does not include paid carers (care workers), who are included in the definition of staff.

Adults with learning disabilities require support in their daily lives, and many use paid carers/support workers for this. Throughout this guideline we distinguish between family carers and paid carers.

2.1.4 Staff

NICE defines staff as healthcare professionals and social care practitioners, including those working in community teams for adults or children (such as psychologists, psychiatrists, social workers, speech and language therapists, nurses, behavioural analysts, occupational therapists, physiotherapists), paid carers (care workers) in a variety of settings (including residential homes, supported living settings and day services) and educational staff.

2.2 Prevalence

2.2.1 Learning disabilities

Learning disabilities are common. More children and young people are identified as having learning disabilities than adults with learning disabilities, because children and young people with learning disabilities are found to need additional support at school to get the best chance to learn academic skills. Then, as young people and adults gradually learn skills, they may no longer need support to lead independent lives. Additionally, people with learning disabilities do not live as long as other people, reducing the proportion of adults with learning disabilities in the population.

According to the School Census conducted in England each year, in 2014, 2.1% of children and young people attending state school had learning disabilities; 1.6% of children had moderate learning disabilities, 0.4% had severe learning disabilities, and 0.1% had profound and multiple learning disabilities (ONS, 2014). The collection of information on children with special educational needs (SEN) changed in 2015, with a new category of children requiring SEN Support, a combination of the previous School Action Plus and School Action stages in the assessment of SEN (previously, information on type of SEN was only collected for children at School Action Plus). This wider classification of SEN has given a higher figure of 3.6% of children and young people with learning disabilities; 3.1% with moderate learning disabilities, 0.4% with severe learning disabilities, and 0.1% with profound and multiple (Hatton et al., 2016). According to information provided by General Practices in England in 2014 as part of their contractual arrangements with the Government, 0.5% of their registered patients aged 18 and over had learning disabilities.

2.2.2 Mental health problems

Mental health problems are very common, with 1 in 4 people experiencing mental health problems in their lifetime (McManus et al., 2009). Mental health problems contribute to 13% of the global burden of disease, much more than both cardiovascular disease and cancer (Collins et al., 2011; World Health Organization, 2008). Depression alone is the third leading contributor to the global disease burden, and in the equivalent of every 7 seconds, someone develops dementia (Ferri, 2005). Mental health problems in people with learning disabilities are even more common than in the rest of the population with a point prevalence of about 30% (Cooper et al., 2007b; Emerson & Hatton, 2007).

Evidence on the prevalence of mental health problems was recently synthesised for adults with learning disabilities (Buckles et al., 2013), and children and young people with learning disabilities (Einfeld, 2011), and was further reviewed to inform this guideline. Widely different prevalence rates have been reported, most easily explained by the differing methodologies employed (Smiley, 2005). For example, some studies have not included problem behaviours or autism within their definition of mental health problems whereas other studies have, but have not separately reported rates. Different studies have used different criteria to define types of mental health problems, and it has been shown that this impacts on the detected prevalence rates (Cooper et al., 2007b). The type and depth/quality of assessments varies. Some studies report prevalence rates including past conditions, whereas others restrict this to current conditions. The study setting also affects results. For example, studies conducted in psychiatric care settings report much higher prevalence rates than those which are population based due to the inherent sample bias. Therefore it is important to consider if studies are population-based and representative, or based on administrative samples (such as people known to Local Authorities), or special settings where findings are unlikely to generalise to the whole population with learning disabilities in England.

Considering population-based studies for adults with learning disabilities, prevalence rates of mental health problems (excluding problem behaviours) are reported to be from 14.5%, when also excluding ADHD, autism, dementia, and personality disorder, and people aged 65 and over (Deb et al., 2001), to 43.8%, in adults with moderate to profound learning disabilities only (Bailey, 2007). The largest prevalence study amongst adults in which each person was individually assessed and diagnoses made was conducted in the UK and included 1,023 adults with learning disabilities (Cooper et al., 2007b). It found that 28.3% of adults had current mental health problems (excluding problem behaviours, or 40.9% including them), similar to results from previous smaller studies within England (Cooper & Bailey, 2001; Corbett, 1979). With regards to children and young people, prevalence rates of mental health problems including problem behaviours (in view of how these studies were reported), have been reported in the range of 30% (Birch et al., 1970; Rutter et al., 1970) to 50% (Dekker & Koot, 2003). Emerson and Hatton (2007) reported a rate of 36% in 641 children and young people (aged 5-16 years) with learning disabilities in the UK, compared with 8% of 17,774 children without learning disabilities participating in the same surveys: the children with learning disabilities accounted for 14% of all children with a mental health problem.

Some specific types of mental health problems are notably more common in people with learning disabilities than in other people, including schizophrenia (Cooper et al., 2007c; Turner, 1989), bipolar disorder (Cooper et al., 2007b), dementia (Cooper, 1997a; Strydom, 2007), ADHD (Emerson & Hatton, 2007), and pica. Autism is considerably more common in people with learning disabilities (Baird et al., 2006; Emerson & Baines, 2010; Emerson & Hatton, 2007). Indeed, prevalence rates of mental health problems for children and young people with learning disabilities have been reported to be higher than for other children and young people for 27 out of 28 ICD-10 diagnostic categories, and statistically significantly so for 20 of these 28 comparisons (Emerson & Hatton, 2007).

For people with learning disabilities, their most common types of experienced mental health problems are depression (Cooper et al., 2007f), anxiety disorders (Emerson & Hatton, 2007; Reid et al., 2011), and also autism (Baird et al., 2006; Emerson & Hatton, 2007), and in adults but not children or young people, schizophrenia (Cooper et al., 2007c; Turner, 1989).

The prevalence of mental health problems is influenced by the underlying cause of the person’s learning disabilities if it has a distinctive ‘behavioural phenotype’, and other factors, which are considered further in section 2.5.

Despite the high prevalence of mental health problems, they are often not recognised in people who have learning disabilities. This can be due to presumptions around the person’s behaviour and symptoms being attributed to their learning disabilities, or changes in their presentation not being noticed by carers. This can result in prolonged distress for the person with learning disabilities.

2.3 Incidence and temporal patterns

The high prevalence of mental health problems for adults with learning disabilities is accounted for by both incident cases and enduring episodes. There are more 'enduring' than 'incident', episodes, and incidence is statistically significantly higher than that reported in the general population (Smiley et al., 2007). The incidence rate for mental health problems (excluding problem behaviours) of adults with learning disabilities over a 2-year period has been reported to be 12.6% (Smiley et al., 2007). Specifically for affective disorders, 2-year incidence was 8.3%, and for anxiety disorders it was 1.7%. Compared with the adult general population, the standardised incidence rate was reported to be 1.87 for common mental disorders (Smiley et al, 2007). For psychotic disorders, 2-year incidence has been reported to be 1.4%, and for first episode of psychosis, 0.5%, giving a standardised incidence ratio for first episode psychosis of 10.0. Full remission of psychosis after 2 years was only 14.3% (Cooper et al., 2007c). Incidence of dementia has also been reported for older adults with learning disabilities not due to Down's syndrome, and found to be considerably higher than for the age-matched general population. At age 65 years or older, the standardised incidence ratio for dementia was 4.98 (Strydom et al., 2013).

Further studies on common mental health problems in adults with learning disabilities also show high, and enduring rates. A longitudinal study defined 'chronic depression' as persons who scored 5 or more on the Malaise Inventory at each of ages 23, 33, and 43 years, and reported that 15% of adults with mild learning disabilities compared with 3% of the cohort without learning disabilities met this definition (Collishaw et al., 2004; Maughan et al., 1999). Another UK longitudinal study of a 1946 birth cohort also included people with mild learning disabilities (Richards et al., 2001). The people with mild learning disabilities at ages 15, 36 and 43 years were found to have significantly more anxiety and depressive symptoms compared with other adults.

Trajectories of psychopathology have also been reported in longitudinal studies across childhood and youth. Australians aged 4-19.5 years were followed over 4 waves of data collection over 14 years. High psychopathology levels were reported, with hyperactivity more prominent at younger ages (and persisting longer in those with the greatest degree of learning disabilities), and emotional disorders emerging later in childhood (Einfeld & Tonge, 1996; Einfeld et al., 2006; Tonge & Einfeld, 2003). Similar findings have been reported from longitudinal studies with children with learning disabilities/borderline learning disabilities (excluding those with more severe learning disabilities or with additional sensory or physical disabilities) in the Netherlands (De Ruiter et al., 2007; Wallander, 2006).

2.4 Comorbidities

Children, young people, and adults with learning disabilities who have mental health problems often have more than 1 mental health problem. Indeed, they also typically coexist with multiple physical health problems. All of the following are extremely common in children, young people, and adults with learning disabilities, and markedly more so than in the general population: problem behaviours, epilepsy, visual impairments, hearing impairments, impacted cerumen, gastro-oesophageal reflux disorder, constipation, diabetes, osteoporosis, contractures, mobility and balance impairments, injuries, thyroid dysfunction, eczema, asthma, obesity, pain (Cooper et al., 2015; Hermans, 2014; McCarron et al., 2013). There are a wide range of reasons for this, such as the underlying cause of the person's learning disabilities, socioeconomic, lifestyle and environmental factors, sub-optimal support and healthcare, and combinations of factors. Some problems can predispose to others. For example, certain psychotropic medications prescribed for mental health problems can increase diabetes risk, as can obesity, and sedentary lifestyles. Use of psychotropics (Sheehan et al., 2015), obesity

(Melville et al., 2008), and sedentary lifestyles (Finlayson et al., 2009) are all common in adults with learning disabilities.

Neuro-developmental disorders also seem to cluster together, and indeed Gillberg (2010) has coined the term ‘ESSENCE’ (Early Symptomatic Syndromes Eliciting Neurodevelopmental Clinical Examination), defined as possession of a major problem in 1 or more of 10 domains: motor skills; general development; speech and language; social interaction and communication; behaviour; hyperactivity or impulsivity; hypoactivity; inattention; sleep or feeding difficulties. There is increasing genetic data to support such clustering of neuro-developmental and mental health problems (Moreno-De-Luca et al., 2013).

Co-morbidities are very important to acknowledge. Combined with the communication needs of some people with learning disabilities, co-morbidities contribute to under-recognition of other health problems, including mental health problems, or recognition of health problems only at a late stage of the disease process making recovery less likely. This is further compounded by diagnostic over-shadowing, with problems being attributed to the person’s learning disabilities and so being ignored, rather than being recognised and addressed. Multiple morbidities cause difficulties for health, social care and education staff in identifying that the person with learning disabilities may potentially have additional health needs, seeking help for the person, and also introduces diagnostic complexities for health care professionals.

Co-morbidities are not only important regarding recognition and diagnosis of other conditions, they also impact on medical treatment. Multiple conditions can result in multiple prescriptions, and several of the commonly experienced conditions are treated with drugs that bring a cholinergic burden, so together compounding cholinergic burden with potential adverse consequences such as impairing cognition (O'Dwyer & et al, 2016). Polypharmacy can introduce both medication-medication interactions, and medication-disease interactions (in addition to single medication side-effects), with adverse consequences, hence the crucial role of regular medication review, and using the minimal effective doses of medications. As people with learning disabilities may have difficulties expressing any new symptoms or side effects they are experiencing, this is particularly important. Indeed, most protocols or care pathways are designed for single conditions, and so are less relevant for a person with multiple morbidities, where deliberate deviations from single-disease protocols may well be in the person’s best interest and highly individualised care is typically needed.

2.5 Associated characteristics and causes

Many factors can contribute to a person with learning disabilities developing mental health problems and, typically, there are several interacting factors, some of which are transactional. Moore and George (2011) provide a detailed model to conceptualise these factors across dimensions and over the life course, illustrating how functions change over time, how factors interact with the environment, and the nature of causal outcomes: ‘ACORNS’ (Accessible Cause-Outcome Representation and Notation System). A knowledge of this can help in terms of developing ways to help prevent or reduce the risk of a person developing mental health problems, and finding ways to aid recovery. At present, much of the supporting evidence we have is based on clinical experience, and cross-sectional studies of associations. Therefore definite directions of cause and effect cannot be inferred, and further research is needed to better understand the interaction of biological, psychological, social, and developmental factors in the aetiology and trajectories of mental health problems in people with learning disabilities.

2.5.1 Biological

Genetic studies indicate that intelligence is highly heritable and can itself be conceptualised as a spectrum of syndromes (Davies et al., 2011). Additionally, there are many genetic causes of learning disabilities and the genetic condition can cause a range of other physical, cognitive, behavioural, and mental health problems. The term ‘behavioural phenotype’ is often used to describe this. Examples of behavioural phenotypes include the high rates of dementia in middle-aged and older adults with Down’s syndrome (Oliver & Holland, 1986; Prasher, 1995); affective psychosis in Prader–Willi syndrome (Beardsmore et al., 1998; Soni et al., 2008); anxiety and autism (Kerns & Kendall, 2013); depression in phenylketonuria (Pietz et al., 1997). In these situations, it is important to avoid therapeutic nihilism and diagnostic over-shadowing, and to offer assessments and person-centred intervention and support plans as one would for other persons with learning disabilities. This is because while there is a strong genetic driver in aetiology there may be other mediating factors that have resulted in the person developing the mental health problem and its maintenance, and there are psychosocial approaches and in some cases medications that can be effective just as there are for some physical health problems.

A second consideration is physiology. Some of the genetic syndromes cause different physiology compared with other people, and this might mean that they require different medical treatments and medications, or do not require others. For example, the low rates of heart disease and low blood pressure in Down’s syndrome, differing immunology causing high rates of thyroid disorders and other immunological disorders, and different mechanisms in dementia aetiology compared to typical Alzheimer disease. There is such a large number of genetic disorders that can cause learning disabilities, so healthcare professionals need to find out if a person they are working with has a recognised disorder, and the associated physiological patterns.

In addition to behavioural phenotypes, other biological factors may be implicated in mental health problems. Some conditions do have a degree of genetic inheritance and so the person may have acquired the condition even if they did not have learning disabilities, for example schizophrenia.

Neurological conditions, which are common in people with learning disabilities, may also impact on additional mental health problems. Epilepsy is more common in people with learning disabilities, with a prevalence of about 22%, or 40% excluding people with mild learning disabilities (Robertson et al., 2015), In the general population, it is widely accepted that epilepsy increases risk of mental health problems. Studies with people with learning disabilities might also support this, but the results are a little mixed (Cooper et al., 2007b; Corbett, 1979; Deb & Hunter, 1991; Deb, 1998; Espie et al., 2003; Lund, 1985). Other physical health problems and impairments might also increase risk for mental health conditions, such as deafness and pain, and our knowledge and understanding of multi-morbidity is still developing. Deb et al. (2001) reported a statistical association between physical disability and mental health conditions. Moss et al. (1993) did not find such a relationship, and Cooper (1999) found an association between physical ill-health and dementia but not common mental disorders; but these 2 reports were specifically about older people with learning disabilities, and so comprised a larger proportion of people with mild rather than severe learning disabilities (due to premature death of people with more severe learning disabilities), so the results may not be relevant to children, young persons or younger adults with learning disabilities. Polypharmacy can also be implicated in mental health problems in people with learning disabilities.

Allostatic load is the physiological cost of making adaptive shifts across a range of physiological systems to match internal functioning to environmental demands: stressful environments negatively interact, leading to these secondary metabolic and immunological consequences. There is preliminary evidence that people with learning disabilities have higher levels of inflammatory cytokines, and increased level of oxidative stress (Carmelli et al., 2012), suggesting that allostatic load may be an underpinning mechanism for their poor mental health.

Some immutable constitutional characteristics have been found to be associated with mental health problems in people with learning disabilities, such as age (the emergence of ADHD and emotional problems at different stages of childhood; psychoses in older teenage/young adulthood and then again at old age; dementia in older age), and gender (association of male gender with higher rates of inappropriate sexual behaviours, and forensic mental health problems, and also with autism; female gender with mental health problems in general, and possibly depression).

2.5.2 Psychological

A person’s experiences shape their personality development, approaches to life, locus of control, confidence, self-esteem, and coping strategies and capacity for resilience, impacting on mental health. For example, former experiences of abuse, neglect, or exploitation have been shown to predict incident episodes of mental health problems (Smiley et al., 2007), and low self-esteem is associated with depression (MacMahon & Jahoda, 2008).

Drawing from the general population, we know that the quality of interactions with environment is dependent on a child’s abilities to regulate early attention (Scerif, 2010), on their impact on memory (Astle & Scerif, 2011), learning (Steele, 2012), and on developing sensitivities to emotional information from infancy (Moore et al., 2002). Child environment transactions are a key factor in developing secure attachments, and in forming relationships in typically developing infants and children, and secure and sensitive early relationships are predictors of later mental health problems (Murray et al., 1996).These factors may well be relevant to children with learning disabilities, and if so suggest that interventions geared towards better attentional control may be protective (Johnson, 2012). Attentional control also interacts with emotional processing and memory biases in predicting risk for psychopathology such as anxiety (Bishop, 2009). The neural circuits supporting attention, memory, and emotional regulation overlap heavily with the pathways on which allostatic load has an influence (McEwen, 2003). This suggests that these risk and protective pathways may be modulated by environmental stress to predict later mental health problems.

2.5.3 Social

Social and environment factors are likely to influence and mediate the development of mental health problems in people with learning disabilities. Exposure to social disadvantages such as lone parent family, poor family functioning, lack of parental educational qualifications, income poverty, and households with no paid employment have been shown to be associated with mental health problems in children and young people with learning disabilities (Emerson, 2015; Emerson & Hatton, 2007). Indeed, the cumulative exposure to social disadvantage was associated with higher prevalence of both emotional disorders and ADHD; and also children and young people with learning disabilities were at significantly greater risk of experiencing all types of social disadvantages (Emerson & Hatton, 2007). Another study did not find a relationship with socio-economic status (Dekker & Koot, 2003).

Socioeconomic status impacts on cognitive, social, attention, and emotional development in typically developing children (Conger & Donnellan, 2007; Kishiyama et al., 2009). This may be affected by parenting. Theoretical paradigms include (1) the family stress model of economic hardship, which predicts economic pressure leads to parental emotional and marital problems, thus impacting on parenting (e.g. harsher, more authoritarian parenting style and physical punishment), with parenting behaviour being the key predictor of child development, (2) the family investment model which focuses on investment of economic and human resources (e.g. toys, books, more stimulating and resourced activities Conger and Donnellan (2007)), with parental investment the key mediator between income and child behaviours, after controlling for parental education/intelligence and other social factors (Linver, 2002). A contrary social selection theory suggests socio-economic status is influenced by individual factors (e.g. intelligence and personality) facilitating social advantages, and transmitted from parent to child via a third variable (e.g. genetic), influencing child outcomes. Child outcomes are probably influenced by both social selection and social factors, interacting over time (Conger & Donnellan, 2007). Importantly, for typically developing children, some adverse effects are reversible with early interventions (Fisher et al., 2007; McEwen, 2003; Rutter & the English and Romanian Adoptees (ERA) study team, 1998; Zeanah, 2009), and evidence is emerging to suggest this may also be the case for children with learning disabilities (Einfeld et al., 2013). Additionally, social support has a stress-buffering role on parenting, reducing effects of poverty on typically developing children (Belsky, 1984; Seagull, 1987). It may reduce initial perception of a threat preventing a full stress response, or influence strategies employed after a full stress response.

Transactional models are likely to be relevant – the parenting environment interacting with the characteristics of the child, and the child’s behaviour having a critical impact on the parenting environment, and how parents behave when highly stressed. A meta-analysis reports increased risk of distress in parents of children with learning disabilities, especially mothers (Singer et al., 2007). Other protective factors may also influence stress levels such as parental mental health, social supports, and socio-economic factors.

Maternal optimism has been reported to moderate the relationship between child mental health problems, and maternal depression and marital adjustments (Zeanah, 2009). Consideration of such factors might provide insights to the types of parental psychological interventions, skills training and parenting programmes or supports that might then benefit these children, which may require components on parents’ belief systems.

In adults with learning disabilities, mental health problems have been found to be associated with not living with family, and this was also predictive of future episodes of mental health problems over the following 2 years. However, it was unclear if there were former reasons for having left the family home (Smiley et al., 2007). Looked after children also have very high rates of mental health problems, but the direction of causation is unclear. Living with paid carer support may result in repeated broken relationships, as staff leave posts for a wide range of reasons.

For both children and adults, life events are associated with and predictive of mental health problems (Cooper et al., 2007b; Emerson & Hatton, 2007; Hulbert-Williams et al., 2011), and also specifically with risk for depression (Esbensen &

Benson, 2006; Hastings et al., 2004), and anxiety (Reid et al., 2011). Life events may occur more frequently for people with learning disabilities, and may be more likely to be multiple when they do occur, due to the numerous disadvantages they experience and their necessary reliance on others for support.

Some adults with learning disabilities have poverty of environment, with limited choices for day-time activities, problems accessing transport, limited 1-to-1 attention, and restricted social networks. They may experience social exclusion. People with learning disabilities can be the victim of bullying, harassment, hate crimes, and sadly stigma is not uncommon, and is associated with mental health problems in people with learning disabilities (Ali et al., 2012; Ali et al., 2015; Cooney et al., 2006; Jahoda & Markova, 2004).

Smoking is also reported as being related to mental health problems in adults with learning disabilities (Cooper et al, 2007a), which is similar to findings in the general population.

2.5.4 Developmental

Across the whole population, a gradient is seen between health and ability level (Gale, 2009), so the consequences of this are most marked for people with learning disabilities. Greater degrees of learning disabilities are associated with more physical health problems and more mental health problems, although this depends in part on the specific type of mental health problem. Autism is markedly more prevalent the greater the degree of learning disabilities.

A common saying is ‘a problem shared is a problem halved’. The communication needs of some people with learning disabilities disadvantages them and their health when staff do not have capacity and skills to communicate effectively. Communication is a 2-way process, so all staff need to follow communication guidance to maximise 2-way understanding and expression.

Skills training might provide avenues to intervene or support people with learning disabilities who have mental health problems. Learning new skills, or developing and relearning skills already acquired might provide a means through to developing confidence, increasing independence, and building resilience. Such approaches might be useful adjuncts within intervention care plans.

2.6 Current care

Learning disabilities policy in England over the last 15 years has driven progress via Valuing People: A New Strategy for Learning Disability for the 21st Century (Department of Health, 2001), and Valuing People Now: A New Three-Year Strategy for People with Learning Disabilities (Department of Health, 2009). More recently, the shocking revelations on the BBC Panorama programme of the criminal and abusive actions by paid carers to people with learning disabilities living in Winterbourne View Hospital led to Transforming Care: A National Response to Winterbourne View Hospital (Department of Health, 2012), and accompanying concordat, Winterbourne View: Transforming Care Two Years On (Department of Health, 2015b), and Building the Right Support (ADASS, 2015) produced by the Department of Health and partners – the Association of Directors of Adult Social Services, Care Quality Commission, Health and Social Care Information Centre, Local Government Association, NHS England, and Public Health England. Core visions include a reduction in the number of people with learning disabilities living in hospitals, reduced length of hospital stays, and improved quality of care and life for people with learning disabilities in hospital, and in community settings. The transformation programme is aimed at changing a whole system and embedding new approaches.

Most people with learning disabilities live in the community with family or with paid carer support; however, a proportion of people are receiving treatment in, or are inappropriately resident in mental health or learning disabilities hospitals. The Health and Social Care Information Centre's Learning Disabilities Census report for England with a census date of 30.9.15 (findings from the previous census date of 30.9.14 are in parentheses) identified 3,000 (3,230) people resident in hospitals, of whom 2,370 (2,690) had learning disabilities, and 165 (160) were children/young people. 145 (155) were experiencing a delayed discharge due to placement unavailability/lack of appropriate discharge support package. 42% (39%) were in hospital more than 50 km from their original home address, and specifically for the children and young people, 62% (44%) were more than 50 km from their home address. Provision was roughly equally split between NHS and independent sector providers.

There is an expectation that people with learning disabilities are supported to access mainstream services used by the whole population as far as possible, that reasonable adjustments are made by services to enable this, and local specialist learning disabilities teams have a role in supporting access. Learning disabilities teams also provide direct mental health assessments and care for people with learning disabilities and complex mental health problems. People with learning disabilities are registered with a general practitioner (GP), the same as for everyone else in the country (with the small exception of some communal establishments).

Local community learning disabilities teams are typically in place across England, and adopt a multi-disciplinary approach to their work with adults with learning disabilities and mental health problems (and also for some other health and care needs). Teams are often joint health and social care teams, employ staff with expertise and training in working with people with learning disabilities, and may include for example psychiatrists, psychologists, nurses, speech and language therapists, occupational therapists, physiotherapists, dieticians, social workers. In commissioning and organising services, there may be differences in local pathways and responsibilities between the local mental health services, the local learning disabilities services, and primary care. Generic child and adolescent mental health services are used by children and young persons with learning disabilities; in some cases tertiary services can provide more specialist support to these services, and in some services there are dedicated mental health services for children and young people with learning disabilities. This may be less than comprehensive in some parts of England. For children and young people with complex needs impacting upon their learning, Local Authorities now have a duty to offer Education, Health and Care needs assessments, and if indicated put in place a tailored Education, Health and Care Plan, to support the child's development and transition through to age 25.

In addition to the drive for better integrations of services, the Government's introduction of personal budgets and personal health budgets is intended to provide greater flexibility, choice and control over the healthcare and support people receive.

Mental health problems are under-recognised in people with learning disabilities (Hassiotis & Turk, 2012). There is some, and increasing, awareness of the problem of diagnostic overshadowing (inadvertently attributing a person's additional mental health or physical health problems to their learning disabilities, and hence omitting to provide suitable and required care and support). This is an issue for people living in residential care or private households with paid carer support, people using primary health care, and/or using community or secondary health care services; it is an issue throughout the whole system for people with learning disabilities. It leads to under-identification of potentially treatable needs and distress, and the late identification of health needs which can then lead to impaired treatment response.

In keeping with the Mental Capacity Act 2005, all staff are accountable in ensuring that the person's capacity to make specific decisions is assessed (on a decision by decision basis), and this underpins ALL aspects of their assessment and care. Capacity to make decisions must always be supported, as adjustments must be made to accommodate the person's disabilities, such as enhancing 2-way communication and supporting sensory impairments. On rare occasions, individual decisions of the person being assessed/treated are over-ridden by the Mental Health Act, amended 2007, but these restrictions should be minimised as far as possible.

The United Kingdom is a signatory to the United Nations' 2006 Convention on the Rights of Persons with Disabilities, with the overall purpose 'To promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity'. There are 8 guiding principles which underpin all the articles of the Convention:

- respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons
- non-discrimination
- full and effective participation and inclusion in society
- respect for difference and acceptance of persons with disabilities as part of human diversity and humanity
- equality of opportunity
- accessibility
- equality between men and women
- respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserve their identities

Article 19 of the Convention addresses the measures required by 'States Parties', countries which have adhered to the World Heritage Convention, to ensure people with disabilities live independently and are included in the community. This recognizes the equal right of all persons with disabilities to live in the community, with choices equal to others, ensuring full inclusion and participation in the community. Article 25 addresses health, and actions States Parties must take to ensure the right to the enjoyment of the highest attainable standard of health and access to gender-sensitive health services without discrimination on the basis of disability. This includes the same range, quality and standard of free or affordable health care and programmes as provided to other persons, and those health services needed by persons with disabilities specifically because of their disabilities, with provision as close as possible to people's own communities, including in rural areas.

2.7 Family

Family are really important for most people and special for them. This of course is the same for children, young people, and adults with learning disabilities. Family also can provide considerable support, and help their family member with learning disabilities in living with and overcoming mental health problems. They typically know their family member with learning disabilities better than anyone else, and are most likely to recognise if their loved one may have a mental health problem. Provided they are given enough and the right information, they are usually best placed to help support their family member with learning disabilities in care decisions, and to make choices for family members who are children or do not have decision-making capacity to do so themselves.

Person centred services are essential for people with learning disabilities. For children and young people with learning disabilities, family centred services are also essential.

For adults who live independently with their own or shared tenancy and paid carer support, or in residential care, family often remain a very important part of their lives and support for them in managing their on-going care, and their quality of life.

Being a family carer brings many rewards. It is also associated with stress and poorer physical and mental health (Eisenhower et al., 2013; MacDonald, 2010; McGrother et al., 1996; Singer, 2006; Totsika et al., 2011; Totsika, 2011). The mental health of parents of young people with learning disabilities is influenced by the severity of mental health problems of their child, indeed more so than the degree of their learning disabilities (Esbensen et al., 2006; Gray et al., 2011; Hastings, 2006; Tonge & Einfeld, 2003). There may also be a small increased risk of psychological problems in siblings of children with learning disabilities (Hastings, 2014a). Getting it right for persons with learning disabilities helps getting it right for their families.

Family carers depend on local services, the third sector, and informal supports for their own support and advice, which is essential but variable across England.

2.8 Economic costs

The presence of mental health problems in people with learning disabilities can place an additional strain on resources across a range of budgets. Given the diverse sectors of society in which care and support are provided for people with learning disabilities, additional financial costs may be borne by the NHS, social services, local authorities, as well as families.

In an attempt to quantify the financial impact of psychiatric and neurological issues in the UK, Fineberg et al. (2013) found learning disabilities to be the tenth most costly issue costing €5975 million (2010 prices). The annual cost per person with learning disabilities reached approximately €11,000, comprising healthcare expenditure as well as other direct non-healthcare costs; productivity losses were not included in this figure due to lack of relevant data. As the prevalence of mental health problems in people with learning difficulties is high and this study did not control for them, it is reasonable to expect that some of these costs are driven by co-occurring mental health issues in this population.

Doran et al. (2012) used self-completed questionnaires to estimate the cost of learning disabilities to both families and the government in Australia. This was reported to reach $14,720 billion annually (AUS$, 2006 prices). The study reported that families carry the majority of the financial burden and are insufficiently compensated by the government, with an annual net loss per family of approximately $37,000 and $58,000 for mild and severe/profound learning disabilities, respectively.

In addition to the measured financial impacts, it is acknowledged that intangible costs represent a significant component of burden that is not possible to capture (Doran et al., 2012). Among others, these costs include pain and suffering as well as loss of role performance and social participation, which are likely to increase in the presence of mental health problems.

Strydom et al. (2010) investigated the costs associated with the care of older adults with learning disabilities in the UK. The study measured the cost of care across a range of sectors including health, social care and personal accommodation. The average weekly cost per older person with learning disabilities was estimated to reach £790 (£41,080 per year) with the largest part of it (74%) accounting for accommodation costs. Gender, the severity of the learning disabilities, hearing impairment, physical disorder and mental illness had significant independent relationships with costs. Mental health problems were associated with an additional weekly cost of £202 (2010 prices).

Conclusively, the care of people with learning disabilities incurs considerable costs to the health and social services and the wider community, and the presence of mental health problems is likely to increase the potential financial impact of this population on services. For this reason the prevention and management of mental health problems in people with learning disabilities is of great importance as it is expected to lead to considerable benefits and cost-savings for the individual, their families and the society.

3 Methods used to develop this guideline

3.1 Overview

The development for most of this guideline followed The Guidelines Manual (NICE, 2012) , but some sections have used the 2014 version of the manual (where this has been done, it has been explained in the chapter below). A team of healthcare professionals, social care professionals, education professionals, lay representatives and technical experts known as the Guideline Committee (GC), with support from the NCCMH staff, undertook the development of a person-centred, evidence-based guideline. There are 7 basic steps in the process of developing a guideline:

1. Define the scope, which lays out exactly what will be included (and excluded) in the guidance.
2. Define review questions that cover all areas specified in the scope.
3. Develop a review protocol for each systematic review, specifying the search strategy and method of evidence synthesis for each review question.
4. Synthesise data retrieved, guided by the review protocols.
5. Produce evidence profiles and summaries using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.
6. Consider the implications of the research findings for clinical practice and reach consensus decisions on areas where evidence is not found.
7. Answer review questions with evidence-based recommendations for clinical practice.

The clinical practice recommendations made by the GC are therefore derived from the most up-to-date and robust evidence for the clinical and cost effectiveness of the interventions and services covered in the scope. Where evidence was not found or was inconclusive, the GC adopted both formal and informal methods to reach consensus on what should be recommended, factoring in any relevant issues. In addition, to ensure a service user and carer focus, focus groups were also conducted, and the concerns of service users and carers regarding health and social care have been highlighted and addressed by recommendations agreed by the whole GC.

3.2 The scope

Topics are referred by NHS England and the letter of referral defines the remit, which defines the main areas to be covered. The NCCMH developed a scope for the guideline based on the remit (see Appendix A). The purpose of the scope is to:

- provide an overview of what the guideline will include and exclude
- identify the key aspects of care that must be included
- set the boundaries of the development work and provide a clear framework to enable work to stay within the priorities agreed by NICE and the NCCMH, and the remit from the Department of Health
- inform the development of the review questions and search strategy
- inform professionals and the public about expected content of the guideline

- keep the guideline to a reasonable size to ensure that its development can be carried out within the allocated period.

An initial draft of the scope was sent to registered stakeholders who had agreed to attend a scoping workshop. The workshop was used to:

- obtain feedback on the selected key clinical issues
- identify which population subgroups should be specified (if any)
- seek views on the composition of the GC
- encourage applications for GC membership.

The draft scope was subject to consultation with registered stakeholders over a 4-week period. During the consultation period, the scope was posted on the NICE website. Comments were invited from stakeholder organisations The NCCMH and NICE reviewed the scope in light of comments received, and the revised scope was signed off by NICE.

3.3 The Guideline Committee

During the consultation phase, members of the GC were appointed by an open recruitment process. GC membership consisted of: professionals in psychiatry, clinical psychology, speech and language therapy, physiotherapy, paediatrics and general practice; academic experts in education, psychiatry and psychology; commissioning managers; and carers and representatives from service user and carer organisations. The guideline development process was supported by staff from the NCCMH, who undertook the clinical and health economic literature searches, reviewed and presented the evidence to the GC, managed the process, and contributed to drafting the guideline.

3.3.1 Guideline Committee meetings

There were 11 GC meetings, held between October 2014 and January 2016. During each day-long GC meeting, in a plenary session, review questions and clinical and economic evidence were reviewed and assessed, and recommendations formulated. At each meeting, all GC members declared any potential conflicts of interest (see Appendix B), and service user and carer concerns were routinely discussed as a standing agenda item.

3.3.2 Service users and carers

The GC included 3 carers members who contributed as full GC members to writing the review questions, providing advice on outcomes most relevant to service users and carers, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology relevant to the guideline, and bringing service user research to the attention of the GC. Services user involvement was secured through a series of focus groups which were run in collaboration with the British Institute for Learning Disabilities (BILD). Input from both service users and carers was central to the development of the guideline and they contributed to writing the guideline's introduction and the recommendations from the service user and carer perspective.

3.3.3 Expert advisers

Expert advisers, who had specific expertise in 1 or more aspects of treatment and management relevant to the guideline, assisted the GC, commenting on specific aspects of the developing guideline and making presentations to the GC. Appendix C lists those who agreed to act as expert advisers.

3.3.4 National and international experts

National and international experts in the area under review were identified through the literature search and through the experience of the GC members. These experts were contacted to identify unpublished or soon-to-be published studies, to ensure that up-to-date evidence was included in the development of the guideline. They informed the GC about completed trials at the pre-publication stage, systematic reviews in the process of being published, studies relating to the cost effectiveness of treatment and trial data if the GC could be provided with full access to the complete trial report. Appendix E lists researchers who were contacted.

3.4 Review protocols

Review questions drafted during the scoping phase were discussed by the GC at the first few meetings and amended as necessary. The review questions were used as the starting point for developing review protocols for each systematic review (described in more detail below). Where appropriate, the review questions were refined once the evidence had been searched and, where necessary, sub-questions were generated. The final list of review questions can be found in Appendix F.

For questions about interventions, the PICO (Population, Intervention, Comparison and Outcome) framework was used to structure each question (see Table 2).

Table 2: Features of a well-formulated question on the effectiveness of an intervention – PICO

Population:	Which population of service users are we interested in? How can they be best described? Are there subgroups that need to be considered?
Intervention:	Which intervention, treatment or approach should be used?
Comparison:	What is/are the main alternative/s to compare with the intervention?
Outcome:	What is really important for the service user? Which outcomes should be considered: intermediate or short-term measures; mortality; morbidity and treatment complications; rates of relapse; late morbidity and readmission; return to work, physical and social functioning and other measures such as quality of life; general health status?

Questions relating to case identification and assessment tools and methods do not involve an intervention designed to treat a particular condition, and therefore the PICO framework was not used. Rather, the questions were designed to pick up key issues specifically relevant to clinical utility, for example their accuracy, reliability, safety and acceptability to the service user.

In some situations, review questions related to issues of service delivery are occasionally specified in the remit from the Department of Health/Welsh Assembly Government. In these cases, appropriate review questions were developed to be clear and concise.

For each topic, addressed by 1 or more review questions, a review protocol was drafted by the technical team using a standardised template (based on

PROSPERO[1]), review and agreed by the GC (all protocols are included in Appendix F).

To help facilitate the literature review, a note was made of the best study design type to answer each question. There are 4 main types of review question of relevance to NICE guidelines (though, only 3 were used in this guideline). These are listed in Table 3. For each type of question, the best primary study design varies, where 'best' is interpreted as 'least likely to give misleading answers to the question'. For questions about the effectiveness of interventions, where randomised controlled trials (RCTs) were not available, the review of other types of evidence was pursued only if there was reason to believe that it would help the GC to formulate a recommendation.

However, in all cases, a well-conducted systematic review (of the appropriate type of study) is likely to always yield a better answer than a single study.

Table 3: Best study design to answer each type of question

Type of question	Best primary study design
Effectiveness or other impact of an intervention	RCT; other studies that may be considered in the absence of RCTs are the following: internally/externally controlled before and after trial, cohort
Accuracy of information (for example, risk factor, test, prediction rule)	Comparing the information against a valid gold standard in an RCT or inception cohort study
Rates (of disease, service user experience, rare side effects)	Prospective cohort, registry, cross-sectional study
Experience of care	Qualitative research (for example, grounded theory, ethnographic research)

3.5 Clinical review methods

The aim of the clinical literature review was to systematically identify and synthesise relevant evidence from the literature in order to answer the specific review questions developed by the GC. Thus, clinical practice recommendations are evidence-based, where possible, and, if evidence is not available, either formal or informal consensus methods are used to try and reach general agreement between GC members (see section 3.5.7) and the need for future research is specified.

3.5.1 The search process

3.5.1.1 Scoping searches

A broad preliminary search of the literature was undertaken in September 2014 to obtain an overview of the issues likely to be covered by the scope, and to help define key areas. The searches were restricted to clinical guidelines, Health Technology Assessment (HTA) reports, key systematic reviews and RCTs. A list of databases and websites searched can be found in Appendix H.

3.5.1.2 Systematic literature searches

After the scope was finalised, a systematic search strategy was developed to locate as much relevant evidence as possible. The balance between sensitivity

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[1] http://www.crd.york.ac.uk/prospero/

(the power to identify all studies on a particular topic) and specificity (the ability to exclude irrelevant studies from the results) was carefully considered, and a decision made to utilise a broad approach to searching to maximise retrieval of evidence to all parts of the guideline. Searches were restricted to certain study designs if specified in the review protocol, and conducted in the following databases:

- CINAHL
- Cochrane Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Database of Systematic Reviews (CDSR)
- CENTRAL
- Excerpta Medica Database (Embase)
- HTA database (technology assessments)
- Medical Literature Analysis and Retrieval System Online (MEDLINE)/MEDLINE In-Process
- Psychological Information Database (PsycINFO)

The search strategies were initially developed for MEDLINE before being translated for use in other databases/interfaces. Strategies were built up through a number of trial searches and discussions of the results of the searches with the review team and GC to ensure that all possible relevant search terms were covered. In order to assure comprehensive coverage, search terms for mental health and learning disabilities were kept purposely broad to help counter dissimilarities in database indexing practices and thesaurus terms, and imprecise reporting of study populations by authors in the titles and abstracts of records. The search terms for each search are set out in full in Appendix H.

3.5.1.3 Reference Management

Citations from each search were downloaded into reference management software and duplicates removed. Records were then screened against the eligibility criteria of the reviews before being appraised for methodological quality (see below). The unfiltered search results were saved and retained for future potential re-analysis to help keep the process both replicable and transparent.

3.5.1.4 Double-sifting

Titles and abstracts of identified studies were screened by 2 reviewers against inclusion criteria specified in the protocols, until a good inter-rater reliability was observed (percentage agreement ≥90% or Kappa statistics, K>0.60). Any disagreements between raters were resolved through discussion. Initially 10% of references were double-screened. If inter-rater agreement was good then the remaining references were screened by 1 reviewer.

Once full versions of the selected studies were acquired for assessment, full studies were usually checked independently by 2 reviewers, with any differences being resolved. For some review questions (review questions 1.1 and 1.3), a random sample of papers was checked for inclusion. Any studies that failed to meet the inclusion criteria at this stage were excluded.

3.5.1.5 Search filters

To aid retrieval of relevant and sound studies, filters were used to limit a number of searches to systematic reviews and RCTs. The search filters for systematic reviews and RCTs are adaptations of validated filters designed by the Health Information Research Unit (HIRU) at McMaster University.

3.5.1.6 Date and language restrictions

Systematic database searches were initially conducted in November 2014 up to the most recent searchable date. Search updates were generated on a 6-monthly basis, with the final re-runs carried out in December 2015 ahead of the guideline consultation. After this point, studies were only included if they were judged by the GC to be exceptional (for example, if the evidence was likely to change a recommendation).

Although no language restrictions were applied at the searching stage, foreign language papers were not requested or reviewed, unless they were of particular importance to a review question.

Date restrictions were not applied, except for searches of systematic reviews which were limited to research published from 1999. The search for systematic reviews was restricted to the last 15 years as older reviews were thought to be less useful.

3.5.1.7 Other search methods

Other search methods involved: (a) scanning the reference lists of all eligible publications (systematic reviews, stakeholder evidence and included studies) for more published reports and citations of unpublished research; (b) sending lists of studies meeting the inclusion criteria to subject experts (identified through searches and the GC) and asking them to check the lists for completeness, and to provide information of any published or unpublished research for consideration (see Appendix E); (c) checking the tables of contents of key journals for studies that might have been missed by the database and reference list searches; (d) tracking key papers in the Science Citation Index (prospectively) over time for further useful references; (e) conducting searches in ClinicalTrials.gov for unpublished trial reports; (f) contacting included study authors for unpublished or incomplete datasets. Searches conducted for existing NICE guidelines were updated where necessary. Other relevant guidelines were assessed for quality using the AGREE instrument (AGREE Collaboration, 2003). The evidence base underlying high-quality existing guidelines was utilised and updated as appropriate.

Full details of the search strategies and filters used for the systematic review of clinical evidence are provided in Appendix H.

3.5.1.8 Study selection and assessment of methodological quality

All primary-level studies included after the first scan of citations were acquired in full and re-evaluated for eligibility at the time they were being entered into the study information database. More specific eligibility criteria were developed for each review question and are described in the relevant clinical evidence chapters and the review protocols in Appendix F. Eligible systematic reviews and primary-level studies were critically appraised for methodological quality (risk of bias) using a checklist – see The Guidelines Manual (2012a) for templates. However, some checklists which were recommended in the 2014 manual update (NICE, 2014) were used (for example, for qualitative studies, for systematic reviews [AMSTAR checklist] and for cross-sectional and cohort studies [the Newcastle Ottawa checklist for observational studies was used (Wells) for the epidemiological review on incidence and prevalence).

The QUADAS-II (Whiting, 2011) was used for diagnostic studies and was adapted for use with risk assessment studies as follows:

- Index test question signalling question: ‘If a threshold was used, was it pre-specified?’ This was amended to: ‘Is information available to facilitate clinical judgment?’ (that is, how scores should be translated to risk level)
- Flow and timing signalling question: ‘Was there an appropriate interval between index test(s) and reference standard?’ This was interpreted as: ‘Was there sufficient time for events of interest to occur?’

The eligibility of studies was confirmed by the GC. A flow diagram of the search process for selection of studies for inclusion in the clinical literature review conducted for this guideline is provided in Appendix P.

For some review questions, it was necessary to prioritise the evidence with respect to the UK context (that is, external validity). To make this process explicit, the GC took into account the following factors when assessing the evidence:

- participant factors (for example, gender, age and ethnicity)
- provider factors (for example, model fidelity, the conditions under which the intervention was performed and the availability of experienced staff to undertake the procedure)
- cultural factors (for example, differences in standard care and differences in the welfare system).

It was the responsibility of the GC to decide which prioritisation factors were relevant to each review question in light of the UK context.

3.5.1.9 Unpublished evidence

Stakeholders were invited to submit any relevant unpublished data using the call for evidence process set out in the 2012 edition of The Guidelines Manual. The GC used a number of criteria when deciding whether or not to accept unpublished data. First, the evidence must have been accompanied by a trial report containing sufficient detail to properly assess risk of bias. Second, the evidence must have been submitted with the understanding that data from the study and a summary of the study’s characteristics would be published in the full guideline. Therefore, in most circumstances the GC did not accept evidence submitted ‘in confidence’. However, the GC recognised that unpublished evidence submitted by investigators might later be retracted by those investigators if the inclusion of such data would jeopardise publication of their research.

3.5.2 Data extraction

3.5.2.1 Quantitative analysis

Study characteristics, aspects of methodological quality, and outcome data were extracted from all eligible studies, using Review Manager Version 5.3.5 (Cochrane Collaboration, 2014) and an Excel-based form (see Appendix J, K, L and M).

In most circumstances, for a given outcome (continuous and dichotomous), where more than 50% of the number randomised to any group were missing or incomplete, the study results were excluded from the analysis (except for the outcome ‘leaving the study early’, in which case, the denominator was the number randomised). Where there were limited data for a particular review, the

50% rule was not applied. In these circumstances the evidence was downgraded (see section 3.5.4).

Where possible, outcome data from an intention-to-treat analysis (that is, a 'once-randomised-always-analyse' basis) were used. Where intention-to-treat had not been used or there were missing data, the effect size for dichotomous outcomes were recalculated using worse-case scenarios (for example, for positive outcomes this meant that it was assumed that the patients whose data was missing did not have the positive event). Where conclusions varied between scenarios (about the direction of effect or the confidence in the direction of effect or clinical importance), the evidence was downgraded (see section 3.5.4).

Where some of the studies failed to report standard deviations (for a continuous outcome), and where an estimate of the variance could not be computed from other reported data or obtained from the study author, the following approach was taken.[2] When the number of studies with missing standard deviations was less than one-third and when the total number of studies was at least 10, the pooled standard deviation was imputed (calculated from all the other studies in the same meta-analysis that used the same version of the outcome measure). In this case, the appropriateness of the imputation was made by comparing the standardised mean differences (SMDs) of those trials that had reported standard deviations against the hypothetical SMDs of the same trials based on the imputed standard deviations. If they converged, the meta-analytical results were considered to be reliable.

When the conditions above could not be met, standard deviations were taken from another related systematic review (if available). In this case, the results were considered to be less reliable.

Also for continuous outcomes, final scores in each group were the preferred outcome for extraction. However, if final or change scores (from baseline) were not reported for each group in a study (for example, the study reported an F-value, p-value or t-value), the SMD was estimated, if possible, using a statistical calculator.

The meta-analysis of survival data, such as time to any mood episode, was based on log hazard ratios and standard errors. Since individual participant data were not available in included studies, hazard ratios and standard errors calculated from a Cox proportional hazard model were extracted. Where necessary, standard errors were calculated from confidence intervals (CIs) or *p* value according to standard formulae; see the Cochrane Reviewers' Handbook 5.1.0 (Higgins & Green, 2011). Data were summarised using the generic inverse variance method using Review Manager.

Consultation with another reviewer or members of the GC was used to overcome difficulties with coding. Data from studies included in existing systematic reviews were extracted independently by 1 reviewer and cross-checked with the existing dataset. Where possible, 2 independent reviewers extracted data from new studies. Where double data extraction was not possible, data extracted by 1 reviewer was checked by the second reviewer. Disagreements were resolved through discussion. Where consensus could not be reached, a third reviewer or GC members resolved the disagreement. Masked assessment (that is, blind to the journal from which the article comes, the authors, the institution and the magnitude of the effect) was not used since it is unclear that doing so reduces bias (Berlin, 2001; Jadad et al., 1996).

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[2] Based on the approach suggested by Furukawa and colleagues (2006).

The analyses performed for existing systematic reviews incorporated into the guideline were not amended unless the GC considered that additional important aspects needed to be taken into consideration. For example, this could include stratifying data, conducting additional analyses, or using different results from the primary studies in a given analysis. Otherwise, the analyses were not amended.

3.5.3 Evidence synthesis

The method used to synthesise evidence depended on the review question and availability and type of evidence (see Appendix F for full details). Briefly, for questions about the psychometric properties of instruments, reliability, validity and clinical utility were synthesised narratively based on accepted criteria. For questions about test accuracy, bivariate test accuracy meta-analysis would have been conducted but there was not enough data to conduct these types of meta-analyses. For questions about the effectiveness of interventions, standard meta-analysis was used where appropriate, otherwise narrative methods were used with clinical advice from the GC. In the absence of high-quality research, formal and informal consensus processes were used (see 3.5.7).

3.5.4 Grading the quality of evidence

For questions about the effectiveness of interventions and the organisation and delivery of care, the GRADE approach[3]was used to grade the quality of evidence from group comparisons for each outcome (Guyatt et al., 2011). The technical team produced GRADE evidence profiles (see below) using the GRADEpro guideline development tool, following advice set out in the GRADE handbook (Schünemann et al., 2013). All staff doing GRADE ratings were trained, and calibration exercises were used to improve reliability (Mustafa et al., 2013).

For questions about epidemiology, methodology checklists (see Appendix M) were used to assess the risk of bias at the study level, and this information was taken into account when interpreting the evidence. For both types of questions, an overall quality rating was given to each study:

- Epidemiological studies were rated individually as recommended in the Guidelines Manual (2012a): ‘++’, ‘+’ or ‘−‘ on the basis of the assessment with the checklist; the strength of this evidence was considered to be ‘strong’, ‘moderate’, or ‘weak’ , respectively.
- Diagnostic accuracy: while the QUADAS framework does not provide an overall quality index for each study, this was deemed important to assist interpretation of the data on tools to augment assessment of mental health problems. We adopted the terminology used within GRADE (high, moderate, low or very low quality evidence). For each of the first 3 domains (patient selection, index test, reference standard) we used the ‘risk of bias’ and ‘concerns about applicability’ ratings (low, unclear and high risk for each) to create a 3x3 table (see Table 4). For domain 4 (flow and timing), which has only a ‘risk of bias’ rating, the same method was used, but ‘risk of bias’ was entered on both axes. We then used the 4 total domain ratings to generate an overall quality index. For the overall quality rating we took the mode classification and upgraded or downgraded from that point, i.e. if a study had 2 ratings of ‘high’, one of ‘moderate’ and one of ‘very low’, then the final quality rating would be ‘moderate’.

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[3] For further information about GRADE, see www.gradeworkinggroup.org

Table 4: Process for determining overall quality ratings for QUADAS-II domains 1-3 (patient selection', index test and reference standard)

	Concerns about applicability			
Risk of bias		Low risk	Unclear risk	High risk
	Low risk	High	Moderate	Moderate
	Unclear risk	Moderate	Low	Low
	High risk	Moderate	Low	Very low

The analyses performed for existing systematic reviews incorporated into the guideline were not amended unless the GC considered that additional important aspects needed to be taken into consideration. For example, this could include stratifying data, conducting additional analyses, or using different results from the primary studies in a given analysis. Otherwise, the analyses were not amended.

3.5.4.1 Evidence profiles

A GRADE evidence profile was used to summarise both the quality of the evidence and the results of the evidence synthesis for each 'critical' and 'important' outcome (see Table 5 for completed evidence profiles). The GRADE approach is based on a sequential assessment of the quality of evidence, followed by judgment about the balance between desirable and undesirable effects, and subsequent decision about the strength of a recommendation.

Within the GRADE approach to grading the quality of evidence, the following is used as a starting point:

- RCTs without important limitations provide high-quality evidence
- observational studies without special strengths or important limitations provide low-quality evidence.

For each outcome, quality may be reduced depending on 5 factors: limitations, inconsistency, indirectness, imprecision and publication bias. For the purposes of the guideline, each factor was evaluated using criteria provided in Table 6.

For observational studies without any reasons for down-grading, the quality may be up-graded if there is a large effect, all plausible confounding would reduce the demonstrated effect (or increase the effect if no effect was observed), or there is evidence of a dose-response gradient (details would be provided under the 'other' column).

Each evidence profile includes a summary of findings: number of participants included in each group, an estimate of the magnitude of the effect, and the overall quality of the evidence for each outcome. Under the GRADE approach, the overall quality for each outcome is categorised into 1 of 4 groups (high, moderate, low, very low).

Table 5: Example of a GRADE evidence profile

Quality assessment							**No. of patients**		**Effect**		**Quality**	**Importance**
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other consider-ations**	**Intervention**	**Control group**	**Relative (95% CI)**	**Absolute**		
Outcome 1 (measured with: any valid method; better indicated by lower values)												
2	Randomised trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious[1]	None	47	43	-	SMD 0.20 lower (0.61 lower to 0.21 higher)	⊕⊕⊕⊖ MODERATE	CRITICAL
Outcome 2 (measured with: any valid rating scale; better indicated by lower values)												
4	Randomised trials	Serious[2]	No serious inconsistency	No serious indirectness	Serious[1]	None	109	112	-	SMD 0.42 lower (0.69 to 0.16 lower)	⊕⊕⊖⊖ LOW	CRITICAL
Outcome 3 (measured with: any valid rating scale; better indicated by lower values)												
26	Randomised trials	No serious risk of bias	Serious[3]	No serious indirectness	No serious imprecision	None	521/5597 (9.3%)	798/3339 (23.9%)	RR 0.43 (0.36 to 0.51)	136 fewer per 1000 (from 117 fewer to 153 fewer)	⊕⊕⊕⊖ MODERATE	CRITICAL
Outcome 4 (measured with: any valid rating scale; better indicated by lower values)												
5	Randomised trials	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	503	485	-	SMD 0.34 lower (0.67 to 0.01 lower)	⊕⊕⊕⊕ HIGH	CRITICAL
Note. [1] OIS (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met. [2] Risk of bias across domains was generally high or unclear. [3] There is evidence of moderate heterogeneity of study effect sizes. CI = confidence interval; OIS = optimal information size; SMD = standardised mean difference.												

Table 6: Factors that decrease quality of evidence

Factor	Description	Criteria
Limitations	Methodological quality/ risk of bias.	Serious risks across most studies (that reported a particular outcome). The evaluation of risk of bias was made for each study using NICE methodology checklists (see Section 3.5.1).
Inconsistency	Unexplained heterogeneity of results.	Moderate or greater heterogeneity (using the methods suggested by GRADE[1])
Indirectness	How closely the outcome measures, interventions and participants match those of interest.	If the comparison was indirect, or if the available evidence was substantially different from the population, intervention, comparator, or an outcome specified in the protocol for the question being addressed by the GC.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of the effect.	If either of the following 2 situations were met: • the optimal information size (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) was not achieved • the 95% confidence interval around the pooled or best estimate of effect included both (a) no effect and (b) appreciable benefit or appreciable harm (using default minimally important differences, as suggested by GRADE)
Publication bias	Systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies.	Evidence of selective publication. This may be detected during the search for evidence, or through statistical analysis of the available evidence.

Note.
[1] An I^2 of 50% was used as the cut-off to downgrade for inconsistency. If heterogeneity was found, subgroup analysis was performed using the pre-specified subgroups in the protocol (see Appendix F); if subgroup analysis did not explain the heterogeneity, a random-effects model was used and the outcome was downgraded.

3.5.5 Presenting evidence to the Guideline Development Group

Study characteristics tables and, where appropriate, forest plots generated with Review Manager Version 5.3 and GRADE summary of findings tables (see below) were presented to the GC.

Where meta-analysis was not appropriate and/ or possible, the reported results from each primary-level study were reported in the study characteristics table and presented to the GC. The range of effect estimates were included in the GRADE profile, and where appropriate, described narratively.

3.5.5.1 Summary of findings tables

Summary of findings tables generated from GRADEpro were used to summarise the evidence for each outcome and the quality of that evidence (Table 7). The tables provide anticipated comparative risks, which are especially useful when the baseline risk varies for different groups within the population.

Table 7: Example of a GRADE summary of findings table

Outcomes	No of Participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with intervention (95% CI)
Global impression: 1. no improvement – short term	102 (1 study)	⊕⊕⊖⊖ LOW[1,2] due to risk of bias, imprecision	RR 0.89 (0.69 to 1.16)	725 per 1000	80 fewer per 1000 (from 225 fewer to 116 more)
Behaviour: 1. average change score Adaptive Behaviour Scale – medium term	101 (1 study)	⊕⊕⊖⊖ LOW[1,2] due to risk of bias, imprecision		The mean behaviour score was 1	0.60 standard deviations lower (1 to 0.21 lower)
Adverse effects: 1. extrapyramidal symptoms – medium term	243 (2 studies)	⊕⊕⊖⊖ LOW[1,2] due to risk of bias, imprecision	RR 0.34 (0.05 to 2.1)	33 per 1000	21 fewer per 1000 (from 31 fewer to 36 more)

Note.
The basis for the assumed risk was the median control group risk across studies. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[1] Generally unclear risk of bias and funded by manufacturer.
[2] OIS (for dichotomous outcomes, OIS = 300 events; for continuous outcomes, OIS = 400 participants) not met.

CI = confidence interval; OIS = optimal information size; RR = risk ratio.

3.5.6 Extrapolation

When answering review questions, if there is no direct evidence from a primary dataset,[4] based on the initial search for evidence, it may be appropriate to extrapolate from another data set, using that dataset as indirect evidence. In this situation, the following principles were used to determine when to extrapolate:

- a primary dataset is absent, of particularly high risk of bias or is judged to be not relevant to the review question under consideration, and
- a review question is deemed by the GC to be important, such that in the absence of direct evidence, other data sources should be considered, and
- non-primary data source(s) is in the view of the GC available, which may inform the review question.

When the decision to extrapolate was made, the following principles were used to inform the choice of the non-primary dataset:

- the populations (usually in relation to the specified diagnosis or problem which characterises the population) under consideration share some common characteristic but differ in other ways, such as age, gender or in the nature of

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[4] A primary data set is defined as a data set which contains evidence on the population and intervention under review.

the disorder (for example, a common behavioural problem; acute versus chronic presentations of the same disorder), and

- the interventions under consideration in the view of the GC have 1 or more of the following characteristics:
  - share a common mode of action (for example, the pharmacodynamics of drug; a common psychological model of change – operant conditioning)
  - be feasible to deliver in both populations (for example, in terms of the required skills or the demands of the health care system)
  - share common side effects/harms in both populations, and
- the context or comparator involved in the evaluation of the different datasets shares some common elements which support extrapolation, and
- the outcomes involved in the evaluation of the different datasets shares some common elements which support extrapolation (for example, improved mood or a reduction in behaviour that challenges).

When the choice of the non-primary dataset was made, the following principles were used to guide the application of extrapolation:

- the GC should first consider the need for extrapolation through a review of the relevant primary dataset and be guided in these decisions by the principles for the use of extrapolation
- in all areas of extrapolation datasets should be assessed against the principles for determining the choice of datasets. In general the criteria in the 4 principles set out above for determining the choice should be met
- in deciding on the use of extrapolation, the GC will have to determine if the extrapolation can be held to be reasonable, including ensuring that:
  - the reasoning behind the decision can be justified by the clinical need for a recommendation to be made
  - the absence of other more direct evidence, and by the relevance of the potential dataset to the review question can be established
  - the reasoning and the method adopted is clearly set out in the relevant section of the guideline.

3.5.7 Method used to answer a review question in the absence of appropriately designed, high-quality research

In the absence of appropriately designed, high-quality research (including indirect evidence where it would be appropriate to use extrapolation), both formal and informal consensus processes were adopted.

3.5.7.1 Formal method of consensus

The modified nominal group technique (Bernstein et al., 1992) was chosen due to its suitability within the guideline development process. The method is concerned with deriving a group decision from a set of expert individuals and has been identified as the method most commonly used for the development of consensus in health care (Murphy et al., 1998). The nominal group technique requires participants to indicate their agreement with a set of statements about the intervention(s) of concern. These statements were developed by the NCCMH technical team drawing on the available sources of evidence on the methods of delivery and outcomes of the interventions. These sources of evidence could be supplemented by advice from external experts in the intervention(s). Agreement with the statements were rated on a 9-point Likert scale, where 1 represented least agreement and 9 represented most agreement. In the first round participants indicated the extent of their agreement with the statements and also provided written comment on their reason for any disagreement and how the statement could be modified.

In round 1, members were presented with an overview of the modified nominal group technique, a short summary of the available evidence, a consensus questionnaire containing the statements and instructions on the use of the questionnaire. Members were asked to rate their agreement with the statements taking into account the available evidence and their expertise. For the purpose of determining agreement, ratings were grouped into 3 categories to calculate the percentage agreement: 1–3 (inappropriate strategy), 4–6 (uncertain), or 7–9 (appropriate strategy or adaptation).

At the subsequent GC meeting, anonymised distributions of responses to each statement were given to all members, together with members' additional comments and a ranking of statements based on consensus percentage agreement. Those statements with 80% or greater agreement were used to inform the drafting of recommendations, where appropriate taking into account the initial comments from and subsequent discussions with the GC.

For statements where there were 60 – 80% agreement a judgement was made based on the nature of the comments from the GC. If it appeared from the comments that the general principle included within the statement was agreed but that the comments could be addressed with some minor amendments incorporating the comments, the statements were used to inform the development of recommendations. Other statements that fell within this range were re-drafted based on the comments from the first rating and re-rated as in round 1 (round 2). If agreement at 80% or above on the re-rated was achieved, the statements were used to inform recommendations. Those that did not were discarded.

Any distribution of ratings with less than 60% agreement in round 1 was generally regarded as no consensus and discarded, unless obvious and addressable issues were identified from the comments.

3.5.7.2 Informal method of consensus

The informal consensus process involved a group discussion of what is known about the issues. The views of GC were synthesised narratively by a member of the review team, and circulated after the meeting. Feedback was used to revise the text, which was then included in the appropriate evidence review chapter.

3.6 Health economics methods

The aim of the health economics was to contribute to the guideline's development by providing evidence on the cost effectiveness of interventions and services examined in this guideline. This was achieved by a systematic literature review of existing economic evidence in all areas covered in the guideline.

Economic modelling was planned to be undertaken in areas with likely major resource implications, where the current extent of uncertainty over cost effectiveness was significant and economic analysis was expected to reduce this uncertainty, in accordance with The Guidelines Manual. Prioritisation of areas for economic modelling was a joint decision between the Health Economist and the GC. The rationale for prioritising review questions for economic modelling was set out in an economic plan agreed between NICE, the GC, the Health Economist and the other members of the technical team. The following economic questions were selected as key issues that were addressed by economic modelling:

- Interventions to prevent mental health problems in people with learning disabilities
- Interventions to reduce and manage mental health problems in people with learning disabilities
- Organisation and delivery of care for people with learning disabilities and mental health problems or at risk for mental health problems.

In addition, literature on the health-related quality of life of people covered by this guideline was systematically searched to identify studies reporting appropriate utility scores that could be utilised in a cost-utility analysis.

The identified clinical evidence on the areas prioritised for economic modelling was very sparse and did not allow for the construction of a robust and informative economic model. Therefore, no economic modelling was carried out for this guideline. Nevertheless, the GC took into consideration resource implications and anticipated cost effectiveness of interventions and services for people with learning disabilities and mental health problems or at risk for mental health problems when making recommendations.

The methods adopted in the systematic literature review of economic evidence are described in the remainder of this section.

3.6.1 Search strategy for economic evidence

3.6.1.1 Scoping searches

A broad preliminary search of the literature was undertaken in September 2014 to obtain an overview of the issues likely to be covered by the scope, and help define key areas. Searches were restricted to economic studies and HTA reports, and conducted in the following databases:

- Embase
- MEDLINE/MEDLINE In-Process
- HTA database (technology assessments)
- NHS Economic Evaluation Database (NHS Economic Evaluation Database).

Any relevant economic evidence arising from the clinical scoping searches was also made available to the health economist during the same period.

3.6.1.2 Systematic literature searches

After the scope was finalised, a systematic search strategy was developed to locate all the relevant evidence. The balance between sensitivity (the power to identify all studies on a particular topic) and specificity (the ability to exclude irrelevant studies from the results) was carefully considered, and a decision made to utilise a broad approach to searching to maximise retrieval of evidence to all parts of the guideline. Searches were restricted to economic studies and health technology assessment reports, and conducted in the following databases:

- Embase
- HTA database (technology assessments)
- MEDLINE/MEDLINE In-Process
- NHS Economic Evaluation Database
- PsycINFO.

Any relevant economic evidence arising from the clinical searches was also made available to the health economist during the same period.

The search strategies were initially developed for MEDLINE before being translated for use in other databases/interfaces. Strategies were built up through a number of trial searches, and discussions of the results of the searches with the review team and GC to ensure that all possible relevant search terms were covered. In order to assure comprehensive coverage, search terms for the guideline topic were kept purposely broad to help counter dissimilarities in database indexing practices and thesaurus terms, and imprecise reporting of study interventions by authors in the titles and abstracts of records.

For standard mainstream bibliographic databases (Embase, MEDLINE and PsycINFO) search terms for the guideline topic combined with a search filter for health economic studies. For searches generated in topic-specific databases (HTA, NHS Economic Evaluation Database) search terms for the guideline topic were used without a filter. The sensitivity of this approach was aimed at minimising the risk of overlooking relevant publications, due to potential weaknesses resulting from more focused search strategies. The search terms are set out in full in Appendix I.

3.6.1.3 Reference Management

Citations from each search were downloaded into reference management software and duplicates removed. Records were then screened against the inclusion criteria of the reviews before being quality appraised. The unfiltered search results were saved and retained for future potential re-analysis to help keep the process both replicable and transparent.

3.6.1.4 Search filters

The search filter for health economics is an adaptation of a pre-tested strategy designed by the Centre for Reviews and Dissemination (2007). The search filter is designed to retrieve records of economic evidence (including full and partial economic evaluations) from the vast amount of literature indexed to major medical databases such as MEDLINE. The filter, which comprises a combination of controlled vocabulary and free-text retrieval methods, maximises sensitivity (or recall) to ensure that as many potentially relevant records as possible are retrieved from a search. A full description of the filter is provided in Appendix I.

3.6.1.5 Date and language restrictions

Systematic database searches were initially conducted in November 2014 up to the most recent searchable date. Search updates were generated on a 6-monthly basis, with the final re-runs carried out in December 2015. After this point, studies were included only if they were judged by the GC to be exceptional (for example, the evidence was likely to change a recommendation).

Although no language restrictions were applied at the searching stage, foreign language papers were not requested or reviewed, unless they were of particular importance to an area under review. All the searches were restricted to research published from 2000 onwards in order to obtain data relevant to current healthcare settings and costs.

3.6.1.6 Other search methods

Other search methods involved scanning the reference lists of all eligible publications (systematic reviews, stakeholder evidence and included studies from the economic and clinical reviews) to identify further studies for consideration.

Full details of the search strategies and filter used for the systematic review of health economic evidence are provided in Appendix I.

3.6.2 Inclusion criteria for economic studies

The following inclusion criteria were used to select studies identified by the economic searches for further consideration:

1. Only studies from Organisation for Economic Co-operation and Development member countries were included, as the aim of the review was to identify economic information transferable to the UK context.
2. Selection criteria based on types of clinical conditions and service users as well as interventions assessed were identical to the clinical literature review.
3. Studies were included provided that sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed, and provided that the study's data and results were extractable. Poster presentations of abstracts were excluded.
4. Full economic evaluations that compared 2 or more relevant options and considered both costs and consequences as well as costing analyses that compared only costs between 2 or more interventions were included in the review. Non-comparative studies were not considered in the review.
5. Economic studies were included if they used clinical effectiveness data from a clinical trial, a prospective or retrospective cohort study, a study with a before-and-after design, or from a literature review.

3.6.3 Applicability and quality criteria for economic studies

All economic papers eligible for inclusion were appraised for their applicability and quality using the methodology checklist for economic evaluations recommended in The Guidelines Manual (NICE, 2014). All studies that fully or partially met the applicability and quality criteria described in the methodology checklist were considered during the guideline development process. The completed methodology checklists for all economic evaluations considered in the guideline are provided in Appendix Q.

3.6.4 Presentation of economic evidence

The economic evidence considered in the guideline is provided in the respective evidence chapters, following presentation of the relevant clinical evidence. The references to included studies and the respective evidence tables with the study characteristics and results are provided in Appendix R. Characteristics and results of all economic studies considered during the guideline development process are summarised in economic evidence profiles provided in Appendix S.

3.6.5 Results of the systematic search of economic literature

The titles of all studies identified by the systematic search of the literature were screened for their relevance to the topic (that is, economic issues and information on health-related quality of life). References that were clearly not relevant were excluded first. The abstracts of all potentially relevant studies (124 references) were then assessed against the inclusion criteria for economic evaluations by the health economist. Full texts of the studies potentially meeting the inclusion criteria (including those for which eligibility was not clear from the abstract) were obtained. Studies that did not meet the inclusion criteria, were duplicates, were secondary publications of 1 study, or had been updated in more recent publications were subsequently excluded. An economic evaluation conducted for a previously published NICE guideline was also included in the systematic review as eligible for this guideline. All economic evaluations eligible for inclusion (5 studies) were then appraised for their applicability and quality using the methodology checklist for economic evaluations. Finally, those studies that fully or partially met the applicability and quality criteria set by NICE were considered at formulation of the guideline recommendations. A flow diagram of the search process for selection of studies for inclusion in the economic literature review conducted for this guideline is provided in Appendix P.

3.7 From evidence to recommendations

Once the clinical and health economic evidence was summarised, the GC drafted the recommendations. In making recommendations, the GC took into account the trade-off between the benefits and harms of the intervention/instrument, as well as other important factors, such as the relative value of different outcomes reported in the evidence, quality of the evidence, trade-off between net health benefits and resource use, values and experience of the GC and society, current clinical practice, the requirements to prevent discrimination and to promote equality[5], and the GC's awareness of practical issues (Eccles et al., 1998; NICE, 2012a).

Finally, to show clearly how the GC moved from the evidence to the recommendations, each chapter (or sub-section) has a section called 'recommendations and link to evidence'. Underpinning this section is the concept of the 'strength' of a recommendation (Schünemann et al., 2003). This takes into account the quality of the evidence but is conceptually different. Some recommendations are 'strong' in that the GC believes that the vast majority of healthcare professionals and service users would choose a particular intervention if they considered the evidence in the same way that the GC has. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. However, there is often a closer balance between benefits and harms, and some service users would not choose an intervention whereas others would. This may happen, for example, if some service users are particularly averse to some side effect and others are not. In these circumstances the recommendation is generally weaker, although it may be possible to make stronger recommendations about specific groups of service users. The strength of each recommendation is reflected in the wording of the recommendation, rather than by using ratings, labels or symbols.

Where the GC identified areas in which there are uncertainties or where robust evidence was lacking, they developed research recommendations. Those that were identified as 'high priority' were developed further in the NICE version of the guideline, and presented in Appendix G.

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[5] See NICE's equality scheme: www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp

3.8 Stakeholder contributions

Professionals, service users, and companies have contributed to and commented on the guideline at key stages in its development. Stakeholders for this guideline include:

- service user and carer stakeholders: national service user and carer organisations that represent the interests of people whose care will be covered by the guideline
- local service user and carer organisations: but only if there is no relevant national organisation
- professional stakeholders' national organisations: that represent the healthcare professionals who provide the services described in the guideline
- commercial stakeholders: companies that manufacture drugs or devices used in treatment of the condition covered by the guideline and whose interests may be significantly affected by the guideline
- providers and commissioners of health services in England
- statutory organisations: including the Department of Health
- Government, NHS Quality Improvement Scotland, the Care Quality Commission and the National Patient Safety Agency
- research organisations: that have carried out nationally recognised research in the area.

NICE clinical guidelines are produced for the NHS in England, so a 'national' organisation is defined as 1 that represents England, or has a commercial interest in England.

Stakeholders have been involved in the guideline's development at the following points:

- commenting on the initial scope of the guideline and attending a scoping workshop held by NICE
- commenting on the draft of the guideline.

3.9 Validation of the guideline

Registered stakeholders had an opportunity to comment on the draft guideline, which was posted on the NICE website during the consultation period. Following the consultation, all comments from stakeholders and experts (see Appendix D) were responded to, and the guideline updated as appropriate. NICE also reviewed the guideline and checked that stakeholders' comments had been addressed.

Following the consultation period, the GC finalised the recommendations and the NCCMH produced the final documents. These were then submitted to NICE for a quality assurance check. Any errors were corrected by the NCCMH, then the guideline was formally approved by NICE and issued as guidance to the NHS in England.

4 Identification and assessment of mental health problems

4.1 Introduction

Lack of early recognition of mental disorders in people with learning difficulties leads to negative consequences for the person affected, and for their family. Factors that influence this poor recognition include: a lack of knowledge in health and social care staff, and families of carers, about the signs and symptoms of mental disorders; diagnostic overshadowing by the learning disability or physical illness; how well paid carers know the person and how well information is shared within and across paid carer teams; and difficulties the person with learning disabilities may have communicating their distress. This lack of recognition can lead to no or ineffective treatment or inappropriate resource-use. Effective treatment requires an assessment and the development of a care plan to ensure that the best available interventions are provided.

Family members and carers of people with learning disabilities are likely to be sensitive to any changes in, for example, behaviour, loss of skills, requiring more prompting, or other indications of distress. Therefore, when families raise such concerns staff should investigate them. Paid carers are less likely to know the person they support as long as, or as well as a family carer, and may support several people with diverse needs; hence, they may be less sensitive to such changes than family carers, Staff and paid carers need to also be aware that a person with learning disabilities might have more than 1 mental health problem. Effective training and supervision for paid carers, policies on sharing information within and across support teams, documentation of skills and needs, and support should be geared towards promoting effective recognition, because of the importance of early identification in optimising treatment outcomes.

Facilitating communication is fundamental to all aspects of the identification and assessment of mental health problems (and the care and support that follows) for people with learning disabilities. Communication can be influenced by (a) the person’s developmental level, (b) additional neurological, sensory, or mental health needs, (c) confidence, (d) medication side effects, (e) being brought by someone else for health and not being used to speaking up, and (f) the accessibility of the communication style of the healthcare staff; (g) social circumstances; and (i) setting/environment.

The first point of contact for the family or paid carer of a person with learning disabilities is usually the GP, and primary care is responsible for 90–95% of treatment of mental health problems in the general population (Meltzer, 1995). However, the in-depth, comprehensive assessment needed to identify a suspected mental health problem in people with learning disabilities is not possible in primary care. A GP therefore typically seeks to establish the following: whether or not there is a medical problem; the risk of diagnostic over-shadowing; that family members and carers of the person with learning disabilities might not have all of the information about the person’s symptoms and distress; and that mental health problems can present differently to those presented by the general population with the same mental health problem. Once obvious physical health causes are ruled out, GPs may investigate and initiate treatment for general health needs and common mental disorders in adults, and also refer to secondary services or the specialist learning disabilities service (depending upon local care pathways) for assessment of complex presentations in adults and young people with learning disabilities.

In secondary care, time is typically scheduled for more comprehensive assessments, using information from multiple sources. Assessments are often multidisciplinary, to access the expertise of different professional groups, and the sharing of information and coordination of care is important. Professionals will involve family members or paid carers as well as the person with learning disabilities unless there is a specific reason not to, such as safeguarding or the expressed preference of the adult or young person with learning disabilities. Assessments without carer input may lead to omission of information and inadequate risk assessment. Information collected from interviews, mental state examination, physical examination, investigations and case-note reviews are integrated and interpreted (Cooper et al., 2006). This includes the effective measurement of psychopathology, including distinguishing it from long-standing traits and considering all possible psychopathology. Differential diagnosis is undertaken, taking account of multiple-morbidity, high prevalence of epilepsy, polypharmacy, and other physical conditions and impairments which might mimic mental health problems, affect the most appropriate management of the person's care and require treatment.

The resulting formulation will inform the management and support plan, which needs to be developmentally appropriate, and usually involves family and/or paid carers in addition to the person with learning disabilities.

The capacity of the person with learning disabilities to make decisions about treatment and give consent is fundamental to all aspects of the assessment process, and it is important to recognise that they may have capacity for making some but not all decisions. Also, their capacity is not fixed over time and can vary, such as during episodes of mental ill-health problems.

The British Psychological Society and Royal College of Psychiatrists jointly published guidance on assessment, diagnosis and management of dementia (British Psychological Society, 2015). They found that standard approaches are not appropriate in people with dementia due to pre-existing cognitive impairments, and that diagnosis requires comparison with what is normal for that person, rather than by a neuropsychological assessment or questionnaire rating scale. Differential diagnosis is essential, in view of the under-recognition of multiple morbidities. Because of the high prevalence of dementia in people with Down's syndrome, where there is a prevalence of 40% over 50 years of age (Oliver & Holland, 1986; Prasher, 1995), some services offer baseline neuropsychological assessments to people with Down's syndrome in their early adult life. Other services view such assessments as potentially intrusive and overly labour-intensive. Functional assessments of skills are necessary to inform all care planning by paid carers and in learning disabilities services, and, if formalised and documented, can be useful in subsequent dementia assessments. Primary health care services usually have regular contact with people with Down's syndrome who are under their care because of their known predisposition to other physical conditions. These consultations, as well as annual health checks, provide opportunities for the brief assessment of alert signs of dementia, to trigger secondary care referral for assessment when indicated.

4.2 Review question: What is the incidence and prevalence of mental health disorders in people (children, young people and adults) with learning disabilities?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 8. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 8: Clinical review protocol summary for the review on the incidence and prevalence of mental health problems

Component	Description
Review question	What is the incidence and prevalence of mental health disorders in people (children, young people and adults) with learning disabilities? (RQ1.1)
Population	People (children, young people and adults) with or without learning disabilities
Exposure(s)	Presence of learning disabilities
Comparison	• People (children, young people and adults) without learning disabilities
Critical outcomes	• Risk of mental health problems (relative risk preferred but odds ratio also extracted if only outcome provided) • Incidence or prevalence of mental health problems
Study design	Reviews conducted for existing guidelines and published systematic reviews. If no existing systematic reviews address the review question, individual prospective or retrospective cohorts and cross-sectional studies may be considered.

4.2.1 Clinical evidence

Due to the large amount of existing systematic reviews considering the incidence and prevalence of mental health problems, and the volume of work that would be required to conduct a de novo search, the GC agreed to use existing reviews as a source of evidence and to update these papers. Primary papers identified in the existing reviews were obtained and extracted because the existing reviews did not describe specific characteristics of the included studies that the GC were interested in examining (such as, the degree of learning disabilities and the source of the sample).

However, because a large number of relevant systematic reviews of varying quality were identified, a pragmatic approach was taken to only consider systematic reviews considering a number of different mental health problems as these were considered by the GC to be the potentially most informative. Systematic reviews focusing on only one mental health problem were not considered.

Furthermore, only studies with population-based or administrative samples (samples identified through contact with a range of services for people with learning disabilities) were included. Studies with specific populations of people (such as an inpatient or outpatient population) were excluded because of the likely overestimation of rates of mental health problems in these studies, unless they were on genetic conditions (for example, all participants in a register of people with Fragile X syndrome).

While the relative risk of a mental health problem in a population with learning disabilities compared to a non-learning disabled population was the preferred outcome, there were very few studies which included a non-learning disabled population and reported these outcomes. As a result, rates of mental health problems in people learning disabilities were also extracted and presented. Where more than 1 study reported a particular mental health problem and when the data did not appear to be skewed, the range of rates was presented. Intraquartile ranges were presented if 4 or more studies reported a particular mental health problem.

There were 4 existing systematic reviews (Buckles et al., 2013; Einfeld, 2011; Kerker, 2004; Whitaker & Read, 2006) which were used as a source for papers and a new search was conducted to identify papers examining a number of different mental health problems which were published after the search date of the reviews:

- Adults: 3 reviews included adults and covered unique studies from different time periods (Buckles et al., 2013; Kerker, 2004; Whitaker & Read, 2006). These existing reviews identified 38 potentially relevant studies on adults, 3 papers with mixed age groups, and 2 with unclear age which were examined against the inclusion criteria. Of these, 19 studies were included in the evidence synthesis (others were excluded for reasons including that they considered specific populations, did not report incidence and prevalence data or did not report data for those with learning disabilities).
- Children and young people: 1 review focused on children and young people only (Einfeld, 2011). This existing review identified 9 potentially relevant studies on children which were examined against the inclusion criteria. Of these, 7 studies were included in the evidence synthesis (others were excluded for reasons including that they considered specific populations or that they did not include incidence or prevalence data). There were 5 additional studies relating to children and young people which were also identified through the Whitaker (3 papers) and Kerker (2 papers) reviews.

The update search identified 22 studies that were included in the evidence synthesis:

- 15 for adults.
- 7 for children and young people.

All studies were published in peer-reviewed journals between 1968 and 2014. Further information about included and excluded studies can be found in Appendix J.

4.2.1.1 Adults

There were 34 studies that examined the incidence or prevalence of mental health problems in adults with learning disabilities.

Of the included studies:

- 19 were population-based (N =354, 997): Bailey (2007); Bhaumik et al. (2008); Bielska et al. (2012); Corbett (1979); Gostason (1985); Lund (1985); Mantry et al. (2008); Matthews et al. (2008); McCarron et al. (2013); Melville et al. (2008); Nettelbladt et al. (2009); Pikora et al. (2014); Smiley et al. (2007);

Turky et al. (2011); White (2005) and 4 studies from 1 cohort (Cooper et al., 2007a; Cooper et al., 2007d; Cooper et al., 2007e; Cooper et al., 2007f)

- 13 included administrative samples (N=335, 994): Bakken et al. (2010); Cooper (1997b); Deb et al. (2001); Grey et al. (2010); Gustafsson (2004); Hemmings et al. (2006); Holden and Gitlesen (2004); Hove and Havik (2008); Iverson (1989); Jacobson (1990); Morgan (2008); Myrbakk and von Tetzchner (2008); Rojahn J. (1993)
- 2 examined the risk of mental health problems in adults with a genetic condition in studies classified has having specific populations (N=248): Soni et al. (2008); Stinton et al. (2010) (Prader Willi syndrome and William syndrome, respectively).

Summary of findings can be found in Table 9 (population-based studies), Table 10 (administrative-based studies), and Table 11 (studies with specific populations considering genetic conditions). The methodological quality of all papers is reported in Table 12.

There were 2 studies that examined the risk of mental health problems in adults with autism (N=271): 1 population-based (Melville et al., 2008) and 1 administrative-based (Bakken et al., 2010). Rates for these studies are reported in the footnotes in Table 9 and Table 10 below.

Most studies reported the rates of mental health problems across all degrees of learning disabilities; some reported rates for different levels of learning disabilities. This is summarised in the summary of findings tables below.

Only 2 studies included a non-learning disabled population and were able to provide data on relative risk (all population-based): (Gostason, 1985;Melville et al., 2008). Most other studies reported prevalence and some reported incidence (whether it is incidence or prevalence is indicated in the footnotes).

Table 9: Summary of findings table for the review of the prevalence (and some incidence) of mental health problems in adults with learning disabilities (population-based studies)

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Any mental health problem	RR 1.42 (0.93-2.18) 19.9-34.4%	22.0%	29.4-71.0%	40.0-45.1% 12.2%[2]	16.30 (28.00-44.30)[1] 14.7-14.9%[2]
Dementia		7.1%	8.8%	4.0%	2.72 (1.92-4.64)[1] 5.2%[2]
Substance misuse	1.8%			0.0% 0.0%[2]	0.80 (0.00-0.80)[1] 0.0-0.3%[2]
Schizophrenia	2.6-3.0%	1.2%	28.0%		4.72 (1.85-6.57)[1]
Delusional disorders					0.0-3.9%
Schizoaffective disorders					0.0-0.10%
Psychosis	1.3-5.8%	1.2%	11.8%	1.6-32.0% 0.0%[2]	7.60 (0.60-8.20)[1] 0.0 – 1.4%[2]
Affective disorders	RR 3.00 (0.32-28.08) 2.6-6.5%	1.2%	0.0-2.9%	0.0% 5.3%[2]	7.46 (1.20-8.66)[1] 5.2-7.7%[2]
Mania					1.73 (0.08-1.80)[1]
Bipolar disorder					2.20 (0.30-2.50)[1]

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Depression					11.60 (3.00-14.60)[1]
Anxiety disorder	RR 0.67 (0.02-2.25) 3.9-6.0%	1.2%	6.3%	1.6% 0.8%[2]	14.95 (2.00-16.95)[1] 1.5%[2]
Agoraphobia (including agoraphobia without panic)					0.8-3.3%
Social phobia					0.8%
Specific phobias					12.4%
Panic					0.8%
OCD	0.8%			0.0% 0.0%[2]	5.80 (0.00-5.80)[1] 0.0%[2]
Adjustment disorder	RR 0.33 (0.04-3.12)		0.0%		0.8-3.9%
Eating disorder					0.0-0.2% 0.0-0.2%[2]
Personality disorder	0.8%			0.0%	0.0-0.8% 0.0%[2]
ASD	1.3-3.5%	5.9%	5.9%	4.0-11.4%	2.48 (1.70-4.20)[1]

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
ADHD	0.0%			4.3%	0.0-2.0%
Pica	0.3%			6.5% 0.8%[2]	3.45 (0.05-3.50)[1] 0.0–0.2%[2]

Note.
ADHD = attention deficit hyperactivity disorder; ASD = autism spectrum disorder; OCD = obsessive–compulsive disorder.
All figures are prevalence unless otherwise specified; all confidence intervals are 95%, unless otherwise specified.
Rate of any mental health problem in a population with ASD was 37%, RR of 0.69 (0.33-1.46) and OR of 0.50 (0.35-0.73).
[1] Intraquartile range (lower quartile to upper quartile).
[2] Incidence rates.

Table 10: Summary of findings table for the review of the prevalence of mental health problems in adults with learning disabilities (administrative-based studies)

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Any mental health problem		64.7%	22.6%	9.7%	21.50 (14.40-35.90)[1]
Dementia					2.7-21.6%
Substance misuse					1.10 (0.00-1.10)
Schizophrenia					2.81 (1.59-4.40)[1]
Delusional disorders					1.1-1.4%
Psychosis		14.7%	0.0%	0.0%	4.52 (3.20-7.72)[1]
Affective disorders					0.7-10.6%

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Mania		8.8%	3.2%	3.2%	6.19 (0.32-6.51)[1]
Bipolar disorder					0.0-0.8%
Depression		20.6%	3.2%	0.0%	6.43 (2.15-8.58)[1]
Suicidal ideation					0.0-0.3%
Anxiety disorder		47.1%	16.1%	9.7%	23.51 (1.49-25.00)[1]
Agoraphobia					1.4-3.9%
Specific phobias					3.0-6.8%
Panic disorder or panic anxiety					0.0-0.2%
GAD					2.2-9.0%
OCD		17.7%	6.5%	3.2%	6.66 (0.94-7.60)[1]
Adjustment disorder					0.5-27.5%
Somatoform disorders					11.3%
Personality disorder					5.65 (1.13-6.77)[1]
Sexually inappropriate behaviour					1.60 (1.45-3.05)[1]
ASD (including Rett syndrome)					6.20 (0.38-6.58)[1]
ADHD					0.2%

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Pica					2.2%
Note. ADHD = attention deficit hyperactivity disorder; ASD = autistic spectrum disorder; GAD = generalised anxiety disorder; OCD = obsessive–compulsive disorder. All figures are prevalence; all confidence intervals are 95% unless otherwise specified. [1] Intraquartile range (lower quartile to upper quartile). Rates of the following in individuals with autism and severe–profound learning disabilities: mental health problem = 53.20%; depression = 37.10%; anxiety = 33.90%; OCD = 12.90%; psychosis = 25.10%.					

Table 11: Summary of findings table for the review of the prevalence of mental health problems in adults with learning disabilities – genetic conditions (specific population studies only)

	All levels of learning disabilities
Any mental health problem	Prader–Willi syndrome: delPWS 30.4%, mUPD 45.7% Williams syndrome 10.1%
Schizophrenia	Prader–Willi syndrome: delPWS 10.9%, mUPD 8.7% Williams syndrome 0.0%
Psychosis (including depressive psychosis)	Prader–Willi syndrome: delPWS 19.6%, mUPD 13.0% Williams syndrome 1.1%
Mania	Williams syndrome 0.0%
Bipolar disorder with psychotic symptoms	Prader–Willi syndrome: delPWS 0.0%, mUPD 23.9%
Depression	Prader–Willi syndrome: delPWS 21.7%, mUPD 2.2% Williams syndrome 4.5%
Anxiety	Williams syndrome 5.6%
Agoraphobia	Williams syndrome 1.1%
Social phobia	Williams syndrome 0.0%
Specific phobia	Williams syndrome 3.4%
Panic disorder	Williams syndrome 1.1%
GAD	Williams syndrome 1.1%
Note. delPWS = Prader–Willi syndrome deletion genotype; GAD = generalised anxiety disorder; mUPD = Prader–Willi syndrome maternal uniparental disomy genotype. All figures are percent prevalence.	

Table 12: Quality assessment of the studies included in the review of the incidence and prevalence of mental health problems in adults with learning disabilities

Study ID	**Quality**			
	Participant selection	**Group comparability**	**Assessment of outcome**	**Overall assessment of quality**
Population-based studies				
Bailey 2007	High	n/a*	High	++
Bhaumik 2008	High	n/a	High	++
Bielska 2012	Very low	n/a	Low	–
Cooper 2007a	High	n/a	High	++

Study ID	**Quality** **Participant selection**	**Group comparability**	**Assessment of outcome**	**Overall assessment of quality**
Cooper 2007d	High	n/a	High	++
Cooper 2007e	High	n/a	High	++
Cooper 2007f	High	n/a	High	++
Corbett 1979	Very low	n/a	Very low	−
Gostason 1985	High	High	High	++
Lund 1985	High	n/a	Low	+
Mantry 2008	High	n/a	High	++
Matthews 2008	Low	n/a	High	+
McCarron 2013	High	n/a	Low	+
Melville 2008	High	High	High	++
Nettelbaldt 2009	High	n/a	High	++
Pikora 2014	Very low	n/a	Very low	−
Smiley 2007	High	n/a	High	++
Turky 2011	High	n/a	High	++
White 2005	Low	Very low	Low	−
Administration-based studies				
Bakkhen 2010	High	n/a	High	++
Cooper 1997	Very low	n/a	Low	−
Deb 2001	Low	n/a	High	+
Grey 2010	Low	n/a	High	+
Gustafsson 2004	High	n/a	High	+
Hemmings 2006	High	n/a	High	++
Holden 2004	High	n/a	High	++
Hove 2008	High	n/a	High	++
Iverson 1989	High	n/a	High	++
Jacobson 1990	Very low	n/a	Low	−
Morgan 2008	High	n/a	High	++
Myrbakk 2008	Low	n/a	High	+
Rojahn 1993	Very low	n/a	High	+

Study ID	Quality			
	Participant selection	**Group comparability**	**Assessment of outcome**	**Overall assessment of quality**
Specific studies				
Soni 2008	High	n/a	High	−
Stinton 2010	Very low	n/a	High	+

Note.
* n/a = not applicable.
++ All or most of the checklist criteria have been fulfilled, and where they have not been fulfilled the conclusions are very unlikely to alter.
+ Some of the checklist criteria have been fulfilled, and where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.
− Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

4.2.1.2 Children and young people

19 studies examined the prevalence of mental health problems in children and young people with a learning disability.

Of the included studies:

- 10 studies were population-based (N=138, 915): (Boulet et al., 2009; Einfeld, 1996; Emerson, 2003a; Emerson et al., 2010; Emerson & Hatton, 2007; Gillberg, 1986; Linna, 1999; Oeseburg et al., 2010; Rutter et al., 1970; Stromme, 2000).
- 9 studies included administrative samples (N=108, 742): (Dekker & Koot, 2003; Hassiotis & Turk, 2012; Jacobson, 1982; Jacobson, 1990; Koskentausta & Almqvist, 2004; Koskentausta et al., 2002; Koskentausta et al., 2004; Molteno et al., 2001; Rojahn J., 1993).
- 2 specifically examined the risk of mental health problems in children and young people with a genetic condition (N=362): both were population-based (Gillberg, 1986; Stromme, 2000) (Acrofacial dysostosis, Atypical methylmalonic aciduria, Fragile X, Prader–Willi syndrome, Rett's syndrome, Soto, Spielmeyer Vogt, XLMR, Angelman, Down's syndrome).

Summary of findings can be found in Table 13 (population-based studies), Table 14 (administrative-based studies), and Table 15 (population-based studies considering genetic conditions). The methodological quality of all papers is reported in Table 16.

No studies examined the risk of mental health problems in children and young people with autism in addition to learning disabilities.

Most studies reported the rates of mental health problems across all degrees of learning disabilities; some reported rates for different levels of learning disabilities. This is summarised in the summary of findings tables below.

Only 5 studies included a non-learning disabled population and were able to provide data on relative risk (Emerson, 2003b; Emerson et al., 2010; Emerson &

Hatton, 2007; Linna, 1999; Rutter et al., 1970). All other studies reported prevalence.

Table 13: Summary of findings table for the review of the prevalence of mental health problems in children and young people with learning disabilities (population-based studies)

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Any mental health problem	1.0%				OR 6.50 (5.40-7.70) RR 3.69 (1.54-8.87) – 16.78 (9.50-29.65) 6.0-36.0%
Schizophrenia	1.0%		1.5%		
Psychosis	14.0%		50.0%		RR 1.00
Depression	10.0%		1.5%		OR 1.70 (0.80-3.30) – 2.23 RR 1.56 (0.80-3.04) – 3.70 (2.41 – 5.67) 0.9-1.5%
Anxiety					OR 3.90 (3.00-5.00) RR 2.42 (1.62-3.62) – 3.56 (2.82-4.48) 8.7-11.4%
Agoraphobia					OR 1.70 (0.20-13.10) RR 1.54 (0.21-11.52) -3.85 (0.50-30.00) 0.2-0.4%
Social phobia	2.0%		14.0%		OR 3.30 (1.40-7.70) RR 2.49 (0.60-10.33) – 3.14 (1.35-7.28) 0.8-0.9%
Specific phobia					OR 2.40 (1.40-4.30) RR 1.89 (0.78-4.60) – 2.54 (1.45-4.45) 1.9-2.0%

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Panic disorder or panic anxiety					OR 1.00 (0.10-7.30) RR 0.77 (0.11-5.61) – 3.85 (0.50-30.00) 0.2-0.4%
GAD					OR 2.50 (1.30-4.90) RR 2.53 (0.93-6.90) – 2.59 (1.36-4.93) 1.5-1.6%
OCD					OR 0.70 (0.10-5.10) RR 0.77 (0.11-5.61) – 1.93 (0.26-14.30) 0.2-0.4%
PTSD					OR 3.10 (0.90-10.20) RR 2.31 (0.71-7.48) – 3.85 (0.91-16.40) 0.5-0.8%
Somatising conditions	11.0%		3.0%		
Eating disorders					OR 1.30 (0.20-9.40) RR 0.77 (0.11-5.61) – 3.85 (0.50-30.00) 0.2-0.4%
ASD	4.0%		8.0%		OR 33.40 (22.30-50.20) RR 26.68 (18.31-38.87) 8.0-12.1%
ADHD					OR 3.71 – 8.40 (6.10-11.50) RR 3.23 (2.40-4.36) – 9.63 (6.20-14.96) 24.25 (8.60-32.85)
Conduct disorder	4.0%		4.5%		OR 3.39 – 5.70 (4.60–7.00) RR 2.96 (2.16-4.06) – 5.96 (4.74-7.49) 14.35 (10.15-24.50)

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Separation anxiety					OR 4.90 (2.90-8.30) RR 3.80 (1.76-8.18) – 4.41 (2.66-7.30) 2.7%
ODD					OR 5.30 (4.10-6.90) RR 4.81 (3.79-6.12) – 5.76 (4.13-8.05) 11.10-13.9%
Tic disorder					OR 5.20 (2.00-13.50) RR 15.3 (3.00-79.30) – 19.98 (3.00-79.30) 0.8%

Note.

ADHD = attention deficit hyperactivity disorder; ASD = autism spectrum disorder; GAD = generalised anxiety disorder; ODD = oppositional defiant disorder; OR = odds ratio; RR = risk ratio.

All figures are prevalence; all confidence intervals are 95% unless otherwise specified.

Intraquartile range (lower to upper quartile).

Rates of mental health problems in children and young people with learning disabilities and epilepsy: conduct disorder, depression and schizophrenia = 0%; ASD = 11-20%; social anxiety = 11%; psychosis = 12%; psychosomatic disorders = 50%; any mental health problem = 64%.

Table 14: Summary of findings table for the review of the prevalence of mental health problems in children and young people with learning disabilities (administrative-based studies)

Condition	All levels of learning disabilities
Any mental health problem	21.30 (33.55-54.85)[1] - mild: 21.0-24.0% - moderate: 15.0-62.5% - severe: 7.0-42.0% - profound: 5.0-49.0%
Substance misuse	2.6%
Schizophrenia	0.0-0.3%
Psychosis	6.7%
Mania	0.2-0.4%
Depression	3.89 (0.08-3.98)[1]
Anxiety	14.06 (0.24-14.30)[1]
Agoraphobia (including agoraphobia with panic)	0.4-1.3%
Social phobia	2.5-2.7%
Panic	0.2%
OCD	2.7%
PTSD	0.0%
Adjustment disorder	0.2-0.6%
Personality disorder	4.09 (0.03-4.12)[1]
ASD	8.59 (0.76-9.35)[1]
ADHD	13.10 (1.10-14.20)[1]
Conduct disorder	16.52 (0.28-16.80)[1]
Separation anxiety	2.1%
Tic disorder	1.3%

Note.

ADHD = attention deficit hyperactivity disorder; ASD = autism spectrum disorder; OCD = obsessive–compulsive disorder; PTSD = post-traumatic stress disorder.

All figures are prevalence, all confidence intervals are 95% unless otherwise specified.

[1] Intraquartile range (lower to upper quartile).

Table 15: Summary of findings table for the review of the prevalence of mental health problems in children and young people with learning disabilities – genetic conditions (population-based studies only)

Condition	Mild	Moderate	Severe	Profound	All levels of learning disabilities
Any mental health problem	Down’s syndrome 0.0%		Down’s syndrome 17.0%		Mild–severe: Acrofacial dysostosis 0.6% Atypical methylmalonic aciduria 0.6% Fragile X syndrome 0.6% Prader–Willi syndrome 0.6% Rett syndrome 0.56% Sotos syndrome 0.6% Spielmeyer-Vogt-Sjögren-Batten disease 0.6% X-linked mental retardation 0.6% Angelman syndrome 1.1% Down’s syndrome 7.0%
Schizophrenia, psychotic behaviour, emotional disorder, social anxiety, psychosomatic disorder, ASD, conduct disorder	Down’s syndrome 0.0%				
Depression	Down’s syndrome 6.0%				

Note.
ASD = autism spectrum disorder. All figures are prevalence unless otherwise specified.

Table 16: Quality assessment of the studies included in the review of the prevalence of mental health problems in children and young people with learning disabilities

Study ID	**Quality**			
	Participant selection	**Group comparability**	**Assessment of outcome**	**Overall assessment of quality**
Population-based studies				
Boulet 2009	Very low	n/a	Low	−
Einfeld 1996	High	n/a	High	++
Emerson 2003	High	Very low	High	+
Emerson 2007	High	High	High	++
Emerson 2010	High	High	High	++
Gillberg 1986	High	n/a	Low	+
Linna 1999	Very low	Very low	Low	+
Oeseburg 2010	High	n/a	High	++
Rutter 1970	Very low	Uncertain	Very low	−
Stromme 2000	High	n/a	High	+
Administrative-based studies				
Dekker 2003	Low	n/a	High	+
Hassiotis 2012	High	n/a	High	++
Jacobson 1982	Low	n/a	Low	+
Jacobson 1990	Very low	n/a	Low	−
Koskentausta 2002	High	n/a	High	++
Koskentausta 2004a	High	n/a	High	++
Koskentausta 2004b	High	n/a	High	++
Molteno 2001	Low	n/a	High	+
Rojahn 1993	Very low	n/a	High	+

Note.

++ All or most of the checklist criteria have been fulfilled, and where they have not been fulfilled the conclusions are very unlikely to alter.

+ Some of the checklist criteria have been fulfilled, and where they have not been fulfilled, or not adequately described, the conclusions are unlikely to alter.

− Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

Uncertain: Available data came from an included systematic review, but the original data was published in a book which could not be obtained and therefore this could not be assessed.

4.2.2 Economic evidence

Knowing the incidence and prevalence of mental health disorders in people with learning disabilities may lead to better prediction, identification (and thus more timely management) and possibly prevention of mental health problems in this population and has therefore, indirectly, potentially important resource implications. However, this is an epidemiological review question and economic analysis is not applicable.

4.2.3 Clinical evidence statements

- Weak to strong evidence from 19 (− to ++) population-based studies (N= 354, 997) suggests that mental health problems such as dementia, depression, and schizophrenia may be higher in adults with learning disabilities than in the general population.
- Weak to strong evidence from 13 (− to ++) studies from administrative samples (N=335, 994) suggests that mental health problems such as mania, depression, anxiety disorders (including OCD, GAD, panic disorder, agoraphobia, social or specific phobias) may be higher in adults with learning disabilities than in the general population. One study (N=194) reported that rates of any mental health problem as well as specific mental health problems (such as depression, anxiety, OCD and psychosis) in adults with autism and severe to profound learning disabilities were highly prevalent (from 12.9 to 53%).
- Weak to moderate evidence from 2 (− to +) studies (N=248) from studies on specific populations of Prader–Willi syndrome and Williams syndrome suggests mental health problems may be prevalent in adults with Prader–Willi syndrome and Williams syndrome (from 10 to 45.7%).
- Weak to strong evidence from 10 (− to ++) population-based studies (N=138, 915) suggests that overall mental health problems and a number of mental health disorders such as depression, anxiety and anxiety disorders (including agoraphobia, social or specific phobias, GAD and PTSD), autism spectrum disorders, ADHD, conduct disorders, separation anxiety and ODD may be higher in children and young people with learning disabilities than in the general population.
- Weak to strong evidence from 9 (− to ++) studies from administrative samples (N=108, 742) suggests that overall mental health problems and mental health problems such as anxiety have a high prevalence in children and young people with learning disabilities than in the general population; however, it was unclear from the evidence if other mental health problems were higher in people with learning disabilities.
- Moderate evidence from 2 (+) population-based studies reporting rates among people with specific genetic conditions (N=362 with specific phenotype in larger study) suggests the following:
  - mental health problems may be prevalent in children and young people with Down's syndrome who also have learning disabilities (and particularly high in more severe learning disabilities)
  - depression may be prevalent in children and young people with Down's syndrome who also have a mild learning disability, but that other conditions such as schizophrenia, social anxiety, autism spectrum disorder and conduct disorder may have low prevalence in this group
  - prevalence rates of mental health problems in other genetic conditions such as arofacial dysostosis and Prader–Willi syndrome are lower (<1.1%).

4.3 Review question: What are the most appropriate methods/instruments for case identification of mental health problems in people (children, young people and adults) with learning disabilities?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 17. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 17: Clinical review protocol summary for the review on methods/instruments for case identification of mental health problems in people (children, young people and adults) with learning disabilities

Component	Description
Review question	What are the most appropriate methods/instruments for case identification of mental health problems in people (children, young people and adults) with learning disabilities? (RQ1.2)
Population	People (children, young people and adults) with learning disabilities
Index test	Brief methods/instruments for case identification (for example, with no more than 3 items or lasting no longer than 10 minutes).
Reference standard	• Diagnosis from full psychiatric or psychological assessment
Critical outcomes	• Sensitivity and specificity • Validity and reliability
Study design	Reviews conducted for existing guidelines and published systematic reviews. If none of the above are found addressing the review question, cross-sectional studies.

4.3.1 Clinical evidence and group consensus for case identification

No evidence was found on case identification methods or instruments for mental health problems for people with learning disabilities. In the context of the particular profile of difficulties, including communication difficulties, experienced by people with learning disabilities the GC deemed it inappropriate to consider indirect evidence from case identification tools used in non-learning disabled populations as the diagnostic accuracy and psychometric properties were likely to be significantly different. Due to the lack of evidence, the GC agreed to use the nominal group technique in order to develop recommendations. The nominal group technique method used in this guideline is described in Chapter 3

Key issues in case identification for this population were identified from the available literature (for example Cooper & Simpson, 2006), including the competence frameworks covering the identification of mental disorders (Roth et al., 2011) and from discussions during the GC meetings. These were used to generate nominal statements to be rated by the GC. Nominal statements relating to accessibility were designed to cover a range of factors that make identification of mental health particularly challenging in this population. An example of a statement that was rated highly by the committee is: ‘Changes in behaviour that could indicate the presence of a mental health problem in a person with a learning disability include behaviour that challenges, social withdrawal, avoidance and agitation’.

Questionnaires were distributed (round 1), and completed and returned by 13 of 17 committee members. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member's comments in relation to the draft recommendations. One completed questionnaire was received after the results had been collated and was therefore not presented to the GC. The ratings presented below are the final ratings and include all completed questionnaires. A sensitivity analysis was also conducted to ascertain whether these additional ratings would have dramatically influenced the results. A second round of ratings was conducted by the GC, immediately following the presentation and discussion of results, and the results from round 2 were collated and presented to the GC. A brief summary of the process is provided in Table 18 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used can be found in Appendix T.

Table 18: Summary of nominal group technique process followed for the development of recommendations on case identification of mental health problems in people with learning disabilities

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (total=17)	Level of agreement	Statements N (total=5)	7 recommendations
High	10	High	4	
Moderate	4	Moderate	1	
Low	3	Low	0	

4.3.2 Economic evidence

No studies assessing the cost effectiveness of methods/instruments used for case identification of mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

4.3.3 Clinical evidence statements (developed through formal consensus)

- The GC agreed that it is important for all staff who come into contact with people with learning disabilities to be aware that mental health problems may develop and present differently in this population, and that family members and carers should be aware that changes in behaviour such as avoidance might indicate mental health difficulties.
- The GC agreed that when identifying a mental health problem, it is important to consider what has changed at a personal or environmental level for an individual
- In case of changes in behaviour such as social withdrawal and agitation, ask open questions about whether anything is bothering someone that focus on behaviour as well as symptoms, ask identification questions as laid out in other guidelines or with minor adaptations in those with mild learning disabilities and that family members should be consulted about changes in behaviour and associated fluctuations in mood. The GC expressed support for prospective monitoring and for using records and relevant outcome data to help identify a possible mental health problem.

- Following identification the GC agreed that a referral should be made to a professional for assessment and the person and their family should be offered support and advice on how to obtain this, that all staff working with the person should be made aware of the nature of the person's difficulties, and that in people with possible psychosis a referral should be made specifically to a psychiatrist with specialist experience in learning disabilities. The GC expressed support for health and social workers conducting a mental health assessment to be offered supervision or consultation from a specialist.

4.3.4 Economic evidence statements

No evidence on the cost effectiveness of methods/instruments used for case identification of mental health problems in people with learning disabilities is available.

4.4 Recommendations and link to evidence

Recommendations	**1. If a person with learning disabilities shows any changes in behaviour (such as loss of skills or needing more prompting to use skills, social withdrawal, irritability, avoidance or agitation), staff should consider a mental health problem.** **2. Staff should consider using identification questions, adjusted as needed, as recommended in the NICE guidelines (see mental health and behavioural conditions on the NICE website) to identify common mental health problems in people with learning disabilities.** **3. Paediatricians should explain to parents of children identified with learning disabilities that mental health problems are common in people with learning disabilities, and may present in different ways.** **4. If a mental health problem is suspected in a person with learning disabilities, staff should conduct a triage assessment to establish an initial formulation of the problem. This should include:** **• a description of the problem, including its nature, severity and duration** **• an action plan including possible referral for further assessment and interventions.** **5. Refer people with learning disabilities who have suspected psychosis or suspected dementia to a psychiatrist with expertise in assessing and treating mental health problems in people with learning disabilities.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence. The group were interested in the difference in risk of mental health problems between people with learning disabilities and people without learning disabilities. If this was not available in the literature, they were also interested in the rates of incidence or prevalence of mental health problems. The group were particular interested in which mental health problems are

	more common in people with learning disabilities and in which populations (that is, different degrees of learning disabilities, children and young people or adults, underlying genetic disorders). This could then inform which case identification tools might prove most useful and guide staff behaviour when identifying mental disorders in this population. When assessing tools or methods for case identification, the GC agreed that using a tool which accurately identified cases, and therefore chose sensitivity and specificity as the primary outcomes. While sensitivity and specificity are usually the most valuable for case identification instruments, the psychometric properties of validity and reliability were also chosen as important outcomes to help assess these characteristics of tools in the learning disabilities population, particularly those which have been validated and found reliable in the general population.
Trade-off between clinical benefits and harms	While no evidence was found on case identification tools in this population with the criteria specified in the protocol: with no more than 3 items or lasting no longer than 10 minutes), there was evidence on the prevalence (and some incidence) of mental health problems in this population. Unfortunately, there were only 11 papers which included a comparison population of people without learning disabilities in order to examine the relative risk in people with learning disabilities. These studies did not cover the rates of degrees of disability or usually the different types of mental health problems. The GC appreciated the difficulty in determining any additional potential risk of mental health problems where this was not reported or calculable from the existing evidence. However, in the absence of comparative data, they considered the rates of prevalence and incidence in light of what is reported in the relevant NICE guidelines for different mental health problems. The GC agreed that in addition to separating the evidence by types of mental health problems, the evidence should also be presented separately for children and young people and adults, by source of sample (that is, population versus administrative samples), and were available for specific phenotypes. The intention was to be able to identify specific groups at higher risk of specific mental health problems, and so on. However, this limited the data further as many studies did not report the rates in the desired ways (for example, by degree of learning disability). The GC noted that it was difficult to draw conclusions from the evidence presented about higher rates of mental health problems by the above groupings. This view was based on both the quantity of the data, the way the evidence was reported, and the confidence in the estimates reported (see ‘Quality of the evidence’ overleaf). The GC noted that for some conditions, the rates reported in the evidence are higher for adults with learning disabilities than those without learning disabilities including schizophrenia, dementia, and depression. Rates of specific mental health problems were also notably high in adults with autism. Rates of conduct disorder, ODD, and ADHD also appeared from the literature to be higher in children and young people with learning disabilities than those without learning disabilities. However, the group noted that the relative rates for some conditions and the prevalence or incidence rates from some studies where relative rates were high did not appear to be higher than the general population. The GC noted also the lack of data on mental health problems in people with genetic conditions. They noted that data on some conditions which their experience indicates have higher rates of mental health problems was not demonstrated in the evidence.

	The GC particularly discussed the harms of not identifying mental health problems in a person with learning disabilities in that those who are not identified as having mental health problems will go untreated. However, as there was no evidence identified on tools to help aid this identification, they discussed the need for more research into the development and validation of these tools. While the GC were unable to identify specific populations at higher risk of specific mental health problems from the evidence to inform recommendations, they were of the opinion that people with learning disabilities are an underserved population whose mental health problems often go unnoticed (as their behaviours are often thought to be related to the learning disability) and therefore untreated. As such, they agreed that case identification is an area that should be addressed in the guideline and so the GC developed recommendations using formal consensus methods (the nominal group technique, see section 3.5.7) in the absence of evidence.
Trade-off between net health benefits and resource use	Identification of mental health problems in people with learning disabilities may have modest resource implications. The GC estimated that initial assessment of a suspected mental health problem in a person with learning disabilities may last about 30 minutes and can be done by professionals with skills and knowledge in the care of this population. The GC agreed that identification questions already recommended in NICE guidelines should be used for this purpose, adjusted, as appropriate, for people with learning disabilities. The GC considered that a percentage of people with suspected psychosis or suspected dementia need to be referred to specialist services, in line with existing NICE guidance for people with suspected psychosis or dementia, and, specifically, to a psychiatrist with expertise in assessing and treating mental health problems in people with learning disabilities. The GC acknowledged the additional resource implications relating to such referrals and also to any adjustments required in the process of identification of mental health problems in this population. However, the GC expressed the view that having the same identification pathways with necessary adjustments ensure equality of care between people with learning disabilities and those without learning disabilities assessed for a suspected mental health problem. Furthermore, the GC considered the current under-detection of mental health problems in people with learning disabilities and, based on their experience and evidence in the general population, advised that undiagnosed, and thus often untreated, mental health problems incur much higher health and social care costs compared with the costs associated with the initial assessment of a suspected mental health problem. The GC expressed the opinion that identification of mental health problems in people with learning disabilities is going to lead to more timely, effective and cost-effective assessment and management of the mental health problems. This, in turn is expected to result in better outcomes for people with learning disabilities, their family and carers as well as in potential cost savings to health and social care services, as mental health problems will be managed appropriately and at earlier, and possibly less severe, stage.
Quality of evidence	The GC were concerned about the source of the samples from which studies were based including the fact that studies with administrative samples may overestimate the rate of mental health populations. However, the GC agreed that removing studies with administrative samples completely would leave minimal population-based studies for which to consider. They agreed that administrative studies should be presented in a table, supplementary to the population-based studies, with an added caveat of quality.

	While population-based studies are ideal, administrative populations (those defined by the participants having learning disabilities) can potentially miss participants who are not using learning disabilities services, particularly those with mild learning disabilities. As such, the studies from administrative populations might not represent the learning disabilities population as a whole. However, the GC noted that most people with learning disabilities, particularly those who may at any point call upon the use of services suitable for people with learning disabilities who have mental health problems, are likely to be included within administrative populations; they agreed that presenting them was informative. The GC noted that where the relative risk was reported, the confidence intervals were often very wide, covering both the possibility that the true rate of mental health problems in the studies was lower or higher than the general population. The GC noted as well some inconsistency within the existing studies with the results being heterogeneous with wide ranges of rates of mental health problems across different studies. However, it was difficult to formally assess the reasons for this. The methodological quality of the evidence ranged from weak to strong among the included studies. Given the variation in the quality of the included studies, the GC was not very confidence in the results.
Other considerations	The GC decided, on the basis of the outcome of the nominal group technique, to develop recommendations in the following areas: - that staff should consider an assessment for a mental health problem if there is a person with learning disability who has a change in behaviour. The group agreed that such changes should alert services to the possibility that they have a mental health problem and therefore need an assessment. These changes may include any change in behaviour or development of new symptoms, such as loss of skills, needing more prompting, social withdrawal, irritability, avoidance or agitation. - in the absence of specific tools for case identification of mental health problems in learning disability, the GC agreed that staff should consider using disorder relevant identification questions from existing NICE guidelines on common mental health problems. The questions may need to be adjusted for people with learning disabilities, bearing in mind the recommendations on facilitating involvement and communication with the person in section 8.2.6.2. - for people with possible psychosis a referral should be made specifically to a psychiatrist with specialist experience in learning disabilities A number of additional contextual factors were identified through the nominal group technique which were deemed to be important to address, and recommendations were made to incorporate these issues: - the GC agreed that it would be too complex to ensure that all staff who come into contact with people with learning disabilities are fully aware of all the ways that mental health problems may present in people with learning disabilities. Instead, the group agreed that all health and social care and education providers should know that people with learning disabilities are at increased risk, that these problems develop and present in different ways, and that these problems are often overlooked (see recommendations on training in section 8.8.3). Furthermore, they agreed that all staff should know how to refer someone with suspected mental health problems (see commentary on

	this in the text below). - Further to the above bullet, the GC agreed that paediatricians should discuss with parents the possible increased risk of mental health problems in people with learning disabilities and that these problems may present in different ways. The aim is to increase awareness to help recognise symptoms, if they present. - As with people with suspected psychosis, the GC agreed that people with suspected dementia should be referred to a psychiatrist with expertise in assessing and treatment mental health problems. The GC did not agree that an assessment should necessarily be conducted by the staff member identifying a possible problem. Although they did acknowledge that it may be better to have someone who knows the person involved trained in the assessment; instead, they The GC were of the view that clarity about where to refer to was important (see recommendations on training in section 8.8.3). While the group initially agreed through the nominal group technique that a referral should be made to a specialist healthcare professional for assessment after identification, on further discussion they agreed that this may not always be necessary. They agreed there could be an initial triage assessment after identifying a potential problem, which sufficient to develop an effective care plan prior to considering referral. Given the overlap between content of the 2 types of assessment initially proposed (brief and comprehensive) the GC agreed to remove this distinction from the guideline recommendations. The triage assessment should include assessment review of the nature, severity and duration of the problem and lead to the development of an action plan including possible referral for further assessment and intervention. Given the lack of evidence on case identification tools to aid the identification of mental health problems in people with learning disabilities and the persisting difficulties in identifying mental health problems in this population, the GC recommended research in developing reliable and valid tools for case identification. They noted that brief case identification tools (for use in any setting) exist for the identification of common mental health disorders in people without learning disabilities and so, they recommended future research into this area.

4.4.1 Research recommendations

1. **Develop reliable and valid tools for the case identification of common mental health problems in people with learning disabilities, for routine use in primary care, social care and education settings.**

4.5 Review question: In people (children, young people and adults) with learning disabilities, what are the key components of, and the most appropriate structure for, an assessment of mental health problems?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 19. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 19: Clinical review protocol summary for the review on assessment of mental health problems in people (children, young people and adults) with learning disabilities

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, what are the key components of, and the most appropriate structure for, an assessment of mental health problems? (RQ1.3)
Population	People (children, young people and adults) with learning disabilities who are suspected of having mental health problems.
Index test	Methods for assessment of mental health problems. (see review protocol in Appendix H for full list)
Reference standard	• Diagnosis from full psychiatric or psychological assessment (for studies assessing risk of an event, the reference standard was the occurrence of that event)
Critical outcomes	• Sensitivity and specificity • Validity and reliability For consideration of the key components, and the most appropriate structure, consideration will be given to: • the nature and content of the interview and observation • formal diagnostic methods/psychological instruments for the assessment of mental health problems • the setting(s) in which the assessment takes place • the role of the any informants • degree of learning disability • diagnostic overshadowing • genetic syndromes.
Study design	Reviews conducted for existing guidelines and published systematic reviews. If none of the above are found addressing the review question, individual prospective or retrospective cohorts and cross-sectional studies may be considered.

4.5.1 Clinical evidence and group consensus on the most appropriate structure for, and assessment of mental health problems

There were no studies found which addressed the most appropriate structure for an assessment of mental health problems. As such, the nominal group technique was used to determine general principles for assessment. The method of the nominal group technique used in this guideline is described in Chapter 3.

The assessment process was originally split into brief and comprehensive assessment and a separate questionnaire was developed for each area. However, later this delineation was discarded as the nominal statements were reviewed (there was very considerable overlap on agreed statements) and recommendations developed (see discussion in the recommendations and link to evidence in section 4.6). Key issues for each area were similar, and were identified through the same sources; available literature, GC discussion and feedback from the service user focus groups. Nominal statements relating to brief and comprehensive assessment were developed from these sources in order to be distributed to the GC. Separate questionnaires were developed and distributed for each of brief and comprehensive assessment. Both sets of statements were designed to address a range of relevant areas including methods of data collection, risk assessment, competencies of staff and outcomes from each type of assessment.

4.5.1.1 Brief assessment

The round 1 questionnaire for brief assessment was completed and returned. Percentage values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members at a GC meeting and used to inform a discussion of the issues raised by member's comments in relation to the draft recommendations. Following this process, 2 further completed questionnaires were received and were not included in the data presented to the GC. These data points are included in the data presented. An example of a statement that was rated highly by the GC is: 'Staff conducting a brief assessment should be aware that what presents as a mental health problem might be caused by an underlying physical health problem'.

There was a high level of agreement with many of these statements; however, a second round of rating to further clarify some issues raised through the GC's comments was undertaken. Nominal statements were developed using this feedback, and presented to the GC for rating in questionnaire format at a GC meeting immediately following the discussion of the results from round 1. Percentage agreement values and comments were again collated, and presented and discussed at a subsequent GC meeting. A brief summary of the process can be found in Table 20 below. The full list of statements and ratings can be found in appendix U whilst blank copies of questionnaires used can be found in Appendix T.

Table 20: Summary of nominal group technique process followed for the development of recommendations on brief assessment of mental health problems in people with learning disabilities

Round 1		Round 2		Resulting recommendations generated
Level of agreement	Statements N (Total=99)	Level of agreement	Statements N (Total=5)	11 recommendations
High	65	High	2	
Moderate	27	Moderate	1	
Low	7	Low	2	

4.5.1.2 Comprehensive assessment

The round 1 questionnaire for comprehensive assessment was completed and returned by GC members. Percentage values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members at a committee meeting and used to inform a discussion of the issues raised by member's comments in relation to the draft recommendations. An example of a statement that was rated highly by the GC is: 'A comprehensive assessment should be undertaken in a collaborative manner and maximise the contribution of all people involved'. A second round of ratings was not considered to be necessary as it was agreed that any comments made by the GC could be incorporated adequately into the wording of recommendations. A brief summary of the process can be found in Table 21 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used can be found in Appendix T.

Table 21: Summary of nominal group technique process followed for the development of recommendations on comprehensive assessment of mental health problems in people with learning disabilities

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=108)	Level of agreement	Statements N (Total=0)	13 recommendations
High	95	High	n/a	
Moderate	12	Moderate	n/a	
Low	1	Low	n/a	

4.5.2 Clinical evidence on formal assessment methods/instruments

In total, 29 studies met the eligibility criteria for this review, covering 19 instruments. The included studies are summarised narratively below. Further information about both included and excluded studies as well as the methodology checklists can be found in Appendix K.

The identified studies predominantly included adults. One study, which focused solely on a general measure of mental health problems in children and young people, used a sample which excluded adults (Einfeld & Tonge, 1995). However, 2 studies used mixed populations of young people and adults: 1 (Verbrugge et al., 2011) investigated a range of risk assessment tools and another investigated the PAS-ADD interview (Moss et al., 1997). Both studies were presented in the review for adults only as most of the participant were adults.

Identified studies which met the inclusion criteria covered a general measure of mental health problems, depression, dementia, and the assessment of outcomes. No studies were identified which met the inclusion criteria for other areas (including anger, anxiety disorders, personality disorders, post-traumatic stress disorder, and the assessment of communication).

Studies which included the pre-specified reference standard, full psychiatric or psychological assessment, were included in this review (except for studies considering the risk of an event). However, many studies compared results against another tool instead of this reference standard so a 2-staged approach was taken:

- Stage 1: Studies using the appropriate reference standard
- Stage 2: All studies which compared a tool against another tool (as the reference standard) found to be ‘adequate’ against full psychiatric or psychological assessment.

As studies reporting data on the same tool did not often report sufficient data to synthesise the results (for example, reporting data for the 2×2 table used to calculate sensitivity and specificity) it was not possible to perform meta-analysis of the results for any tool. As such, the results are summarised narratively below. Where there was sufficient data reported (true positives, true negatives, false positive, false negative or a 2×2 table to calculate these figures), receiver operating characteristic curves were produced; these are found in Appendix O.

4.5.2.1 Adults

4.5.2.1.1 General measures of mental health problems

There were 15 studies (N=4069) covering 8 tools which met the eligibility criteria for stage 1 of this review: Charlot et al. (2007); Devine et al. (2010); Gerber and

Carminati (2013); Glenn et al. (2013); Gonzalez-Gordon et al. (2002); Gustafsson (2005); Hove and Havik (2008); Janssen and Maes (2013); Matson and Smiroldo (1997); Matson et al. (1997); Moss et al. (1997); Moss et al. (1998); Prosser et al. (1998); Sturmey et al. (2005); Swiezy et al. (1995); van Minnen (1994).

No studies met the eligibility criteria for stage 2 of this review as there were no studies using tools found adequate in stage 1 as a reference standard.

Diagnostic Assessment for the Severely Handicapped-II

The DASH-II is a questionnaire measure designed to identify psychopathology in adolescents and adults with severe or profound learning disabilities. The measure has 84 items across 13 subscales; anxiety, depression, mania, PDD/Autism, schizophrenia, stereotypies, self-injury, elimination, eating, sleeping, sexual, organic and impulse control. It is rated by a staff or family-member familiar with the individual and takes around 10-15 minutes to complete. The DASH-II costs £192.

Matson 1997 and Matson & Smiroldo 1997 investigated the utility of the DASH-II to identify psychopathology in adults with learning disabilities. Of the 13 subscales, the authors found that only the mania subscale had adequate sensitivity and specificity to identify mental illness in people with severe to profound learning disabilities and a Diagnostic and Statistical Manual of Mental Disorders (fourth edition) (DSM-IV) Axis 1 diagnosis (n=22; sensitivity=92.3%, specificity=99.5%). The sensitivity of the anxiety subscale was 21.2% whilst the sensitivity of the depression subscale was 73.3%. The internal consistency (Cronbach's alpha) for the DASH-II was 0.79 whilst the convergent validity was r=0.43-0.91.

Mood and Anxiety Semi-structured Interview (MASS)

The MASS is a free, clinician-administered, semi-structured interview, based upon DSM-IV-TR (Text Revision) criteria that is designed to identify mood and anxiety difficulties in people with learning disabilities. It consists of 36 items and takes between 30 and 60 minutes to administer.

Charlot 2007 investigated the utility of the MASS in adult inpatients (n=93) with all degrees of learning disability. They found that the MASS could be used to identify any anxiety disorder with 96% sensitivity and 81% specificity, of GAD with 73% sensitivity and 69% specificity, of depression with 92% sensitivity and 73% specificity and of mania with 60% sensitivity and 100% specificity.

Psychiatric Assessment Schedule for Adults with Developmental Disabilities (PAS-ADD) – Interview

The PAS-ADD interview is a clinician-administered measure designed to identify psychopathology, providing either ICD-10 or DSM-5 (DSM 5th edition) diagnoses, for use in people with learning disabilities and a level of expressive language that enables them to make a verbal contribution to the interview. The core interview consists of 66 items, takes roughly 3 hours to administer, and can be supplemented with other assessments where necessary. The PAS-ADD interview costs £225 and clinicians are required to attend training in both interviewing and coding before using it.

An older version of the PAS-ADD interview was assessed in 2 studies: Gonzalez-Gordon 2002 (n=80), assessed the PAS-ADD interview in adult populations whilst Moss 1997 investigated its' effectiveness in a mixed population of children and adults (from ages 16 to 69) (n=95). Gonzalez-Gordon found that the PAS-ADD interview identified neurotic symptoms with 63% sensitivity and 84%

specificity. In their study, Moss 1997 found that the PAS-ADD interview identified anxiety disorders across all levels of learning disabilities, when compared with psychiatric diagnosis alone, with 100% sensitivity and 97% specificity. The PAS-ADD interview had lower sensitivity and specificity for symptoms of schizophrenia (sensitivity=76.1%, specificity=88%), depression (sensitivity=75% specificity=88%), and any psychiatric disorder (sensitivity=75.9%) in this study.

Psychiatric Assessment Schedule for Adults with Developmental Disabilities (PAS-ADD) – Checklist

The PAS-ADD checklist is a 25-item screening questionnaire for psychopathology in adults with learning disabilities, designed to be completed by individuals who know the person with learning disabilities well. The PAS-ADD checklist produces 3 sub-scores; affective or neurotic, possible organic condition (including dementia) and psychotic disorder. The scoring system includes threshold scores which can be used as indication for further assessment. The PAS-ADD checklist costs £60 for a pack of 20 forms.

The PAS-ADD checklist was assessed in 3 studies of people with mixed degrees of learning disabilities: Moss 1998 (n=201) and Sturmey 2005 (n=226) assessed the PAS-ADD checklist in adult populations and Gerber 2013 which investigated a French version of the PAS-ADD checklist in adults (n=126) with all levels of learning disability. Sturmey 2005 found that the sensitivity of the PAS-ADD checklist affective/neurotic disorders subscale was 66%, and the specificity was 70%. In their study Moss 1998 found that the PAS-ADD checklist had Spearman's rank correlation inter-rater reliability of 0.79 and Cohen's kappa inter-rater reliability of mean 0.42 across the subscales. The internal consistency of the PAS-ADD checklist subscales ranged from 0.6-0.84 in these 2 studies.

The Gerber 2013 study reported that the total score on the French version of the PAS-ADD checklist had poor sensitivity and specificity compared to the ICD-10 (sensitivity=59%, specificity=59%). The internal consistency of the organic, psychotic and affective/neurotic subscales ranged from 0.72-0.81, whilst the inter-rater reliability ranged from 0.66-0.73.

Psychiatric Assessment Schedule for Adults with Developmental Disabilities (PAS-ADD) – Mini

The mini PAS-ADD is measure of psychopathology in adults with a learning disability. It is designed to be used by staff who have received training in the measure, but who do not need to have a background in applied psychology or psychiatry. The mini PAS-ADD has 86 items and produces scores relating to depression, anxiety, expansive mood, OCD, psychosis, unspecified disorder (typically dementia and other organic disorders) and autism spectrum disorder. Threshold scores are intended to be used in combination with clinical judgement to make decisions about the provision of diagnoses. The tool costs £179.95, and staff must undergo 2 days of training prior to using the instrument.

Devine 2009 investigated the mini PAS-ADD in adults with mild-moderate learning disabilities (n=96), whilst Janssen 2013 (n=467) and Prosser 1998 (n=68) investigated the mini PAS-ADD in adults across the full spectrum of the degrees of learning disabilities. Devine found that the mini PAS-ADD had 100% sensitivity and 77% specificity. Janssen, with a Dutch version of the measure, found high levels of variability in sensitivity and specificity within both a general and a clinical sample. The anxiety subscale appeared to be the most sensitive identifying 60% of cases correctly in the clinical sample. The unspecified disorder subscale had the highest reported specificity at 100%.The internal consistency of the subscales ranged from 0.46 to 0.81 in this study. Prosser 1998 found that the sensitivity and specificity of the mini PAS-ADD in individuals with moderate to profound learning disabilities was higher when scored by a psychiatrist than a member of the community support team (psychiatrist: sensitivity=87%, specificity=100%; Community support: sensitivity=57%, specificity=83%).

Psychopathology Inventory for Mentally Retarded Adults (PIMRA)

The PIMRA is a 56-item questionnaire and is a general measure of mental health problems for use in adults with learning disabilities. It is designed to be completed by an informant familiar with the person with a learning disability and produces 7 subscale scores on the basis of DSM-III (DSM 3rd edition) criteria; schizophrenia, affective disorder, psychosexual disorder, adjustment disorder, anxiety disorder, somatoform disorder and personality disorder, as well as a measure of inappropriate adjustment. The PIMRA costs £163.

The PIMRA has been investigated by 3 authors; Gustafsson 2005 (n=83) in adults with mild to severe learning disabilities, van Minnen 1994 (n=89) in adults with mild learning disabilities and Swiezy 1995 (n=65) in adults with mild to moderate learning disabilities. Gustaffson 2005 found that the 41-item total score of the PIMRA had 68% sensitivity and 84% specificity, whilst the psychosis, adjustment/anxiety and hallucinations subscales ranged in sensitivity from 53-86% and in specificity from 76-94%. The internal consistency of the total score scale was 0.81 and test-retest reliability value was 0.35. Similarly, van Minnen 1994 found that the internal consistency of the subscales ranged from 0.68 to 0.9, whilst the convergent validity of the affective disorders subscale was 0.74. Swiezy 1995 reported inter-rater agreement values of 78-81% for the schizophrenia, depression and dysthymia subscales, and internal consistency values for these subscales ranging from 0.16-0.43.

Psychopathology Checklists for Adults with Intellectual Disabilities (P-AID)

The P-AID is a measure designed for use in adults with learning disability. It consists of 18 different checklists.

Hove 2008 investigated the agoraphobia, social and specific phobia subscales of the P-AID in an adult population with all levels of learning disability (n=35), finding that the internal consistency of these scales was 0.83-0.87 and the inter-rater reliability was 0.65-0.75. In a population of adults with mild learning disabilities (n=35) the GAD and panic disorder subscales had internal consistency of 0.89 and inter-rater reliability of 0.49-0.55. In adults with a history of psychopathology (n=111) across all levels of learning disability the P-AID had sensitivity of 30% and specificity of 89%.

Strengths and Difficulties Questionnaire (SDQ) (used in children)

The SDQ is a free, commonly-used, brief behavioural screening questionnaire designed for use in children and young people aged 3-16 years. There are 3 versions that exist: a parent-report (ages 3-16), a teacher-report (ages 3-16) and a self-report (ages 11-16). There is also an impact supplement that provides additional information for clinicians about the severity and chronicity of a young person’s difficulties. The SDQ consists of 25 items across 5 different subscales and covers emotional symptoms, conduct problems, hyperactivity and inattention, peer relationship problems and prosocial behaviour, and additionally produces a total score.

Glenn 2013 investigated the usefulness of SDQ to identify psychopathology, compared to the ICD-10, in a population of adults with Down’s syndrome (n=125). They found that the mean value of the area under the curve (AUC) was 0.689 (SE=0.056).

4.5.2.1.2 *Depression*

1 study (N=115) covering 1 tool (Child Depression Inventory) met the eligibility criteria for this review: (Meins, 1993).

1 study (N=65) on 1 tool (Glasgow Depression Scale for people with a learning disability) met the eligibility criteria for stage 2 of this review as it used the PAS-ADD Mini as the reference standard: (Cuthill et al., 2003).

Child Depression Inventory (CDI) (used in adults)

The CDI (now the CDI-2) is a 28-item questionnaire-measure of depression symptomatology in children and young people aged 7-17 years. There are 3 full-length versions that exist: a parent-report version, a teacher-report and a youth-report. There is also a 12-item short-form version. The CDI produces 2 scales; emotional and functional problems, and 4 subscales; negative mood, negative self-esteem, ineffectiveness and interpersonal problems. A starter kit for the CDI-2 costs $400.

Meins 1993 evaluated the effectiveness of the CDI at identifying depression in an adult population (n=115), with 3 items relating to school attendance removed. When a cut-off of 13 was used the CDI had 83% sensitivity and 93% specificity, whilst with a cut-off of 17 they found a sensitivity of 75% and specificity of 98%. The CDI had an internal consistency of 0.86 in this population and inter-rater agreement of 82%.

Glasgow Depression Scale for People with a Learning Disability (GDS-LD) and GDS Carer Supplement (GDS-CS)

The GDS-LD is a free 20-item questionnaire measure designed to identify depression in people with a mild-moderate learning disability. It takes around 10-15 minutes to complete. Items are rated on a 3-point Likert scale ranging from 0 ‘no’ to 2 ‘a lot’. A score of over 13 indicates probable depression. A carer supplement (GDC-CS), consisting of the 16 items considered to be directly observable, is also free.

Cuthill 2003 investigated the validity and reliability of depression diagnosis with the GDS-LD compared with the DSM-IV in adults with mild to moderate learning disability (n=65). They found that the GDS-LD identified depression with 90% sensitivity and 100% specificity. The carer supplement also had good test-retest reliability (r=0.98) and internal consistency (Cronbach’s alpha = 0.88).

4.5.2.1.3 *Dementia*

There were 4 studies (N=515) which covered 5 tools met the eligibility criteria for this review: (Cosgrave et al., 1998; Deb & Braganza, 1999; Deb et al., 2007; Li et al., 2015).

No studies met the eligibility criteria for stage 2 of this review as there were no studies using tools found adequate in stage 1 as a reference standard.

Test for Severe Impairment

The TSI is a clinician-administered 24-item questionnaire-measure designed to identify decline in cognitive function due to dementia in adults aged 51-91 years. The measure is not specifically designed for people with a learning disability. It takes between 10 and 20 minutes to administer. There are 8 questions which the individual is required to respond to verbally. The TSI costs £283.

Cosgrave 1998 assessed the usefulness of the TSI at identifying cognitive decline in adults with Down's syndrome and moderate-severe learning disabilities (n=60), compared with diagnosis using the ICD-10. They found that the internal consistency of the TSI was 0.89, and the test-retest reliability ranged from 0.74 in severe learning disabilities to 0.97 across all levels of learning disabilities. The convergent validity of the TSI ranged from 0.74 in severe learning disabilities to 0.94 in the full sample.

Dementia Screening Questionnaire for Individuals with Intellectual Disabilities

The DSQIID is a free carer-rated questionnaire screening measure for dementia in people with learning disabilities. It consists of 53 items, takes 10-15 minutes to complete and is appropriate for use in people with mild to severe learning disabilities. A score of 20 or above indicates possible dementia.

Deb 2007 (n=116) investigated the effectiveness of the DSQIID at identifying dementia in adults with Down's syndrome across all levels of learning disabilities, compared with the ICD-10. The authors found that the DSQIID had 92% sensitivity and 97% specificity, internal consistency of 0.91 and inter-rater reliability of 0.9. Li 2015 (n=200) compared the DSQIID with the Diagnostic Criteria for Psychiatric Disorders for Use with Adults with Learning Disabilities/mental Retardation in adults over the age of 40 across all levels of learning disabilities, reporting sensitivity of 92.3% and specificity of 99.5%. They reported internal consistency of 0.945 and inter-rater reliability of 1.

Dementia Questionnaire for Persons with Mental Retardation

The DMR (now named the Dementia Questionnaire for People with Learning Disabilities) is a carer-rated screening questionnaire for cognitive deterioration resulting from dementia in people with a mild to severe learning disability. It consists of 50 items scored on 3-point Likert scales ranging from 0 'no deficit' to 2 'severe deficit', and takes 15 to 20 minutes to administer. The Dementia Questionnaire for People with Learning Disabilities produces 8 subscales; short-term memory, long-term memory, orientation, speech, practical skills, mood, activity and interest, and behavioural disturbance. The first 4 subscales produce the sum of cognitive scores scale, and the last 4 produce a sum of social scores scale. The DMR costs £129.50.

Deb 1999 investigated the usefulness of the DMR, compared to the ICD-10, in a population of adults with Down's syndrome (n=62) over the age of 35. They reported sensitivity and specificity of 92%.

Down Syndrome Dementia Scale (DSDS)

The DSDS (now G-DSDS) is a clinician-rated questionnaire measure of dementia symptoms designed for use in people with Down's syndrome. It consists of 60 items, takes around 30 minutes to administer and is suitable for use in people with all levels of learning disabilities. The DSDS costs $80.

Deb 1999 investigated the usefulness of the DSDS, compared to the ICD-10, in a population of adults with Down's syndrome (n=62) over the age of 35. They reported sensitivity of 85% and specificity of 89%.

4.5.2.1.4 *Assessment of risk*

There were 5 studies (N=277) which covered 4 tools met the eligibility criteria for this review: (Fitzgerald et al., 2013; Morrissey et al., 2007a; Morrissey et al., 2007b; Pouls & Jeandarme, 2014; Verbrugge et al., 2011).

No studies met the eligibility criteria for stage 2 of this review as there were no studies using tools found adequate in stage 1 as a reference standard.

Historical, Clinical, Risk Management – 20 item scale

The HCR-20 (version 3) is a structured violence risk assessment tool for use by clinicians with adults with learning disabilities. The HCR-20 does not have numerical cut-off values. It has 20 items and is used in combination with clinical judgement to assess an individual as posing low, moderate or high risk of future violence. The manual costs £75, a 50-pack of worksheets costs £75 per unit when 1-24 are ordered and £60 per unit when over 25 sets are ordered.

Fitzgerald 2013 investigated the usefulness of the HCR-20 at predicting risk in a population of adults with mild to moderate learning disabilities based within a medium-secure unit (n=25). The authors reported an AUC value of 0.73 (SE 0.11) for the risk of any physical aggression and 0.81 (SE 0.1) for severe physical aggression over 6 months. The study also reported a Spearman’s rho inter-rater reliability value of 0.6. Morrissey 2007a investigated the same tool (n=54) in individuals detained under the MCA within a national high-secure unit, with mild to moderate learning disabilities. This study reported an AUC value of 0.68 (interpersonal physical aggression) and 0.77 (verbal or property aggression), and a Spearman’s rho test-retest reliability value of 0.45 over 12 months. Morrissey 2007b investigated the HCR-20 at the same unit, again with individuals with mild to moderate learning disabilities who were detained under the MCA, over 2 years (n=73). The authors reported an AUC value of 0.69 (SD 0.53-0.81) for prediction of positive progress on the basis of HCR-20 values, and of 0.49 (SD 0.28-0.70) for negative progress. In a mixed community-based sample of young people and adults with mild to moderate learning disabilities Verbrugge 2011 (n=59) used an intellectual disability supplement for the HCR-20 in a population of people who were no longer in custody and reported an AUC value for general recidivism in individuals classified as moderate to high risk of 0.97 (SE 0.03), and for violent recidivism of 0.8 (SE 0.09). In this study inter-rater reliability was 0.65.

Psychopathy Checklist – Revised (PCL-R)

The PCL-R is a 20-item clinician-rated questionnaire-measure of psychopathy designed for use in adults. The full kit costs $460, a pack of 25 ‘QuikScore forms’ is $100 and a pack of 25 ‘interview guides’ is $160.

Both Morrissey 2007a (n=60) and Morrissey 2007b (n=66) investigated the PCL-R in a population of adults with mild to moderate learning disabilities detained in National high-security facilities under the MCA. Morrissey 2007a reported an AUC value for the prediction of aggressive incidents over 12 months from PCL-R score of 0.54 (SD 0.39-0.68), internal consistency (Cronbach’s alpha) of 0.73, Spearman’s rho test-retest reliability value of 0.11 and inter-rater reliability value of 0.8. Morrissey 2007b reported an AUC value for the prediction of positive progress after 2 years on the basis of PCL-R score of 0.69 (SD 0.53-0.81) and of negative progress of 0.49 (SD 0.28-0.70). Pouls 2014 investigated the PCL-R at predicting institutional violence and violation of conditions in detained adult patients with mild to severe learning disabilities in forensic units (n=60). They reported an AUC value of 0.68 (SD 0.52-0.84), internal consistency of 0.75 and inter-rater reliability of 0.73.

Psychopathy Checklist – Screening Version (PCL-SV)

The PCL-SV is a 12-item screening measure for psychopathy. The PCL-SV kit costs $240, a pack of 25 Interview guides is $85 and a pack of 25 'QuikScore forms' is $90.

Pouls 2014 investigated the PCL-SV in detained adult patients with mild to severe learning disabilities in forensic units (n=60). They reported an AUC value of 0.69 (SD 0.55-0.84), internal consistency below 0.6 (Cronbach's alpha) and inter-rater reliability of 0.44 (kappa).

Violence Risk Appraisal Guide (VRAG)

The VRAG is a free 12-item questionnaire measure designed to assess risk of violence in.

Fitzgerald 2013 (n=23) investigated the usefulness of the VRAG to predict aggression in adults with mild to moderate learning disabilities placed within medium-secure units. They reported an AUC value for any physical aggression of 0.87 (SE 0.08) and for severe physical aggression of 0.78 (SE 0.1). They reported a Spearman's rho inter-rater reliability value of 0.53 for risk of any physical aggression. Verbrugge 2011 in a community sample of young people and adults with mild to moderate learning disabilities (n=59) reported an AUC value for violent recidivism of 0.79 (SE 0.07) and of general recidivism of 0.92 (SE 0.06). The inter-rater reliability was reported as 0.66.

4.5.2.2 Children

Only 1 study (N=664) was identified in children and young people and met the eligibility criteria for stage 1 of the review (Einfeld & Tonge, 1995); no studies met the eligibility criteria for stage 2 as there were no studies using tools found adequate in stage 1 as a reference standard.

4.5.2.2.1 General measures of mental health problems

Developmental Behaviour Checklist – Parent version

The DBC-P is a 96-item parent or carer-rated measure of emotional and behavioural problems in children and adolescents aged 4-18 years. The measure is in the process of being licensed for use. At the time of writing no information was available on the anticipated cost of the tool to services. A score of 46 or above has been identified as the optimal cut-off for this instrument. There is also a version of the DBC for adults, however we did not find evidence of sufficient quality for the utility of that version. Einfeld 1995 found that the DBC-P had an AUC value of 0.92 in young people with mild–severe learning disabilities, test-retest reliability of 0.83 (intraclass correlation, 95% CI 0.69-0.90) and inter-rater reliability between parents of 0.80 (intraclass correlation, 95% CI 0.59-0.90).

4.5.3 Economic evidence

No studies assessing the cost effectiveness of key components of, and the most appropriate structure for, an assessment of mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

4.5.4 Clinical evidence statements on the most appropriate structure for, an assessment of mental health problems (developed through formal consensus)

4.5.4.1 Brief assessment

- The GC decided that a brief assessment should be conducted with an understanding of the context including the physical environment, should draw on information sources directly relevant to the purpose of the assessment and take into account symptom severity, service user distress and impairment. They decided that confidentiality should be explained prior to commencement, that the assessment should consider any physical health problems or syndromes, that the staff should be aware of diagnostic overshadowing and confusion between physical and mental health complaints and should understand how neurodevelopmental disorders impact upon presentation and that a summary should be provided upon completion. The GC expressed support for a brief assessment to have an agreed outcome, to identify service user strengths, to be repeated if further information emerges and to be conducted by staff aware of the likely presentations of mental health disorders in particular syndromes.
- The GC decided that the assessment should be collaborative and maximise everybody's contribution, should consider involving someone known to the service user to facilitate engagement and potentially to help with decision making, that staff should acknowledge areas of disagreement between themselves and the service-user and that they should ensure the service user feels able to ask any questions. The GC expressed support for the preferred format for feedback from the assessment to be established in advance and for a collaborative formulation to be developed during the assessment that addresses factors identified as relevant by the service user.
- The GC decided that the environment should be free of distractions, the assessment should be adapted to the person's needs, any neurodevelopmental difficulties, understanding and stress levels including in its' pace, that questions should be clear and unambiguous and staff should be competent in communicating with people with sensory and communication difficulties, and that the assessment should be responsive to new concerns. The GC expressed support for tools such as visual timelines to be used to explain the process and for staff conducting the assessment to be aware of the impact of neurodevelopmental conditions on presentation of mental health problems.
- The GC agreed that, to ensure rigour, any tools used should be validated and relevant to the disorders to problems being assessed, and a record of assessment content and outcome should be kept.
- The GC agreed that brief assessment should focus on specific areas of need, increase understanding of the problem including its' nature, duration and severity, take into account symptom severity and impairment and coexisting

difficulties and potentially develop a plan of action, and that the purpose should be clear to everyone involved. The GC agreed that a brief assessment should be broad and aim to identify areas that require more comprehensive assessment. The GC expressed support for a brief assessment to focus on specific identified areas of need and for identification of a mental health diagnosis or problem specification to be an important component of the assessment.

- The GC decided that the need for a risk assessment should always be considered, that this should include safeguarding concerns, risk to self, risk to others, the nature and severity of risky behaviours and any triggers, the likelihood of adverse events, that this assessment should be informed by knowledge of the service user and their social context and should identify protective factors. The GC expressed support for a risk assessment to be included in a brief assessment and for vulnerability to exploitation to be included in this, for a risk assessment to consider a range of factors and for the risk management plan to be communicated to relevant services.
- The GC decided that a brief assessment should incorporate a formulation which should provide a shared understanding of the person's difficulties, factors leading to their development and maintenance, the focus and barriers to engagement in interventions, and consider risk factors and the impact of the environment.
- The GC decided that involved staff should be competent in the use of assessment tools and methods in people with learning disabilities as well as routine outcome measures, and should have knowledge of classification systems and diagnostic overshadowing. The GC decided that brief assessments should be conducted by professionals with specialist knowledge of learning disabilities. The GC expressed support for brief assessments to be conducted in collaboration with other professionals and for reliable pre-existing information to be used where possible.
- The GC decided that the assessment should seek views from people who help care for the service user where possible, that the service user should be able to speak to the clinician alone about any safeguarding concerns, that information should be gathered from relevant sources and informants familiar with the service user and corroborate information with families and carers. The GC expressed support for brief assessments to use information from a range of sources, consider how the service user functions across settings and review relevant history, and for staff conducting the brief assessment to capable of appraising the reliability of evidence and use measures developed in or adapted for people with a learning disability.
- The GC agreed that the impact of environmental factors upon the availability and reliability should be considered. The GC expressed support for information from a range of sources to be evaluated and incorporated in a brief assessment, for variability in functioning across settings to be considered, for relevant history to be reviewed and for staff to be able to appraise the reliability and validity of data sources and use measures developed in or adapted for people with learning disabilities.
- The GC agreed that referrers should make sure that they provide enough information to the service to be able to make an informed decision. The GC expressed support for staff to agree outcome measures with the service user at this stage, and for the identification of realistic and optimistic short- and medium-term goals.
- The GC decided that a care plan should be developed collaboratively as soon as possible and communicated in an appropriate format and timely fashion, should be informed by brief assessment, the resulting formulation and the

service user's goals, should identify appropriate evidence-based interventions, should include adaptations to the environment if necessary, should take into account the needs of families and carers, should incorporate risk and crisis management plans and should identify the roles and responsibilities of all involved parties. The GC expressed support for the involvement of carers and advocates to explain feedback to the service user after a brief assessment.

- The GC agreed that a brief assessment should inform routine outcome monitoring and establish a timetable for review of goals. The GC expressed support for the selection of outcome measures to detect changes in targeted areas and for systems to be developed for routine data sharing between agencies to reduce replication of effort.

4.5.4.2 Comprehensive assessment

- In terms of principles of the assessment the GC agreed that a comprehensive assessment should be understood in context, draw on a wide range of sources, confidentiality should be clearly explained prior to assessment, a summary should be provided which lists implications and an appointment should be offered to discuss this, should have an identified outcome and agreed review date and be updated as further information emerges. The GC agreed that it is important to consider symptom severity and service-user understanding and adapt to these, beware of diagnostic overshadowing and unusual presentations in people with specific syndromes, take into account the impact of neurodevelopmental disorders on presentation and possible confusion between symptoms of physical health and mental health problems. They also agreed that it should consider drug or alcohol misuse as either a problem or contributor to other disorders.
- The GC agreed that the assessment should be collaborative, maximise everyone's involvement and may need to involve someone known to the service-user to enable this and should result in a collaborative formulation. They agreed that families and carers should be involved if appropriate, that format for feedback and procedures for information-sharing should be agreed in advance, that reasons for differences in opinion should be clarified and that the assessment process should be conducted in a way that ensures the service-user is comfortable asking questions.
- Regarding accessibility the GC agreed that the environment should be free from unnecessary distractions, that the assessment should be adapted adequately to the person's needs and stress level including in its' pace, should facilitate communication and understanding with aids and clear unambiguous language, should be responsive to new concerns, should take into account the impact of neurodevelopmental conditions on mental health presentation and session participation and should be conducted by staff competent in communicating with people with sensory and communication impairments. The GC expressed agreement with the need to use tools such as a visual timeline to explain the assessment process.
- The GC agreed that the assessment should use validated tools, that if the tools have not been adapted or developed specifically for people with learning disabilities that this should be taken into account in their interpretation and that a record of assessment content and outcome should be maintained.
- The GC agreed that the purpose of the assessment and the way that data will be used should be transparent, that the assessment should seek to increase understanding of the problem by determining its' nature, duration and severity and assessing multiple areas of need, including coexisting health problems, resulting in a diagnosis or problem specification and understanding of how the mental health problem may impact upon treatment. The GC expressed

agreement with the need for a reassessment to occur on transfer between or out of care settings.

- The GC agreed that a risk assessment should always be considered and if conducted should include assessment of a range of relevant environmental and service user factors as well as vulnerability to exploitation, safeguarding concerns, risk to self and others, the nature and severity of risky behaviours and triggers and likelihood of adverse events, and result in a risk plan which is communicated to relevant services. The GC expressed support for risk assessments always being part of a comprehensive assessment and for risk management plans always identifying interventions and protective factors that may reduce risk.
- The GC decided that a formulation is a key component of an assessment and should provide a shared understanding of the issue and factors leading to its' development and maintenance and therefore an agreement on the focus and impact of interventions, including barriers to engaging in these, as well as considering risk factors and the impact of the environment.
- The GC decided that the assessment should be completed by multidisciplinary team staff including a specialist in learning disability, who should understand diagnostic classification systems including their limitations and the concept of diagnostic overshadowing and who are competent in the use of a range of relevant assessment methods and tools and outcome measures, and that staff should use reliable pre-existing data as far as possible to avoid duplication of effort. The GC expressed support for comprehensive assessments being conducted only by a clinician with specialist knowledge.
- The GC decided that the assessment should seek the views of and information from people involved in the care of the service user where possible but that the clinician should additionally ensure that they speak to the service user alone to elicit safeguarding concerns. The GC expressed support for eliciting service user's views and corroborating these with those of families, carers and involved professionals.
- The GC decided that the assessment should aim to capture a baseline of typical behaviour for the person for comparison, should capture information from a range of sources and the clinician should evaluate the reliability and validity of these, should review relevant past history and behaviour, consider changes in functioning across settings and the impact of environmental factors on data availability and reliability. The GC expressed support for the need to use measures developed in or adapted for learning disabled populations in the assessment where possible.
- Regarding outcomes of the assessment the GC decided that appropriate outcome measures to evaluate the care plan should be agreed, that realistic and optimistic short and medium-term goals should be established and that sufficient information should be provided when making a referral. The GC expressed support for the need to identify realistic and optimistic long-term goals, prioritising these to start with the areas most amenable to change.
- The GC decided that the care plan should be developed as soon as possible and informed by the multidisciplinary team assessment, formulation and collaborative discussion with the service-user and family of intervention options, that these should be communicated in an appropriate format and timely manner, possibly involving a family member, carer or advocate to help explain feedback adequately. The GC decided that the care plan should include a profile of the service-user's needs, take into account the needs of families and carers, incorporate risk and crisis management plans where appropriate and identify roles and responsibilities of involved individuals. The

GC expressed support for the care plan identifying appropriate evidence-based interventions.

- With regards to referral to other services the GC decided that the assessment should identify appropriate referral and treatment options in line with relevant NICE guidance.
- The GC decided that the assessment should inform routine monitoring of outcomes and choice of measures that are designed to detect change in targeted areas, should establish a timetable for review of progress, and that systems should be developed for routine data sharing between relevant agencies to avoid duplication of effort.

4.5.5 Clinical evidence statements on formal assessment methods/instruments

4.5.5.1 Adults

4.5.5.1.1 General measures of mental health problems

4.5.5.1.1.1 Diagnostic Assessment for the Severely Handicapped-II

- Low to moderate quality evidence from 2 studies (N =91) reported adequate sensitivity and specificity in people with severe or profound disabilities on the mania subscale of the DASH-II, but not on other subscales; internal consistency was also adequate but convergent validity varied for the subscales.

4.5.5.1.1.2 Mood and Anxiety Semi-structured Interview (MASS)

- High quality evidence from 1 study (N=93) on adult inpatients with all degrees of learning disabilities found adequate sensitivity and specificity for 'any anxiety disorder' subscale on the MASS but only had adequate specificity for identifying a manic episode and adequate sensitivity for identifying a major depressive episode. These values were found to be inadequate for generalised anxiety disorder.

4.5.5.1.1.3 Psychiatric Assessment Schedule for Adults with Developmental Disabilities (PAS-ADD) – Interview

- Moderate to high quality evidence from across 2 studies (N=175) showed varied results on an older version of the PAS-ADD Interview subscales (but no composite scores were reported): sensitivity ranged from 75% on the depression subscale to 100% on the anxiety disorders subscale and specificity ranged from 64% on the neurotic symptoms subscale to 88% on the schizophrenia and depression subscales.

4.5.5.1.1.4 Psychiatric Assessment Schedule for Adults with Developmental Disabilities (PAS-ADD) – Checklist

- Moderate to high quality evidence from 3 studies (N=372) reported various results. One study showed 1 subscale (affective/neurotic) had sub-adequate results (66% sensitivity and 70% specificity). Only 1 study looking at the French version of the PAS-ADD Checklist reported diagnostic accuracy on the composite score showing poor sensitivity and specificity in a population of adults with all degrees of learning disabilities. Internal consistency on the subscales was generally adequate but inter-rater reliability was variable.

4.5.5.1.1.5 Psychiatric Assessment Schedule for Adults with Developmental Disabilities (PAS-ADD) – Mini

- Moderate quality evidence from 3 studies (N=631) showed somewhat mixed results for the PAS-ADD Mini: 1 study in people with mild to moderate learning disabilities reported adequate sensitivity on the composite score but inadequate specificity; another reported both were adequate when comparing to the reference standard of a psychiatrist across the spectrum of learning disabilities but sensitivity and specificity were both inadequate when compared to a diagnosis made by a community support team; a Dutch version reported adequate specificity on most subscales when used across the spectrum of learning disabilities but inadequate sensitivity on all subscales. Internal consistency ranged from unreliable to relatively reliable across the studies and subscales.

4.5.5.1.1.6 Psychopathology Inventory for Mentally Retarded Adults (PIMRA)

- Low to moderate quality evidence from 3 studies (N=237) reported mostly adequate internal consistency and inter-rater reliability across the studies in people with learning disabilities on the PIMRA. A Swedish version of the tool reported adequate specificity overall and on the psychosis and hallucination subscales but inadequate on the adjustment/anxiety scale; sensitivity was inadequate overall and on all but the hallucinations subscale.

4.5.5.1.1.7 Psychopathology Checklists for Adults with Intellectual Disabilities (P-AID)

- Very low quality evidence from 1 study (N=35) reported adequate internal consistency on the P-AID but inadequate inter-rater reliability for most subscales across the spectrum of learning disabilities; sensitivity and specificity were inadequate but the specificity was adequate when considering a population with a history of psychopathology.

4.5.5.1.1.8 Strengths and Difficulties Questionnaire (SDQ)

- High quality evidence from 1 study (N=125) showed the SDQ to have poor results in an adult population with learning disabilities, in terms of area under the ROC curve.

4.5.5.1.2 Depression

4.5.5.1.2.1 Child Depression Inventory (CDI)

- Moderate quality evidence from 1 study (N=115) showed adequate internal consistency and inter-rater agreement on the CDI in a population of adults with learning disabilities. The CDI had adequate sensitivity and specificity using a cut-off of 13 but the sensitivity lowered to being no longer adequate with a cut-off of 17.

4.5.5.1.2.2 Glasgow Depression Scale for People with a Learning Disability (GDS-LD) and GDS Carer Supplement (-CS)

- Moderate quality evidence from 1 study (N=65) showed the GDS-LD (the self-report version) had adequate sensitivity and specificity at both a cut off of 13 and 15 in a population with mild to moderate learning disabilities. Internal consistency, test-retest reliability and inter-rater reliability was adequate on both the self-report and carer supplement.

4.5.5.1.3 Dementia

4.5.5.1.3.1 Test for Severe Impairment (TSI)

- High quality evidence from 1 study (N=60) showed the TSI had adequate internal consistency, inter-rater reliability, test-retest reliability, and concurrent validity against ICD-10 diagnoses in a population of people with moderate to severe learning disabilities.

4.5.5.1.3.2 Dementia Screening Questionnaire for Individuals with Intellectual Disabilities

- Moderate to high quality evidence from 2 studies (N=316) showed the DSQIID had adequate specificity and sensitivity at cut offs of 20 or 22 across all levels of learning disability; internal consistency, test-retest reliability and inter-rater reliability were also adequate.

4.5.5.1.3.3 Dementia Questionnaire for Persons with Mental Retardation (DMR)

- High quality evidence from 1 study (N=62) showed the DMR had adequate specificity and sensitivity in people with learning disabilities.

4.5.5.1.3.4 Down Syndrome Dementia Scale (DSDS)

- High quality evidence from 1 study (N=62) showed the DSDS had adequate specificity and sensitivity in people with learning disabilities.

4.5.5.1.4 Assessment of risk

4.5.5.1.4.1 Historical, Clinical, Risk Management – 20 item scale

- Moderate to high quality evidence from 4 studies (N=211) reported somewhat mixed results on the adequacy of the HCR-20 to predict violence in people with mild to moderate learning disabilities.
  - One study reported the tool was fair at predicting any physical aggression and good at predicting severe physical aggression over 6 months.
  - One study reported the tool had poor to fair discrimination at predicting violence over 12 months among people in a secure ward; after 2 years, the tool was poor at predicting negative progress and was not discriminate at predicting positive progress; however, there were very wide intervals so there is limited confidence in the result.
  - Another study reported excellent ability of the intellectual disability supplement of the HCR-20 to predict general recidivism in individuals classified as moderate to high risk who were not in custody and a fair ability to predict violent recidivism.
  - Overall, the HCR-20 ranged from unreliable to marginally reliable in this population.

4.5.5.1.4.2 Psychopathy Checklist – Revised (PCL-R)

- Moderate to high quality evidence from 3 studies (N=186) reported the PCL-R to be relatively reliable in people with learning disabilities in terms of inter-rater reliability and internal consistency. However the outcomes across the studies were less clear about its ability to predict aggression or violence and there was uncertainty in the results from each study: 1 study reported the tool had very poor ability to predict aggressive events after 1 or 2 years in people with mild to moderate learning disabilities and another study showed the tool to be marginally reliable at predicting violence in people with mild to severe learning disabilities.

4.5.5.1.4.3 Psychopathy Checklist – Screening version (PCL-SV)

- Moderate quality evidence from 1 study (N=60) shoed the PCL-SV to be marginally reliable in people with mild to severe learning disabilities, but there was uncertainty in this result.

4.5.5.1.4.4 Violence Risk Appraisal Guide (VRAG)

- High quality evidence from 2 studies (N=82) reported that the VRAG was good or excellent in predicting violence in people with mild to moderate learning disabilities. However, there was poor inter-rater reliability.

4.5.5.2 Children

4.5.5.2.1 General measures of mental health problems

4.5.5.2.1.1 Development Behaviour Checklist – Parent (DBC-P)

- Moderate quality evidence from 1 study (N=664) showed that the DBC-P was excellent and reliable at detecting emotional or behavioural problems in children with mild to severe learning disabilities.

4.5.6 Economic evidence statements

No evidence on the cost effectiveness of key components of, and the most appropriate structure for, an assessment of mental health problems in people with learning disabilities is available.

4.6 Recommendations and link to evidence

Recommendations	**Conducting a mental health assessment** **6. A professional with expertise in mental health problems in people with learning disabilities should coordinate the mental health assessment, and conduct it with:** • **the person with the mental health problem, in a place familiar to them if possible, and help them to prepare for it if needed** • **the person’s family members, carers or care workers (as appropriate)** • **other professionals (if needed) who are competent in using a range of assessment tools and methods with people with learning disabilities and mental health problems.** **7. Speak to the person on their own to find out if they have any concerns (including safeguarding concerns) that they don’t want to talk about in front of their family members, carers or care workers.** **8. Before mental health assessments:** • **agree a clear objective, and explain it to the person, their family members, carers or care workers (as appropriate),**

and all professionals involved

- **explain the nature and duration of the assessment to everyone involved**
- **explain the need to ask certain sensitive questions**
- **address any queries or concerns that the person may have about the assessment process.**

9. When conducting mental health assessments, be aware:

- **that an underlying physical health condition may be causing the problem**
- **that a physical health condition or cognitive impairment may mask an underlying mental health problem**
- **that mental health problems can present differently in people with more severe learning disabilities**

10. When conducting mental health assessments, take into account:

- **the person's level of distress**
- **the person's understanding of the problem**
- **the person's living arrangements and settings where they receive care**
- **the person's strengths and needs.**

11. During mental health assessments:

- **establish specific areas of need to focus on**
- **assess all potential psychopathology, and not just the symptoms and signs that the person and their family members, carers or care workers first report**
- **describe the nature, duration and severity of the presenting mental health problem**
- **review psychiatric and medical history, past treatments and response**
- **review physical health problems and any current medication**
- **review the nature and degree of the learning disabilities, including behavioural phenotypes (for example, autism and**

Prader–Willi syndrome)

- **assess the person’s family and social circumstances and environment, and recent life events**
- **assess the level of drug or alcohol use as a potential problem in itself and as a factor contributing to other mental health problems**
- **establish or review a diagnosis using:**
    - **a classification system, such as those adapted for learning disabilities (for example the Diagnostic Manual – Intellectual Disability [DM-ID] or Diagnostic Criteria for Psychiatric Disorders for Use with Adults with Learning Disabilities/Mental Retardation [DC-LD])** ***or***
    - **problem specification**
    - **assess whether a risk assessment is needed (see recommendation 27).**

12. Assess recent changes in behaviour using information from family members, carers or staff, and information from relevant records and previous assessments. Take into account the nature, quality and length of their relationship with the person.

13. Use the results of the mental health assessment to develop a written statement (formulation) of the mental health problem, which should form the basis of the care plan (see recommendation 28) and cover:

- **an understanding of the nature of the problem and its development**
- **precipitating and maintaining factors**
- **any protective factors**
- **the potential benefits, side effects and harms of any interventions**
- **the potential difficulties with delivering interventions**
- **the adjustments needed to deliver interventions**
- **the impact of the mental health problem and associated risk factors on providing care and treatment.**

14. Provide the person, their family members, carers or care workers (as appropriate), and all relevant professionals with a summary of the assessment:

- **in an agreed format and language**
- **that sets out the implications for care and treatment.**

15. Give the person and their family members, carers or care workers (as appropriate) another chance to discuss the assessment after it has finished, for example at a follow-up appointment.

Further assessment

16. Consider conducting a further assessment that covers any areas not explored by the initial assessment, if:

- **new information emerges about the person's mental health problem *or***
- **there are significant differences between the views of the person and the views of their family members, carers, care workers or staff about the problems that the assessment has focused on.**

Assessment tools

17. During any mental health assessment:

- **consider using tools that have been developed or adapted for people with learning disabilities *and***
- **take cost into account if more than one suitable tool is available.**

18. If using tools that have not been developed or adapted for people with learning disabilities, take this into account when interpreting the results.

19. When assessing an adult with learning disabilities, consider using tools such as the Mini Psychiatric Assessment Schedules for Adults with Developmental Disabilities (Mini PAS-ADD) to support a clinical assessment.

20. When assessing a child or young person with learning disabilities, consider using tools such as the Developmental Behavior Checklist – parent version (DBC-P) or the Strengths and Difficulties Questionnaire (SDQ).

21. When assessing depressive symptoms in an adult with learning disabilities, consider using a formal measure of depression to monitor change over time, such as the Glasgow Depression Scale (the self-report for people with mild or moderate learning disabilities or the carer supplement for people with any degree of learning

	disabilities). 22. Consider supplementing an assessment of dementia with an adult with learning disabilities with: • measures of symptoms, such as the Dementia Questionnaire for People with Learning Disabilities (DLD), the Down Syndrome Dementia Scale (DSDS) or, the Dementia Screening Questionnaire for Individuals with Intellectual Disabilities (DSQIID) and • measures of cognitive function to monitor changes over time, such as the Test for Severe Impairment (TSI) • measures of adaptive function to monitor changes over time. 23. Designated practitioners in specialist learning disabilities services should complete a baseline assessment of adaptive behaviour with all adults with Down's syndrome who are receiving care from the service. Risk assessment 24. When conducting risk assessments with people with learning disabilities and mental health problems, assess: • risk to self • risk to others (including sexual offending) • risk of self-neglect • vulnerability to exploitation • potential triggers • causal and maintaining factors • whether safeguarding protocols should be implemented • the likelihood and severity of any particular risk. 25. Repeat risk assessments regularly. 26. If indicated by the risk assessment, develop a risk management plan with the person and their family members, carers or care workers (as appropriate). 27. Risk management plans should: • set out individual, social or environmental interventions to

	reduce risk • **be communicated to family members, carers or care workers (as appropriate) and all relevant staff and agencies** • **be reviewed regularly and adjusted if risk levels change.** **The mental health care plan** **28. Develop a mental health care plan with each person with learning disabilities and a mental health problem and their family members, carers or care workers (as appropriate), and integrate it into their other care plans.** **29. Base mental health care plans on the written statement (formulation) and include in them:** • **goals agreed with the person and the steps to achieve them** • **treatment decisions** • **agreed outcome measures that are realistic and meaningful to the person, to monitor progress** • **risk and crisis care plans, if needed** • **steps to minimise future problems.** **30. Ensure that the mental health care plan sets out the roles and responsibilities of everyone involved in delivering it, and that:** • **the person can easily access all interventions and services in the plan** • **it is communicated to everyone involved, including the person and their family members, carers or care workers (as appropriate)** • **there is an agreement on when the plan will be reviewed.**
Relative values of different outcomes	The GC discussed the importance and relevance of the purpose and outcome of the assessment of need and of risk. In doing so they took in to account the time needed to undertake the assessment, the skills and knowledge required to complete the assessment, the resources required and which individual might need to be involved. In addition they considered what assessment tools might help inform the assessment process, whether these tools may have value in monitoring the outcome of any interventions and the reliability, validity and sensitivity to change of the tools (validity, sensitivity, specificity were considered critical outcomes). The GC also used their expert knowledge to inform the overall structure of the assessment process with a particular emphasis on ensuring that the outcomes of the assessment were integrated with the existing care planning and reviews systems that operate in services for people with learning disabilities.

Trade-off between clinical benefits and harms	No evidence was found to address the most appropriate content and structure for an assessment of mental health problem, the GC agreed to develop recommendations using formal consensus methods. However, evidence was identified on the use of various tools for assessing mental health problems in this population. Many studies combined different levels of learning disabilities so it was difficult to determine the differential psychometric properties of the tools by level of learning disability. Only 1 study (Einfeld & Tonge, 1995) considering a single tool (DBC-P) specifically looked at the use of tools in children; all others considered adults. **General measures of mental health problems – children** The DBC-P was found to have good diagnostic accuracy at identifying emotional and behavioural problems in children and young people with learning disabilities so the GC agreed to recommend the tool. While the SDQ had poor quality in adults (see below), the SDQ has been validated in a large number studies of mental health problems including children with a range of developmental and physical disorders (Goodman, 2001) and has excellent psychometric properties in this context. In view of this, the GC drawing on their expert judgement decided to recommend the use of the SDQ in the assessment process for children and young people. It also has the advantage of having versions that can be self-completed or by a parent / carer and teacher. **General measures of mental health problems – adults** It was difficult to compare tools given the variety of outcomes reported in the studies. However, the evidence suggested that the DASH-II had good diagnostic accuracy on the mania subscale only. The MASS had better diagnostic accuracy for any anxiety disorder and on the depression subscales, but lower sensitivity on the GAD and mania subscales. The PAS-ADD interview had relatively good diagnostic accuracy on anxiety disorders subscale but the neurotic symptoms, depression and schizophrenia subscales were not as good. Also, the GC noted that the evidence on the PAS-ADD interview was on an earlier version of the tool that is currently available. The GC also noted that the PAS-ADD interview is a very long interview (lasting 3 hours) and that it focuses on descriptive phenomenology. However, the PAS-ADD Mini was shorter and could be used by a broader range of professional staff than the PAS-ADD interview. The evidence on the PAS-ADD Mini was generally adequate on both sensitivity and specificity, when using a psychiatric diagnosis as a reference standard. The PAS-ADD checklist had little evidence supporting the use and was viewed by the GC as essentially a screening instrument and, therefore, not suitable for assessment purposes. The GC were of the view that the PAS-ADD Mini could add to both the structure and content of a fuller assessment. As there is less evidence about the use of the PAS-ADD checklist, it was not recommended. The PIMRA was also a screening instrument and although it has reasonable psychometric properties the GC were of the view that it would not contribute much to the assessment process. The P-AID is a series (18) of symptom/behavioural checklist; it has relatively poor psychometric properties and was not viewed by the GC as likely to make a significant contribution to the assessment process. One study examined the use of SDQ in adults with learning disabilities and it performed poorly which, given that it is measure developed for children and young people, is not surprising. **Depression** The GC were interested in measures of symptomatology which could inform an assessment and which may also serve as a tool for routine outcome monitoring. Given the time constraints inherent in routine outcome

monitoring this favours the use of measure which focus either on single domains of symptomatology (e.g. depression) or provide a brief global rating of outcomes. The review of the literature identified only 2 such measures both of which were measures of depressive symptoms. After reviewing the evidence on the 2 measures of depressive symptoms were the GC decided to recommend the GDS-LD and the GDS-CS for use in children and young people, and adults. It had good psychometric properties and the GC took the view it could be of value in both the assessment of depressive symptoms and their routine monitoring. While the study included participants with mild to moderate learning disabilities, the GC considered that it would be reasonable to expect the carer supplement of the GDS (the GDS-CS) would be appropriate for people with severe or profound learning disabilities as it was being completed by a carer.

Dementia

The identification, diagnosis and assessment of dementia present particular challenges in people with learning difficulties. Dementia is more common in people with learning disabilities than in the general population, and particularly so for people with Down syndrome. Existing cognitive deficits mean that standard instruments cannot be used. The GC therefore looked carefully at the existing measures to see how they could help in addressing these issues. The DSQIID and the DMR are both carer focused screening measures of dementia psychopathology with the evidence showing both had good psychometric properties which could be used to inform an assessment, particularly carer input into the process. Both appear use across the range of disabilities and can be used for people with Down’s syndrome. The Down Syndrome Dementia Scale (DSDS) is a clinician-rated questionnaire measure of dementia symptoms designed for use in people with Down’s syndrome but which the GC consider may have use beyond just people with Downs syndrome. The evidence showed it also has reasonable psychometric properties. The Test for Severe Impairment (TSI) is a clinician-administered measure of cognitive function. The measure is not specifically designed for people with learning disabilities but the GC considered that it would be useful as a measure of change in cognitive function over time in people with learning disabilities. Again the evidence showed that it has reasonable psychometric properties.

Assessment of risk

Several tools were identified which assessed risk but all of these were instruments designed for use in forensic environments and were particularly concerned with the prediction of violence. They did not look at risk to self or self-neglect or exploitation. Given the focus of the guideline on mental health the GC decided not to recommend these measures but instead developed the recommendations for risk assessment by informal consensus drawing on their expert knowledge and experience.

Adaptive function/behaviour

While the evidence was searched for a number of tools measuring adaptive function or behaviour, there was no evidence found on these tools that met the inclusion criteria specified in the protocol. However, the GC agreed that it would be inappropriate not to recommend a measure of adaptive function to monitor changes over time, particularly for dementia. As such, they developed a recommendation in this area through informal consensus that adaptive function should be measured to monitor changes over time in people diagnosed with dementia but they were unable to recommend a specific tool for this use. However, given the lack of evidence to make a specific recommendation about a tool for adaptive function, they considered that the judgement about which tool to use should be made by the specialist who are monitoring changes over time in the person with dementia.

	The GC noted that it was important to have tools with higher sensitivity in order to prevent the harms associated with not identifying and treating mental health problems. Many of the tools reviewed did not have high sensitivity in order to adequately identify mental health problems and this is why few tools were recommended.
Trade-off between net health benefits and resource use	Formal assessment of a mental health problem in people with learning disabilities is likely to have important resource implications. However, the GC expressed the view that comprehensive, effective assessment followed by the development of an appropriate mental health care plan will allow more timely, appropriate and cost-effective management of the mental health problem, that is targeted to the specific needs of the person with learning disabilities and thus can result in cost-savings that offset, fully or partially, the costs associated with assessment. In contrast, inadequate assessment may lead to sub-optimal, less clinically and cost-effective care pathways and inappropriate treatments, ultimately leading to sub-optimal outcomes for the person and higher health and social care costs. Regarding the specific resource implications associated with formal assessment of a mental health problem in people with learning disabilities, the GC advised that the assessment needs to be co-ordinated by a clinician with expertise in mental health problems in this population, to ensure appropriate assessment according to the service user's individual needs and circumstances. The GC acknowledged that the assessment may require a considerable amount of staff time and incur a range of costs that are determined by: - the time the clinician needs to spend with the person, their family, carers and care workers before the assessment in order to explain to them the process and agree on the goals of the assessment; the GC expressed the opinion that this component has small resource implications and is essential for the successful conduct of the assessment - the time it takes to review the person's previous history (both physical and mental health) and personal circumstances, which, according to the GC, has modest resource implications but is also essential in the assessment of the person's mental health problem and the development of a mental health care plan - the time it takes to complete the formal assessment questionnaire(s), selected according to the age of the person, their level of learning disability and the mental health condition assessed. The GC noted that completion time varies considerably across assessment tools; for example, the PAS-ADD – Interview takes approximately 3 hours to administer whereas the DASH-II takes 10-15 minutes to complete. Therefore, this part of the assessment, if conducted by the clinician and the tool is not self- or carer-administered, is likely to bear important resource implications in terms of staff time. The GC considered the completion times when recommending formal assessment tools. Moreover, the GC noted that many of the tools available for the assessment come with a cost associated with training, examiner manuals, licences and testing materials. The GC decided to recommend that this cost be taken into account if more than 1 suitable tools are available, so that tools available for free or at a small cost be used, if suitable - the need for a follow-up appointment if the person with the mental health problem or their family need to discuss further. The GC expressed the view that such a follow-up appointment was not essential for an effective assessment but had minor resource implications and was important to ensure the person's and family's understanding and trust in the process, therefore leading to better acceptability of diagnosis and adherence to future care relating to the mental health problem. - the need for further assessment if new information emerged about the person's mental health problem or if there were significant differences between the views of the person and the views of their family members,

	carers, care workers or staff regarding the mental health problem that is the focus of the assessment. The GC acknowledged that further assessment entails extra resource implications but considered it an integral part of an effective and cost-effective assessment, for those who meet criteria for it. - the potential need for an initial and repeat risk assessments; these require extra clinician's time but the GC decided to make recommendations considering safety issues and the need for minimisation of the risk for the person and their environment. - the time required to developing an initial written formulation of the mental health problem and a mental health care plan, which the GC deemed as a prerequisite for the clinically and cost-effective planning and delivery of appropriate care that meets the needs of the person. The GC expressed the view that the above components were essential for the effective assessment of a mental health problem in people with learning disabilities and that, on equality grounds, people with learning disabilities should have access to effective assessment of their mental health problems as people with mental health problems without learning disabilities. Assessment of mental health problems may cause distress to people with learning disabilities. The GC expressed the view that, where possible, the assessment should be conducted in a place (e.g. room) within the care setting where the person with learning disabilities may have been familiar with, so that the level of distress is minimised. Conducting assessments in places people with learning disabilities are familiar with, where possible, would not incur any extra resource implications.
Quality of evidence	The evidence was limited, studies were small in size and some had restricted samples (for example, people with Down's syndrome). In most cases for those measures recommended the psychometric properties were acceptable. However, there were notable gaps in the evidence including: very limited evidence for children (here, the GC chose to recommend the SDQ as it is common practice in other populations with neurodevelopmental problems, such as autism). In other cases, the evidence on risk assessment was confined to violence assessment in forensic settings and there was an absence of evidence on the structure of the assessment process and so in these cases the GC used both formal and informal consensus methods to develop recommendations.
Other considerations	The group noted that no studies were identified which met the inclusion criteria for other areas (including anger, personality disorders, post-traumatic stress disorder, trauma, and the assessment of communication). The GC decided not to make any recommendations other than referring to relevant NICE guidelines for those disorders where effective implementation of the assessment and intervention recommendations requires, that practitioners follow advice on assessment and outcome measures provided in the guideline. Given the lack of high quality evidence demonstrating valid and reliable tools, the GC decided to recommend research into the development and validation of tools for assessment of mental health problems in this population. **Brief and Comprehensive Assessment** While the assessment process was originally split into brief and comprehensive assessment, after reviewing the outcome of the nominal group technique the GC decided this was not an appropriate delineation of the assessment process and was amended (see section 4.5.1 for further details). The GC noted that conducting assessments in a setting that is familiar to the

	person may reduce feelings of distress. They noted that this may not always be possible but that it is generally standard practice so is not likely to incur extra resources so agreed it was appropriate to include a recommendation on this.

4.6.1 Research recommendations

2. Development of and validation (including diagnosis) of assessment tools for mental health problems in people with learning disabilities.

5 Psychological interventions

5.1 Introduction

People with learning disabilities are more likely than people in the general population to experience living circumstances and life events associated with an increased risk of mental health problems, including birth trauma, stressful family circumstances, unemployment, deprivation, stigmatisation, lack of self-determination, and a lack of supportive friendships and intimate relationships (Cooper et al., 2007f; Martorell et al., 2009). In addition, people in this population are likely to have fewer psychological resources available to cope effectively with stressful events, including poorer problem-solving and planning skills associated with their cognitive impairments (van den Hout, 2000).

Over the last 30 years psychological therapies, especially cognitive behavioural therapy (CBT), have become established in the treatment of common mental health problems and some severe mental health problems such as psychosis (Department of Health, 2011). Many therapists have been reluctant, however, to offer these therapies to people with intellectual disabilities (Stenfert Kroese, 1998) because of the different challenges that come with developing a collaborative working relationship, and the difficulties of achieving treatment gains. Bender (1993) used the term the ‘the unoffered chair’ to describe this ‘therapeutic disdain’.

Recently there has been more professional interest in and research on the application of psychological therapies with people with learning disabilities (Taylor, 2013), but the supporting research is limited compared with that on the general population (Gustafsson et al., 2009; Prout & Browning, 2011). The most researched area with this population is that of anger associated with aggression and violence (Nicoll et al., 2013; Taylor & Novaco, 2013). This topic was covered in the NICE guidance on challenging behaviour and learning disabilities, which recommends that cognitive behavioural interventions are considered for adults with anger management problems (NICE, 2015; p255).

In relation to other mental health and emotional problems, effective psychological interventions for people with learning disabilities are based on careful assessment and individual formulation, as they are for other patient groups (Hatton, 2010). Beyond this, therapists will need to consider appropriate adaptations to the therapy environment and treatment framework, to enable people with learning disabilities to access and benefit from psychological therapies (Dagnan et al., 2013). In addition, modifications to the treatment interventions (manuals and protocols) will be required for clients with learning disabilities, and these adjustments will depend on the nature and degree of the impairments associated with each person’s learning disabilities (Lindsay et al., 2013). Therapists should adopt a functional approach to the adaptations and modifications that are required to enable people with learning disabilities to engage effectively in psychological therapy rather than basing judgements about an individual’s suitability for a particular intervention on their IQ measurement or global level of functioning (for example, mild or moderate learning disabilities).

In this chapter, recommendations are given for adaptations and modifications to psychological interventions that may be required for people with learning disabilities. Further recommendations are made for adapted interventions that should be considered for particular mental health problems experienced by people with learning disabilities based on the available research evidence.

5.2 Review questions: In people (children, young people and adults) with learning disabilities, do psychological interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do psychological interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summaries, including the review questions and the eligibility criteria used for this section of the guideline, can be found in Table 22 and Table 23. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 22: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do psychological interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.1)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any psychological intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, and controlled before and after studies and cohort studies.

Table 23: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do psychological interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.1)
Population	People (children, young people and adults) with learning disabilities

Component	Description
	and mental health problems.
Intervention(s)	Any psychological intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

5.2.1 Group consensus for adaptations to psychological interventions

As a result of limited quality evidence (section 5.2.2 below), the group decided to develop a set of general principles for adapting psychological treatments developed for people without a learning disability so that such interventions can be delivered to people with learning disabilities. They developed these recommendations using the modified nominal group technique.

The modified nominal group technique used in this guideline is described in Chapter 3.

Key issues relating to the types of adaptations required when conducting psychological interventions to treat mental health problems in people with learning disabilities were identified by reviewing the available evidence (for example Hassiotis et al., 2013; Lindsay et al., 2015) and through GC meeting discussions. These sources were used to generate nominal statements to be rated by the GC. As the GC agreed that they did not have the sufficient expertise in psychological interventions, they identified practicing expert clinical psychologists to act as expert advisors. The expert advisors were asked initially simply to review the draft nominal statements. Following feedback from the advisors and consequent amendment, the nominal statements were distributed to the GC in the form of a questionnaire (round 1), for rating and comment.

Percentage agreement was calculated for each statement and comments were collated. The results were then presented and discussed. On initial review, the GC decided that the existing statements were not comprehensive and as not all expert advisers had responded on the first statements, the set of statements was re-generated using the comments and discussions of the GC members, as well as input from the advisors. These were again distributed in questionnaire format (round 2), for rating and comment. As the statements applied to interventions for people with mild and moderate learning disabilities, a separate set of statements were adapted for people with severe and profound learning disabilities, using the comments and discussions of the GC members, as well as input from the advisors.

5.2.1.1 Mild to moderate learning disabilities (round 2)

As before, percentage agreement was calculated for each statement and comments collated. An example of a statement that was rated highly by the committee is: ‘The choice of intervention and introduction of adaptations should be informed by the person’s strengths and needs identified during assessment, drawing on areas of relative strength as much as possible'. Recommendations were then produced on the basis of statements with moderate to high agreement, or those with lower agreement where any issues identified by the GC could be easily addressed in the wording of recommendations. The results of round 2, and the resulting recommendations were then presented and discussed. A brief summary of this process is depicted in Table 24 below. A complete list of statements and ratings can be found in Appendix U and blank copies of questionnaires used can be found in Appendix T.

Table 24: Summary of nominal group technique process followed for the development of recommendations on adaptations to psychological interventions for mental health problems in people with mild to moderate learning disabilities

Round 1		Round 2		Resulting recommendations generated
Level of agreement	Statements N (Total=24)	Level of agreement	Statements N (Total=43)	5 recommendations
High	17	High	40	
Moderate	7	Moderate	3	
Low	0	Low	0	

5.2.1.2 Severe to profound learning disabilities

As above, percentage agreement was calculated for each statement and comments collated. An example of a statement that was rated highly by the committee is: 'For people with severe or profound learning disabilities, it may be particularly useful to help to manage the person's environment to reduce stressors or to help them to manage change'. Recommendations were then produced on the basis of statements with moderate to high agreement, or those with lower agreement where any issues identified by the GC could be easily addressed in the wording of recommendations. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member's comments. A second round of ratings was not deemed necessary as it was agreed by the GC that all important issues raised in the GC comments could be addressed in the wording of recommendations. A brief summary of this process is depicted in Table 25. A complete list of statements and ratings can be found in Appendix U and blank copies of questionnaires used can be found in Appendix T.

Table 25: Summary of nominal group technique process followed for the development of recommendations on adaptations to psychological interventions for mental health problems in people with severe to profound learning disabilities

Round 1		Round 2		Resulting recommendations generated
Level of agreement	Statements N (Total=5)	Level of agreement	Statements N (Total=0)	1 recommendation
High	3	High	n/a	
Moderate	2	Moderate	n/a	
Low	0	Low	n/a	

5.2.2 Clinical evidence

A small number of RCTs (N=10) were found on psychological interventions for the prevention or treatment and management of mental health problems. As many of these studies were pilot studies with very small numbers of participants and the GC were aware of the existence of a number of non-randomised controlled studies, these were also searched for. An existing and recent systematic review which included any controlled studies (randomised or not) was used to identify relevant studies and an update search was conducted (Vereenooghe & Langdon, 2013). All the non-randomised studies identified in this review were on anger or aggression which was addressed in the challenging behaviour guideline (NICE, 2015). The new searches identified 7 additional non-randomised controlled studies which have been included here (n=7).

Most studies were conducted in adults; 1 study was in children on the treatment of PTSD (Holstead & Dalton, 2013). Furthermore, most studies included people with mild to moderate learning disabilities.

5.2.2.1 Mixed mental health problems

5.2.2.1.1 Psychological interventions versus control: prevention or treatment

For this review, 3 RCTs (N =87) and 1 controlled before-and-after study (N=24) met the eligibility criteria: Matson 1981, Matson & Senatore 1981, Nezu 1991, and Lindsay 2015 (Lindsay et al., 2015; Matson, 1981; Matson & Senatore, 1981; Nezu, 1991). Psychological interventions used in the trials included social skills training, participant modelling/graded exposure, social problem solving followed by assertiveness, assertiveness followed by social problem solving, traditional psychotherapy, and cognitive behavioural therapy (CBT).

An overview of the trials included can be found in Table 26 and Table 27. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 28. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

Studies included were a combination of prevention and treatment. All participants in these trials had mild to moderate learning disabilities.

Of the 3 RCTs, 2 (Matson & Senatore, 1981; Nezu, 1991) were 3-armed trials. Data from each of the active arms compared with the control were included in the analysis (it was not possible to average the data for both active arms because of the way the data was reported in the studies).

It was not possible to conduct subgroup analyses with the limited number of studies included so a random effects model was used and the outcome was downgraded for inconsistency.

No data were available for the critical outcomes of community participation and quality of life.

Table 26: Study information table for RCTs included in the analysis of psychological interventions for mental health problems

	Social skills training versus control	**Traditional psychotherapy versus control**	**Social problem solving, then assertiveness versus control**	**Assertiveness training, then social problem solving versus control**	**Participant modelling versus waitlist control**
Total no. of studies (N[1])	1 (35)[2]	1 (35)[2]	1 (19)[4]	1 (19)[4]	1 (24)
Study ID	Matson & Senatore 1981	Matson & Senatore 1981	Nezu 1991	Nezu 1991	Matson 1981
Country	US	US	US	US	US
Diagnosis/ degree of learning disabilities	Mild to moderate[3]	Mild to moderate[3]	Mild[5]	Mild[5]	Mild to moderate[7]
Age (mean)	34 years	34 years	36 years	36 years	Not reported (all adults between 25 and 45)
Sex (% female)	35%	35%	36%	36%	50%
Ethnicity (% white)	Not reported	Not reported	92.9%	92.9%	Not reported
IQ (mean)	Not reported	Not reported	Not reported	Not reported	Not reported
Living arrangements	Community (with parents or in a group home)	Community (with parents or in a group home)	Not reported	Not reported	Community (group homes or independent living arrangements)
Coexisting conditions/ treatments received	3 had chronic schizophrenia stabilised with psychotropic drugs, 73% (23) had prior history of psychiatric	3 had chronic schizophrenia stabilised with psychotropic drugs, 73% (23) had prior history of psychiatric hospitalisation	9 taking antipsychotic medication, 2 benzodiazepines, 2 anti-seizure medication	9 taking antipsychotic medication, 2 benzodiazepines, 2 anti-seizure medication	58% had schizophrenia or some other neurosis

	Social skills training versus control	**Traditional psychotherapy versus control**	**Social problem solving, then assertiveness versus control**	**Assertiveness training, then social problem solving versus control**	**Participant modelling versus waitlist control**
	hospitalisation				
Targeted behaviour	All had deficits in interpersonal functioning ’Target behaviours’ (verbal), social competence and ‘psychotic characteristics’	All had deficits in interpersonal functioning ’Target behaviours’ (verbal), social competence and ‘psychotic characteristics’	Mixed[6]	Mixed[6]	Fear associated with activities in the community e.g. going to stores
Treatment length (weeks)	5 weeks	5 weeks	10 weeks	10 weeks	13 weeks
Intervention (mean dose; mg/day)	Social skills training: 2 weekly, 1-hour, group sessions aimed at specific ‘target behaviours’ such as increasing positive statements about others or decreasing complaining statements.	Traditional psychotherapy: 2 weekly, 1-hour, group sessions focussed on improving group cohesion and the expression of feelings.	Social problem solving: weekly 1-hour group sessions including systematic training in 5 problem-solving processes (problem orientation, problem definition and formulation, generation of alternative solutions, decision making, and solution implementation and verification) Assertiveness training: weekly 1-hour group sessions aimed at decreasing inhibition of assertive responding, focusing on substituting aggressive behaviour with assertive behaviour.		36 hours’ graded exposure: involving rehearsal and exposure to shopping in a community grocery store
Comparison	No treatment	No treatment	Waitlist (bimonthly supportive sessions)	Waitlist (bimonthly supportive sessions)	Waitlist control

Notes.

[1] Number randomised.

[2] Study has 3 arms with N=35: 11 waiting list control and 12 in each intervention group.

[3] Stanford-Binet test or WAIS and AAMD ABS (Grossman, 1977).

[4] Study has 3 arms with N=28: 10 waitlist control and 9 in each intervention group.

	Social skills training versus control	Traditional psychotherapy versus control	Social problem solving, then assertiveness versus control	Assertiveness training, then social problem solving versus control	Participant modelling versus waitlist control

[5] WAIS-R (1981) and ABS-revised (1975).

[6] Using PIMRA) with diagnoses including anxiety (n=7), schizophrenia (n=2), intermittent explosive disorder (n=4), adjustment disorder (n=3), various personality disorder (n=12) (all also presented with maladaptive social behaviour such as issues with anger control, verbal or physical aggression, destructive behaviour).

[7] Determined using the AAMD criteria.

AAMD = American Association for Mental Deficiency; ABS(-R) = Adaptive Behavior Scale (Revised); IQ = intelligence quotient; PIMRA = Psychopathology Instrument for Mentally Retarded Adults; WAIS(-R) = Wechsler Adult Intelligence Scale (Revised).

Table 27: Study information table for controlled before-and-after studies included in the analysis of psychological interventions versus control for mental health problems

	CBT versus control
Total no. of studies (N[1])	1 (24)
Study ID	Lindsay 2015
Country	UK
Diagnosis/degree of learning disabilities	Mild
Age (mean)	31
Sex (% female)	50
Ethnicity (% white)	Not reported
IQ (mean)	63.15
Living arrangements	Mixed
Coexisting conditions/treatments received	Not reported
Targeted behaviour	Mixed[2]
Treatment length (weeks)	10.75 (from 8-14)
Intervention (mean dose; mg/day)	Weekly trans-diagnostic individual CBT with assistance from significant other person (family member or carer) [3]
Comparison	Wait-list control (matched to those receiving intervention)

Notes.

[1] Number randomised.

[2] Diagnosis included 8 anxiety, 6 depression, 2 mixed anxiety and depression, 2 interpersonal conflict, 4 bereavement and anxiety and depression, 1 experience of sexual abuse with anxiety and depression.

[3] length of each weekly session not reported.

[4] all had capacity to consent and participate in the assessment but no IQ reported.

[5] 9 aggressive behaviour, 3 sexually inappropriate behaviour, 3 psychotic/bizarre behaviour, 1 relationship difficulties, 1 self-injury, 1 depression, 1 bulimia and 1 OCD.

CBT = cognitive behavioural therapy; IQ = intelligence quotient; N = total number of participants; OCD = obsessive–compulsive disorder.

Table 28: Summary of findings table for the analysis of psychological interventions versus control for mental health problems

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with psychological interventions
Mental health – (RCTs) assessed with: various scales follow up: mean 13.25 weeks	73 (3 RCTs)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 1.24 lower (2.31 lower to 0.18 lower)
Mental health – (controlled before-and-after studies) assessed with:	24 (1 observational study)	⊕◯◯◯ VERY LOW [3,4]	-	The mean mental health symptoms- (controlled before-and-after	MD 0.83 lower (1.29 lower to 0.37 lower)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with psychological interventions
Brief Symptom Inventory: Global Severity Index (GSI) follow up: 12 weeks				studies) was 1.38	
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Low problem behaviour assessed with: Role-play test of anger arousing situations follow up: 10 weeks	28 (1 RCT)	⊕⊕◯◯ LOW [1,5]	-	The mean low problem behaviour was 13.7	MD 11.69 more (7.06 more to 16.32 more)
Maladaptive functioning assessed with: Adaptive behaviour scale - revised (ABS-R) - part II follow up: 10 weeks	28 (1 RCT)	⊕⊕◯◯ LOW [1,3]	-	The mean maladaptive functioning was 74.9	MD 21.74 lower (36.45 lower to 7.02 lower)
Interpersonal skills (Adaptive functioning) assessed with: Social performance survey schedule (SPSS) follow up: 18 weeks	32 (1 RCT)	⊕◯◯◯ VERY LOW [1,6]	-	The mean interpersonal skills was 43.6	MD 20.45 more (9.74 fewer to 50.74 more)

Note

1. Risk of selection and performance bias
2. I^2 suggests considerable heterogeneity
3. Confidence intervals cross minimally important difference in one direction. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)
4. Risk of selection and performance bias and unclear risk of selective outcomes, attrition and detection bias
5. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
6. Confidence intervals cross two minimally important differences. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

				Anticipated absolute effects	
Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Risk with control	Risk difference with psychological interventions
ABS-R = Adaptive Behaviour Scale – Revised; MD = mean difference; RCT = randomised controlled trial; SMD = standardised mean difference; SPSS = Social Performance Survey Schedule.					

5.2.2.1.2 *Social problem solving then assertiveness training versus assertiveness training then social problem solving: treatment*

There was 1 RCT (N=18) which met the eligibility criteria for this review: Nezu 1991.

An overview of the trial included can be found in Table 29. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 30. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcomes of community participation and quality of life.

Table 29: Study information table for RCTs included in the analysis of social problem solving then assertiveness training versus assertiveness training then social problem solving for mental health problems

	Social problem solving then assertiveness training versus assertiveness training then social problem solving
Total no. of studies (N[1])	1 (18)[2]
Study ID	Nezu 1991
Country	US
Diagnosis/degree of learning disabilities	Mild[3]
Age (mean)	36 years
Sex (% female)	36%
Ethnicity (% white)	92.9%
IQ (mean)	Not reported
Living arrangements	Not reported
Coexisting conditions/treatments received	9 taking antipsychotic medication, 2 benzodiazepines, 2 anti-seizure medication
Targeted behaviour	Diagnoses[4] of anxiety (m=7), schizophrenia (n=2), intermittent explosive disorder (n=4), adjustment disorder (n=3), various personality disorder (n=12) (all also presented with maladaptive social behaviour such as issues with anger control, verbal or physical aggression, destructive behaviour)
Treatment length (weeks)	10 weeks
Intervention (mean dose; mg/day)	2 groups: 1 with social problem solving then assertiveness training, 1 with assertiveness then problem-solving

	Social problem solving then assertiveness training versus assertiveness training then social problem solving
	training. Social problem solving: weekly 1-hour group sessions including systematic training in 5 problem-solving processes (problem orientation, problem definition and formulation, generation of alternative solutions, decision making, and solution implementation and verification) Assertiveness training: weekly 1-hour group sessions aimed at decreasing inhibition of assertive responding, focusing on substituting aggressive behaviour with assertive behaviour.
Comparison	Waitlist (bimonthly supportive sessions)
Notes. N=total number of participants. [1] Number randomised. [2] Study has total 28 patients but the arm with a waiting list control has been removed from this total. [3] Wechsler Adult Intelligence Scales (WAIS) – Revised (1981) and Adaptive Behaviour Scale-revised (1975). [4] Using Psychopathology Instrument for Mentally Retarded Adults (PIMRA) with diagnoses including anxiety (n=7), schizophrenia (n=2), intermittent explosive disorder (n=4), adjustment disorder (n=3), various personality disorder (n=12) (all also presented with maladaptive social behaviour such as issues with anger control, verbal or physical aggression, destructive behaviour).	

Table 30: Summary of findings table for the analysis of social problem solving then assertiveness training versus assertiveness training then social problem solving for mental health problems

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with assertiveness, then social problem solving (A-PS)**	**Risk difference with social problem solving, then assertiveness training (PS-A)**
Psychiatric/psychological symptoms (Mental health) assessed with: Brief Symptom Inventory (BSI) follow up: 23 weeks	18 (1 RCT)	⊕⊕◯◯ LOW ^{1,2,3}	-	The mean psychiatric/psychological symptoms was 0.73	MD 0.02 more (0.43 fewer to 0.47 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Psychological distress (Mental health) assessed with: Subjective unit of distress scale (SUDS) follow up: 23 weeks	18 (1 RCT)	⊕◯◯◯ VERY LOW ^{1,2,4}	-	The mean psychological distress was 2.98	MD 0.22 fewer (2.82 fewer to 2.38 more)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with assertiveness, then social problem solving (A-PS)	**Risk difference with social problem solving, then assertiveness training (PS-A)**
Low problem behaviour - Follow-up assessed with: Role-play test of anger arousing situations follow up: 23 weeks	18 (1 RCT)	⊕⊕◯◯ LOW[1,2,3]	-	The mean low problem behaviour - Follow-up was 24	MD 4.11 more (1.07 fewer to 9.29 more)
Adaptive behaviour assessed with: Adaptive Behavior Scale - Revised (ABS-R) follow up: 23 weeks	18 (1 RCT)	⊕◯◯◯ VERY LOW[1,2,4]	-	The mean adaptive behaviour was 53.81	MD 2.02 fewer (18.88 fewer to 14.84 more)
Adaptive behaviour assessed with: Problem-solving task (PST) follow up: 23 weeks	18 (1 RCT)	⊕◯◯◯ VERY LOW[1,2,4]	-	The mean adaptive behaviour was 67.11	MD 4 fewer (20.7 fewer to 12.7 more)

Note

1. Risk of selection bias (unclear allocation method, no details of allocation concealment)
2. Risk of performance bias (not blind)
3. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
4. Confidence intervals cross minimally important difference in both directions (downgrade 2). Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

5.2.2.1.3 *Psychodynamic psychotherapy of differing treatment lengths*

There was one cohort study (N=28) which met the eligibility criteria for this review: (Beail et al., 2007).

An overview of the study included can be found in Table 31. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 32. The full GRADE evidence profiles can be found in Appendices N and O.

The differences are reported narratively only; the study reported that there were no significant differences between global severity scores at all time-points (8, 12 and 24 weeks and at 13 weeks' follow-up).

No data were available for the critical outcomes of community participation and quality of life.

Table 31: Study information table for cohort studies included in the analysis of psychodynamic psychotherapy at 8 sessions versus 12 sessions versus 24+ sessions for mental health problems

	Psychodynamic psychotherapy for differing treatment lengths (8 sessions versus 12 sessions versus 24+ sessions)
Total no. of studies (N[1])	1 (30)
Study ID	Beail 2007
Country	UK
Diagnosis/degree of learning disabilities	Mild[2]
Age (mean)	29.3
Sex (% female)	15
Ethnicity (% white)	Not reported
IQ (mean)	Not reported
Living arrangements	Mixed
Coexisting conditions/treatments received	Not reported
Targeted behaviour	Mixed[3]
Treatment length (weeks)	8 (group 1) versus 12 (group 2) versus average 33 (range: 24-28; group 3)
Intervention (mean dose; mg/day)	Weekly 50 minute psychodynamic psychotherapy
Comparison	Weekly psychodynamic psychotherapy for different lengths of time

Notes. N=total number of participants.

[1] Number randomised.

[2] all had capacity to consent and participate in the assessment but no IQ reported.

[3] 9 aggressive behaviour, 3 sexually inappropriate behaviour, 3 psychotic/bizarre behaviour, 1 relationship difficulties, 1 self-injury, 1 depression, 1 bulimia and 1 OCD.

Table 32: Summary of findings table for the analysis of psychodynamic psychotherapy of 8 sessions versus 12 sessions versus 24+ sessions for mental health problems

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with psychodynamic psychotherapy (12 or 24+ sessions)	**Risk difference with psychodynamic psychotherapy (8 sessions)**
Mental health assessed with: SCl-90-R follow up: not reported	21 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]		No statistically significant differences were found between arms with differing lengths of treatment	
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with psychodynamic psychotherapy (12 or 24+ sessions)	Risk difference with psychodynamic psychotherapy (8 sessions)
Interpersonal problems (Adaptive functioning, including communication) assessed with: Inventory of Interpersonal Problems-32 follow up: ?	21 (1 observational study)	⨁◯◯◯ VERY LOW [1,2]		No statistically significant differences were found between arms with differing lengths of treatment	

Note

1. Risk of selection, detection and performance bias.
2. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

5.2.2.2 Substance misuse

5.2.2.2.1 *Psychological interventions versus control: prevention or treatment*

There was 1 3-armed RCT (N=84) which met the eligibility criteria for this review: McGillicuddy and Blane (1999). The study compared assertiveness building with modelling and social inference, and a waitlist control group.

An overview of the trial (by pairwise comparison) included can be found in Table 33. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 34. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The study included participants with and without substance misuse (therefore, was both preventative and treatment) and it was unclear what level of learning disabilities the included participants had.

The arms for the trial were combined in the analysis of psychological interventions with control.

No data were available for the critical outcomes of community participation and quality of life.

Table 33: Study information table for RCTs included in the analysis of psychological interventions versus control for substance misuse

	Assertiveness versus waitlist	Modelling and social inference versus waitlist
Total no. of studies (N[1])	1 (63)[2]	1 (63)[2]
Study ID	McGillicuddy 1999	McGillicuddy 1999
Country	US	US
Diagnosis/degree of learning disabilities	Not reported[3]	Not reported[3]
Age (mean)	27 years	27 years

	Assertiveness versus waitlist	Modelling and social inference versus waitlist
Sex (% female)	51%	51%
Ethnicity (% white)	81%	81%
IQ (mean)	64[4]	64[4]
Living arrangements	Not reported	Not reported
Coexisting conditions/treatments received	Not reported	Not reported
Targeted behaviour	Increasing substance-related skills and knowledge, and reducing substance use[5]	Increasing substance-related skills and knowledge, and reducing substance use[5]
Treatment length (weeks)	10 weeks	10 weeks
Intervention (mean dose; mg/day)	**Assertiveness building:** training to refuse substances when offered	**Modelling and social inference:** training "to infer normative behaviour in new social situations and how to distinguish between appropriate and inappropriate role models in various situations"
Comparison	Waitlist control (received the intervention after 10-week trial	Waitlist control (received the intervention after 10-week trial

Notes. N=total number of participants.

[1] Number randomised.

[2] Study has 3 arms with N=84: 42 waiting list control and 21 in each intervention group.

[3] However, 91% of patients were employed and 80% had no history of institutionalisation so possibly mild/moderate learning disabilities.

[4] assessed using the Peabody Picture Vocabulary Test; mean includes 38 people in an initial prevalence study who did not go onto be included in the RCT.

[5] 18% considered misusers, 20% users, 61% nonusers (past month use of alcohol, nicotine and illicit drugs was reported by 39%, 23%, and 4%, respectively)

Table 34: Summary of findings table for the analysis of psychological interventions versus control for substance misuse

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with psychological interventions
Alcohol misuse (Mental health) follow up: 34 weeks	84 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean alcohol misuse was 0.71	MD 0.12 fewer (1.01 fewer to 0.77 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Note					

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with psychological interventions

1. Risk of selection bias (no details of allocation method or concealment but, most importantly and not comparable risk at baseline), risk of performance bias
2. Confidence intervals cross minimally important difference in both directions (downgrade 2). Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

5.2.2.2.2 *Assertiveness training versus modelling and social inference: prevention or treatment*

There was 1 RCT (N=42) which met the eligibility criteria for this review: McGillicuddy and Blane (1999).

An overview of the trial included can be found in Table 35. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 36. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcomes of community participation and quality of life.

Table 35: Study information table for RCTs included in the analysis of assertiveness building versus modelling and social inference for substance misuse

	Assertiveness versus modelling and social inference
Total no. of studies (N[1])	1 (42) [2]
Study ID	McGillicuddy 1999
Country	US
Diagnosis/degree of learning disabilities	Not reported[3]
Age (mean)	27 years
Sex (% female)	51%
Ethnicity (% white)	81%
IQ (mean)	64[4]
Living arrangements	Not reported
Coexisting conditions/treatments received	Not reported
Targeted behaviour	Increasing substance-related skills and knowledge, and reducing substance use[5]
Treatment length (weeks)	10 weeks
Intervention (mean dose; mg/day)	**Assertiveness building:** training to refuse substances when offered **Modelling and social inference:** training “to infer normative behaviour in new social situations and how to distinguish between appropriate and inappropriate role models in various situations”
Comparison	Waitlist control (received the intervention after 10 week trial

	Assertiveness versus modelling and social inference
Notes. N=total number of participants. [1] Number randomised. [2] Study has 3 arms with N=84: 42 waiting list control and 21 in each intervention group; number included in the waitlist control group is removed from this total. [3] However, 91% of patients were employed and 80% had no history of institutionalisation so possibly mild/moderate learning disabilities. [4] assessed using the Peabody Picture Vocabulary Test; mean includes 38 people in an initial prevalence study who did not go onto be included in the RCT. [5] 18% considered misusers, 20% users, 61% nonusers (past month use of alcohol, nicotine and illicit drugs was reported by 39%, 23%, and 4%, respectively)	

Table 36: Summary of findings table for the analysis of assertiveness training versus modelling and social inference for substance misuse

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with modelling and social inference**	**Risk difference with assertiveness training**
Alcohol misuse (Mental health) follow up: mean 34 weeks	42 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean alcohol misuse was 0.62	MD 0.07 fewer (0.82 fewer to 0.68 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Note 1. Risk of selection bias (no details of allocation method or concealment but, most importantly, not comparable risk at baseline), Risk of performance bias 2. Confidence intervals cross minimally important difference in both directions (downgrade 2). Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).					

5.2.2.3 Anxiety disorders

There were 5 RCTs (N=139) and 2 controlled before-and-after studies (N=118) which were found on the treatment or prevention of anxiety. The included studies were a mixture of treatment, selective prevention, or indicated prevention, covered a mixture of levels of learning disabilities and addressed different type of anxiety (see summary below in Table 37). Only 1 study considered children and young people while all others included adults only.

Table 37: Summary of included studies on anxiety

	Type of anxiety	**Mild**	**Moderate**	**Severe**
Adults	Anxiety symptoms	**1 RCT:** Hassiotis 2013 (CBT versus control)[1,2] **1 controlled-before-and after:** Lindsay 2015 (CBT versus control)[1,2]		-
			1 RCT: Lindsay 1989 (various types of relaxation versus control)[2]	

	Type of anxiety	Mild	Moderate	Severe
		1 RCT: Peck 1977 (various types of desensitisation versus placebo and no treatment)[2]	**1 RCT:** Morrison 1997 (relaxation versus story-telling control)[3]	-
	Social anxiety	**1 RCT:** Valenti-Hein 1994 (dating skills versus control)[2]		–
Children	Post-traumatic stress disorder	**1 controlled before-and after:** Holstead 2013 (CBT versus ABA)[2]	–	–

Note.
[1] Not all participants had anxiety – some had other mental health problems such as depression.
[2] All participants had clinical levels of anxiety so the trial would be considered treatment.
[3] Not all participants had clinical levels of anxiety so the trial could be considered a mixture of prevention and treatment.

5.2.2.3.1 *Anxiety symptoms in mild to moderate learning disabilities: psychological interventions versus control: prevention or treatment*

There were 4 RCTs (N=112) and 1 controlled before-and-after study (N=24) which met the eligibility criteria for this review: Hassiotis et al. (2013), Lindsay et al. (1989), Morrison and Lindsay (1997), Peck (1977) and Lindsay et al. (2015).

The studies used a mixture of psychological interventions including CBT, dating skills therapy, and desensitisation. Peck 1977 and Lindsay 1989 were both 3-armed trials.

An overview of the trials included can be found in Table 38 and Table 39. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 40. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

It was not possible to present the results for Peck 1976 so data is presented here narratively: contact desensitisation appeared better than placebo after 5 weeks of treatment on the Behaviour Avoidance Test, Behaviour Checklist ratings, Fear Thermometer, and the Modified Fear Survey. Neither vicarious symbolic desensitisation nor systematic desensitisation appeared better than placebo.

Considerable heterogeneity was found in the outcome on anxiety in the RCTs but there were too few studies to assess the reasons for this. As such, a random-effects model was used and the outcome was downgraded for inconsistency.

No data were available for the critical outcome of quality of life.

Table 38: Study information table for RCTs included in the analysis of psychological interventions for anxiety symptoms in people with mild to moderate learning disabilities

	CBT +treatment as usual versus treatment as usual only	**Contact desensitisation versus placebo**	**Vicarious symbolic desensitisation versus placebo**	**Systematic desensitisation versus placebo**	**Relaxation versus story-telling**
Total no. of studies (N¹)	1 (32)	1 (20)	1 (20)	1 (20)	1 (30)
Study ID	Hassiotis 2013	Peck 1976	Peck 1976	Peck 1976	Morrison 1997
Country	UK	US	US	US	UK
Diagnosis/degree of learning disabilities	Mild-moderate	Mild[2]	Mild[2]	Mild[2]	Moderate[4]
Age (mean)	36	19-61	19-61	19-61	37
Sex (% female)	62.5	Not reported	Not reported	Not reported	56.6
Ethnicity (% white)	68.8	Not reported	Not reported	Not reported	Not reported
IQ (mean)	Not reported	2.15 [2]	2.15 [2]	2.15 [2]	range: 48-59
Living arrangements	Independent or with intermittent support	private residential homes (1 foster home)	private residential homes (1 foster home)	private residential homes (1 foster home)	Institution
Coexisting conditions/treatments received	None	75% tranquilizers	75% tranquilizers	75% tranquilizers	Not reported
Targeted behaviour	Anxiety	fear (of height or rats)	fear (of height or rats)	fear (of height or rats)	Anxiety
Treatment length (weeks)	16	5	5	5	Not reported
Intervention (mean dose; mg/day)	Manualised-individual CBT	Contact desensitisation	Vicarious symbolic desensitisation	Systematic desensitisation	Behavioural relaxation therapy
Comparison	Treatment as usual	Placebo[3]	Placebo[3]	Placebo[3]	Story-telling control
Notes. N=total number of participants.					

	CBT +treatment as usual versus treatment as usual only	Contact desensitisation versus placebo	Vicarious symbolic desensitisation versus placebo	Systematic desensitisation versus placebo	Relaxation versus story-telling

[1] Number randomised.
[2] Based on American Association for Mental Deficiency criteria (1973).
[3] No treatment group also reported but placebo (attention control) preferred for comparison.
[4] Based on American Association for Mental Deficiency scales.
[5] Wechsler Adult Intelligence Scale IQ 30-55.
[6] mean of means of each groups.
[7] all were considered to be extremely anxious or agitated (based on clinical assessment).
[8] Total of 14 daily sessions except on weekends, Determined using the AAMD criteria.
[9] Behavioural and abbreviated progressive relaxation training arms were combined.
AAMD = American Association for Mental Deficiency

Table 39: Study information table for controlled before-and-after studies included in the analysis of psychological interventions for anxiety symptoms in people with mild to moderate learning disabilities

	CBT versus Control
Total no. of studies (N[1])	1 (24)
Study ID	Lindsay 2015
Country	UK
Diagnosis/degree of learning disabilities	Mild
Age (mean)	31
Sex (% female)	50
Ethnicity (% white)	Not reported
IQ (mean)	63.15
Living arrangements	Mixed
Coexisting conditions/treatments received	Not reported
Targeted behaviour	Mixed[2]
Treatment length (weeks)	10.75 (from 8-14)
Intervention (mean dose; mg/day)	Weekly trans-diagnostic individual CBT with assistance from significant other person (family member or carer) [3]
Comparison	Wait-list control (matched to those receiving intervention)

Notes. N=total number of participants.

[1] Number randomised.

[2] Diagnosis included 8 anxiety, 6 depression, 2 mixed anxiety and depression, 2 interpersonal conflict, 4 bereavement and anxiety and depression, 1 experience of sexual abuse with anxiety and depression.

[3] length of each weekly session not reported.

Table 40: Summary of findings table for the analysis of psychological interventions for anxiety symptoms in people with mild to moderate learning disabilities

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with control**	**Risk difference with psychological intervention**
Anxiety symptoms (RCTs) (Mental health) assessed with: various scales follow up: mean 42 weeks	57 (2 RCTs)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.87 fewer (1.14 fewer to 1.36 more)
Anxiety symptoms (controlled before-and-after) (Mental health) assessed with: Brief Symptom Inventory: anxiety	24 (1 observational study)	⊕◯◯◯ VERY LOW [4,5]	-	The mean anxiety symptoms (controlled before-and-after) was not reported	MD 0.4 lower (1.23 lower to 0.43 higher)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with psychological intervention
symptom dimension follow up: 12 weeks					
Quality of life - not reported	-	-			
In paid employment after treatment (Community participation and meaningful occupation) follow up: 16 weeks	30 (1 RCT)	⊕◯◯◯ VERY LOW [5,6]	RR 0.22 (0.03 to 1.73)	Study population	
				286 per 1000	223 fewer per 1000 (277 fewer to 209 more)
Voluntary work (Community participation and meaningful occupation) follow up: 16 weeks	30 (1 RCT)	⊕◯◯◯ VERY LOW [3,6]	RR 1.31 (0.46 to 3.72)	Study population	
				286 per 1000	89 more per 1000 (154 fewer to 777 more)

Note

1. Risk of selection, performance and detection bias
2. I^2 suggests considerable heterogeneity
3. Confidence intervals cross minimally important difference in both directions. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)
4. Risk of selection and performance bias and unclear risk of attrition and detection bias
5. Confidence intervals cross minimally important difference in one direction. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)
6. Risk of performance and selection bias

Experience of care with CBT

Hassiotis et al. (2013) conducted face-to-face or telephone interviews with 13 patients in the CBT arm at least 1 month after completion. The questionnaire included 6 open-ended questions. The study also extracted qualitative data on the patient experience from discussions with professionals from community teams where participants were recruited.

There were 7 themes presented from the interviews, and they are summarised in Table 40.

The study is of high quality overall (83.3% of criteria met), with mixed reporting of aspects of rationale and the methods used but well-reported analysis and ethics. This study appears to show that manualised individual CBT (M-iCBT) is generally valued as a useful intervention for symptoms of anxiety and depression and is both appropriate for use with and well-tolerated by service users with learning disabilities.

Table 40: Summary of themes from experience of care with CBT

Identified themes	Description	Quotes from patients
Participant views of CBT	All patients identified their therapist, differentiated this treatment from other therapies, recalled reasons for participation and what they had discussed during sessions.	"I thought the therapy was different to counselling…if you're doing (CBT) therapy they take you out and make you do (things)." "Yes, it was about dealing with anxiety and emotions."
Positive changes due to therapy	8 of 13 patients gave examples of implementing techniques. 7 of 13 acknowledged the positive impact upon their mood but said it had not resolved their difficulties.	"More relaxed around people which I wasn't since childhood." "It's a positive thing that I had CBT therapy. So some of the techniques have worked, it's good to make little improvement."
Challenges of therapy	1 of the 13 patients had previously had CBT and did not respond on this occasion, 3 patients felt distressed after sessions and 6 would have preferred 'free-floating' to task-oriented sessions.	"When I have arguments it's hard to concentrate on these techniques." "What was hard like problems in your life, like you're obsessed with it…won't fade away easily." "What wasn't helpful was like when the therapist said we already discussed this so let's just stop talking about this…"
Therapeutic relationship	7 of the 13 patients were openly positive about the therapist.	"The therapist is just saying: in your own way…does it in a way that you do pay so much attention to what you do and it works."
Role of the support worker	Most patients expressed positive views about involvement of the support worker in therapy.	"The support worker helped me to fill in stuff, arrange what day I had to come and see the therapist and just asked me how I was feeling to make sure I wasn't sad again."
CBT materials and homework	Patients reported session materials were easy to use but that the use of homework tasks felt persecutory.	"Helpful to write things down, it helped me talk about my problems." "I didn't like that aspect…that this lady would have to check up on you for your homework."
Further suggestions	8 patients said they would recommend the therapy to others with similar problems and that they would have liked further contact at the end of the allocated sessions.	"My advice to people…this does work, I mean if you go out and do it."

5.2.2.3.2 *Anxiety symptoms in people with moderate to severe learning disabilities: relaxation training versus control: prevention or treatment*

There were 2 RCTs (N = 60) which met the eligibility criteria for this review: Lindsay et al. (1989) and Morrison and Lindsay (1997).

An overview of the trials included can be found in Table 41 Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 42. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The RCT by Lindsay 1989 had 4 active arms with varying types of relaxation therapy, and these are presented separately in the analysis of relaxation therapy versus control.

There was inconsistency in the results for the anxiety symptom outcome for the subgroup of individual group training and was not possible to explore in sensitivity or subgroup analyses due to the small number of trials. As a result, a random-effects model was used and the outcome was downgraded for inconsistency.

No data were available for the critical outcomes of community participation and quality of life.

Table 41: Study information table for trials included in the analysis of relaxation training versus control for anxiety symptoms in people with moderate to severe learning disabilities

	Individual relaxation training versus control	**Group relaxation training versus control**	**Relaxation versus story-telling**
Total no. of studies (N[1])	1 (30)	1 (30)	1 (30)
Study ID	Lindsay 1989	Lindsay 1989	Morrison 1997
Country	UK	UK	UK
Diagnosis/degree of learning disabilities	Moderate and severe[2]	Moderate and severe[2]	Moderate[7]
Age (mean)	44[3]	42.8[3]	37
Sex (% female)	50%	50%	56.6
Ethnicity (% white)	Not reported	Not reported	Not reported
IQ (range)	30-55	30-55	48-59
Living arrangements	Living in hospital	Living in hospital	Institution
Coexisting conditions/treatments received	Not reported	Not reported	Not reported
Targeted behaviour	Anxiety[4]	Anxiety[4]	Anxiety
Treatment length (weeks)	2.29 weeks[5]	2.29 weeks[5]	Not reported
Intervention (mean dose; mg/day)	Individual behavioural or abbreviated progressive relaxation training[6]	Group behavioural or abbreviated progressive relaxation training[6]	Group behavioural relaxation therapy
Comparison	Control (not described)	Control (not described)	Story-telling control

Notes. N=total number of participants.
[1] Number randomised.
[2] Wechsler Adult Intelligence Scale IQ 30-55.
[3] mean of means of each groups.
[4] all considered to be extremely anxious or agitated (based on clinical assessment).
[5] Total of 14 daily sessions except on weekends, determined using the AAMD criteria.
[6] Behavioural and abbreviated progressive relaxation training arms were combined.
[7] Based on AAMD scales.
AAMD = American Association for Mental Deficiency

Table 42: Summary of findings table for the analysis of relaxation training versus control for anxiety symptoms in people with moderate to severe learning disabilities

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with control	**Risk difference with relaxation training**
Anxiety symptoms (Group relaxation training vs control) (Mental health) assessed with: Various tools	60 (2 RCTs)	⊕◯◯◯ VERY LOW[1,2]	-	-	SMD 2.31 lower (2.92 lower to 1.7 lower)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with relaxation training
follow up: range 2.29 weeks to unclear					
Anxiety symptoms (Individual relaxation training vs control) (Mental health) assessed with: 5-point scale on 10 ratings Scale from: relaxed to very anxious follow up: 2.29 weeks	30 (2 RCTs)	⊕◯◯◯ VERY LOW [2,3,4]	-	-	SMD 2.97 SD lower (4.36 lower to 1.57 lower)
Quality of life (relaxation vs story-telling) - not reported	-	-			
Community participation and meaningful occupation (relaxation vs story-telling) - not reported	-	-			
Note 1. Risk of selection, performance and possible detection bias 2. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes) 3. Risk of selection bias (no details of allocation method or concealment); Risk of performance bias (no blinding); Possible risk of detection bias (unclear if outcome assessors blind to treatment and confounding) 4. I^2 suggests substantial heterogeneity.					

5.2.2.3.3 *Social anxiety symptoms: dating skills training versus control: treatment*

There was 1 RCT (N=27) which met the eligibility criteria for this review: Valenti-Hein et al. (1994).

An overview of the trial included can be found in Table 43. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 44.The full GRADE evidence profiles and associated forest plots can be found in Appendix N and Appendix O.

No data were available for the critical outcomes of community participation and quality of life.

Table 43: Study information table for RCTs included in the analysis of dating skills versus control for social anxiety symptoms

	Dating skills training versus waitlist
Total no. of studies (N[1])	1 (27)
Study ID	Valenti-Hein 1994
Country	US
Diagnosis/degree of learning disability	Moderate to borderline intellectual functioning[2]

	Dating skills training versus waitlist
Age (mean)	18-50
Sex (% female)	48
Ethnicity (% white)	Not reported
IQ (mean)	2.15[2]
Living arrangements	11 group home, 8 with family, 7 independently
Coexisting conditions/treatments received	Not reported
Targeted behaviour	Social anxiety[3]
Treatment length (weeks)	12
Intervention (mean dose; mg/day)	Dating skills programme
Comparison	Waitlist control
Notes. N=total number of participants. Note. [1] Number randomised. [2] Based on a scale of 1 to 3 with 1 as borderline, 2 as mild and 3 as moderate. [3] Patients who were 'not psychotic' were included and had scores on the Institute for the Study of Developmental Disabilities (ISDD) Symptom checklist less than 20 (considered low psychopathology.	

Table 44: Summary of findings table for the analysis of dating skills versus control for social anxiety symptoms

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with control	**Risk difference with dating skills training**
Social anxiety symptoms (Mental health) assessed with: Social avoidance and distress scale follow up: 24 weeks	25 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean social anxiety symptoms was not reported	MD 0.39 lower (1.18 lower to 0.4 higher)
Proportion with significant change in social anxiety symptoms (Mental health) assessed with: Social avoidance and distress scale follow up: 20 weeks	25 (1 RCT)	⊕◯◯◯ VERY LOW [1,3]	not estimable	Study population	
				0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Note 1. Risk of selection and detection bias 2. Confidence intervals cross one minimally important difference. Sample size less than					

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with dating skills training
optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes). 3. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).					

5.2.2.3.4 *Post-traumatic stress disorder: CBT versus applied behaviour analysis*

There was 1 controlled before-and-after study (N=88) which met the eligibility criteria for this review: Holstead and Dalton (2013).

An overview of the trial included can be found in Table 45. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 46. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcomes of community participation and quality of life.

Table 45: Study information table for controlled before-and-after studies included in the analysis of CBT versus applied behaviour analysis for PTSD

	CBT versus applied behaviour analysis
Total no. of studies (N[1])	1 (88)
Study ID	Holstead 2013
Country	US
Diagnosis/degree of learning disabilities	Mild
Age (mean)	12-17
Sex (% female)	18
Ethnicity (% white)	Not reported
IQ (mean)	58-69
Living arrangements	Residential care
Coexisting conditions/treatments received	Not reported
Targeted behaviour	PTSD or trauma-based symptoms[3]
Treatment length (weeks)	Not clear
Intervention (mean dose; mg/day)	Trauma-focused CBT (average 3 sessions per week) with or without parental involvement and including similar interventions for parents such as parenting skills
Comparison	Applied behaviour analysis / individualised intensive behavioural interventions (3 sessions per week)

Note. N=total number of participants.
[1] Number randomised.
[2] 34% also had a diagnosis of autism.
[3] All experienced at least 4 but not more than 6 adverse childhood experiences.

Table 46: Summary of findings table for the analysis of CBT versus applied behaviour analysis for PTSD

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with ABA/IBI	Risk difference with CBT
Somatic symptoms (Mental health) assessed with: Achenbach: Somatic subscale follow up: not reported	87 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	-	The mean somatic symptoms was 53.71	MD 3.74 more (0.69 more to 6.79 more)
Withdrawn symptoms (Mental health:) assessed with: Achenbach: withdrawn subscale follow up: not reported	87 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	-	The mean withdrawn symptoms was 55.4	MD 4.58 more (1.12 more to 8.04 more)
Anxious/depressed symptoms (Mental health) assessed with: Achenbach: Anxious/depressed subscale follow up: not reported	87 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	-	The mean anxious/depressed symptoms was 59.82	MD 6.89 more (3.68 more to 10.1 more)
Thought problems (Mental health) assessed with: Achenbach: Thought problems subscale follow up: not reported	87 (1 observational study)	⊕◯◯◯ VERY LOW [1,3]	-	The mean thought problems was 61.47	MD 7.53 more (4.83 more to 10.23 more)
Attention subscale (Mental health) assessed with: Achenbach: attention subscale follow up: not reported	87 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	-	The mean attention subscale was 64.47	MD 4.58 more (1.56 more to 7.6 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Social problems (Mental health) assessed with: Achenbach: social problems subscale follow up: not reported	87 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	-	The mean social problems was 59.93	MD 2.97 more (0.38 fewer to 6.32 more)
Aggressive behaviour	87	⊕◯◯◯	-	The mean	MD 7.22

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with ABA/IBI**	**Risk difference with CBT**
(Mental health) assessed with: Achenbach: Aggressive behaviour subscale follow up: not reported	(1 observational study)	VERY LOW[1,3]		aggressive behaviour was 62.4	more (4.66 more to 9.78 more)
Rule breaking symptoms (Mental health) assessed with: Achenbach: Rule breaking subscale follow up: not reported	87 (1 observational study)	⊕◯◯◯ VERY LOW[1,3]	-	The mean rule breaking symptoms was 60.84	MD 9.18 more (6.95 more to 11.41 more)
Note 1. Risk of selection bias, performance bias (no blinding) and unclear risk of attrition bias 2. Confidence intervals cross minimally important difference in one direction. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes) 3. Confidence intervals cross minimally important difference in both directions. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)					

5.2.2.4 Depressive symptoms

5.2.2.4.1 CBT versus control: prevention or treatment

There were 3 RCTs (N=130) and 3 controlled before-and-after studies (N=130) which met the eligibility criteria for this review: McCabe et al. (2006), McGillivray et al. (2008), Hassiotis et al. (2013), Hartley et al. (2015), Lindsay et al. (2015), and McGillivray and Kershaw (2013).

An overview of the trials included can be found in Table 47 and Table 48. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 49. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

All but 1 study were conducted in participants with depressive symptoms or diagnosed with depression so would be considered to be treatment studies. A different study included participants who were at risk for depression (McGillivray & Kershaw, 2013); this was defined as the presence of at least 4 items/symptoms on the Depression Screening Checklist (with 22 items/symptoms/risk factors) and at least 1 mood and/or activities item (BDI-II: 34% were minimally, 40% mildly, 19% moderately and 7% severely depressed).

Most studies included both patients with mild and moderate learning disabilities, though 1 only included mild learning disabilities. Those that included both mild and moderate learning disabilities did not present the results for mild and moderate learning disabilities separately so it was not possible to see if the results differed by degree of learning disabilities.

While most studies reported outcomes immediately after treatment, 2 studies reported outcomes after a period of follow-up and this was used in the analyses (Hassiotis 2013, Hartley 2015). A sensitivity analysis using the outcomes immediately after treatment (and more comparable with the other studies included in the analysis) had similar results.

No data were available for the critical outcome of quality of life.

Hassiotis 2013 conducted qualitative interviews of the patient experience of CBT. These are presented above in the section on anxiety (see section 5.2.2.3.3).

Table 47: Study information table for RCTs included in the analysis of cognitive behavioural training versus control for depressive symptoms

	CBT versus control
Total no. of studies (N¹)	3 (130)
Study ID	(1) McCabe 2006 (2) McGillivray 2008 (3) Hassiotis 2013
Country	(1, 2) Australia (3) UK
Diagnosis/degree of learning disabilities	(1,3) Mild and moderate[2] (2) Mild
Age (mean)	(1) 35.59, (2) 34.47, (3) 36
Sex (% female)	(1, 2) Not reported (3) 62.5
Ethnicity (% white)	(1, 2, 3) Not reported
IQ (mean)	(1, 3) Not reported (2) IQ range 50-70
Living arrangements	(1) Not reported (but all working in supported employment) (2) 51% with parents or family (3) living independently or with intermittent support
Coexisting conditions/treatments received	(1) not reported (2) 12% people were on anti-depressants and 49% on other medications other than anti-depressants (3) 50% had other problems including epilepsy, asthma or other physical health problems / 61% were on other medications including anxiolytics, antidepressants, antipsychotics, antiepileptics alone or in combination
Targeted behaviour	(1, 2) Depression[3] (3) Depression or anxiety[3]
Treatment length (weeks)	(1) 5, (2) 12, (3) 16
Intervention (mean dose; mg/day)	(1, 2) 2 hour weekly group CBT (3) 1 hour weekly manualised individual CBT + treatment as usual[4]
Comparison	(1,2) Waitlist control, (3) treatment as usual[4]

Notes. N=total number of participants.
[1] Number randomised.
[2] not reported in McCabe 2006 but presumed as paper says recruitment setting was

	CBT versus control
mild/moderate learning disabilities supported employment agency. [3] inclusion criteria based on BDI scores (1; including mild depression), symptoms of depression (2; not otherwise specified), and mini PAS-ADD (3; score > 10 included); however, Beck Depression Inventory used to assess outcomes in all (all with minimal changes to the tool). [4] this included multi-disciplinary, community based services including psychiatrists (with or without nurses) to monitor mental state and adjusting any medications, care managers for assessment of any social care needs (such as accommodation and activities of daily living), and psychologists for general support in coping skills, behavioural interventions, counselling	

Table 48: Study information table for controlled before-and-after studies included in the analysis of cognitive behavioural training versus control for depressive symptoms

	CBT versus control
Total no. of studies (N[1])	3 (130)
Study ID	(1) Hartley 2015 (2) Lindsay 2015 (3) McGillivray 2013
Country	(1) US (2) UK 3) Australia
Diagnosis/degree of learning disabilities	(1, 2, 3) Mild
Age (mean)	(1) 39.5, (2) 31, (3) 37
Sex (% female)	(1) 35.8, (2) 50, (3) 42.7
Ethnicity (% white)	(1) 93.8 (2, 3) not reported
IQ (mean)	(1) 61.8, (2) 63.15, (3) IQ range 50-70
Living arrangements	(1) group home (n=17), with family (n=2), alone (n=5) (2) both private hospital and community residential settings (3) 39% with parents/family, 34% supported accommodation, 23% independent
Coexisting conditions/treatments received	(1) 33.3% with 1 or more mental health problem[2], 84% psychotropic drugs (2) not reported (3) 22% antidepressants (+31% took another unspecified prescribed medication)
Targeted behaviour	(1, 3) Depressive disorder/symptoms[3] (2) Mixed[4] (3) At risk of depression[5]
Treatment length (weeks)	(1) 12 (2) 10.75 (from 8-14) 3) 10 weeks
Intervention (mean dose; mg/day)	(1, 3[6]) 1.5 hour weekly group CBT (2) Weekly ‘trans-diagnostic’ individual CBT (1 and 2 had caregiver component)
Comparison	(1, 3) Treatment as usual (CBT 3 months later or referral to GP) (2) Wait-list control matched to those receiving intervention)
Note. N=total number of participants.	

	CBT versus control
[1] Number randomised. [2] Four anxiety, 2 OCD, 1 ADHD, 1 alcohol use in sustained remission, 1 stereotypic movement disorder, 1 schizotypal personality disorder. [3] Based on PAS-ADD but final diagnostic decisions with DM-ID criteria (authors report that the study considered partial responders to medication as many had depressive symptoms despite psychotropic medication). [4] Outcomes measured included depression (indications: 8 anxiety, 6 depression, 2 mixed anxiety and depression, 4 bereavement with anxiety and depression, 1 pathological jealousy, 2 interpersonal conflict, and 1 previous experience of sexual abuse with current anxiety and depression. [5] Inclusion if presence of at least 4 items/symptoms on the Depression Screening Checklist (with 22 items/symptoms/risk factors) and at least 1 mood and/or activities item (BDI-II: 34% were minimally, 40% mildly, 19% moderately and 7% severely depressed). [6] The study had 2 arms that were included in 1 analysis here: CBT only and CBT + TAU.	

Table 49: Summary of findings table for the analysis of CBT versus control for depressive symptoms

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with CBT
Depressive symptoms (RCT) (Mental health) assessed with: BDI follow up: range 6 weeks to 42 weeks	123 (3 RCTs)	⊕◯◯◯ VERY LOW [1,2]	-	-	SMD 0.82 fewer (1.64 fewer to 0)
Depressive symptoms (Controlled before-and-after) (Mental health) assessed with: Various follow up: range 12 weeks to 46.7 weeks	130 (3 observational studies)	⊕◯◯◯ VERY LOW [2,3]	-	-	SMD 0.81 lower (1.39 lower to 0.23 lower)
Depression: at least small improvement (Mental health) assessed with: BDI follow up: 12 weeks	47 (1 RCT)	⊕⊕◯◯ LOW [2,4]	RR 1.51 (1.11 to 2.05)	Study population	
				630 per 1000	321 more per 1000 (69 more to 661 more)
Quality of life - not reported	-	-			
In paid employment after treatment (Community participation and meaningful occupation) follow up: 16 weeks	30 (1 RCT)	⊕◯◯◯ VERY LOW [2,5]	RR 0.22 (0.03 to 1.73)	Study population	
				286 per 1000	223 fewer per 1000 (277 fewer to 209 more)
In voluntary work after treatment (Community participation and meaningful occupation) follow up: 16 weeks	30 (1 RCT)	⊕◯◯◯ VERY LOW [5,6]	RR 1.31 (0.46 to 3.72)	Study population	
				286 per 1000	89 more per 1000 (154 fewer to 777 more)
Problem behaviour (Controlled before-and-after)	24 (1 observational	⊕◯◯◯ VERY LOW [2,3]	-	The mean problem behaviour (Controlled before-and-after) was 19	MD 7 fewer (18.58 fewer to

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with CBT
assessed with: SIB-R follow up: 23 weeks	study)				4.58 more)
Social skills (mild to moderate LD) (Adaptive functioning) assessed with: Social comparison scale follow up: 6-12 weeks	96 (2 RCTs)	⊕◯◯◯ VERY LOW 2,5,7,8	-	The mean social skills (mild to moderate LD) was 8.4	MD 1.24 more (0.66 more to 1.82 more)
Social behaviours (Controlled before-and-after) (Adaptive functioning) assessed with: Social performance survey schedule follow up: 23 weeks	24 (1 observational study)	⊕◯◯◯ VERY LOW 3,8,9	-	The mean social behaviours (Controlled before-and-after) was 100.5	MD 11.12 fewer (17.11 fewer to 5.13 fewer)

Note

1. Risk of selection and performance bias in studies contributing to >50% weighting in analysis
2. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
3. Risk of selection, performance and detection bias
4. Risk of selection bias
5. Risk of selection and performance bias
6. Confidence intervals cross minimally important differences in both directions. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
7. No explanation was provided
8. Inconsistency in the impact on social skills between RCTs and controlled before-and-after studies.
9. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

5.2.2.4.2 *CBT versus behavioural or cognitive strategies only: prevention or treatment*

There was 1 controlled before-and-after study (N=70) which met the eligibility criteria for this review: McGillivray (2015).

An overview of the trial included can be found in Table 50. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 51 and Table 52. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The study included patients with mild learning disabilities only.

No data were available for the critical outcomes of community participation and quality of life.

Table 50: Study information table for controlled before-and-after studies included in the analysis of CBT versus behavioural or cognitive strategies only for depressive symptoms

	CBT versus behavioural strategy only	**CBT versus cognitive strategy only**
Total no. of studies (N[1])	1 (70)	1 (70)
Study ID	McGillivray 2015	McGillivray 2015
Country	Australia	Australia
Diagnosis/degree of learning disabilities	Mild	Mild
Age (mean)	36	36
Sex (% female)	40	40
Ethnicity (% white)	Not reported	Not reported
IQ (mean)	Not reported	Not reported
Living arrangements	44% with parents or family, 34% supported accommodation, 12% independently	44% with parents or family, 34% supported accommodation, 12% independently
Coexisting conditions/treatments received	26% anti-depressants	26% anti-depressants
Targeted behaviour	At risk of depression[2]	At risk of depression[2]
Treatment length (weeks)	12	12
Intervention (mean dose; mg/day)	1.5-hour weekly CBT	1.5-hour weekly CBT
Comparison	1.5-hour weekly behavioural strategy including role play	1.5-hour weekly cognitive strategy including teaching the way thoughts, feelings and behaviours are linked

Note.
N=total number of participants.
[1] Number randomised.
[2] outcomes measured included depression (indications: 8 anxiety, 6 depression, 2 mixed anxiety and depression, 4 bereavement with anxiety and depression, 1 pathological jealousy, 2 interpersonal conflict, and 1 previous experience of sexual abuse with current anxiety and depression.

Table 51: Summary of findings table for the analysis of CBT versus behavioural strategies only for depressive symptoms

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with behavioural strategies only	Risk difference with CBT
Depressive symptoms (Mental health) assessed with: Becks depression inventory II follow up: 38 weeks	47 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	-	The mean depressive symptoms was 11.17	MD 1.56 fewer (6.57 fewer to 3.45 more)
Improvement in those with clinical depression at baseline (Mental health) assessed with: Becks depression inventory II (reduced score) follow up: 38 weeks	31 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	RR 1.20 (0.94 to 1.53)	Study population	
				824 per 1000	165 more per 1000 (49 fewer to 436 more)
Recovery in those with clinical depression at baseline (Mental health) assessed with: Becks depression inventory II (score 12 or less) follow up: 38 weeks	31 (1 observational study)	⊕◯◯◯ VERY LOW [1,3]	RR 0.81 (0.47 to 1.40)	Study population	
				706 per 1000	134 fewer per 1000 (374 fewer to 282 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			

Note

1. Risk of selection, performance and detection bias
2. Confidence intervals cross minimally important difference in one direction. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)
3. Confidence intervals cross minimally important difference in both directions. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)

Table 52: Summary of findings table for the analysis of CBT versus cognitive strategies only for depressive symptoms

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with cognitive strategies only	Risk difference with CBT
Depressive symptoms (Mental health) assessed with: Becks depression inventory II follow up: 38 weeks	46 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	-	The mean depressive symptoms was 10.91	MD 1.3 fewer (5.89 fewer to 3.29 more)
Improvement in those with clinical depression at baseline (Mental health) assessed with: Becks depression inventory II (reduced score) follow up: 38 weeks	29 (1 observational study)	⊕◯◯◯ VERY LOW [1,2]	RR 1.34 (0.98 to 1.85)	Study population	
				733 per 1000	249 more per 1000 (15 fewer to 623 more)
Recovery in those with clinical depression at baseline (Mental health) assessed with: Becks depression inventory II (score 13 or less) follow up: 38 weeks	29 (1 observational study)	⊕◯◯◯ VERY LOW [1,3]	RR 1.22 (0.60 to 2.48)	Study population	
				467 per 1000	103 more per 1000 (187 fewer to 691 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			

Note

1. Risk of selection, performance and detection bias
2. Confidence intervals cross minimally important difference in one direction. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)
3. Confidence intervals cross minimally important difference in both directions. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)

5.2.2.5 Sexually inappropriate behaviour

5.2.2.5.1 Psychodynamic psychotherapy versus control: treatment

There was 1 cohort study (N=18) which met the eligibility criteria for this review: (Beail, 2001).

An overview of the trial included can be found in Table 53. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 54. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

Table 53: Study information table for cohort studies included in the analysis of psychodynamic psychotherapy versus control for sexually inappropriate behaviour

	Psychodynamic psychotherapy versus control
Total no. of studies (N[1])	1 (18)[2]
Study ID	Beail 2001
Country	UK
Diagnosis/degree of learning disabilities	Not reported
Age (mean)	23.5
Sex (% female)	0
Ethnicity (% white)	Not reported
IQ (mean)	Not reported
Living arrangements	Intervention: 11 lived with parents, 1 lived in supported housing and 1 in hospital; no intervention: 4 lived with parents and 1 in supported housing
Coexisting conditions/treatments received	Not reported
Targeted behaviour	Sexually inappropriate behaviour[2]
Treatment length (weeks)	17.3 to 186
Intervention (mean dose; mg/day)	Weekly 1 hour psychodynamic psychotherapy
Comparison	No treatment[3]
Note. N=total number of participants. [1] Number randomised. [2] 13 of 18 had committed sexual offences (3 theft, 1 arson and 1 public order offence). [3] Those who refused treatment were discharged but their re-offending outcomes measured over time.	

Table 54: Summary of findings table for the analysis of psychodynamic psychotherapy versus control for sexually inappropriate behaviour

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with no treatment	**Risk difference with psychodynamic psychotherapy**
Recidivism	18	⊕◯◯◯	RR 0.26	Study population	

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with no treatment**	**Risk difference with psychodynamic psychotherapy**
follow up: 208 weeks	(1 observational study)	VERY LOW [1,2,3]	(0.06 to 1.11)	600 per 1000	444 fewer per 1000 (564 fewer to 66 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Note 1. Risk of selection bias, performance bias 2. Participants are only those who were arrested by the criminal justice system and, therefore, are unlikely to represent all individuals with LD who present with sexually inappropriate behaviour as not all will be in contact with the criminal justice system. 3. Confidence intervals cross minimally important difference in both directions. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes)					

5.2.3 Clinical evidence statements on adaptations to psychological interventions developed through formal consensus

5.2.3.1 Mild to moderate learning disabilities

- The GC decided that given people with learning disabilities have a broad range of difficulties, any adaptations to psychological treatments should be informed by careful assessment of the person and tailored to their needs.
- With respect to setting, the GC supported the need to ensure the chosen setting provides sufficient privacy, ensuring the appointment location takes into account the person’s health and sensory needs, and that mode of intervention delivery should be based upon the person’s preferences.
- Regarding structure of sessions the GC decided that the choice of intervention and adaptations should be strengths-based, the frequency, length and pace of sessions may need to be modified, breaks in sessions may need to be provided and key concepts repeated and reinforced, the course of treatment may need to be longer, the need or benefit of routine in appointment-scheduling should be considered, the person’s ability to identify their emotions should be evaluated before starting treatment and reminders about homework tasks provided. The GC expressed support for scheduling appointments at the same time, in the same place and following a consistent format, particularly for those with autistic traits or memory impairments.
- Regarding involving others, the GC decided it may be appropriate to involve a family member or carer, after asking the person with learning disabilities for their views on this and only if the person is not in conflict with these individuals, to facilitate engagement, implementation of the intervention and provide support to continue using new strategies once the intervention is complete. They also decided that if the person is having difficulties generalising new skills this should be discussed with the person and liaison should occur with relevant individuals and services to implement required support.

- Regarding communication, the GC decided that it was important to communicate directly with the person, adapt interventions to the person's understanding, to use the person's own words for emotions throughout, communicate the agenda for the session in the most appropriate format for the individual, to use clear and straightforward language and to explain the meaning and purpose of any abstract visual stimuli.
- Regarding content of the intervention the GC decided that it may be helpful to undertake work to help the person identify emotions, to develop the intervention collaboratively, to employ techniques such as role play and modelling, to repeat key messages, regularly summarise the material covered and clarify areas of confusion, to reduce reliance on written materials and support the use of these as necessary. They also decided it may be important, to provide in-session opportunities to practise and generalise new skills, to support the identification and reflection upon change, and to choose outcome measures most suited to the person.

5.2.3.2 Severe to profound learning disabilities

- The GC decided that it was important to manage a person's environment to reduce stressors and help them cope with change, and include clear, structured activities as part of any psychological or psychosocial interventions and support the person to engage with these. In addition they stressed the importance of, working with the person's family or carers to ensure sensitive and consistent care. The GC expressed support for the use of demonstration techniques to treat mental health problems, and the use of graded exposure for those experiencing anxiety or tackling phobias.

5.2.4 Economic evidence

The systematic search of the literature identified 1 study that assessed the cost effectiveness of psychological interventions for the management of mental health problems in adults with learning disabilities, which was conducted in the UK (Hassiotis et al., 2013). Details on the methods used for the systematic review of the economic literature are described in Chapter 3; full references and evidence tables for all economic evaluations included in the systematic literature review are provided in Appendix R. Completed methodology checklists of the studies are provided in Appendix Q. Economic evidence profiles of studies considered during guideline development (that is, studies that fully or partly met the applicability and quality criteria) are presented in Appendix S.

Hassiotis and colleagues (2013) evaluated the cost effectiveness of manualised individual cognitive behavioural therapy (CBT) added to treatment as usual versus treatment as usual alone, for the management of adults with a mild to moderate learning disability who had a mood disorder or symptoms of depression and /or anxiety. The economic analysis was conducted alongside a feasibility RCT (Hassiotis 2013, N=32). CBT consisted of 16 weekly 1-hour sessions. Treatment as usual comprised follow-up appointments of service users with their clinicians or care coordinators as described in their care plans. The perspective of the analysis was the NHS and social care services. Costs consisted of intervention costs (CBT), inpatient and outpatient care, emergency visits, community care, day care and paid care. National unit costs were used. The primary measures of outcome were the mean change in the Beck Depression Inventory-Youth (BDI-Y) and the Beck Anxiety Inventory-Youth (BAI-Y) score from baseline to endpoint. The duration of the study was 16 weeks.

Before treatment, the total mean cost per person was £4,551 (SD £7,568) for the CBT group and £2,420 (SD £6,289) for the control group, resulting in a cost difference of £2,131 (2010 prices); over the 16 weeks of treatment the total mean cost per person was £7,327 (SD £8,007) for the CBT group and £1,677 (SD £2,415) for the control group, so that the cost difference between the 2 arms of the trial was £5,650. The paper did not report whether the cost differences were statistically significant, but it is very unlikely they were due to the small number of participants and the wide confidence intervals around the mean costs. In terms of outcomes, changes in the BDI-Y score favoured CBT, while changes in the BAI-Y score favoured treatment as usual; none of the changes were statistically significant. Based on these results, it is unclear whether the addition of CBT on treatment as usual is a cost-effective option for the management of mood disorders or symptoms of depression and/or anxiety in people with mild to moderate learning disabilities.

The study is partially applicable to the NICE decision-making context, as no Quality Adjusted Life Years (QALYs), which is the preferred outcome measure by NICE for economic analyses, were estimated and therefore it is difficult to make judgements on the cost effectiveness of the intervention using the NICE cost effectiveness threshold. Moreover, the study population, which consisted of people with a mild to moderate learning disability who had a mood disorder or symptoms of depression and /or anxiety, comprises only a sub-group within the population of people with learning disabilities and mental health problems. Therefore, the results of this study may not be applicable to people with more severe learning disabilities, or people with learning disabilities experiencing different types of mental health problems. The economic study is characterised by very serious limitations, as it was conducted alongside a feasibility RCT, and therefore had a very small study sample (N=32), a short time horizon of 16 weeks, and, unsurprisingly, high uncertainty around costs and outcomes. For this reason, it was not considered further at formulation of recommendations.

5.2.5 Clinical evidence statements on psychological interventions

5.2.5.1.1 Mixed mental health problems: prevention or treatment

Mild to moderate learning disabilities

- Low to very low quality evidence from 3 RCTs and 1 controlled before-and-after study suggests that psychological interventions may have some clinically meaningful benefit over control in improving mental health, problem behaviour and adaptive functioning (RCTs: number of studies (k)=3; N=73 and controlled-before-and-after: k=1; N=24).
- Low to very low quality evidence from 1 RCT showed no difference between whether or not social problem solving occurs before or after assertiveness training in mental health, problem behaviour or adaptive functioning outcomes after 3 months (k=1; N=18).

5.2.5.1.2 Substance misuse: prevention or treatment

Unclear level of learning disabilities

- Very low quality evidence from 1 RCT showed no difference between psychological interventions and control on alcohol misuse after 34 weeks' follow-up (k=1; N=84).
- Very low quality evidence from 1 RCT showed no difference between assertiveness training and modelling plus social inference on alcohol misuse after 34 weeks' follow-up (k=1; N=84).

5.2.5.1.3 Anxiety symptoms: prevention or treatment

Mild to moderate learning disabilities

- Very low quality evidence from 2 RCTs and 1 controlled before-and-after study was inconclusive if there was a difference between psychological interventions and control on anxiety symptoms or improve paid or voluntary employment after unclear or 42 weeks follow-up (RCT: k=2; N=112 and controlled before-and-after: k=1; N=24).

Moderate to severe learning disabilities

- Very low quality evidence from 2 RCTs showed that relaxation training had a clinically meaningful improvement in anxiety symptoms over control after unclear or 2.29 weeks follow-up (k=2; N=60).

5.2.5.1.4 Social anxiety symptoms: treatment

Mild to moderate learning disabilities

- Very low quality evidence from 1 RCT showed no difference between a dating skills programme over control in social anxiety at 20 weeks' follow-up (k=1; N=88).

5.2.5.1.5 Post-traumatic stress disorder: treatment

Mild learning disabilities

- Very low quality evidence from 1 RCT suggested that applied behaviour analysis may have improved mental health, problem and adaptive behaviour over CBT at unclear follow-up (k=1; N=27).

5.2.5.1.6 Depressive symptoms – prevention or treatment

Mild to moderate learning disabilities

- Low to very low quality evidence from 3 RCTs and 3 controlled before-and-after studies suggests that CBT may result in a clinically meaningful reduction in depressive symptoms over placebo at 38 weeks' follow-up (RCT: k=3; N=130 and controlled before-and-after: k=3; N=130).
- Very low quality evidence from 1 RCT shows little difference between CBT and behavioural or cognitive techniques on their own at 38 weeks' follow-up (k=1; N=70).

5.2.5.1.7 Sexually inappropriate behaviour – treatment

Unclear level of learning disabilities

- Very low quality evidence from 1 cohort study is inconclusive about whether psychodynamic psychotherapy is better than no treatment at reducing recidivism at 208 weeks follow-up (k=1; N=18).

5.2.6 Economic evidence statements

- Very low quality evidence from a feasibility RCT (N=32) is inconclusive about whether manualised individual CBT added to treatment as usual is cost-effective compared with treatment as usual alone in the management of symptoms of depression and/or anxiety in adults with a mild to moderate learning disability. This evidence, although derived from a UK study, is partially applicable to the NICE decision-making context as it did not report outcomes in the form of QALYs, and is characterised by very serious limitations, including a very small study sample, short time horizon (16 weeks) and high uncertainty characterising costs and outcomes. Moreover, as the study population consisted of people with a mild to moderate learning disability who had a mood disorder or symptoms of depression and /or anxiety, the results of this study may not be applicable to people with more severe learning disabilities, or people with learning disabilities experiencing different types of mental health problems.

5.2.7 Recommendations and link to evidence

5.2.7.1 Psychological interventions

Recommendations	**Delivering psychological interventions for mental health problems in people with learning disabilities** **31. For psychological interventions for mental health problems in people with learning disabilities, refer to the NICE guidelines on specific mental health problems (see mental health and behavioural conditions on the NICE website) and take into account:** **• the principles for delivering psychological interventions (see recommendations 32 and 34.** **• the specific interventions recommended in this guideline (see recommendations 157).** **32. Use the mental health assessment to inform the psychological intervention and any adaptations to it, and:** **• tailor it to their preferences, level of understanding, and strengths and needs** **• take into account any physical, neurological, cognitive or sensory impairments and communication needs** **• take into account the person’s need for privacy (particularly when offering interventions on an outreach basis)** **• agree how it will be delivered (for example, face-to-face or remotely by phone or computer), taking into account the person’s communication needs and how suitable remote working is for them.** **33. If possible, collaborate with the person and their family members, carers or care workers (as appropriate) to:** **• develop and agree the intervention goals** **• develop an understanding of how the person expresses or describes emotions or distressing experiences**

	• **agree the structure, frequency, duration and content of the intervention, including its timing, mode of delivery and pace** • **agree the level of flexibility needed to effectively deliver the intervention** • **agree how progress will be measured and how data will be collected (for example, visual representations of distress or wellbeing).** **34. Be aware that people with learning disabilities might need more structured support to practise and apply new skills to everyday life between sessions. In discussion with the person, consider:** • **providing additional support during meetings and in the planning of activities between meetings** • **asking a family member, carer or care worker to provide support and assistance (such as reminders) to practise new skills between meetings.** **Specific psychological interventions** **35. Consider cognitive behavioural therapy, adapted for people with learning disabilities (see the intervention adaptation methods in 1.8.2), to treat depression or subthreshold depressive symptoms in people with mild or moderate learning disabilities** **36. Consider relaxation therapy to treat anxiety symptoms in people with learning disabilities.** **37. Consider using graded exposure techniques to treat anxiety symptoms or phobias in people with learning disabilities.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of interventions at preventing or treating mental health problems. In addition to the effect on the mental health problem which was the aim of the intervention (for dementia, this was cognitive function as well as psychopathology), the GC were of the view that quality of life, and community participation and meaningful occupation were particularly critical outcomes which they wished to consider in the literature. The GC noted in particular the difficulties with measuring self-reported outcomes in this population, given communication needs and cognitive impairments so there should be caution in the interpretation of these outcomes from the trials. Reported outcomes from multiple sources may be helpful (eg. teachers, parents) in addressing this issue. Additional important outcomes included problem behaviours, adaptive functioning such as communication skills, service user or carer satisfaction or experience of care, carer health and quality of life, adverse effects of

	interventions, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	The group noted that while there was more evidence on psychological interventions than other types of interventions, there is still relatively little evidence of psychological interventions in people with learning disabilities. In addition, all but 1 study (Holstead & Dalton, 2013) was in adults so there is a particular lack of evidence on children and young people. They also noted that most studies included people with mild to moderate learning disabilities, only 1 study (Lindsay et al., 1989) on relaxation therapy for anxiety included some people with severe learning disabilities. They noted the overall lack of evidence on community participation and meaningful occupation and quality of life in this area. They also noted that there was very little evidence on harms from psychological treatment but that there was unlikely to be major harms from most of the types of treatments considered in this section. There is the possibility of harm from desensitisation or exposure therapy but there was no evidence of this. **Mixed mental health problems** The group noted that psychological interventions, in general, appear to be better than no treatment or waitlist control at reducing mental health problems in people with mild to moderate learning disabilities but this is based on small number studies. One RCT compared the difference between social problem solving then assertiveness training with assertiveness training then social problem solving and a non-randomised study compared different lengths of psychodynamic psychotherapy but there was no difference between groups. **Substance misuse** There was 1 study which was a 3-armed trial on prevention or treatment of substance misuse, and it considered assertiveness training with modelling plus social inference or control. However, it showed very little difference between arms and the sample was small so may have not been able to detect differences. **Anxiety disorders** The evidence on psychological interventions for anxiety symptoms in mild-to-moderate learning disabilities was inconclusive. The RCTs showed that there may be an effect of psychological interventions over control in terms of anxiety symptoms; the controlled before-and-after study was more uncertain. However, see notes below on quality considerations. There was some RCT evidence that there were less people in paid employment with psychological interventions compared to control but more were in voluntary work. However, there was much uncertainty around these estimates so it was difficult to draw any conclusions. There was some evidence to suggest that contact desensitisation is better than placebo at reducing fears but this was based a small and older study. The evidence on psychological interventions for moderate to severe learning disabilities was only on relaxation therapy and appeared to be consistent in showing that relaxation is better than placebo at reducing anxiety symptoms. While the evidence on relaxation was from small studies and was of limited quality, the results were considered to be clinically important and precise. As such, the GC agreed that they could make a weak recommendation on relaxation therapy; while the evidence supported the use of this in moderate and severe learning disabilities, the GC considered that it is reasonable to expect that it would be similarly effective in mild learning disabilities so did

not limit the population in the recommendation.

There was 1 trial on social anxiety which found no difference between a dating skills programme and a control in a group of people with mild to moderate learning disabilities. The trial appears to have included people with borderline intellectual functioning but it’s not clear how many would be considered to have learning disabilities (and, thus, not be the population of interest) as the study used an atypical measurement of intellectual functioning on a 3-point scale.

The GC agreed that more research is needed on more targeted and structured interventions for anxiety and that these should involve a social component. They considered that these types of interventions are likely to be quite useful in people with learning disabilities but there was no data to support this.

PTSD

There was 1 controlled before-and-after trial which compared CBT versus applied behaviour analysis (ABA) for children with trauma which appeared to show that ABA is favourable over CBT on most subscales on the Achenbach assessment tool. However, see quality considerations below.

As such, the GC did not consider that they could draw any conclusions from this evidence on the treatment of PTSD. They were particularly concerned about the lack of evidence on PTSD in people with learning disabilities as they are a vulnerable group who are at risk of trauma, abuse and neglect.

Depressive symptoms

All the evidence on psychological interventions for depression was for CBT (adapted for learning disabilities) in people with mild to moderate learning disabilities. While the trials included appeared to have some variations in the adaptations to the intervention and suffered from the same issues as most other studies in learning disabilities (being mostly pilot feasibility studies so small in size and leading to imprecision in estimates), the evidence appeared to suggest that CBT may be beneficial for depression.

There was some RCT evidence (from the same study reported above for anxiety) that there were less people in paid employment with CBT compared to control but more were in voluntary work. However, there was much uncertainty around these estimates so it was difficult to draw any conclusions. The effects on social skills were less clear but the GC considered that this may be due to the variations in CBT across the studies (see further details below under quality).

Given the GC’s expert knowledge and some demonstrated evidence of a benefit for CBT over control, the GC decided to make a recommendation on adapted CBT for depression. However, as the evidence was from small studies and very low quality (see ‘Quality of the evidence’ overleaf), they were not confident enough in the results to make a strong recommendation so recommended that CBT be considered for use in depression.

There was little difference between CBT and behavioural strategies only or CBT compared with cognitive strategies only but the evidence was based on one small controlled before-and-after study.

Sexually inappropriate behaviour

One very small observational study which considered psychodynamic psychotherapy against no treatment in a population of offenders (13 of 18) reported reduced recidivism in the treatment group but there was a lot of uncertainty in the results, possibly due to the small numbers of patients in the study, so it was not possible to draw any conclusions.

	No evidence was found on the use of psychological interventions for the treatment and prevention of other mental health problems in people with learning disabilities, such as substance misuse (other than alcohol misuse), eating disorders, personality disorders, or serious mental illness such as psychosis or schizophrenia.
Trade-off between net health benefits and resource use	Limited evidence on the cost effectiveness of psychological interventions for adults was inconclusive and characterised by very serious limitations and therefore was not considered further. The GC considered the economic consequences arising from the presence of mental health problems in people with learning disabilities that is associated with consumption of extra healthcare resources. The GC also considered the impact of mental health problems on the health-related quality of life (HRQoL) of people with learning disabilities, their family and carers and concluded that provision of effective psychological interventions for the prevention and management of mental health problems is likely to improve the HRQoL of service users and carers and reduce healthcare costs resulting from the management of mental health problems in more resource-intensive settings, such as secondary care. The GC took into account the fact that provision of psychological interventions to people with learning disabilities may be more resource-intensive compared with provision of psychological interventions in populations without learning disabilities, and this may have implications for the cost effectiveness of such interventions. Nevertheless, the GC agreed that adaptations of psychological interventions were necessary for this population in order to achieve a positive outcome. The GC considered also issues relating to equality, and agreed that psychological interventions for the prevention and/or management of mental health problems that have been shown to be cost-effective in populations without learning disabilities should also be offered to people with learning disabilities, following necessary adaptations.
Quality of evidence	The overall quality of the evidence was low to very low quality. The GC were particularly concerned about the nature of much of the existing RCT data, particularly as most are feasibility studies and are not likely to be powered appropriately to determine effectiveness against a comparator. However, they also appreciated the additional risk of bias by considering controlled before and after studies. For the most part, the controlled before and after studies were consistent with the results from the RCTs. There was inconsistency within the analyses for a number of comparisons: - psychological interventions compared to control for mental health problems – there were too few studies to perform subgroup analyses, such as by type of psychological intervention or other possible reasons which the group wished to examine as specified in the protocol. - psychological interventions for anxiety symptoms in people with mild to moderate learning disabilities – it appeared that relaxation therapy may be of more benefit than CBT but there were not enough data to explore this robustly. - CBT for people with depressive symptoms – for the outcome social skills/behaviour, the RCT evidence showed social skills were higher for CBT but the controlled before-and-after evidence showed social behaviours were lower in the CBT group. However, the controlled before-and-after study that contributed to this evidence was very small (24 patients) so it was difficult to draw conclusions from the evidence. The authors of this study reported that those in the CBT did not improve on social skills and concluded that social skills may need to be specifically targeted within CBT programs. As such, the difference in impact on social skills may be due to differences between

	the delivery of CBT between the RCTs and the non-randomised study. The GC were particularly concerned about the potential for bias in the trial data on PTSD comparing CBT with ABA (1 controlled before-and-after study), notably the comparability of the groups which is a risk without randomisation between comparator groups (those in CBT group were referred by juvenile services and had higher number of pre-admission juvenile justice contacts). The group were also concerned that the outcomes used in the trial were not specific to PTSD and may therefore favour ABA. The GC noted again that many of outcome measurements used in the included trials were experimental or bespoke measures or had not been validated in this population (such as the BDI) and that there should be caution in the interpretation of some of the outcomes from the trials. As a result of the quality of the evidence, the GC did not have confidence in the results from the evidence.
Other considerations	As a result of limited quality evidence the group agreed to develop a set of general principles for adapting psychological treatments for people with learning disabilities. The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas: - adapt psychological interventions to the needs (including communication needs) and preferences of the person, as assessed during the assessment, including in the structure of the sessions such as by adjusting the frequency, length and pace of sessions, - develop an understanding of how the person expresses or describes emotions or distressing experiences, and that the person’s ability to identify their emotions should be evaluated before starting treatment and reminders about homework tasks may need to be provided - take into account the person’s need for privacy, particularly when offering interventions on an outreach basis - involving family members or carers in treatment (the group appreciated this was important, in general, and was not specific to psychological interventions so covered this in an overall section rather than repeated throughout) – they considered that there may be exceptions to this where the family may be the cause of the problem or person may not want their family involved - communication – should be directly with the person (not talking over them), adapt interventions to the person’s understanding, to use the person’s own words for emotions throughout, communicate the agenda for the session in the most appropriate format for the individual, to use clear and straightforward language and to explain the meaning and purpose of any abstract visual stimuli; the use of different methods and formats for communication, if needed and regularly checking understanding and summarise purpose of every meeting (the group appreciated this was important, in general, and was not specific to psychological interventions so covered this in an overall section rather than repeated throughout) - provide support to practise and apply skills in everyday life situations, which may include involvement of the family member, carer or care worker - reducing stressors to manage a person’s environment may be useful (while the statement agreed was for severe and profound learning disabilities, it was thought this was also likely to apply to people with mild to moderate learning disabilities) - use of grade exposure techniques to treat anxiety symptoms or phobias (while the statement agreed was for severe and profound

	learning disabilities, it was thought this was also likely to apply to people with mild to moderate learning disabilities; as mentioned above, there was some evidence to suggest that contact desensitisation is better than placebo for fear/phobias) A number of additional contextual factors were identified by the nominal group technique which were deemed to be important to address, and recommendations were made to incorporate these issues: - While separate nominal group statements were developed for adapting interventions for people with mild to moderate learning disabilities, and for people with severe to profound learning disabilities, the resulting recommendations appeared to potentially apply to all degrees of learning disability (due to the flexibility of adapting to an individual's needs and abilities within the text) so the group removed this distinction - the importance of collaboration with the person and their family members, carers or care workers was emphasised - communication, consent and capacity are essential considerations (the group appreciated this was important, in general, and was not specific to psychological interventions so covered this in an overall section rather than repeated throughout) - the need or benefit of routine in appointment-scheduling could be considered and that breaks may be necessary but agreed these were covered by wording in existing recommendations - checking the person has communicated what they wanted to - while the GC had a high level of agreement for incorporating the person's specific interest and acknowledged that it may be helpful in some situations, on reflection they agreed to remove this as it may be counterproductive to sessions - while there was agreement on the use of clear, structured activities as part of any psychological or psychosocial intervention for people with severe or profound learning disabilities, this was adequately covered by recommendations about involving the person and their family members to adjust the structure, frequency, duration, etc of the intervention While the evidence for CBT for depression was a bit clearer, the evidence for psychological interventions for anxiety disorders (including PTSD) was less clear. As such, the group made a recommendation for future research into interventions for anxiety. The group also noted the lack of evidence on psychological interventions for conditions other than common mental health problems such as eating disorders, schizophrenia, and bipolar disorder so recommended more research in these areas, as well. The group noted that the existing evidence on psychological interventions was in adults but decided, in the absence of evidence for children, that the recommendations should also apply to children to prevent children from falling between the gaps and ensure they receive treatment, when needed. However, the group recommended that future research on individual treatments for children should be conducted in order to inform specific recommendations on treatment for children.

5.2.7.2 All interventions for mental health problems

Recommendations	**Interventions for mental health problems in people with learning disabilities** **38. Use this guideline with the NICE guidelines on specific mental health problems (see mental health and behavioural**

	conditions on the NICE website), and take into account: • **differences in the presentation of mental health problems** • **communication needs (see recommendation 38)** • **decision-making capacity (see recommendation 60)** • **the degree of learning disabilities** • **the treatment setting (for example, primary or secondary care services, mental health or learning disabilities services, in the community or the person's home)** • **interventions specifically for people with learning disabilities (see recommendations 39 to 54).**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of interventions at preventing or treating mental health problems. In addition to the effect on the mental health problem which was the aim of the intervention (for dementia, this was cognitive function as well as psychopathology), the GC were of the view that quality of life, and community participation and meaningful occupation were particularly critical outcomes which they wished to consider in the literature. The GC noted in particular the difficulties with measuring self-reported outcomes in this population, given communication needs and cognitive impairments so there should be caution in the interpretation of these outcomes from the trials. Reported outcomes from multiple sources may be helpful (eg. teachers, parents) in addressing this issue. Additional important outcomes included problem behaviours, adaptive functioning such as communication skills, service user or carer satisfaction or experience of care, carer health and quality of life, adverse effects of interventions, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	Please see this section for each intervention section (5.2.7.1, 5.3.5, 6.3, 7.5, 7.6.5, and 7.7.5)
Trade-off between net health benefits and resource use	Please see this section for each intervention section (5.2.7.1, 5.3.5, 6.3, 7.5, 7.6.5, and 7.7.5)
Quality of evidence	Please see this section for each intervention section (5.2.7.1, 5.3.5, 6.3, 7.5, 7.6.5, and 7.7.5)
Other considerations	With the exception of some specific psychological interventions for which the GC were able to make recommendations from the available evidence, there was a paucity of high quality research to inform recommendations on interventions for people with learning disabilities and mental health problems. The GC agreed that people with learning disabilities should be offered the same services and interventions as people without learning disabilities and judged that it was appropriate to refer into other NICE guidelines on mental health problems. However, they appreciated that there are some additional considerations that need to be made when considering interventions for people with learning disabilities. Some of these considerations are covered in recommendations developed through formal

	consensus on adapting psychological interventions as well as on the use of pharmacological interventions. The GC developed a general set of principles to inform the approach to assess the relevance of other mental health guidelines for the treatment of people with learning disabilities and mental health problems. For people with mild learning disabilities, the GC considered that all NICE guideline recommendations were relevant. For moderate and severe learning disabilities, the GC took the view that the general principles they developed were the best guide to the appropriate use and adaptation of existing guidance. The GC noted that variations exist within the population of people with learning disabilities (in the nature of learning disabilities, the presentation of mental health problems, and different coexisting conditions which occur in many people with learning disabilities) and this means that individual clinicians will have to make a judgment on the relevance of a particular recommendation in NICE guidelines on mental health problems, depending on the specific needs of the individual. They also agreed that special considerations about the ideal treatment setting for a person should be made on an individual basis. Specific recommendations around communication and decision-making (with respect to consent and capacity) are important considerations which have been highlighted elsewhere in this guideline (see 8.2.6.1 and 8.2.6.2).

5.2.8 Research recommendations

3. **For people with mild to moderate learning disabilities, what is the clinical and cost effectiveness of cognitive behavioural therapy (modifications for people with learning disabilities) for treating anxiety disorders?**

4. **For people with mild to moderate learning disabilities, what is the clinical and cost effectiveness of psychological interventions (either modifications of existing interventions or new interventions) for treating depressive disorders?**

5. **For children with learning disabilities, what is the clinical and cost effectiveness of individual therapeutic work/psychosocial interventions for mental health problems?**

5.3 Review question: In people (children, young people and adults) with learning disabilities, does family carer or staff training aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 55. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 55: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, does family carer or staff training interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.12)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any family carer or staff training intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

5.3.1 Clinical evidence

A number of RCTs were found on the use of parent training interventions; however there were no studies found on staff training or training for other family carers which were focused on mental health problems in people with learning disabilities.

The review completed for the guideline on behaviour challenges on parent training was adapted for use in this guideline (NICE, 2015). However, some additional information was extracted from the papers such as the underlying cause of learning disabilities, any coexisting conditions/treatments received, whether or not the intervention was tailored for learning disabilities (see the study information tables below), and additional outcome measures to indicate mental health (when reported). There was 1 analysis from the review for parent training versus any control that was amended to include these different outcome measures that the GC considered as measures of mental health, rather than just behaviour that challenges (that is, total scores on the Developmental Behaviour Checklist [DBC] rather than the disruptive behaviour subscale on this tool). The guideline on behaviour that challenges also included pairwise comparisons of studies comparing different types of parent training (individual versus group, parent training plus optimism training versus parent training alone, and enhanced versus standard parent training) but these have not been considered here as the studies included did not report an outcome that would be considered a measure of mental health as a primary outcome.

The GC did not consider it necessary to go down the evidence hierarchy for parent training as the existing RCT evidence was considered to be adequate to support recommendations. Furthermore, the group did not update the challenging behaviour review as it was considered unlikely that new research would alter the findings significantly.

5.3.1.1 Parent training versus any control

There were 15 RCTs (N=819) that met the eligibility criteria for this review: Aman (2009), Bagner and Eyberg (2007), Brightman et al. (1982), Hand et al. (2012), Leung et al. (2013), McIntyre (2008), Oliva et al. (2012), Plant and Sanders (2007), Prieto-Bayard and Baker (1986), Reitzel et al. (2013), Roberts et al. (2006), Roux et al. (2013), Sofronoff et al. (2011), Tellegen and Sanders (2013) and Whittingham et al. (2009). Of the eligible studies, 13 included sufficient data to be included in a meta-analysis, 1 trial (Prieto-Bayard 1986) included no critical outcome data (N=20) and 1 trial (Brightman 1982; N=66) included critical outcomes that could not be included in the meta-analysis because of the way the data had been reported. A brief narrative synthesis of Brightman (1982) is given to assess whether the findings support or refute the meta-analysis. An overview of the trials included in the meta-analysis can be found in Table 56.

Further information about both included and excluded studies can be found in the challenging behaviour guideline (NICE, 2015).

Summary of findings can be found in Table 57. The full GRADE evidence profiles and any amended forest plots can be found in Appendix N and Appendix O, respectively.

While some studies did not report the level of learning disabilities of the included participants, others included patients across differing levels of disabilities without reporting separate results by level of disabilities. As a result, it was not possible to group the results by level of disabilities.

There were 3 studies which considered mixed populations of learning disabled and non-learning disabled participants (Aman 2009; Tellegen 2014; Whittingham 2009). To explore the robustness of the findings, a second sensitivity analysis excluding these 3 studies was conducted. All but 1 effect remained consistent with the main analysis (the removal of Aman 2009 led to insufficient evidence to assess adaptive functioning).

Subgroup analysis was carried out to compare the effectiveness of parent training delivered to individuals with that of parent training delivered to groups. Both subgroups were shown to be equally effective at reducing mental health/behavioural symptoms.

Subgroup analyses were also conducted to see if studies explicitly addressing parents of children with specific symptoms (treatment) produced different results than those directed at any parent of a child with learning disabilities, whether or not they had any existing symptoms or diagnoses (mixed prevention or treatment). There was no significant difference in the effect in the subgroups. Subgroup analyses comparing studies with programs explicitly tailored for parents of children with learning disabilities with those that were not tailored also showed no difference between groups. All subgroup analyses showed parent training as effective at improving mental health/behavioural outcomes for all subgroups.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 56: Study information table for trials included in the analysis of parent training versus any control

	Parent training versus any control
Total no. of studies (N[1])	14 (799)
Study ID	(1) Aman 2009[2] (2) Bagner 2007 (3) Brightman 1982[3,4] (4) Hand 2012 (5) Leung 2013 (6) McIntyre 2008 (7) Oliva 2012 (8) Plant 2007[3] (9) Reitzel 2013 (10) Roberts 2006 (11) Roux 2013 (12) Sofronoff 2011 (13) Tellegen 2014[2] (14) Whittingham 2009[2]
Country	(1, 2, 3, 6, 9) USA/Canada (4) Ireland (5) China (7) Italy (8, 10, 11, 12, 13, 14) Australia
Diagnosis/degree of learning disabilities	(1) pervasive developmental disorders (2) Mild to moderate learning disabilities (3) Moderate to severe learning disabilities (31% Down's, 29% unknown, 9% autism) (4, 7) Mild learning disabilities[5] (5, 6, 10, 11, 12) Developmental disabilities (mixed)[6] (8) Mild to severe learning disabilities[7] (9) Autism with significant early learning skills impairments such as verbal and non-verbal communication and imitation (13, 14) ASD
Child age (mean)	4-8 (range from 2 to 15) (4) Not reported
Child sex (% female)	13-50 (3, 4, 9) Not reported
Child ethnicity (% white)	67-100 (5) 0 (3, 4, 8, 9, 10, 11, 12, 14) Not reported
Child IQ (mean)	37-75 (3, 4, 5, 6, 7, 8, 11, 12, 13, 14) Not reported
Coexisting conditions/treatments received (child)	(2) Not reported (3) 94% were receiving some education services in preschool or special classes

	Parent training versus any control
	(13) 15% had ADHD
Targeted behaviour	(1) Serious behaviour problems (tantrums, self-injury, aggression) (2) Oppositional defiance disorder (7) non-compliant behaviour (3-7, 9-11, 13) Not specified (8) behaviour problems (at least 131 on ECBI or 15 on problem score) (12) Not specified (but 38% had emotional or behavioural problems) (14) behaviour problems (as described by parent)
Treatment length (weeks)	8-24 (12) 1
Intervention (mean dose; mg/day) (tailored for learning disabilities unless otherwise specified)	(1) Individualised parent training (plus treatment as usual/risperidone) (individual) (2) Parent–Child Interaction Therapy (not tailored for learning disabilities) (individual) (3) Behaviour modification training, 'Steps to Independence' series (group and individual) (4) Parents Plus Children's Programme (group) (5) Triple P Level 4 (not tailored for learning disabilities) (group) (6) Incredible Years Parent Training Program – Developmental Disabilities (group) (7) Behavioural parent training (unclear if tailored for learning disabilities) (group) (8, 10) Stepping Stones Triple P (individual) (11, 12) Stepping Stones Triple P (group) (14) Stepping Stones Triple P (partial group/individual) (9) Functional Behaviour Skills Training programme (tailored for early learning skills impairment in those with autism) (group) (13) Primary Care Stepping Stones Triple P (group)
Comparison	(1) Treatment as usual/risperidone monotherapy (2, 3, 5, 8, 11) Waitlist (4, 6, 9, 10, 13, 14) Treatment as usual (7, 12) No treatment

Note.

N=total number of participants.

[1] Number randomised.

[2] Study excluded in sensitivity analysis due to mixed sample of learning disabled and non-learning disabled participants.

[3] 3-armed trial; 2 active intervention arms combined in analysis.

[4] Data not reported in a meta-analysable format; findings are described narratively.

[5] 15 learning disabilities, 2 autism, 3 Down's syndrome, 1 Prader–Willi syndrome Prader–Willi syndrome, 1 Williams-Beuren syndrome, 2 dyspraxia, 1 epilepsy, 1 speech delay in Hand 2013

[6] 23 autism, 15 Down's syndrome, 5 cerebral palsy and 2 other learning disabilities (Roux 2013) and 45% ASD, 19 learning disabilities, 11% developmental delay, 9% specific learning difficulty, 4% cerebral palsy, 4% vision impairment, 2% Maroteaux–Lamy syndrome, 6% acquired brain injury (Sofronoff 2011)

[7] 33% ASD, 18% developmental delay, 11% Down's syndrome, 9.5% other chromosomal abnormality, 7% cerebral palsy; study also included children who were borderline IQ or 'at

	Parent training versus any control
risk' (7%)	

Table 57: Summary of findings table for the analysis of parent training versus control

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with any control	Risk difference with parent training
Behavioural and emotional problems (severity) - post-treatment (Mental health) assessed with: Various scales	645 (13 RCTs)	⊕⊕⊕◯ MODERATE [1]	-	-	SMD 0.4 SD lower (0.55 lower to 0.24 lower)
Behavioural and emotional problems (severity) - follow-up (Mental health) assessed with: Various scales follow up: range 26- 52 weeks to 0	139 (2 RCTs)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.13 fewer (0.45 fewer to 0.19 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Problem behaviour (severity, non-improvement) - post-treatment assessed with: Various scales	428 (8 RCTs)	⊕⊕⊕◯ MODERATE [1]	RR 0.67 (0.59 to 0.77)	Study population	
				883 per 1000	291 fewer per 1000 (362 fewer to 203 fewer)
Problem behaviour (frequency) - post-treatment assessed with: Various scales	437 (8 RCTs)	⊕⊕◯◯ LOW [1,4]	-	-	SMD 0.6 fewer (0.9 fewer to 0.3 fewer)
Problem behaviour (frequency) - follow-up assessed with: Various scales follow up: mean 26 weeks	64 (1 RCT)	⊕◯◯◯ VERY LOW [5,6]	-	-	SMD 0.36 fewer (0.85 fewer to 0.14 more)
Problem behaviour (frequency, non-improvement) - post-treatment assessed with: Various scales	343 (6 RCTs)	⊕⊕◯◯ LOW [1,2]	RR 0.63 (0.55 to 0.73)	Study population	
				948 per 1000	351 fewer per 1000 (427 fewer to 256 fewer)
Adaptive functioning (communication) - post-treatment	124 (1 RCT)	⊕◯◯◯ VERY LOW [2,5,6]	-	-	SMD 0.47 more (0.11 more to 0.84 more)
Adaptive functioning (total) - post-treatment	135 (2 RCTs)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.51 more (0.15 more to 0.86 more)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with any control	Risk difference with parent training
Note 1. Most information is from studies at moderate risk of bias 2. Concerns with applicability - different populations 3. Optimal information size not met 4. $I^2 > 40\%$ 5. Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect 6. Optimal information size not met; small, single study 7. Publication bias strongly suspected					

5.3.2 Economic evidence

No economic evidence was identified for family carer or staff training aimed at preventing and/or managing mental health problems in people with learning disabilities. Details on the methods used for the systematic review of the economic literature are described in Chapter 3. Because of lack of direct economic evidence, the GC considered economic evidence that was reported in the NICE Guideline on Challenging Behaviour and Learning Disabilities (NICE, 2015) for children and young people with learning disabilities and behaviour that challenges. An economic model was developed for that guideline, which assessed the cost effectiveness of parent training for the management of behaviour that challenges in children and young people with learning disabilities. A summary of the methods and the results of this model are presented in this section, as the GC considered the findings of this economic analysis as indirect evidence on the cost effectiveness of parent training for the management of mental health problems in children and young people with learning disabilities. The completed methodology checklist, the evidence table and the economic profile of this economic study are provided in Appendix Q, Appendix R and Appendix S, respectively.

The economic analysis developed to inform recommendations in the NICE clinical guideline on Challenging Behaviour and Learning Disabilities (NICE, 2015) compared parent training with waitlist for the management of behaviour that challenges in children and young people with learning disabilities. The analysis considered group parent training because available evidence suggested that there was no difference in the clinical effectiveness between individual and group parent training; therefore group parent training was selected for modelling as it is more cost-effective than parent training delivered individually (because the intervention cost is lower). Waitlist was selected as the comparator as this was the most common control used in the RCTs that informed that economic analysis. In those RCTs that did not use waitlist as the comparator, parent training was predominantly provided in addition to treatment as usual versus treatment as usual alone, so the control intervention did not incur any extra costs.

The economic model, which had the form of a decision-tree, followed hypothetical cohorts of families of children and young people with a learning disability and behaviour that challenges, who either received group parent training for 9 weeks or were included in a waitlist. Families of children and young people whose symptoms improved at the end of the 9 weeks received 2 booster sessions; children and young people with improved symptoms could relapse over the following year. Children and young people whose behaviour did not improve at the end of the 9 weeks were conservatively assumed to retain behaviour that challenges over the following year. The time horizon of the model was 61 weeks (9 weeks of treatment and 52 weeks of follow-up). The analysis adopted the perspective of the NHS and personal social services. Costs consisted of intervention costs only, as no data on costs associated with behaviour that challenges in children and young people with a learning disability were identified in the relevant literature. The measure of outcome was the QALY.

Efficacy data regarding the relative effect of parent training versus waitlist and the baseline effect of waitlist were taken from 8 RCTs on parent training that were included in the guideline systematic review, which reported outcomes in the form of improvement in behaviour that challenges regarding its severity. Improvement was defined as a clinically significant change score in 1 of the following scales: the Eyberg Child Behavior Inventory (ECBI) – Problem, the CBCL – Externalising behaviour, or the Developmental Behavior Checklist – Total Behavior Problem (DBC-TBPS). The probability of relapse was based on the GDG expert opinion, due to lack of relevant data in the literature. Utility data used for the estimation of QALYs were taken from Tilford et al. (2012), following a systematic review of relevant literature. The study reported utility data for children with autism in the US, derived from their parents' responses to the Health Utility Index 3 (HUI3). The economic analysis used utility scores reported in that study for different levels of hyperactivity as a proxy for changes in behaviour that challenges in children and young people with a learning disability. The analysis conservatively assumed that at initiation of treatment the health-related quality of life (HRQoL) of children and young people corresponded to moderate levels of hyperactivity that improved to mild symptoms following response to treatment

The intervention cost of parent training was calculated by combining relevant resource use (based on data reported in the 8 RCTs included in the guideline systematic review that were considered in the economic analysis) with respective national unit costs (Curtis, 2013). The economic analysis modelled parent training comprising 8 group sessions lasting 2 hours each plus 2 booster group sessions of the same duration provided to families whose children showed improvement in their behaviour; each group was formed by 10 families and was run by a clinical psychologist Band 8a and a mental health nurse Band 5 (according to Agenda for Change of the July 2012-June 2013 NHS staff earnings estimates for qualified Allied Health Professionals and qualified nurses, respectively), who acted as co-facilitator. The intervention cost of waitlist was zero.

According to the results, provision of parent training resulted in 1.33 additional QALYs per 100 children and young people with learning disabilities and behaviour that challenges, compared with waitlist, at an additional cost of £36,219 (2013 prices). The ICER of parent training versus waitlist was £27,148/QALY, which is above the lower (£20,000/QALY) but below the upper (£30,000/QALY) NICE cost effectiveness threshold. The probability of parent training being cost-effective relative to waitlist under the NICE lower and upper cost effectiveness thresholds was 0.29 and 0.52, respectively. When a lower risk of relapse over 1 year was assumed for parent training (that is, 0.40 instead of 0.50), its ICER versus waitlist fell at £24,895/QALY and its probability of being cost-effective under the lower and upper NICE cost effectiveness thresholds rose at 0.34 and 0.56, respectively. When the HRQoL of children and young people was assumed to correspond to severe hyperactivity at initiation of treatment, the ICER versus waitlist became £13,037/QALY; the probability of parent training being cost-effective under the lower and upper NICE cost effectiveness thresholds was 0.81 and 0.93, respectively, under this scenario.

The results of this analysis indicated that parent training might be marginally cost-effective for the management of behaviour that challenges in children and young people with learning disabilities, although the cost effectiveness of parent training improved when the long-term benefit was assumed to be better retained, and, in particular, when the severity of symptoms was higher at initiation of treatment, as there was more scope for improvement in terms of the children's and young people's HRQoL.

The analysis is only partially applicable in the context of this guideline, as the study population of the economic model was children and young people with learning disabilities and behaviour that challenges. The analysis is characterised by potentially serious limitations, including lack of follow-up data (beyond 9 weeks) and omission of costs associated with the presence of behaviour that challenges in children and young people with learning disabilities due to lack of any relevant data. Moreover, the analysis did not consider other benefits to the families and carers associated with group parent training, arising from meeting with other families and carers with similar experiences, sharing ideas and receiving peer support. It should also be noted that the economic analysis modelled only group parent training; individual parent training was expected to be less cost-effective, as it was no more effective and incurred higher intervention costs. However, there may be instances where group parent training is not available or not appropriate for some sub-populations, and individual parent training may be the only treatment option to offer.

The GC of this guideline considered this evidence and decided that it is adequately applicable to the population and context of this guideline.

5.3.3 Clinical evidence statements on parent training

5.3.3.1.1 Parent training versus any control

- Moderate-quality evidence from 13 studies (N=645) suggested that parent training had a clinically meaningful reduction in behavioural and emotional problems over control at the end of intervention.
- Very low-quality evidence from 2 studies (N=139) was inconclusive as to the effectiveness of parent training when compared with control in reducing behavioural and emotional problems at 26- to 52-week follow-up.
- Moderate-quality evidence from 8 studies (N=428) suggested that parent training had a clinically meaningful reduction in the risk of problem behaviour at the end of intervention when compared with control.
- Low-quality evidence from 9 studies (N=633) suggested that parent training was more effective than control in reducing the frequency of problem behaviour at the end of intervention.
- Very low-quality evidence from 2 studies (N=258) suggested that parent training was more effective than control in reducing the frequency of problem behaviour at 26-week follow-up. However, the precision of this estimate is poor.
- Low-quality evidence from 6 studies (N=343) suggested that parent training reduced the risk of the frequency of problem behaviour not being improved at the end of intervention when compared with control.

- Very low-quality evidence from up to 2 studies (N=135) suggested that parent training was more effective than control in increasing communication and adaptive functioning at the end of intervention.
- There was 1 trial which could not be included in the meta-analysis (N=66). The authors reported that parent training was more effective than control in reducing behavioural difficulties at end of intervention.

5.3.4 Economic evidence statements

- Low quality, indirect evidence from a model-based study on children and young people with learning disabilities and behaviour that challenges suggests that group parent training may be cost-effective for the management of mental health problems in children and young people with learning disabilities, especially in children and young people with more severe levels of behaviour that challenges at initiation of treatment. The analysis is only partially applicable in the context of this guideline, as the study population was children and young people with learning disabilities and behaviour that challenges. This evidence is characterised by potentially serious limitations, including lack of long-term clinical data and consideration of intervention costs only.

5.3.5 Recommendations and link to evidence

Recommendations	**39. Consider parent training programmes specifically designed for parents or carers of children with learning disabilities to help prevent or treat mental health problems in the child.** **40. Parent training programmes should:** • **be delivered in groups of parents or carers** • **be accessible (for example, take place outside normal working hours or in community settings with childcare facilities)** • **focus on developing communication and social functioning skills** • **typically consist of 8 to 12 sessions lasting 90 minutes** • **follow the relevant treatment manual** • **use all of the necessary materials to ensure consistent implementation of the programme** • **seek parent feedback.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of interventions at preventing or treating mental health problems. In addition to the effect on the mental health problem which was the aim of the intervention (for dementia, this was cognitive function as well as psychopathology), the GC were of the view that quality of life, and community participation and meaningful occupation were particularly critical outcomes which they agreed to consider in the literature.

	The GC noted in particular the difficulties with measuring self-reported outcomes in this population, given communication needs and cognitive impairments so there should be caution in the interpretation of these outcomes from the trials. Reported outcomes from multiple sources may be helpful (eg. teachers, parents) in addressing this issue. Additional important outcomes included problem behaviours, adaptive functioning such as communication skills, service user or carer satisfaction or experience of care, carer health and quality of life, adverse effects of interventions, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	Parent training appeared consistently to improve problem behaviour outcomes for children with learning disabilities with mixed degrees over learning disabilities over control but there was a lack of long-term data and data on harms with parent training. The GC recognised the potential value of early interventions because they equip parents to better manage behaviour so that they may not develop into long-term problems resulting in greater burden for the person, the family and the wider service system. In doing so the GC drew on their experience that parent training is common practice for children with behavioural problems and other neurodevelopmental disorders (for example, ADHD and autism). In particular, this knowledge was used to provide advice about the number of sessions and other aspects of parent-training programmes. The GC noted that parent training also has a positive effect on parental mental health and well-being; however, these outcomes were not extracted for the challenging behaviour review which was adapted for use in this guideline and so were not presented to the group. The participants in the studies included range of behavioural problem and some had a diagnosis of oppositional defiance disorder but in most cases the studies were assessed as being selective or indicated prevention studies. As such, the GC agreed that they should recommend the use of parent training programmes for both prevention and treatment.
Trade-off between net health benefits and resource use	Evidence suggests that group parent training is potentially cost-effective for the management of problem behaviour in children and young people with learning disabilities, especially in children and young people with more severe levels of behaviour that challenges at initiation of treatment. The GC considered this evidence and decided that it was applicable to the population of children and young people with learning disabilities and mental health problems. In addition, the GC noted the limitations of this evidence, such as the lack of long-term clinical data and the consideration of intervention costs only. The economic evidence was based on an economic model that had considered group parent training, because available evidence suggested that there was no difference in the clinical effectiveness between individual and group parent training; therefore group parent training was selected for modelling as it would be more cost-effective than parent training delivered individually (because the intervention cost is lower). The GC noted the evidence suggesting no difference in clinical effectiveness between individual and group mode of delivery, in combination with the lower intervention costs associated with provision of parent training delivered in groups, and decided to recommend group parent training. The GC considered other benefits resulting from group psychological interventions, such as meeting with other parents and carers experiencing

	similar situations and exchanging such experiences, sharing ideas and receiving peer support, which was not captured within the existing evidence. The economic evidence was based on provision of 8 sessions of group parent training plus 2 booster sessions following symptom improvement. In total, this required 20 hours of staff’s direct time. This estimate of resource use resulted from summarising the reported resource use in the trials that provided the clinical data that informed the economic model. The GC noted that the NICE guideline on people with learning disabilities and behaviour that challenges (NICE, 2015)recommended group parent training typically consisting of 8 to 12 sessions lasting 90 minutes each. This translates into 12-18 hours of staff’s time, which does not exceed the resource use considered in the economic model, and therefore ensures that provision of parent training is cost-effective. The GC considered the number and duration of parent training sessions recommended in the NICE guideline on people with learning disabilities and behaviour that challenges and found it reasonable from a clinical and cost-effectiveness perspective. Moreover, the GC considered that a percentage of children with learning disabilities have both behaviour that challenges and mental health problems and parent training might be used to address both. Therefore, the GC decided to recommend the same number and duration of group parent training sessions for children with learning disabilities and mental health problems, given also that the same economic evidence base was used in both areas (i.e. children with learning disabilities and behaviour that challenges and children with learning disabilities and mental health problems).
Quality of evidence	Unlike some of the other evidence on psychological interventions, the evidence on parent training was moderate to very low quality. The studies on parent training compared to a control were larger than many of the other studies and, partly as a consequence of this, the outcomes did not suffer from imprecision. As the quality of the evidence for parent training was better than in most other areas in this guideline, the GC had relative confidence in the results from the evidence.
Other considerations	The GC agreed that getting feedback from parents is good practice so they recommended this. This can be informative for any issues like why people may have dropped out.

6 Pharmacological interventions

6.1 Introduction

Following significant concerns that psychotropic drugs in general, and antipsychotics in particular, are used inappropriately in people with learning disabilities (Brylewski & Duggan, 2004; Matson et al., 2000; Molyneux et al., 1999; Sheehan et al., 2015; Tsiouris, 2010), there has been a concerted effort to improve clinical practice in this area (Slowie & Ridge, 2015). It is important to note, as these references indicate, that these concerns have been driven by the prescription of antipsychotic drugs for people with learning disabilities who have challenging behaviour, rather than mental illness.

Broadly speaking, people with learning disabilities are prescribed psychotropic drugs including antipsychotics in 2 sets of circumstances: either because they have a psychiatric diagnosis or because they have behaviour that challenges (NICE, 2015)

A significant proportion of people with learning disabilities display behaviour that challenges. Challenging behaviour is defined as behaviour of an intensity, frequency, or duration that threatens the physical safety of the person or others, or restricts access to community facilities (Emerson et al, 2001). It is a socially constructed, descriptive concept that has no diagnostic significance and makes no inferences about the aetiology of the behaviour. It covers a heterogeneous group of behavioural phenomena across different groups of people, for example oppositional behaviour in children, faecal smearing in those with a severe learning disabilities, and self-harm in adult mental illness. Challenging behaviour may be unrelated to psychiatric disorder, but can also be a primary or secondary manifestation of it (Xeniditis et al., 2001). Likewise it can be related to physical health problems, communication difficulties or environmental changes and in many cases a combination of all of these. A number of authors have devised guidelines around the use of psychotropic medication for those with this condition (Bhaumik et al., 2015; Deb et al., 2006; Deb et al., 2009; Faculty of Psychiatry of Intellectual Disability, 2015, in preparation; Kalachnik et al., 1998; NICE, 2015; Rush et al., 2000) and NICE offers the most comprehensive guidance to date on this topic (NICE, 2015).

The above definition of challenging behaviour is broad enough to cover acts of aggression towards people, aggression to property, self-neglect, self-harm and the risk of exploitation. It therefore appears that almost anyone who has a mental health problem that reaches the threshold to need attention from primary or secondary care services would have some form of behaviour that challenges as a presenting feature (Faculty of Psychiatry of Intellectual Disability, 2015, in preparation).

People with learning disabilities develop psychiatric conditions including mental illnesses at rates similar to or higher than the general population (see Chapter 4), but failure of staff to recognise it, communication needs and health literacy, atypical presentations, diagnostic overshadowing, and difficulties in accessing services might mean that this is under-recorded (Sheehan et al., 2015) and underdiagnosed. This can be particularly problematic in those patients who are unable to give a clear verbal account of their mental health problems or ask for help. When mental ill-health is accompanied with aggression and/or destructiveness, the latter can be a trigger for seeking help. Even in those who do have expressive speech, many find it difficult to describe precisely their mental health problems. Thus in clinical practice, a psychiatric diagnosis may be recorded only when the main syndromes are present (for example, schizophrenia or bipolar disorder), while the narrative account of mental health problems (for example, transient psychotic symptoms and affective lability in someone with a mild learning disabilities and a personality disorder) is left out (Faculty of Psychiatry of Intellectual Disability, 2015, in preparation). This may contribute to under-recording of psychiatric diagnoses and in adequate monitoring of prescriptions.

Current best practice would suggest (Bhaumik et al., 2015; Deb et al., 2006; Deb et al., 2009; Rush et al., 2000) that the most important part of psychotropic medication prescribing for this group is the need for a clear assessment before the prescribing followed by regular review and monitoring of the prescribing.

That assessment should include a full recording of all the diagnoses and a clear identification of the psychotic, affective and behavioural symptoms including clusters of symptoms (Bhaumik et al., 2015) that are the target of treatment. Clinicians should bear in mind the possibility of atypical presentations and modifications of typical symptoms due to concurrent medication use for other indications. There should be evidence of sufficient explanation to patients and/or their families and carers and a record of the patient’s consent and capacity or of any best interest decisions, time frames for reviews and the tapering off or stopping of medication that is ineffective. This is particularly so when the prescribing may be off-license.

The issues of whether the dosages required for treating psychiatric conditions in people with learning disabilities are the same as for the general population, and whether they have more side effects, have been examined. The evidence is not very clear, but the current l consensus is that the drugs are equally effective and there is no conclusive evidence of them having more side-effects (Faculty of Psychiatry of Intellectual Disability, 2015, in preparation).

The high rates of dementia incurred by people with Down syndrome highlight the need for special focus on this group. Results from studies with the general population on the use of drugs to delay the decline in dementia may be extrapolated to provide evidence likely to be relevant for people with learning disabilities. Conversely, people with Down syndrome are physiologically different to the general population, due to the genetic material coded on chromosome 21, and so stratified and precision pharmacological approaches are indicated.

6.2 Review questions: In people (children, young people and adults) with learning disabilities, do pharmacological interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared with an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do pharmacological interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared with an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 58 and Table 59. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 58: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do pharmacological interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared with an alternative approach? (RQ2.4)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any licensed pharmacological interventions
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 59: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do pharmacological interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared with an alternative approach? (RQ3.4)
Population	People (children, young people and adults) with learning disabilities

Component	Description
	and mental health problems.
Intervention(s)	Any licensed pharmacological interventions
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

6.2.1 Group consensus for adaptations to pharmacological interventions for people with a mental health problem and learning disabilities

As a result of the very limited RCT evidence (see section 6.2.2 below), and in view of considerable risk of bias in lower level evidence of drug studies, the GC considered it inappropriate to go down the evidence hierarchy for pharmacological interventions. The GC, therefore, decided to develop a set of general principles to inform the delivery of pharmacological treatments for people with a mental health problem and learning disabilities. They developed these recommendations using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in the methods section in Chapter 3.

Key issues related to the use of drugs for the treatment of mental problems in people with learning disabilities and a mental health problem were identified from the Frith (Bhaumik et al., 2015) and Maudsley (Taylor, 2012) prescribing guidelines, and from discussions during the GC meetings. These were used to generate nominal statements to be rated by the GC, which were distributed in the form of a questionnaire. The nominal statements were developed to cover a range of areas that had been identified as important by the GC, including deciding upon and obtaining consent for treatment, choice of drugs for particular disorders, dose regimens, drug interactions and side-effects, the impact on comorbid mental and physical disorders, monitoring and adherence, and communication between professionals of different disciplines. An example of a statement that was rated highly by the committee is ‘Before prescribing a drug to treat a mental health problem in people with learning disabilities, clinicians should ensure that they liaise with any other involved specialists (such as neurologists for epilepsy care) to discuss existing drug regimens and possible interactions’.

The questionnaires were completed by all members of the GC. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members, and used to inform a discussion of the issues raised by member’s comments. A second round of ratings was not deemed necessary as it was agreed by the GC that all important issues raised in the GC comments could be addressed in the wording of recommendations. A brief summary of the outcome from this process is depicted in Table 60 below; the complete list of statements and ratings can be found in Appendix U and blank copies of the questionnaires used can be found in Appendix T.

Table 60: Summary of nominal group technique process followed for the development of recommendations on pharmacological interventions for mental health problems in people with learning disabilities

Round 1		Round 2		Resulting recommendations generated
Level of agreement	Statements N (Total=30)	Level of agreement	Statements N (Total=0)	7 recommendations
High	13	High	n/a	
Moderate	11	Moderate	n/a	
Low	6	Low	n/a	

6.2.2 Clinical evidence

Very few RCTs were found on pharmacological interventions for the prevention or treatment and management of mental health problems. The existing RCTs were limited to children and adolescents and covered only 2 mental health problems: the treatment of ADHD and the prevention or treatment of dementia in young adults or adults with Down’s syndrome.

6.2.2.1 Treatment of ADHD

Amphetamine versus placebo (children)

There was 1 RCT (N=21) which met the eligibility criteria for this review: Alexandris and Lundell (1968).

An overview of the trial included can be found in Table 61. Further information about both included and excluded studies can be found in Appendix L.

The actual between group outcomes with variance were not reported so the results are narratively summarised below. Summary of findings can be found in Table 62. The full GRADE evidence profiles can be found in Appendix N.

The study reported results on a 14-item patient evaluation form completed by nurses, teachers, physicians and the principal investigator after treatment. The 14 items included hyperkinesis, concentration, attention, aggressiveness, sociability, interpersonal relationship, comprehension, mood, work interest, work capacity, reading, spelling, arithmetic and class standing. Each scale was rated on a 5-point rating scale (lower scores being worse). The differences between most subscales were reported as not significant; however, the study reported that comprehension and work interest were significantly better in the amphetamine group than the placebo group ($p < 0.05$).

The study also reported that there were no significant side effects in either group during the study.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 61: Study information table for trials included in the analysis of amphetamine versus placebo for ADHD in children with learning disabilities

	Amphetamine versus placebo
Total no. of studies (N[1])	1 (21)

	Amphetamine versus placebo
Study ID	Alexandris 1968
Country	Canada
Diagnosis/degree of learning disabilities	no details on degree
Age (mean)	7 – 12 years
Sex (% female)	33%
Ethnicity (% white)	Not reported
IQ (mean)	55-85[2]
Living arrangements	Institutional hospital (for at least 1 year)
Coexisting conditions/other treatments received during study	Not reported
Targeted behaviour	hyperkinetic behaviour syndrome
Treatment length (weeks)	26 (6 months) [3]
Intervention (mean dose; mg/day)	Amphetamine: 52 mg (7.5 – 75) [4] (orally with capsules, 3 times per day)
Comparison	Placebo (identical capsules)
Notes. N=total number of participants [1] Number randomised. [2] Mentally deficient as determined from Wechsler IQ; as a result, some included have borderline intelligence but it is unclear how many/what proportion do not have learning disabilities. [3] Study reported that the investigation was limited to 6 months; unclear if this was the length of treatment or follow-up (with shorter treatment duration). [4] Study also included an arm on thioridazine but this was not extracted as this drug is not licensed in the UK for any indication.	

Table 62: Summary of findings table for the analysis of amphetamine versus placebo for ADHD in children with learning disabilities

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Impact**
Overall effect of treatment on bespoke form assessed with: 14-item 'patient evaluation form' follow up: mean 23 weeks	14 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	The differences between groups on 10 subscales (hyperkinesis, concentration, attention, aggressiveness, sociability, interpersonal relationship, mood, work capacity, reading, spelling, arithmetic and class standing) were reported as not significant; however, the comprehension and work interest subscales were reported to be significantly better in the amphetamine group than the placebo group ($p < 0.05$).
Quality of life - not reported	-	-	
Community participation and meaningful occupation - not reported	-	-	
Note 1. Risk of selection and selective outcomes bias; unclear risk of detection, attrition and			

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Impact
performance bias. 2. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).			

Methylphenidate versus placebo (children and young people)

There was 1 RCT (N=122) which met the eligibility criteria for this review: Simonoff et al. (2013).

An overview of the trial included can be found in Table 63. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 28. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The paper combined the results of all degrees of learning disabilities so it was not possible to examine the results by different levels of learning disabilities. However, the study performed an analysis of moderators of treatment response which included degrees of learning disabilities and found no significant effect of degree on the results.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 63: Study information table for trials included in the analysis of methylphenidate versus placebo for ADHD in children and young people with learning disabilities

	Methylphenidate versus placebo
Total no. of studies (N^1)	1 (122)
Study ID	Simonoff 2013
Country	UK
Diagnosis/degree of learning disabilities	Mixed learning disabilities (but 32% had IQ < 50)
Age (mean)	11.2 (SD 2.3)
Sex (% female)	30%
Ethnicity (% white)	not reported
IQ (mean)	53 (SD10.1, range: 30-69)^2
Living arrangements	not reported
Coexisting conditions/other treatments received during study	Excluded current stimulant use, use of neuroleptic medication in the last 6 months and many coexisting conditions
Targeted behaviour	ADHD (severe) /hyperkinetic syndrome
Treatment length (weeks)	16
Intervention (mean dose; mg/day)	titrated over 3 weeks to optimal dose: 0.5 mg/kg (n=8), 1.0 mg/kg (n=14), 1.5 kg/mg (n=28)
Comparison	Placebo
Notes. N=total number of participants.	

	Methylphenidate versus placebo
[1] Number randomised. [2] Using Wechsler Intelligence Scales for Children-IV (WISC-IV-UK), the Wechsler Preschool and Primary School Intelligence Scales (WPPSI-III) or the Mullen Scale of Early Learning (Mullen, 1997), according to the child's age and estimated ability.	

Table 64: Summary of findings table for the analysis of methylphenidate versus placebo for ADHD in children and young people with learning disabilities

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with placebo**	**Risk difference with Methylphenidate**
ADHD (Mental health) assessed with: Connors' ADHD index (parent rated) follow up: mean 16 weeks	122 (1 RCT)	⊕⊕⊕◯ MODERATE [1]	-	The mean ADHD was 22.4	MD 3.3 fewer (6.79 fewer to 0.19 more)
ADHD (Mental health) assessed with: Connors' ADHD index (teacher rated) follow up: mean 16 weeks	122 (1 RCT)	⊕⊕⊕◯ MODERATE [1]	-	The mean ADHD was 18.6	MD 4.1 fewer (7.57 fewer to 0.63 fewer)
Hyperactivity (Mental health) assessed with: Conners' hyperactivity scale (parent rated) follow up: mean 16 weeks	122 (1 RCT)	⊕⊕⊕◯ MODERATE [2]	-	The mean hyperactivity was 9.2	MD 1.5 fewer (3.44 fewer to 0.44 more)
Hyperactivity (Mental health) assessed with: Conners' hyperactivity scale (teacher rated) follow up: mean 16 weeks	122 (1 RCT)	⊕⊕⊕◯ MODERATE [1]	-	The mean hyperactivity was 9	MD 2.6 fewer (4.68 fewer to 0.52 fewer)
'Improved' or 'better' assessed with: Clinical Global Impressions-Improvement follow up: mean 16 weeks	122 (1 RCT)	⊕⊕⊕◯ MODERATE [1]	RR 6.00 (2.21 to 16.26)	Study population 66 per 1000	328 more per 1000 (79 more to 1001 more)
Quality of life - not reported	-	-			

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with Methylphenidate
Community participation and meaningful occupation - not reported	-	-			
Weight assessed with: kg follow up: mean 16 weeks	122 (1 RCT)	⊕⊕⊕◯ MODERATE [2]	-	The mean weight was 43.8 kg	MD 4.2 kg fewer (10.25 fewer to 1.85 more)

Note

1. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
2. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

Clonidine versus placebo (children and young people)

There was 1 crossover RCT (N=10) which met the eligibility criteria for this review: Agarwal et al. (2001).

An overview of the trial included can be found in Table 65. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 66. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The paper combined the results of all degrees of learning disabilities so it was not possible to examine the results by different degrees.

The study reported that there were some reports of drowsiness with clonidine but did not report if any drowsiness occurred in the control group.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 65: Study information table for trials included in the analysis of clonidine versus placebo for ADHD in children and young people with learning disabilities

	Clonidine versus placebo
Total no. of studies (N[1])	1 (10)
Study ID	Agarwal 2001
Country	India
Diagnosis/degree of learning disabilities	Mixed (4 mild, 5 moderate, 1 severe)
Age (mean)	7.6 (SE 0.54)
Sex (% female)	20
Ethnicity (% white)	Not reported
IQ (mean)	48.2 (30-69)[2]
Living arrangements	Not reported but 4 were in primary school (those with mild learning disabilities)

	Clonidine versus placebo
Coexisting conditions/other treatments received during study	Drugs for hyperkinetic disorder were excluded 5 had conduct problems[3], 2 had seizure disorder
Targeted behaviour	Hyperkinetic disorder[4]
Treatment length (weeks)	6
Intervention (mean dose; mg/day)	Clonidine (sugar-mixed suspension with a strength of 10 mcg/ml) in doses of 4-, 6- and 8-mc/kg/day for 2 weeks each)
Comparison	Placebo (sugar-mixed suspension of calcium carbonate)
Notes. ¹ Number randomised. [2] WISC (Wechsler Intelligence Scale for Children) – Indian Adaptation. [3] conduct problems measured on the Parent Symptom Questionnaire and Kiddie Schedule for Affective Disorder and Schizophrenia – Parent Version but was not serious enough to warrant ICD-10 classification. [4] mean duration was 4.6 years (SE 0.6).	

Table 66: Summary of findings table for the analysis of clonidine versus placebo for ADHD in children and young people with learning disabilities

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with placebo	**Risk difference with Clonidine**
ADHD symptoms: conduct (Mental health) assessed with: Parent connor's score - conduct scale follow up: 6 weeks	19 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean ADHD symptoms: conduct was 15.3	MD 7.4 fewer (10.34 fewer to 4.46 fewer)
ADHD symptoms: impulsive hyperactivity (Mental health) assessed with: Parent connor's score - Impulsive hyperactive scale follow up: 6 weeks	19 (1 RCT)	⊕◯◯◯ VERY LOW [1,3]	-	The mean ADHD symptoms: impulsive hyperactivity was 6.7	MD 2.6 fewer (6.54 fewer to 1.34 more)
ADHD symptoms: overall (Mental health) assessed with: Parent connor's score - Total score follow up: 6 weeks	19 (1 RCT)	⊕◯◯◯ VERY LOW [1,3]	-	The mean ADHD symptoms: overall was 76.5	MD 24.7 fewer (49.35 fewer to 0.05 fewer)
ADHD symptoms (clinician rated) (Mental health) assessed with: Clinical global impression scale	19 (1 RCT)	⊕◯◯◯ VERY LOW [1,3]	-	The mean ADHD symptoms (clinician rated) was 4.5	MD 1.8 fewer (3.11 fewer to 0.49 fewer)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with Clonidine
follow up: 6 weeks					
Much or very much improved (Mental health) assessed with: Clinical global impression scale follow up: 6 weeks	19 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	RR 16.50 (1.07 to 253.40)	Study population	
				0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			

Note

1. Risk of selection and selective outcome reporting bias
2. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
3. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

Risperidone versus methylphenidate (children and young people)

There was 1 RCT (N=46) which met the eligibility criteria for this review: Correia Filho et al. (2005).

An overview of the trial included can be found in Table 67. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 68. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The between group values on some measures were not reported in the study so these are summarised narratively here. The study reported the effect of medication on ADHD symptoms on 2 scales which were completed by an independent psychiatrist based on parental reports: SNAP-IV, a revision of the SNAP questionnaire, which includes a total score and scores on 3 subscales, inattentive, hyperactive/impulsive, oppositional subscales; and the hyperactivity subscale of the Nisonger Child Behavior Rating Form (NCBRF). The paper reported that there was a significant effect for time and group assignment on SNAP-IV total scores, a non-significant trend for hyperactivity subscales but no significant effects for inattentive and oppositional defiance disorder subscales. The paper reports no significant difference between changes scores on the NCBRF. The author was contacted for more information but this was not received.

The study also reported a mean reduction of 0.53 kg in the methylphenidate group compared with a weight increase of 1.01 kg in the risperidone group and that this was significant.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 67: Study information table for trials included in the analysis of risperidone versus methylphenidate for ADHD in children and young people with learning disabilities

	Risperidone versus methylphenidate
Total no. of studies (N¹)	1 (46)
Study ID	Correia 2005
Country	Brazil
Diagnosis/degree of learning disabilities	moderate[2]
Age (mean)	11.8 (mean of means among both groups)
Sex (% female)	24%
Ethnicity (% white)	55.6% African-Brazilian
IQ (mean)	47.6[3]
Living arrangements	Not reported
Coexisting conditions/other treatments received during study	62.5% with MPH and 66.7% with risperidone had disruptive behaviour disorder (conduct or ODD), multiple anxiety disorder in 54.2% and 42.9%, dysthymia in 20.8% and 19% and major depression in 8.3% and 4.8%
Targeted behaviour	ADHD (31 'combined' and 14 'inattentive' ADHD-type)
Treatment length (weeks)	4
Intervention (mean dose; mg/day)	Risperidone: individualised flexible titration, mean 2.9 mg/day (range not provided)
Comparison	Methylphenidate: individualised flexible titration, mean 25 mg/day (0.5 – 4)
Use of other medication	Before exclusion period: history of carbamazepine (n=4), imipramine (n=5), divalproex sodium (n=2), sulpiride (n=1), older antipsychotics (haloperidol or chlorpromazine) (n=10)
Coexisting conditions	Disruptive behaviour disorder (conduct or ODD) in 62.5% with MPH and 66.7% with risperidone, multiple anxiety disorder in 54.2% and 42.9%, dysthymia in 20.8% and 19% and major depression in 8.3% and 4.8%

Notes. N=total number of participants.
[1] Number randomised. [2] Using DSM-IV criteria. Patients were assessed on a 7-point Likert scale to determine impairment level (from 1 no impairment to 7 extreme impairment); median score was 5 or marked impairment. [3] Full-scale IQ based on WISC-III (Wechsler 1991).

Table 68: Summary of findings table for the analysis of risperidone versus methylphenidate for ADHD in children and young people with learning disabilities

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with methylphenidate	**Risk difference with Risperidone**
ADHD symptoms assessed with: SNAP-IV total score	46 (1 RCT)	⊕○○○ VERY LOW [1,2]	-	-	SMD 0.54 lower (1.14 lower to 0.06 higher)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with methylphenidate	Risk difference with Risperidone
follow up: mean 4 weeks					
Hyperactivity (NCBRF) follow up: mean 4 weeks	46 (1 RCT)	⊕◯◯◯ VERY LOW ^{1,3}		No significant between-group differences in change scores.	
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Side effects (Barkley's Side Effects Rating Scale) follow up: mean 4 weeks	46 (1 RCT)	⊕◯◯◯ VERY LOW ^{1,2}	-	-	SMD 0.08 higher (0.54 lower to 0.69 higher)
Weight assessed with: kg follow up: 4 weeks	46 (1 RCT)	⊕◯◯◯ VERY LOW ^{1,3}		Mean reduction of 0.53 kg in the methylphenidate group compared with a weight increase of 1.01 kg in the risperidone group (reported to be significant).	

Note

1. Risk of selection and selective outcome reporting bias
2. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
3. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

6.2.2.2 Prevention or treatment of dementia

A Cochrane review (Livingstone & Macdonald, 2015) which reviewed the evidence on pharmacological treatments in people with Down's syndrome was adopted for use by this guideline, with permission from the publishers, John Wiley and Sons, and with assistance from the Cochrane Developmental, Psychosocial and Learning Problems Cochrane Review Group (Joanne Wilson, email communication, September 2015; and Nuala Livingstone, email communication, October 2015). Relevant data from this review was considered and analysed according to the strategy set out in the guideline review protocol. Some changes were made for the purposes of this review which included the separation of studies on prevention and treatment and the subgrouping of adverse effects by severity of the side effects.

No trials were found on people with learning disabilities who did not have Down's syndrome.

Donepezil versus placebo – prevention

There were 2 RCTs (N=142) which met the eligibility criteria for this review: Johnson et al. (2003) and Kishnani et al. (2009).

An overview of the trials included can be found in Table 69. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 70. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 69: Study information table for trials included in the analysis of donepezil versus placebo for prevention of dementia in adults with Down's syndrome

	Donepezil versus placebo
Total no. of studies (N^1)	2 (142)
Study ID	(1) Johnson 2003 (2) Kishnani 2009
Country	(1, 2) USA
Diagnosis/degree of learning disabilities	(1, 2) Down's syndrome (degree of learning disabilities not reported)
Age (mean)	(1) 27.1 (young adults) (2) 25 (young adults)
Sex (% female)	(1) 42%, (2) 37.4%
Ethnicity (% white)	(1) not reported (2) 91%
IQ (mean)	(1) 45.9 (2) not reported
Living arrangements	(1, 2) not reported
Targeted behaviour	(1, 2) cognitive functioning
Treatment length (weeks)	(1, 2) 12
Intervention (mean dose; mg/day)	(1, 2) donepezil 5 mg/d for 4-6 weeks, 10 mg/d thereafter
Comparison	(1, 2) placebo
Use of other medication	(1) not reported (2) no antidepressants, antipsychotics
Coexisting conditions	(1, 2) not reported
Notes. N=total number of participants. ^{1} Number randomised.	

Table 70: Summary of findings table for the analysis of donepezil versus placebo for prevention of dementia in people with Down's syndrome

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with placebo	**Risk difference with Comparison 1a: donepezil**
Cognitive abilities assessed with: Severe Impairment Battery	138 (2 RCTs)	⊕◯◯◯ VERY LOW ^{1,2}	-	-	SMD 0.34 higher (0.65 lower to 1.33 higher)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with Comparison 1a: donepezil
follow up: 12 weeks					
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Behavioural problems assessed with: various scales follow up: 12 weeks	130 (2 RCTs)	⊕⊕⊕◯ MODERATE [3]	-	-	SMD 0.28 higher (0.07 lower to 0.63 higher)
Serious adverse events follow up: 12 weeks	141 (2 RCTs)	⊕⊕⊕◯ MODERATE [4]	not estimable	Study population 0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Severe adverse events follow up: 12 weeks	123 (1 RCT) 5	⊕⊕◯◯ LOW [2]	RR 4.92 (0.24 to 100.43)	Study population 0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Any adverse event follow up: 12 weeks	123 (1 RCT) 6	⊕⊕⊕◯ MODERATE [3]	RR 1.56 (1.15 to 2.11)	Study population 475 per 1000	266 more per 1000 (71 more to 528 more)

Note

1. Downgraded two levels for imprecision (wide confidence interval) and inconsistency (I^2 = 73%).
2. Downgraded two levels for serious imprecision (wide confidence interval) and small number of events.
3. Downgraded one level for imprecision (wide confidence interval).
4. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
5. Serious adverse events: hypertension and emotional lability.
6. Most common side effects were asthenia, anorexia, dyspepsia, nausea, vomiting, and insomnia.

Donepezil versus placebo – treatment

There were 2 RCTs (N=52) which met the eligibility criteria for this review: Kondoh et al. (2011) and Prasher et al. (2002).

An overview of the trials included can be found in Table 71. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 72. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcome community participation and meaningful occupation.

Table 71: Study information table for trials included in the analysis of donepezil versus placebo for treatment of dementia in adults with Down's syndrome

	Donepezil versus placebo
Total no. of studies (N[1])	2 (52)
Study ID	(1) Kondoh 2011 (2) Prasher 2002
Country	(1) Japan, (2) UK
Diagnosis/degree of learning disabilities	(1) Down's syndrome (degree of learning disabilities not reported) (2) Down's syndrome (9 mild, 15 moderate, 6 severe learning disabilities)
Age (mean)	(1) 45.6 (middle aged adults) (2) 54. (middle aged adults)
Sex (% female)	(1)100, (2) 50%
Ethnicity (% white)	(1, 2) not reported
IQ (mean)	(1, 2) not reported
Living arrangements	(1) from 2 residential homes (2) 6 family home, 20 group home, 3 nursing home, 1 hospital
Targeted behaviour	(1) severe cognitive impairment (2) dementia[2]
Treatment length (weeks)	(1) 24 (2) 104
Intervention (mean dose; mg/day)	(1) donepezil 3 mg/d for 24 weeks (2) donepezil 5 mg/d for 4-6 weeks, 10 mg/d thereafter
Comparison	(1, 2) placebo
Use of other medication	(1, 2) not reported
Coexisting conditions	(1, 2) not reported
Notes. N=total number of participants. [1] Number randomised, [2] ICD-10 diagnosis; according to DCR-10 criteria, half had mild and half had moderate Alzheimer's disease.	

Table 72: Summary of findings table for the analysis of donepezil versus placebo for treatment of dementia in adults with Down's syndrome

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with placebo	**Risk difference with Comparison 1b: donepezil**
Cognitive abilities assessed with: Severe Impairment Battery follow up: 24 weeks	27 (1 RCT)	⊕⊕⊕◯ MODERATE [1]	-	-	SMD 0.93 higher (0.13 higher to 1.73 higher)
Proportion with improved impression of quality of life (Quality of life) follow up: 24 weeks	21 (1 RCT)	⊕⊕⊕◯ MODERATE [1]	RR 2.34 (1.14 to 4.81)	Study population	
				400 per 1000	536 more per 1000 (56 more to 1524 more)
Community participation and meaningful	-	-			

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with Comparison 1b: donepezil
occupation - not reported					
Behavioural problems assessed with: American Association of Mental Retardation Adaptive Behaviour Scale (AMMR: ABS) follow up: 24 weeks	27 (1 RCT)	⊕⊕⊕◯ MODERATE[1]	-	-	SMD 0.99 higher (0.18 higher to 1.79 higher)
Serious adverse events follow up: 24 weeks	30 (1 RCT)	⊕⊕⊕◯ MODERATE[1]	RR 2.33 (0.76 to 7.13)	Study population	
				214 per 1000	285 more per 1000 (51 fewer to 1314 more)
At least one serious event follow up: 24 weeks	30 (1 RCT)	⊕⊕⊕◯ MODERATE[1]	RR 1.50 (0.83 to 2.72)	Study population	
				500 per 1000	250 more per 1000 (85 fewer to 860 more)
Minor adverse reaction follow up: 24 weeks	21 (1 RCT) 2	⊕⊕◯◯ LOW[3]	RR 0.61 (0.13 to 2.92)	Study population	
				300 per 1000	117 fewer per 1000 (261 fewer to 576 more)

Note

1. Downgraded one level for imprecision (wide confidence interval).
2. Included soft stool and skin rash (donepezil, one placebo) or mild skin rash only (2 placebo).
3. Downgraded two levels for serious imprecision (wide confidence interval).

Memantine versus placebo – prevention or treatment

There were 2 RCTs (N=213) which met the eligibility criteria for this review: Boada (2012) and Hanney et al. (2012)

An overview of the trials included can be found in Table 73. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 74. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 73: Study information table for trials included in the analysis of memantine versus placebo for prevention or treatment of dementia in adults with Down's syndrome

	Memantine versus placebo
Total no. of studies (N^1)	2 (213)
Study ID	(1) Boada 2012

	Memantine versus placebo
	(2) Hanney 2012
Country	(1) USA, (2) UK and Norway
Diagnosis/degree of learning disabilities	(1[2], 2) Down's syndrome (degree of learning disabilities not reported)
Age (mean)	(1) 23.2 (young adults) (2) 51.4 (middle aged adults)
Sex (% female)	(1) 63%, (2) 43.4%
Ethnicity (% white)	(1, 2) not reported
IQ (mean)	(1[2], 2) not reported
Living arrangements	(1, 2) not reported
Targeted behaviour	(1) cognitive and adaptive functioning[3] (2) dementia[4]
Treatment length (weeks)	(1) 16, (2) 52
Intervention (mean dose; mg/day)	(1) memantine 5 mg/d week 1, 5 mg b.i.d. week 2, 5 mg/d and 10/d (1 divided dose) week 3, 10 mg b.i.d. from week 4 to 16 (2) memantine 5 mg/d for 8 weeks, 10 mg/d with fixed titration for remainder
Comparison	(1, 2) placebo
Use of other medication	(1) sertraline for long standing anxiety (n=1), methylphenidate for ADHD (n=1), lamotrigine for seizure disorder (n=1) (2) 5.5% were having cholinesterase inhibitors, 18% antidepressants, 7.9% neuroleptics, 2.4% anxiolytics, 3.9% hypnotics
Coexisting conditions	(1) 5.3% had diabetes, between 15.8-21.2% sleep apnoea, 26.3-36.8% obesity, and 36.8-47.4% hypothyroidism (2) 15.5% also had a mood disorder, 1% a psychotic disorder, and 11% a behaviour disorder
Notes. N=total number of participants. [1] Number randomised, [2] but mental age reportedly 6.1 placebo and 7.6 memantine, [3] Study reported 'There was no specific cognitive level used to exclude participants' but the included participants are unlikely to have dementia at this age so the study appears to be a 'prevention' study. [4] 35% had dementia at randomisation but the trial was considering the preventive effects of the drug in the other 65% (so, the study was a combination of 'prevention' and 'treatment')	

Table 74: Summary of findings table for the analysis of memantine versus placebo for prevention or treatment of dementia in adults with Down's syndrome

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with placebo**	**Risk difference with Comparison 2: memantine**
Cognitive abilities assessed with: various scales follow up: range 16 weeks to 52 weeks	184 (2 RCTs)	⊕⊕◯◯ LOW [1]	-	-	SMD 0.05 more (0.43 fewer to 0.52 more)
Quality of life - not reported	-	-			

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with Comparison 2: memantine
Community participation and meaningful occupation - not reported	-	-			
Behavioural problems assessed with: various scales follow up: range 16 weeks to 52 weeks	186 (2 RCTs)	⊕⊕◯◯ LOW [2]	-	-	SMD 0.17 fewer (0.46 fewer to 0.11 more)
Clinically significant/serious adverse events follow up: range 16 weeks to 52 weeks	211 (2 RCTs)	⊕⊕◯◯ LOW [2]	RR 1.79 (0.72 to 4.50)	Study population	
				58 per 1000	46 more per 1000 (16 fewer to 202 more)
Any adverse event follow up: mean 16 weeks	38 (1 RCT)	⊕⊕◯◯ LOW [2]	RR 4.00 (0.49 to 32.57)	Study population	
				53 per 1000	158 more per 1000 (27 fewer to 1662 more)

Note

1. Downgraded two levels due to imprecision (wide confidence intervals) and inconsistency (I^2 = 48%).
2. Downgraded two levels for serious imprecision (wide confidence interval) and small number of events.

Simvastatin versus placebo – prevention

Unpublished data from 1 RCT (N=21) which was included in the Cochrane review met the eligibility criteria for this review: Cooper 2012 (unpublished; personal communication to R. McShane 12 March 2015).

An overview of the trial included can be found in Table 75. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 76. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcomes of quality of life or community participation and meaningful occupation.

Table 75: Study information table for trials included in the analysis of simvastatin versus placebo for prevention of dementia in adults with Down’s syndrome

	Simvastatin versus placebo
Total no. of studies (N[1])	1 (21)
Study ID	Cooper 2012
Country	UK
Diagnosis/degree of learning disabilities	Down’s syndrome (degree of learning disabilities not reported)
Age (mean)	54.68 intervention and 53.67 control

	Simvastatin versus placebo
Sex (% female)	47.6%
Ethnicity (% white)	not reported
IQ (mean)	not reported
Living arrangements	not reported
Targeted behaviour	cognitive decline
Treatment length (weeks)	52 weeks
Intervention (mean dose; mg/day)	simvastatin 40 mg once daily
Comparison	placebo
Use of other medication	not reported
Coexisting conditions	not reported
Notes. N=total number of participants. [1] Number randomised.	

Table 76: Summary of findings table for the analysis of simvastatin versus placebo for prevention of dementia in adults with Down's syndrome

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with placebo	**Risk difference with Comparison 3: simvastatin**
Cognitive abilities assessed with: NADIID battery follow up: 52 weeks	21 (1 RCT)	⊕⊕◯◯ LOW [1]	-	The mean cognitive abilities was not reported	MD 10 higher (0.4 lower to 1.6 higher)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Adaptive functioning assessed with: AAMR: ABS follow up: 52 weeks	21 (1 RCT)	⊕⊕◯◯ LOW [1]	-	The mean adaptive functioning was not reported	MD 0.7 higher (0 to 1.4 higher)
Note 1. Downgraded two levels for serious imprecision (wide confidence interval) and small number of events.					

6.2.3 Economic evidence

No studies assessing the cost effectiveness of pharmacological interventions aimed at prevention, treatment or management of mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

6.2.4 Clinical evidence statements

6.2.4.1 Adaptations to pharmacological interventions for people with a mental health problem and learning disabilities (developed through formal consensus)

- The GC decided that clinicians should consider the possibility of atypical reactions to psychotropic medication, potential difficulties the service user may experience in tolerating or communicating side effects and the need for increased vigilance for these and symptom exacerbations when commencing or discontinuing pharmacotherapy.
- The GC supported the need for clinicians to consider additional pharmacotherapy factors in the service user as a result of underlying syndromes prior to commencing treatment.
- They did not support the need for additional cardiovascular investigations, above those required for the general population, to be undertaken prior to commencing pharmacotherapy.
- When seeking consent for pharmacotherapy the GC decided that it is important for the clinician to consider the person’s capacity to provide that consent, the mode of communication and the pace at which information is provided. The GC expressed support for the clinician to consider the environment in which consent is sought. The GC did not support the need for clinician to consider their familiarity with the service user.
- To enhance adherence to pharmacotherapy the GC decided that support for people with learning disabilities who live alone to take their medication correctly would be beneficial. The GC expressed support for clinicians to identify any potential difficulties with pharmacotherapy compliance prior to commencing treatment, including whether the person would tolerate blood tests if these would be necessary, and to provide clear written or pictorial instructions to assist with correct use.
- The GC decided that drugs used to treat other conditions (such as epilepsy) should be taken into consideration when prescribing medication for mental health conditions, that regular comprehensive medication review should be undertaken, and that medication regimens and side-effect profiles should be reviewed every 3 to 4 weeks. The GC expressed support for the importance of avoiding polypharmacy, for medication reviews being conducted every 6 weeks, and for very considerable caution to be exercised if pharmacotherapy is ever used to treat behavioural problems in dementia as a being used as a last resort.
- Regarding dosage, the GC decided that it was important for clinicians to balance the need to start with a low dose so that side effects can be adequately monitored whilst avoiding sub-therapeutic dosages. They expressed support for the appropriateness of the mean therapeutic dose recommended for the general population if the service user is physically healthy. They did not support the general adoption of the principle of starting at a low dosage or increasing dosage very gradually.
- The GC decided that prior to commencing pharmacotherapy prescribing clinicians should liaise with other involved specialists to discuss existing treatment regimens and possible interactions. They expressed support for clinicians liaising generally with other involved specialists to discuss the service user’s drug regimen, and for pharmacotherapy to be reviewed by learning disabilities specialists in the absence of locally agreed protocols for shared care. They agreed that learning disabilities specialists do not need to be the only people to commence pharmacotherapy.

6.2.4.2 Treatment of ADHD

- Very low quality evidence from 1 RCT suggests that amphetamine is better than placebo in improving comprehension and work interest after 26 weeks; it does not appear to be better than placebo at reducing hyperkinesis, concentration, attention, aggressiveness, sociability, interpersonal relationship, mood, work capacity, reading, spelling, arithmetic and class standing (k=1; N=21).
- Moderate-quality evidence from 1 RCT suggests that methylphenidate had a clinically meaningful reduction in ADHD symptoms and hyperactivity score over placebo at 16 weeks, but that it may result in poorer appetite, weight loss and trouble falling asleep (k=1; N=122).
- Very low-quality evidence from 1 RCT suggests little difference between methylphenidate and risperidone in the effect on ADHD symptoms or adverse events at 4 weeks, apart from weight loss which was greater with methylphenidate (k=1; N=46). It was not possible to estimate the difference in impact on ADHD symptoms from the evidence.
- Very low-quality evidence from 1 crossover RCT suggests that there may be a benefit of clonidine over placebo in ADHD symptoms and global improvement at 6 weeks (k=1; N=10).

6.2.4.3 Prevention or treatment of dementia in people with Down's syndrome

- Moderate to very low quality evidence from 2 RCTs suggests little difference of donepezil over placebo at preventing cognitive decline or improving adaptive behaviour in people with Down's syndrome who do not yet have dementia (k=2; N=142).
- Moderate quality evidence from 2 RCTs suggests donepezil may be effective in treating cognitive decline and increasing adaptive behaviour in people with Down's syndrome who do not yet have dementia (k=2; N=52).
- Moderate to low quality evidence from 4 RCTs showed adverse effects appear to be more frequent with donepezil than placebo, both when used in prevention and treatment (prevention: k=2; N=123 and treatment: k=2; N=51).
- Low quality evidence from 2 RCTs suggests little difference of memantine over placebo at preventing or treating cognitive decline (and little difference in behavioural problems or in adverse events) in people with Down's syndrome (k=2; N=213).
- Low quality evidence from 1 RCT suggests that simvastatin may be effective in preventing cognitive decline and may improve adaptive functioning in people with Down's syndrome (k=1; N=21).

6.2.5 Economic evidence statements

No evidence on the cost effectiveness of pharmacological interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities is available.

6.3 Recommendations and link to evidence

Recommendations	**41. For pharmacological interventions for mental health problems in people with learning disabilities, refer to the NICE guidelines on specific mental health problems (see mental health and behavioural conditions on the NICE**

website) and take into account the principles for delivering pharmacological interventions (see recommendations 42–48).

42. Only specialists with expertise in treating mental health problems in people with learning disabilities should start medication to treat a mental health problem in:

- **adults with severe or profound learning disabilities (unless there are locally agreed protocols for shared care)**
- **children and young people with any learning disabilities.**

43. Before starting medication for a mental health problem in a person with learning disabilities:

- **consult with specialists prescribing medication for any other conditions the person has (for example, neurologists providing epilepsy care when prescribing antipsychotic medication that may lower the seizure threshold), to avoid possible interactions and polypharmacy**
- **assess the risk of non-adherence to the medication regimen or any necessary monitoring tests (for example, blood tests), and the implications for treatment**
- **provide support to improve adherence (see the NICE guideline on medicines adherence**
- **consider providing support from community learning disabilities nurses, if needed (for example, when carrying out blood tests)**
- **agree monitoring responsibilities between primary and secondary care.**

44. Monitor and review the benefits and possible harms or side effects, using agreed outcome measures and taking into account communication needs. If stated in the relevant NICE guideline, use the timescales given for the specific disorder to inform the review, and adjust it to the person’s needs.

45. When deciding the initial dose and subsequent increases, aim for the lowest effective dose. Take account of both potential side effects and difficulties the person may have in reporting them, and the need to avoid sub-therapeutic doses that may not treat the mental health problem effectively.

46. Prescribers should record:

- **a summary of what information was provided about the medication prescribed, including side effects, to the person**

	and their family members, carers or care workers (as appropriate) and any discussions about this - **when the treatment will be reviewed** - **plans to reduce or discontinue the medication, if appropriate.** **47. For people with learning disabilities who are taking antipsychotic drugs and not experiencing psychosis:** - **reduce or discontinue long-term prescriptions of antipsychotic drugs** - **consider referral to a psychiatrist experienced in working with people with learning disabilities and mental health problems** - **annually document the reasons for continuing the prescription if it is not reduced or discontinued.** **48. When switching medication, pay particular attention to discontinuation effects that may occur during titration.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of interventions at preventing or treating mental health problems in people with learning disabilities. In addition to the effect on the mental health problem which was the aim of the intervention (for dementia, this was cognitive function as well as psychopathology), the GC were of the view that quality of life, and community participation and meaningful occupation were particularly critical outcomes which they agreed to consider in the literature. The GC noted in particular the difficulties with measuring self-reported outcomes in this population, given communication needs and cognitive impairments so there should be caution in the interpretation of these outcomes from the trials. Reported outcomes from multiple sources may be helpful (for example, teachers or parents) in addressing this issue. Additionally, the GC noted the particular difficulty in determining if mental health problems are being effectively treated in people with learning disabilities. Additional important outcomes included problem behaviours, adaptive functioning such as communication skills, service user or carer satisfaction or experience of care, carer health and quality of life, adverse effects of interventions, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending. The GC noted that adaptive behaviour may only be sensitive to treatment effects over a longer period of time.
Trade-off between clinical benefits and harms	The GC noted, overall, that there were very few studies on pharmacological interventions for people with learning disabilities and mental health problems that met the criteria to be included in the review and noted the small size of the few studies which were identified. Studies were only identified for 2 mental health problems: treatment for ADHD in children and young people and treatment and prevention of dementia. All the studies on dementia were on populations with Down's syndrome and did not address the use of these

drugs in other learning disabilities populations. Most studies either did not report the degree of learning disabilities of the participants or included mixed populations so it was not possible to draw any conclusions about differential safety or effectiveness on this basis. Also, of those studies included, there was a lack of evidence on the critical outcomes of community participation and meaningful occupation and quality of life in this area.

Treatment of ADHD

There were 4 studies were included for 4 different pairwise comparisons:

- The GC noted that the result from a small study on methylphenidate compared with placebo showed that methylphenidate appears to reduce symptoms but that it may result in weight loss. The GC agreed that the results generally supported the recommendations in the NICE guideline on ADHD and did not consider that they could recommend otherwise on the basis of the evidence.
- There was inconclusive evidence from another smaller trial about the difference between methylphenidate and risperidone in terms of symptoms and number of side effects. The GC discussed the use of risperidone use in ADHD, noting that antipsychotics are not currently recommended in the ADHD guideline but, drawing from their own experience, were concerned that they are still widely used in practice to treat ADHD in people with learning disabilities.
- 2 very small studies on amphetamine and clonidine (each compared with placebo) reported significant effects on ADHD symptoms for the intervention group and no significant side effects in either group. However, due to the limited quality (see below) the GC was unable to make specific recommendations about these drugs.

The GC noted that there were a number of cross-over studies which had been published but were excluded from the ADHD review because they did not report the results after the first period before crossover (due to the complexity in combining these with parallel RCTs in analyses). However, the GC agreed to include crossover studies on pharmacological interventions when there were no parallel RCTs for a particular pharmacological intervention because of the limited quality of evidence (this resulted in the trial on clonidine being included).

The GC agreed that the results from the limited studies were generally consistent with the ADHD guideline recommendations and there was no evidence which they examined to suggest that there should be different recommendations for pharmacological management of children and young people with learning disabilities than from the general population. However, they were particularly concerned about potential issues with polypharmacy and side effects.

Treatment and prevention of dementia

The evidence covers 3 drugs and is focused on people with Down's syndrome.

- The GC noted that it was unclear if donepezil was beneficial compared with placebo for the prevention of cognitive decline but that given the weakness of this evidence compared to that in non-learning disabled populations the GC were cautious at drawing any conclusions due to the small studies and the relative uncertainty in this result.
- There did not appear to be a beneficial effect of memantine over placebo for the prevention or treatment of dementia but there were some adverse effects associated with memantine. However, the studies were too small, resulting in imprecision in the estimate of the relative effect.
- The GC noted that, when the results were adjusted for baseline and

	stratification values, simvastatin may be effective in the prevention or treatment of dementia but that the study included was a pilot and should be treated with considerable caution. The GC considered that, overall, they could not draw conclusions about the effects of these interventions. **Treatment and prevention of other mental health problems in people with learning disabilities** No evidence was found on the use of pharmacological interventions for the treatment and prevention of other mental health problems in people with learning disabilities.
Trade-off between net health benefits and resource use	The GC considered the economic consequences arising from the presence of mental health problems in people with learning disabilities that is associated with consumption of extra healthcare resources. The GC also considered the impact of mental health problems on the HRQoL of people with learning disabilities, their families and carers and concluded that provision of effective pharmacological interventions for the prevention and management of mental health problems is likely to improve the HRQoL of service users and their families and carers and reduce healthcare costs resulting from the management of mental health problems in more resource-intensive settings, such as secondary care. The GC estimated that people with learning disabilities receiving pharmacological treatment for a mental health problem may not be able to fully estimate and communicate to staff involved in their care the presence, magnitude and severity of side effects of medication. The GC considered that people with learning disabilities receiving pharmacological treatment for a mental health problem would benefit from closer monitoring of their adherence to treatment, side effects and potential polypharmacy. The GC expressed the opinion that, for safety reasons, children and young people with any learning disabilities and adults with severe or profound learning disabilities should start medication for a mental health problem only in the care of specialists with expertise in treating mental health problems. The GC also expressed the view that people with learning disabilities taking antipsychotics might benefit from a referral to a psychiatrist with experience in the care of people with learning disabilities and mental health problems, as this would lead to more appropriate monitoring. The GC concluded that additional monitoring and specialist involvement, where needed, would ensure that service users received adequate and effective pharmacological treatment with an optimal benefit to harm ratio and that potential side effects were identified and managed appropriately. The GC acknowledged that provision of pharmacological interventions to people with learning disabilities may be more resource-intensive compared with provision of pharmacological interventions in populations without learning disabilities, and this may have implications for the cost effectiveness of such interventions, but considered that additional medication monitoring and support, specialist involvement and further adaptations in the pharmacological treatment of people with learning disabilities are essential in order to achieve a positive outcome in this population. The GC also considered issues relating to equality, and judged that pharmacological interventions for the prevention and/or management of mental health problems that have been shown to be cost effective in populations without learning disabilities should also be offered to people with learning disabilities, following necessary adaptations and additional

	monitoring and specialist support.
Quality of evidence	The overall quality of the evidence for the treatment of ADHD was low or very low for most outcomes, apart from all outcomes from the comparisons of methylphenidate with placebo which was moderate quality. The overall quality of the evidence for the prevention and treatment of dementia ranged from moderate to very low quality. Imprecision was the main reasons for downgrading a number of outcomes and this was largely due to the very small size of the trials (many of which were pilot studies), as was the risk of bias. The GC noted, in particular, that: • the 1 trial on amphetamine for ADHD was quite old and that amphetamine is not often used to treat ADHD. They also noted that the study suffered from risk of bias for a number of reasons including that that it used a non-validated outcome measures. • There was inconsistency in the results on donepezil for the prevention of dementia and memantine for the prevention or treatment of dementia in the effects on cognitive ability but considered that this may be also a consequence of the very small size of the included studies. The GC remarked that larger trials are needed on pharmacological interventions for people with learning disabilities and mental health problems to be sure of the effects of these treatments in this population but also to determine if the side effects and if the safety profile is similar to those without learning disabilities. The GC considered the lack of evidence for anxiety disorders, in particular, as it is a common problem in people with learning disabilities (particularly those with autism), warranted a prioritised recommendation in this area. The group also noted the lack of research on children, including high quality evidence on interventions for conduct disorders and ADHD, such as antipsychotics like risperidone so chose to make a research recommendation for this area as well.
Other considerations	**Treatment of ADHD** The GC noted that clonidine is not currently licensed for the treatment of ADHD and, as such, is not currently recommended as first-line treatment in the ADHD NICE guideline. However, the ADHD guideline did recommend considering the use of clonidine or other treatments in tertiary services if ADHD is unresponsive to methylphenidate, atomoxetine or dexamfetamine. **Treatment and prevention of dementia** The GC noted that the evidence for pharmacological interventions for cognitive decline or dementia is only in people with Down's syndrome and that there were no trials in people with learning disabilities that do not have Down's syndrome. The distinction between people with and without Down syndrome is important in view of physiological differences attributable to chromosome 21. **Treatment and prevention of all mental health problems in people with learning disabilities** Despite insufficient evidence to suggest that effectiveness or safety of pharmacological interventions is different for people with learning disabilities compared with the general population, the GC was concerned about a number of issues related to the use of drugs in people with learning disabilities such as the possibility of side effects and inability to communicate/carer observation of these. Since there was insufficient evidence to suggest that there should be different recommendations on pharmacological management in people with learning disabilities than the general population, the GC decided to cross-refer to the recommendations in the existing NICE guidelines (when there are no contra-indications) but to deal with the additional issues through formal consensus. The GC decided on the basis of the outcome of the nominal group technique

	to develop recommendations in the following areas: - the most appropriate clinician to initiate and monitor pharmacotherapy (the GC agreed that only specialists in treating mental health problems in people with learning disabilities should treat more complex cases such as children and young people or adults with complex presentations, dementia and/or psychosis, unless there is a shared care protocol indicating otherwise in place) - the most appropriate dose of a drug (and the importance of balancing potential for side effects while ensuring an effective dose) - a plan for review and to avoid polypharmacy as far as possible - steps to ensure the most appropriate course of treatment is taken, including consideration of factors that may influence adherence. A number of contextual factors were highlighted during the nominal group technique which were deemed to be important to address, and recommendations were made to incorporate these issues: - relationships between underlying genetic syndromes and associated risk from pharmacotherapy, and the need for clinicians to be aware of and vigilant for these - people with mild learning disabilities who live alone may require additional support or information to take their medication correctly - communication between different professionals involved in the person’s care is good practice, but does not always occur - people with learning disabilities often remain on medication regimens for extended periods, potentially inappropriately, and regular review and agreed shared care protocols are necessary to avoid this - when discussing treatment options and seeking consent for pharmacotherapy, as for other interventions, it is important to take steps to facilitate the service user’s understanding - the service user focus group noted that not receiving explanations for the reason for medication and side effect profiles can cause distress.

6.3.1 Research recommendations

6. What is the clinical and cost effectiveness and safety of pharmacological interventions for anxiety disorders in people with autism and learning disabilities?

7. What is the clinical and cost effectiveness and safety of pharmacological interventions such as antipsychotics for ADHD or conduct disorder in children with learning disabilities?

7 Other interventions

7.1 Introduction

As we have seen in Chapters 5 and 6, current prevention and treatment programmes for people with learning disabilities are based on limited research evidence and there is uncertainty about both the magnitude of the effects and the suitability for use with people with learning disabilities for interventions where the main source of evidence is in non-learning disability populations. In addition, as we have seen in Chapter 4 Identification and assessment of mental health problems, the recognition of mental health problems in people with learning disabilities can be challenging. A number of alternative interventions are considered in this chapter which may help address some of these limitations.

Although it might be expected that prevention programmes of mental disorders would be available to people with learning disabilities, it is the case that many may not be able to access them. Lack of reasonable adjustments, inability to seek help when needed, socioeconomic disadvantage and communication needs are some of the reasons mentioned in the literature (Emerson & Hatton, 2007). However, given the vulnerability of people with learning disabilities, selected and indicated prevention programmes should be considered (Cuijpers, 2003). Finally, prevention or treatment programmes may fail to reach vulnerable people who are in need if they are not culturally sensitive and fully supported by policy changes as well as targeting individuals of all ages who are at risk.

Although direct evidence is limited there is some evidence that may have application to people with learning disabilities. For example, early interventions for pre-school children and early education programmes have been shown to reduce the effects of conduct disorders, and reduce anxiety and levels of emotional distress (NICE, 2013) (also, see Chapter 5).

7.2 Review question: In people (children, young people and adults) with learning disabilities, do annual health checks aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 77. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 77: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do annual health checks aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach (RQ2.1)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Annual health checks
Comparison	• Treatment as usual

Component	Description
	• No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs..

7.2.1 Clinical evidence

There were no studies found that looked at the use of annual health checks specifically to prevent mental health problems or which looked at the effect of health checks on the occurrence of mental health outcomes over time. However, the group chose to include evidence considering the use of health checks with indirect outcomes, the identification of health problems and needs and extrapolate from the evidence, using informal GC consensus. The systematic review of annual health checks which was conducted for the guideline on challenging behaviour in people with learning disabilities was included and updated (NICE, 2015). It was considered that this was the best available evidence on annual health checks rather than going down the evidence hierarchy or conducting formal group consensus, which in the GC's view would not be a good use of time and resources.

7.2.1.1 Annual health checks versus treatment as usual

The review included 2 RCTs which met the eligibility criteria for this review (Lennox et al., 2007; Lennox et al., 2010) and 1 additional RCT was identified (Cooper et al., 2014) (N=152).

An overview of the trials included can be found in Table 78. Further information about both included and excluded studies can be found in Appendices L.

Summary of findings can be found in Table 79.

The papers combined the results of all degrees of learning disabilities so it was not possible to examine the results by degree.

While 2 of the included studies measured outcomes after 1 year, none of the included studies measured outcomes over a longer follow-up, after multiple annual health checks, which would be needed to determine if annual health checks prevent mental health problems.

The outcome of the identification of obesity had heterogeneity between the included studies that was not possible to explore in sensitivity or subgroup analyses due to the small number of trials. As a result, a random-effects model was used and the outcome was downgraded for inconsistency.

No data were available for the critical outcomes of community participation and meaningful occupation.

Table 78: Study information table for trials included in the analysis of annual health checks versus treatment as usual

	Annual health checks versus treatment as usual
Total no. of studies (N[1])	3 (882)

	Annual health checks versus treatment as usual
Study ID	(1) Cooper 2014 (2) Lennox 2007 (3) Lennox 2010
Country	(1) UK (2,3) Australia
Diagnosis/degree of learning disabilities	Mild to profound learning disabilities
Age (mean)	(1) 46.8 years (2) 39 years (3) 36 years
Sex (% female)	40-44%
Ethnicity (% white)	Not reported
IQ (mean)	Not reported
Living arrangements	(1) 83.76% family or paid carer, 16.24% independent (2) 65% supported care (3) Not reported
Targeted behaviour	Undetected health-monitoring and health-promoting needs e.g. general health and mental disorders
Treatment length (weeks)	(1) 1 health check and a 39 weeks follow-up (2,3) 1 health check and a 52 weeks follow-up
Intervention (mean dose; mg/day)	(1) Health checks completed with a carer and nurse Stage 1: carer completed brief health questionnaires; Stage 2: retrospective review of GP notes, and guided assessment of health by nurse. (2,3) Health checks completed with a carer and GP. 'CHAP booklet' Stage 1 health history completed by the person/ carer. Stage 2: Retrospective GP review of case notes and guided assessment of the person's health (including prompts).
Comparison	Treatment as usual
Notes. N=total number of participants. [1] Number randomised.	

Table 79: Summary of findings table for the analysis of annual health checks versus treatment as usual for prevention of mental health problems

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with treatment as usual	Risk difference with Annual health check
Psychosis (Identification of mental health needs; all levels of LD) (Mental health) follow up: mean 39 weeks	149 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	RR 0.53 (0.16 to 1.80)	Study population	
				91 per 1000	43 fewer per 1000 (76 fewer to 73 more)
Psychiatric consultation/ visit (Identification of mental health needs; all levels of LD) (Mental	574 (2 RCTs)	⊕◯◯◯ VERY LOW [2,4,5]	RR 0.83 (0.50 to 1.36)	Study population	
				108 per 1000	18 fewer per 1000 (54 fewer to

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with treatment as usual	Risk difference with Annual health check
health) follow up: range 39 weeks to 52 weeks					39 more)
Psychiatric disorders (Identification of mental health needs; all levels of LD) (Mental health) follow up: mean 52 weeks	453 (1 RCT)	⊕◯◯◯ VERY LOW ^{1,2,5}	RR 4.68 (0.23 to 96.96)	Study population 0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Newly detected health issues (all levels of LD) (Quality of life) follow up: range 39 weeks to 52 weeks	719 (3 RCTs)	⊕◯◯◯ VERY LOW ^{1,2,3}	OR 1.69 (1.08 to 2.64)	Study population 0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Newly detected health monitoring needs (all levels of LD) (Quality of life) follow up: mean 39 weeks	149 (1 RCT)	⊕◯◯◯ VERY LOW ^{1,2,6}	OR 2.38 (1.31 to 4.32)	Study population 0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Newly detected health promotion needs (all levels of LD) (Quality of life) follow up: mean 39 weeks	149 (1 RCT)	⊕◯◯◯ VERY LOW ^{1,2,5}	OR 0.98 (0.73 to 1.32)	Study population 0 per 1000	0 fewer per 1000 (0 fewer to 0 fewer)
Obesity (Identification of health needs; all levels of LD) (Quality of life) follow up: range 39 weeks to 52 weeks	602 (2 RCTs)	⊕◯◯◯ VERY LOW ^{1,2,6,7}	RR 1.41 (1.09 to 1.82)	Study population 151 per 1000	62 more per 1000 (14 more to 124 more)
Community participation and meaningful occupation - not reported	-	-			

Note
1. Risk of performance bias
2. Indirect outcome
3. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
4. Risk of performance, selection, attrition bias
5. Confidence intervals cross two minimally important differences. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
6. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
7. I^2 suggests considerable heterogeneity

7.2.2 Economic evidence

No studies assessing the cost effectiveness of annual health checks in the prevention of mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. However, the GC decided to consider indirect economic evidence on the use of health checks for the identification of physical health risks in people with learning disabilities. The systematic search of the economic literature identified 3 studies that addressed this question (Cooper et al., 2014; Gordon et al., 2012; Romeo et al., 2009). Of these, 2 studies were conducted in the UK (Cooper et al., 2014; Romeo et al., 2009) and 1 in Australia (Gordon et al, 2012). Details on the methods used for the systematic review of the economic literature are described in Chapter 3; full references to the included studies and evidence tables for all economic evaluations included in the systematic literature review are provided in Appendix R. Completed methodology checklists of the studies are provided in Appendix Q. Economic evidence profiles of studies considered during guideline development (that is, studies that fully or partly met the applicability and quality criteria) are presented in Appendix S.

Cooper and colleagues (2014) conducted a cost-utility analysis alongside a cluster-design single-blind RCT (Cooper 2014, N=152) that assessed a health-check intervention designed specifically for adults with learning disabilities versus treatment as usual. The study was conducted in Scotland. The health-check intervention was delivered by a trained practice nurse; carers completed health questionnaires in advance of the health check. The nurses used a health-checking instrument, specifically designed for the needs of people with learning disabilities, to direct the health check and inform clinical decision making with respect to further standard investigations and treatments. The time horizon of the analysis was 9 months. The analysis adopted the perspective of the NHS; costs included intervention costs (associated with staff time), primary care, drug acquisition, emergency visits or calls. No screening or home visit checks were costed because these were assumed to be individual occurrences, with the standard being a health check by a nurse in the GP surgery. Apart from emergency visit costs, no secondary care costs were included in the analysis. National unit costs were used. The primary outcome of the clinical analysis was the incidence of new health needs detected and met during the 9 months after randomisation. The primary outcome of the economic analysis was the number of QALYs gained estimated using both the EQ-5D and SF-6D, rated by either the participants themselves or their carers.

At 9 months, the bootstrapped mean difference in total NHS costs between intervention and control was -£51 per person in 2011 prices, indicating a cost-saving for the intervention compared with treatment as usual, although this difference was not statistically significant (95%CI -£362 to £434). More new health needs were met in the intervention group than in the group receiving treatment as usual, but this difference was also not significant. The health monitoring needs of long-term disorders were significantly better met in the health-check intervention group. Few health-promotion needs were addressed in either group. In terms of QALYs, the intervention showed a better effect compared with treatment as usual, which was statistically significant when EQ-5D was used for the estimation of QALYs (bootstrapped incremental QALYs 0.11 per person, 95% CI 0.02 to 0.19) but non-significant when SF-6D was used instead (bootstrapped incremental QALYs 0.02 per person, 95% CI -0.03 to 0.07). Thus the health-check intervention was shown to be dominant over treatment as usual, as it resulted in better outcomes and lower costs. Probabilistic sensitivity analysis demonstrated that the intervention had a probability of being cost-effective lying between 0.6 and 0.8, irrespective of the cost-effectiveness threshold used.

Threshold analysis showed that the intervention cost would need to rise from £51 (which was the estimate in the base-case analysis) to £95 per person before the intervention no longer dominated treatment as usual. The study is directly applicable to the guideline context as it was conducted in the UK and used QALY as an outcome, but is characterised by potentially serious limitations, including its short time horizon (9 months), the omission of secondary care costs from the analysis (apart from emergency visits and calls), and the fact that EQ-5D and SF-6D may not be directly relevant to people with learning disabilities; it should also be noted that some of those measurements were based on proxy ratings, with different carers rating health between baseline and follow-up for some participants. Nevertheless, the intervention was dominant even when the clinical outcome measures relating to identifying and meeting new health needs where used.

Romeo and colleagues (2009) evaluated the costs and outcomes of a health-check intervention versus treatment as usual offered to adults with learning disabilities registered with primary care services in the UK. The health-check intervention comprised a review of participants' GP records by an experienced nurse; assessment of participants' general physical and mental health, development and problem behaviours, selected physical examination and blood tests; discussion of the results with a GP; preparing a report of findings and recommendations to the participants' GP; and referral algorithms to learning disabilities services. The economic analysis was based on a cohort study with matched controls that followed 100 people for a period of 12 months (Cooper et al., 2006). Participants were matched with controls for age, gender and level of learning disability. The analysis adopted a societal perspective; costs consisted of intervention costs (equipment and staff time), primary, inpatient, outpatient & specialist learning disability service costs, costs of other healthcare services, daytime activity costs comprising unsupported and supported paid employment, voluntary work, adult education classes, day centres and additional support, costs of respite care, costs of aids and adaptations, as well as costs associated with paid and unpaid care. Costs were collected prospectively for the intervention group and retrospectively for the control group. Unit costs were based on national sources and further estimates. The effectiveness of the intervention was measured by the levels of health need detection, met new health needs, met health promotion and monitoring needs.

According to the study findings, the mean total cost of the intervention was £82 per person. Total mean service costs were similar for the intervention and standard care. However, the total costs per person were significantly lower for the intervention compared with control (bootstrapped cost difference -£22,772 per person in 2003 prices, 95% CI -£37,569 to -£6,400), resulting from lower mean carer support costs per person associated with the intervention. The intervention resulted in a higher number of newly identified health needs and new health needs that were met per person, and a higher level of met health promotion and health monitoring needs per person; all differences in outcomes between the health-check intervention and standard care were statistically significant. Therefore, the intervention was shown to be dominant over standard care, as it resulted in better outcomes, similar service costs and lower carer support and total costs compared with standard care. The study is partially applicable to the guideline context although it was undertaken in the UK, because outcomes were not expressed in QALYs (which is the NICE preferred measure of outcome for economic evaluations) and the effect of the intervention on the mental health of service users was not considered. Moreover, the study adopted a societal perspective, which is not in line with the NICE reference case, although it is acknowledged that service costs (NHS and PSS) were reported separately. Finally, the study is characterised by potentially serious limitations, mainly relating to the study design (cohort study with retrospective measurement of control costs) and the small number of people participating in the study.

Gordon and colleagues (2012) conducted a cost-consequence analysis alongside a RCT (Lennox et al., 2010; N=242) to assess the cost effectiveness of a one-off health-check intervention for adults with learning disabilities versus a health diary designed for ongoing use. The study was carried out in Australia. The one-off health check intervention comprised a booklet in which the carer provided a detailed medical history; subsequently, the GP reviewed the history, performed the health assessment and developed an action plan in consultation with the service user and their carer. The time horizon of the analysis was 12 months. The perspective of the analysis was that of a public healthcare system (Medicare Australia). Costs consisted of consultation costs, procedure costs, as well as costs of medications and vaccines that were claimed on the Medicare Benefits Schedule (MBS) and the Pharmaceutical Benefits Scheme (PBS); medications and vaccines not claimed on these Schemes as well as secondary care costs were not considered in the analysis. National unit costs were used. The measures of outcome were the number of vision and hearing tests performed in each arm of the study, the immunisation rates for hepatitis A and pneumococcus, and the mean number of weight measurements.

At 12 months, the mean total costs per person were similar between the intervention and the control group (AU$4,523 versus AU$4,466, respectively in 2011 prices; difference not statistically significant). The health-check intervention resulted in a significantly higher number of vision and hearing tests, significantly higher immunisation rates for hepatitis A and pneumococcus, and a significantly higher number of weight measurements. The study is partially applicable to the guideline context as it was conducted in Australia, and is characterised by potentially serious limitations, including a rather short time horizon (12 months), the omission of secondary care costs from the analysis, the potential exclusion of some medications and vaccines \from costings as they are not eligible for Pharmaceutical Benefits Scheme claims, and the fact that only 1 service provider was included in the analysis.

Overall, the existing evidence suggests that health-checks in people with learning disabilities may be improving health by identifying new health needs, at the same, or even lower, cost compared with treatment as usual.

7.2.3 Clinical evidence statements

7.2.3.1 Annual health checks versus treatment as usual – prevention

- Very low quality evidence from 3 studies is inconclusive whether annual health checks are better than treatment as usual in identifying mental health needs (psychosis, psychiatric consultation, and psychiatric disorders) at 39 to 52 weeks (k=1, N=149; k=2, N=574; k=1, N=453).
- Very low quality evidence from 3 studies suggests that annual health checks may be better than treatment as usual in detecting of new health issues after 39 to 52 weeks (k=3, N=719).
- Very low quality evidence from 1 study suggest that annual health checks are better than treatment as usual in detecting health-monitoring needs at 39 weeks but it is less clear if they are better at detecting health promotion needs (k=1, N=149).
- Very low quality evidence from 2 studies suggests that annual health checks may be better than treatment as usual in improving the identification of obesity after 39 to 52 weeks (k=2, N=602).

7.2.4 Economic evidence statements

- Moderate-to-low quality evidence from 2 RCTs (k=2, N=394) and a cohort study with matched controls (k=1, N=100) suggested that regular health checks aiming to identify and manage health needs of people with learning disabilities are cost effective as they result in a higher number of new health needs identified and met, higher QALYs and similar service costs. Part of this evidence is directly relevant to the UK but overall is characterised by potentially serious limitations.

7.3 Review questions: In people (children, young people and adults) with learning disabilities, do dietary interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities, do dietary interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 80 and Table 81. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 80: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do dietary interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.5)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any dietary interventions
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs.

Table 81: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do dietary interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.5)
Population	People (children, young people and adults) with learning disabilities and mental health problems.
Intervention(s)	Any dietary intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs.

7.3.1 Clinical evidence

There were 3 RCTs found on dietary interventions for the prevention or treatment and management of mental health problems. One study for the treatment of ADHD was conducted in children but the 2 studies on the prevention or treatment of dementia, respectively, were conducted in adults. Despite the limited RCT evidence, the group did not find it appropriate to go down the evidence hierarchy, examine indirect evidence, or conduct formal group consensus for dietary interventions as none were judged a good use of time and resources (particularly given the lack of plausible biological mechanisms for the dietary interventions which were examined in the available RCTs).

7.3.1.1 Attention deficit hyperactivity disorder

7.3.1.1.1 Acetyl-L-carnitine versus placebo – treatment

One RCT (N=63), which included participants with Fragile X syndrome, met the eligibility criteria for this review:Torrioli et al. (2008).

Acetyl-L-carnitine is an amino acid which helps the body to produce energy. It is produced naturally by the body but sometimes taken as a dietary supplement. Acetyl-L-carnitine has been investigated as a dietary supplement in ADHD as it is thought to act as a natural stimulant, without the development of undesirable side-effects.

An overview of the trial included can be found in Table 47. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 83. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

It was not clear from the study what level of learning disabilities the participants.

No data were available for the critical outcomes of quality of life and community participation and meaningful occupation.

Table 82: Study information table for trials included in the analysis of acetyl-L-carnitine versus placebo for the treatment of ADHD in children with Fragile X syndrome

	Acetyl-L-carnitine versus placebo
Total no. of studies (N[1])	1 (63)
Study ID	Torrioli 2008
Country	Italy, France and Spain
Diagnosis/degree of learning disabilities	Fragile X Syndrome Unclear level of learning disabilities[2]
Age (mean)	9.18 years
Sex (% female)	0%
Ethnicity (% white)	Not reported
IQ (mean)	45[2]
Living arrangements	Unclear (appears to be family home)
Targeted behaviour	ADHD[3]
Treatment length (weeks)	52 weeks
Intervention (mean dose; mg/day)	500 mg oral sachets of acetyl-L-carnitine administered twice daily.
Comparison	Placebo

Notes.

[1] Number randomised.

[2] Fragile X Syndrome diagnosis was confirmed by the Southern blot test; IQ level assessed using Wechsler Intelligence Scale for Children-Revised (WISC-R).

[3] DSM-IV diagnosis.

Table 83: Summary of findings table for the analysis of L-acetylcarnitine versus placebo for the treatment of ADHD in children with Fragile X syndrome

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with Acetyl-L-carnitine
ADHD (Mental health) assessed with: Conners' Parents follow up: mean 52 weeks	51 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean score was 65	MD 2.8 fewer (7.58 fewer to 1.98 more)
ADHD (Mental health) assessed with: Conners' Teachers follow up: mean 52 weeks	51 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean score was 67	MD 0.5 more (5.08 fewer to 6.08 more)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Adaptive functioning (post-treatment) (Adaptive functioning) assessed with: VABS - full scale follow up: mean 52 weeks	51 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean adaptive functioning (post-treatment) was 40.3	MD 8.2 more (0.04 fewer to 16.44 more)
Adaptive functioning (Adaptive functioning) assessed with: VABS - socialization scale follow up: mean 52 weeks	51 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean adaptive functioning was 56.1	MD 11.3 more (2.18 more to 20.42 more)

Note

1. Risk of selection and detection bias
2. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

7.3.1.2 Dementia

7.3.1.2.1 Acetyl-L-carnitine versus placebo – prevention

There was one RCT (N=40) that met the eligibility criteria for this review: Pueschel (2006). An overview of the included trial can be found in Table 84. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 85. The full GRADE evidence profiles can be found in Appendix N.

The study reported the outcomes narratively only (with p values). The author was contacted for more details but there was no response so the outcomes are summarised narratively here The study reported no significant difference between the acetyl-L-carnitine group and the control group in terms of cognitive functioning (as assessed by The Stanford-Binet Intelligence Scale; the Hiskey-Nebraska Visual Attention Span and Matching Familiar Figure test; Mazes and Coding test; Riddles subtest) and for mental health outcomes as assessed by the emotional disorder rating scale and child behaviour checklist.

The paper included participants with mild to moderate levels of learning disabilities but combined the results so it was not possible to examine the results separately by degree.

No data was available on the critical outcomes of quality of life and community participation and meaningful occupation.

Table 84: Study information table for trials included in the analysis of acetyl-L-carnitine versus placebo for prevention of dementia in people with Down's syndrome

	Acetyl-L-carnitine versus placebo
Total no. of studies (N[1])	1 (40)
Study ID	Pueschel 2006
Country	United States
Diagnosis/degree of learning disabilities	Down's Syndrome. Mild to moderate IQ[2]
Age (mean)	20.85 years
Sex (% female)	0%
Ethnicity (% white)	98.5%
IQ (mean)	Down's syndrome, mild-moderate learning disabilities[2]
Living arrangements	not reported
Targeted behaviour	Dementia
Treatment length (weeks)	26 weeks treatment followed by 13 week 'wash-out' period
Intervention (mean dose; mg/day)	10 to 30 mg (optimal dose) Acetyl-L-carnitine tablets administered daily
Comparison	Placebo

Notes. N=total number of participants.

[1] Number randomised.

[2] based on Stanford-Binet Intelligence Scale; all had mild to moderate IQ so it appears all had IQ < 70 but definition of 'mild to moderate IQ' was not reported (however, 32% had

	Acetyl-L-carnitine versus placebo
IQ <50).	

Table 85: Summary of findings table for the analysis of acetyl-L-carnitine versus placebo for the prevention of dementia in people with Down's syndrome

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Impact
Cognitive functioning (mild to moderate LD) (Mental health) assessed with: Multiple measures follow up: mean 39 weeks	40 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	No significant difference between Acetyl-L-Carnitine and placebo groups for all measures.
Dementia: (mild to moderate LD) (Mental health) assessed with: Emotional disorder rating scale follow up: mean 39 weeks	40 (1 RCT)	⊕◯◯◯ VERY LOW [2,3]	No significant difference between Acetyl-L-Carnitine and placebo groups
Dementia (mild to moderate LD) (Mental health) assessed with: Child behaviour checklist follow up: mean 39 weeks	40 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	No significant difference between Acetyl-L-Carnitine and placebo groups
Quality of life - not reported	-	-	
Community participation and meaningful occupation - not reported	-	-	

Note

1. Risk of selection, selective outcomes and attrition bias.
2. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
3. Risk of selection, selective outcomes, detection bias and attrition bias.

7.3.1.2.2 *Antioxidant versus placebo – treatment*

One RCT (N=58) met the eligibility criteria for this review: Lott et al. (2011).

An overview of the trial included can be found in Table 86. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 87. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O

The study administered antioxidants which included 900 international units (IU) alpha-tocopherol, 200 mg ascorbic acid, 600 mg alpha-lipoic acid and was considered to be a supplement to acetylcholinesterease inhibitor. The hypothesised action of antioxidants was to counteract the effects of oxidative stress upon brain pathology, which has been associated with pre-dementia cognitive dysfunction in Down's syndrome.

Some outcomes were not reported in a way that was possible to enter into review manager (they were reported as mean difference in change scores only). The author was contacted but there was no response so these outcomes are summarised narratively here. The study reported no significant differences between antioxidant and placebo groups on The Dementia Questionnaire for Mentally Retarded Persons (DMR) cognitive scores, Severe Impairment Battery, Brief Praxis Test, and DMR sum of social scores.

The paper combined the results of all degrees of learning disabilities so it was not possible to examine the results by degree.

No data were available for the critical outcomes of quality of life and community participation and meaningful occupation.

Table 86: Study information table for trials included in the analysis of antioxidant versus placebo for treatment of dementia in people with Down's syndrome

	Antioxidant versus placebo
Total no. of studies (N[1])	1 (58)[2]
Study ID	Lott 2011
Country	United States
Diagnosis/degree of learning disabilities	Down's syndrome; Mild to profound learning disabilities (69.6% mild to moderate)[3]
Age (mean)	50 years
Sex (% female)	52.7%
Ethnicity (% white)	87.1%
IQ (mean)	Not reported[3]
Living arrangements	Semi-independently in family homes or community care
Targeted behaviour	Dementia[4]
Treatment length (weeks)	52 weeks
Intervention (mean dose; mg/day)	3 capsules daily (900 mg IU alpha-tocopherol, 200 mg ascorbic acid, 60 mg alpha-lipoic acid)[5]
Comparison	Placebo[5]

Notes.

[1] Number randomised.

[2] 58 were randomised, but only 53 received treatment (27 in intervention arm and 26 control arm).

[3] As assessed using the Weschler Intelligence Scale for Children-Revised (WISC-R).

[4] DSM-IV diagnosis which required 'clinical and neurological examination showing deficits in 2 or more areas of cognitive functioning, and progressive worsening of cognitive performance compared to…baseline functioning' (decline was measured with SIB or DMR SOC); no details provided about severity of dementia; all participants were also receiving acetylcholinesterase inhibitor as standard treatment for dementia.

[5] As part of standard care, both arms received an anticholinesterase inhibitor and vitamins.

Table 87: Summary of findings table for the analysis of antioxidant versus placebo for treatment of dementia in people with Down's syndrome

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with placebo	**Risk difference with Antioxidant**
Mental health (all levels of LD) (Mental health) assessed with: DMR	53 (1 RCT)	⊕⊕◯◯ LOW [1,2]		No significant differences in DMR cognitive scores between	

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	Risk difference with Antioxidant
(sum of cognitive scores) follow up: mean 104 weeks				antioxidant and placebo groups	
Mental health (all levels of LD) (Mental health) assessed with: Severe impairment battery follow up: mean 104 weeks	53 (1 RCT)	⊕⊕◯◯ LOW [1,2]		No significant differences in Severe Impairment Battery scores between antioxidant and placebo groups	
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Adaptive functioning (all levels of LD) (Adaptive functioning) assessed with: Brief Praxis Test follow up: mean 104 weeks	53 (1 RCT)	⊕⊕◯◯ LOW [1,2]		No significant differences in Brief Praxis Test scores between antioxidant and placebo groups	
Adaptive functioning (all levels of LD) (Adaptive functioning) assessed with: DMR (sum of social skills) follow up: mean 104 weeks	53 (1 RCT)	⊕⊕◯◯ LOW [1,2]		No significant differences in DMR sum of social scores between antioxidant and placebo groups	
Adaptive functioning (all levels of LD) (Adaptive functioning) assessed with: Bristol Activities of Daily Living Scale follow up: mean 104 weeks	53 (1 RCT)	⊕⊕◯◯ LOW [1,2]		No significant differences in Bristol Activities of Daily Living Scale scores between antioxidant and placebo groups	
Any serious adverse event (incapacitation and/or inability to sustain daily activities) (all levels of LD) (Adverse events) assessed with: (ITT/analysed as randomised) follow up: mean 104 weeks	58 (1 RCT)	⊕⊕◯◯ LOW [1,2]	RR 1.27 (0.70 to 2.32)	Study population	
				379 per 1000	102 more per 1000 (114 fewer to 501 more)

Note

1. Risk of selective outcomes bias.
2. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

7.3.2 Economic evidence

No studies assessing the cost effectiveness of dietary interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.3.3 Clinical evidence statements

7.3.3.1 ADHD

7.3.3.1.1 L-acetylcarnitine versus placebo – treatment

- Very low quality evidence from 1 study suggests that acetyl-l-carnitine may be more effective than placebo in improving parent rated mental health (as assessed by Conners' Global Index Parents) after 52 weeks in children and young people with Fragile X syndrome, but inconclusive for teacher rated mental health (k=1, N=51).
- Very low quality evidence from 1 study suggests that acetyl-l-carnitine is better than placebo in improving adaptive functioning scores after 52 weeks (k=1, N=51).

7.3.3.2 Dementia

7.3.3.2.1 Acetyl-L-carnitine versus placebo – prevention

- Low to moderate quality evidence from 1 study suggests little difference between acetyl-l-carnitine and placebo in improving cognitive functioning scores and general mental health outcomes after 39 weeks (k=1, N=40).

7.3.3.2.2 Antioxidant versus placebo – treatment

- Moderate quality evidence from 1 study suggests little difference between antioxidant and placebo in terms of mental health at 104 weeks, as assessed by DMR sum of cognitive scores, severe impairment battery and Brief praxis test (k=1, N=58).
- Moderate quality evidence from 1 study suggests that antioxidant is associated with a higher level of serious adverse events than placebo after 104 weeks (k=1, N=58).

7.3.4 Economic evidence statements

No evidence on the cost effectiveness of dietary interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities is available.

7.4 Review questions: In people (children, young people and adults) with learning disabilities, do exercise interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities, do exercise

interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 88 and Table 89. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 88: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do exercise interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.13)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any exercise interventions
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs.

Table 89: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do exercise interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.11)
Population	People (children, young people and adults) with learning disabilities and mental health problems.
Intervention(s)	Any exercise intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs.

7.4.1 Clinical evidence

There were 3 RCTs found on exercise interventions for the prevention or treatment and management of mental health problems. The evidence covered mild to moderate learning disabilities, looked at depression and anxiety, and was a mixture of prevention and treatment. Despite the limited RCT evidence, the group did not find it appropriate to go down the evidence hierarchy, examine indirect evidence, or conduct formal group consensus for exercise interventions as none were judged a good use of time and resources.

7.4.1.1 Anxiety symptoms

7.4.1.1.1 Exercise versus any control – prevention or treatment

There were 2 RCTs (N=51) which met the eligibility criteria for this review: Carraro and Gobbi (2014), which includes Carraro and Gobbi (2012), and Carmeli et al. (2009).

An overview of the trials included can be found in Table 90. Further information about both included and excluded studies can be found in Appendix L.

Summary of findings can be found in Table 91.The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

Carmeli 2009, which included participants with mild learning disabilities and anxiety which was diagnosed with the Hamilton Anxiety Scale, did not report variance in the outcomes and was contacted for more information but no response was received. As a result, it was not possible to pool the results of the 2 studies together. The study reported a significant decrease in anxiety scores (as assessed by the Hamilton Anxiety Scale) for both the aerobic and leisure groups. No significant decrease was found for the control group.

The other study (Carraro 2014) included participants with mild to moderate levels of learning disabilities but combined the results so it was not possible to examine the results separately by level of degree. This study explicitly excluded participants who had either anxiety or depression diagnosis but has been included as prevention or treatment as some may have had subthreshold anxiety.

No data were available for the critical outcomes of quality of life and community participation and meaningful occupation.

Table 90: Study information table for trials included in the analysis of exercise versus control for anxiety symptoms

	Exercise versus painting activity control	**Aerobic exercise versus control**	**Leisure versus control**
Total no. of studies (N¹)	1 (27)	1 (24)	1 (24)
Study ID	Carraro 2014[2]	Carmeli 2009	Carmeli 2009
Country	Italy	Israel	Israel
Diagnosis/degree of learning disabilities	Mild to moderate learning disabilities	Mild learning disabilities	Mild learning disabilities
Age (mean)	40.1 years	51.2 years	51.2 years
Sex (% female)	41	37.5	37.5
Ethnicity (% white)	Not reported	Not reported	Not reported
IQ (mean)	Not reported	Not reported	Not reported
Living arrangements	Home	Not reported	Not reported

	Exercise versus painting activity control	**Aerobic exercise versus control**	**Leisure versus control**
Targeted behaviour	Anxiety and depressive symptoms[3]	Anxiety[4]	Anxiety[4]
Treatment length (weeks)	12 weeks	26 weeks	26 weeks
Intervention (mean dose; mg/day)	Group based physical exercise programme	Aerobic exercise: supervised exercise sessions following an individual training regime (involved walking or jogging)	Leisure programme: games and activities which focused on stability, flexibility and dynamic balance.
Comparison	Painting activity control	Vocational activities	Vocational activities

Notes. N=total number of participants.

[1] Number randomised. [2] Outcomes from the same study but from 2 publications: Carraro 2014 and 2012. Carraro 2012 reported anxiety outcomes and Carraro 2014 reported depression outcomes. [3] Participants were included if they presented to an outpatient daily care centre for people with learning disabilities and were excluded if diagnosed with either anxiety or depression but may have had subthreshold levels so considered prevention or treatment. [4] Assessed using the Hamilton Anxiety Scale. All participants were diagnosed with anxiety but it is not clear how this was defined (ie. if this included mildly clinically anxious as well as moderately and severely clinically anxious).

Table 91: Summary of findings table for the analysis of exercise versus control for anxiety symptoms

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with any control	**Risk difference with Exercise**
Anxiety (mild LD) (Mental Health) assessed with: Hamilton Anxiety Scale follow up: mean 39 weeks	16 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]		Significant decrease in total HAM-A scores in the aerobic and leisure groups only (no significant decrease was found for the vocational activities control group.)	
Anxiety (mild to moderate LD) (Mental Health) assessed with: Zung Self-rating anxiety scale (adapted for LD and named Self-rated Anxiety Scale or SAS-ID) follow up: mean 12 weeks	27 (1 RCT)	⊕◯◯◯ VERY LOW [1,4]	-	The mean anxiety (mild to moderate LD) was 31.62	MD 6.62 fewer (7.97 fewer to 5.27 fewer)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			

Note

1. Risk of selection, performance and detection bias
2. Risk of selective outcome (no variance reported so not possible to use in meta-analysis), performance and selection bias
3. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes). Not possible to assess confidence without variance.
4. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

7.4.1.2 Depressive symptoms

There were 2 RCTs (N=51) which considered met the eligibility criteria for this review: Carraro and Gobbi (2014) and Heller et al. (2004). One trial (Carraro 2014) compared exercise only with a painting control and another compared both exercise plus education compared to no treatment. An overview of the trials included can be found in Table 92. Further information about both included and excluded studies can be found in Appendix L.

Both papers included participants with mild to moderate levels of learning disabilities but combined the results so it was not possible to examine the results separately by degree. While Carraro 2014 excluded participants who had either anxiety or depression diagnosis, it was included as prevention or treatment as some may have had subthreshold anxiety. Heller was also considered either prevention or treatment as depressive symptoms was not an inclusion criterion and participants could have had a range of presentations, from no symptoms (when it would be considered prevention) to clinical levels of depression (when it would be considered treatment).

7.4.1.2.1 Exercise versus painting control – prevention or treatment

Summary of findings for the results for this comparison can be found in Table 93.The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

No data were available for the critical outcomes of quality of life and community participation and meaningful occupation.

7.4.1.2.2 Exercise and education versus no treatment – prevention or treatment

Summary of findings for the results from this comparison can be found in Table 94. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

Table 92: Study information table for trials included in the analysis of exercise (with or without education) versus control for depressive symptoms

	Exercise + education versus no treatment	**Exercise versus painting activity control**
Total no. of studies (N¹)	1 (89)	1 (27)
Study ID	Heller 2004	Carraro 2014[3]
Country	United States	Italy
Diagnosis/degree of learning disabilities	Mild to moderate learning disabilities	Mild to moderate learning disabilities
Age (mean)	39.7 years	40.1 years
Sex (% female)	55%	41
Ethnicity (% white)	60%	Not reported
IQ (mean)	Mild to moderate[2]	Not reported
Living arrangements	57% living with family, 11% independently, 32% in supervised residence.	Home
Targeted behaviour	Depressive symptoms[4]	Anxiety and depressive symptoms[5]

	Exercise + education versus no treatment	Exercise versus painting activity control
Treatment length (weeks)	12 weeks	12 weeks
Intervention (mean dose; mg/day)	Physical exercise programme (cardiovascular, strength and endurance) and education (benefits of exercise, goal setting)	Group based physical exercise programme
Comparison	Control (receiving no training)	Painting activity control

Notes. N=total number of participants.

[1] Number randomised.

[2] Assessment tool unspecified.

[3] Outcomes from the same study but from 2 publications: Carraro 2014 and 2012. Carraro 2012 reported anxiety outcomes and Carraro 2014 reported depression outcomes.

[4] Study did not appear to have used depressive symptoms as an inclusion criterion and is not clear if participants had levels of depression that would be considered clinical depression

[5] Participants were excluded if diagnosed with either anxiety or depression but may have had subthreshold levels so considered prevention or treatment.

Table 93: Summary of findings table for the analysis of exercise versus painting control for depressive symptoms

				Anticipated absolute effects	
Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Risk with painting control**	**Risk difference with Exercise**
Depressive symptoms (mild to moderate LD) (Mental Health) assessed with: Zung self-rating depression scale follow up: mean 12 weeks	27 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean depressive symptoms (mild to moderate LD) was 29.77	MD 6.06 fewer (7.25 fewer to 4.87 fewer)
Quality of life - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			

Note

1. Risk of selection, performance and detection bias
2. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

Table 94: Summary of findings table for the analysis of exercise and education versus no treatment for depressive symptoms

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with control	Risk difference with Exercise and education
Depressive symptoms (mild to moderate LD) (Mental health) assessed with: Child Depression Inventory follow up: mean 12 weeks	53 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean depressive symptoms (mild to moderate LD) was 3.28	MD 1.53 fewer (3.29 fewer to 0.23 more)
Community participation and meaningful occupation (mild to moderate LD) (Mental Health) assessed with: Communication integration scale follow up: mean 12 weeks	53 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean community participation and meaningful occupation (mild to moderate LD) was 7.19	MD 0.78 fewer (2.06 fewer to 0.5 more)
Quality of life (mild-moderate LD) (Quality of life/ service user and carer satisfaction/ experience of care) assessed with: Life Satisfaction Scale follow up: mean 12 weeks	53 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	The mean quality of life (mild-moderate LD) was 49.48	MD 2.52 more (0.87 fewer to 5.91 more)

Note

1. Selection and detection bias
2. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

7.4.2 Economic evidence

No studies assessing the cost effectiveness of exercise interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.4.3 Clinical evidence statements

7.4.3.1 Anxiety symptoms

7.4.3.1.1 Exercise versus any control – prevention or treatment

- Very low quality evidence from 1 study suggests that aerobic and leisure exercise are better than a vocational activity control at improving anxiety symptoms at 39 weeks (k=1, N=16).
- Very low quality evidence from 1 study suggests that exercise is better than a painting activity control in improving anxiety symptoms at 12 weeks (k=1, N=27).

7.4.3.2 Depressive symptoms

7.4.3.2.1 Exercise versus painting control – prevention or treatment

- Very low quality evidence from 1 study suggests that exercise is better than a painting activity control in improving self-rated depressive symptoms at 12 weeks (k=1, N=27).

7.4.3.2.2 Exercise and education versus no treatment – prevention or treatment

- Very low quality evidence from 1 study suggests that exercise and education may be better than no treatment in improving depressive symptomatology and life satisfaction scores at 12 weeks (k=1, N=53).
- Very low quality evidence from 1 study suggests little difference in community participation scores with exercise and education compared to no treatment at 12 weeks (k=1, N=53).

7.4.4 Economic evidence statements

No evidence on the cost effectiveness of exercise interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities is available.

7.5 Recommendations and link to evidence

7.5.1 Physical interventions (annual health checks, dietary interventions, and exercise)

Recommendations	**49. GPs should offer an annual health check using a standardised template to all adults with learning disabilities, and all children and young people with learning disabilities who are not having annual health checks with a paediatrician.** **50. Involve a family member, carer or care worker (as appropriate), or a healthcare professional or social care practitioner who knows the person well, in the annual health check. Take into account that more time may be needed to complete health checks with people with learning disabilities.** **51. Include the following in annual health checks:**

	• a review of any known or suspected mental health problems and how they may be linked to any physical health problems **• a physical health review, including assessment for the conditions and impairments which are common in people with learning disabilities** **• a review of all current interventions, including medication and related side effects, adverse events, interactions and adherence** **• an agreed and shared care plan for managing any physical health problems (including pain).** **52. During annual health checks with adults with Down's syndrome, ask them and their family members, carers or care workers (as appropriate) about any changes that might suggest the need for an assessment of dementia, such as:** **• any change in the person's behaviour** **• any loss of skills (including self-care)** **• a need for more prompting in the past few months.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of interventions at preventing or treating mental health problems. In addition to the effect on the mental health problem which was the aim of the intervention (for dementia, this was cognitive function as well as psychopathology), the GC were of the view that quality of life, and community participation and meaningful occupation were particularly critical outcomes which they wished to consider in the literature. The GC noted in particular the difficulties with measuring self-reported outcomes in this population, given communication needs and cognitive impairments so there should be caution in the interpretation of these outcomes from the trials. Reported outcomes from multiple sources may be helpful (eg. teachers, parents) in addressing this issue. Additional important outcomes included problem behaviours, adaptive functioning such as communication skills, service user or carer satisfaction or experience of care, carer health and quality of life, adverse effects of interventions, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	As with other areas of the guideline, the GC noted the limited number of studies included in the review of exercise interventions. **Annual health checks** The GC noted that there was no direct evidence of annual health checks on their ability to prevent mental health problems. The GC also noted that while 2 of the included studies measured outcomes after one year, none of the included studies measured outcomes over a longer follow-up, after multiple annual health checks. At follow-ups from 39 to 52 weeks, the evidence showed that health checks appear to be better at detecting new health issues, health monitoring needs and may be better at improving the identification of obesity.

	The GC recognised that there was limited evidence for the use of annual health checks as an intervention to prevent mental health problems in people with learning disabilities but the group were of the view that annual checks were likely to increase the identification of mental health problems in this population, and management of associated physical health problems, and therefore decided to recommend annual health checks on the basis of informal consensus. They also noted that detecting health issues or monitoring needs is particularly important in people with learning disabilities and mental health problems as these often are missed. Annual health checks should already be offered to those with a learning disability, and are considered by Public Health England to constitute a reasonable adjustment to primary care services for this population (Robertson, 2010). **Dietary interventions** For the most part, the evidence on dietary interventions was inconclusive so the GC were of the view that it was very difficult to make recommendations on these interventions for the prevention and treatment of mental health problems. The GC noted that the evidence on acetyl-L-carnitine for ADHD in children with Fragile X appeared to reduce ADHD symptoms and have an effect on adaptive functioning. However the study was very small with uncertainty around the estimate, therefore the GC did not think it was appropriate to recommend acetyl-L-carnitine. **Exercise interventions** The GC were of the view that there was limited evidence to support the use of exercise interventions for the prevention or treatment of depressive and anxiety symptoms in people with learning disabilities. There was a brief discussion of the adaption of current recommendations in the depression guidelines (for children and adults). The group were of the view that exercise is a promising intervention in people with learning disabilities and recommended that research be conducted into the use of exercise interventions to prevent or treat mental health problems.
Trade-off between net health benefits and resource use	**Annual health checks** Regular health checks aiming to identify and manage health needs of people with learning disabilities appear to be cost effective, as moderate-to-low quality evidence suggests that they improve physical health outcomes by increasing the number of identified and met physical health needs at a similar total healthcare cost to treatment as usual. Part of this evidence is directly relevant to the UK but overall is characterised by potentially serious limitations. The GC expressed the opinion that people with learning disabilities and mental health needs may have difficulty in articulating their physical health problems, so regular health checks for the identification of physical health problems may be even more beneficial and cost-effective in this population. The GC acknowledged that the available evidence focused on physical health needs and therefore is only indirect regarding the cost effectiveness of health checks in preventing mental health problems. However, the GC expressed the view that checking for mental health problems and needs in the context of an annual health check for physical health problems has only modest resource implications in terms of the extra time required. Moreover, the GC considered that if health checks lead to identification of mental health needs in addition to physical health needs and this results in subsequent treatment and management of underlying mental health problems at an earlier stage, before they require more resource intensive management, then health checks might be expected to result in improved mental health outcomes in the longer term and potential future cost savings to the healthcare system that outweigh the modest costs associated with checking for mental health problems as part of an annual health check in this population.

	Although Public Health England note in their briefing for commissioners that the content (including questions about mental health) and quality of health checks vary across the country (Turner, 2010), they recommend that such checks be comprehensive. Consistent with this, in their information for the public NHS Choices state that health checks should include questions about behaviour and lifestyle, including mental health (NHS Choices, 2015). **Dietary interventions** Offering dietary interventions to people with learning disabilities is likely to have modest resource implications that can be offset by potential improvements in people's HRQoL resulting from prevention, treatment or management of mental health problems. However, evidence suggesting improvement in mental health outcomes resulting from dietary interventions in people with learning disabilities is particularly limited. **Exercise interventions** Offering exercise interventions to people with learning disabilities is likely to have minor resource implications that can be offset by potential improvements in people's HRQoL resulting from prevention, treatment or management of mental health problems. However, evidence suggesting improvement in mental health outcomes resulting from exercise interventions in people with learning disabilities is particularly limited.
Quality of evidence	**Annual health checks** The outcomes from the evidence on annual health checks was of very low quality. In addition to being indirect outcomes for preventing mental health problems, many of the outcomes from the studies were found to be imprecise with wide confidence intervals that are probably largely due to small numbers of events. **Dietary interventions** The evidence for dietary interventions was moderate to very low quality. As with many studies in the guideline, the included studies were small and resulted in imprecise estimates of effectiveness in addition to risk of bias. **Exercise interventions** The evidence for physical interventions was low to very low quality. As with many studies in the guideline, the included studies were small and resulted in imprecise estimates of effectiveness in addition to risk of bias. As a result of the quality of the evidence, the GC did not have much confidence in the results from the evidence.
Other considerations	The GC noted that annual physical health checks were recommended in the challenging behaviour guideline (NICE, 2015). They agreed that in addition to what is currently recommended in the challenging behaviour guideline, the annual health check should also consistently include a review of any known or suspected mental health problems, in order to help ensure that mental health problems are picked up in this population. Further to this, the group decided to emphasise the importance of including someone who knows the person well in the health check for a number of reasons including that it may help the person conducting the health check determine any changes from what is normal for the person. They group also stressed that adequate time needs to be set aside for the health check, in part due to communication needs, and that there should be enough time dedicated to the health checks, as per the needs of the individual person.

7.5.2 Research recommendations

8. **In people with learning disabilities, what is the clinical and cost-effectiveness of physical exercise for reducing anxiety or depressive symptoms?**

7.6 Review questions: In people (children, young people and adults) with learning disabilities, do social and physical environmental interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do social and environmental interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summaries, including the review questions and the eligibility criteria used for this section of the guideline, can be found in Table 95 and Table 96. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 95: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do social and physical environmental interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.2)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any social or physical environmental intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 96: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do social and physical environmental interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.2)
Population	People (children, young people and adults) with learning disabilities and mental health problems.
Intervention(s)	Any social or physical environmental intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

7.6.1 Clinical evidence and group consensus

No evidence was found, such as RCTs, systematic reviews, cohort or controlled before-and-after studies, on the use of social and physical environmental interventions for the prevention or treatment of mental health problems in people with learning disabilities. Despite the lack of evidence, the group did not find it appropriate to consider indirect evidence for social and physical environmental interventions as it was not judged a good use of time and resources. However, the group were of the view that the use of social and environmental interventions was of utmost importance for people with learning disabilities and that it would be inappropriate not to include some recommendations on this area given the importance of the social and physical environment on promoting mental health and well-being in people with learning disabilities and mental health problems. As such, the group decided to develop some recommendations in this area using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in the methods section in Chapter 3.

Key issues related to the use of social and physical environmental interventions for the prevention and treatment of mental problems in people with learning disabilities were identified from the reviewed literature (for example Gustafsson et al., 2009; Taylor, 2015), discussions during the GC meetings and through the service user focus groups. These were used to generate nominal statements to be rated by the GC, which were distributed in the form of a questionnaire. The nominal statements were developed to cover a range of areas that had been identified as important, including living environment, healthcare and education provision and community involvement. An example of a statement that was rated highly by the committee is ‘People with a learning disability should be offered social opportunities that will allow them to develop meaningful social relationships’.

The questionnaires were distributed and completed by 11 GC members. Percentage consensus values were calculated and comments collated for each statement. The rankings and comments were then presented to the GC members, and used to inform a discussion of the issues raised by member’s comments. Based upon feedback from the GC members at this meeting statements were re-drafted and percentage consensus values were again calculated and comments collated for each statement. Again 11 members completed their questionnaires prior to collation of results and 2 members returned their questionnaires after this. The results of round 2 were presented alongside a proposed draft recommendation, and the comments provided by GC members to inform a discussion within the group about the final wording of the recommendation. A brief summary of the outcome from this process is depicted in Table 97 below. The values below include all received questionnaires from GC members. A brief sensitivity analysis was conducted on both occasion to ascertain whether the missing values had a dramatic impact on the results presented. The complete list of statements and ratings can be found in Appendix U whilst blank copies of the questionnaires used are within Appendix T.

Table 97: Summary of nominal group technique process followed for the development of recommendations on social and physical environmental adaptations for the prevention and treatment of mental health problems in people with learning disabilities

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=16)	Level of agreement	Statements N (Total=14)	2 recommendations
High	1	High	11	
Moderate	8	Moderate	2	
Low	7	Low	1	

7.6.2 Economic evidence

No studies assessing the cost effectiveness of social and physical environmental interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.6.3 Clinical evidence statements

- The GC agreed that people with learning disabilities should be supported and empowered to make their own decisions about their living environment, that this may involve living independently or with their family but that they should be supported to remain close to their social and support network, and that where people are cared for by their family that alternatives should be considered as these family members approach later life. The GC expressed support for people being supported to live at home.
- The GC agreed that it was important to provide positive educational environments and that particular care should be taken when arranging care placements for children and young people to try and minimise the risk of placement breakdown. The GC expressed support for the need to provide consistent physical healthcare.
- The GC supported the provision of opportunities to participate in a range of social and community activities of interest to people.
- The GC decided it was important to consider social and environmental factors in the development or exacerbation of mental health problems, and that positive changes to social relationships or environment may result in an improvement.

- For people with severe or profound learning disabilities the GC agreed that it is important to consider the nature and quality of the physical environment and consider the ways in which such changes may have a positive or negative impact upon health and wellbeing.

7.6.4 Economic evidence statements

No evidence on the cost effectiveness of social and physical environmental interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities is available.

7.6.5 Recommendations and link to evidence

Recommendations	**53. Health, social care and education services should consider the impact of the social and physical environment on the mental health of adults with learning disabilities when developing care plans, and:** • **support people to live where and with whom they want** • **encourage family involvement in the person's life, if appropriate** • **support people to get involved in activities that are interesting and meaningful to them** • **plan for and help people with any significant changes to their living arrangements.** **54. Health, social care and education services should consider the impact of the social and physical environment on the mental health of children and young people with learning disabilities when developing care plans, and:** • **provide positive educational environments that are appropriate to their needs** • **when care placements (such as birth family to foster care, foster care to adoptive placement, home to residential school/college) are required, minimise the risk of placement breakdown by taking particular care to fit these to the needs of the young person** • **give special consideration and support to looked-after children and young people with learning disabilities and their foster parents or care workers, to reduce the child or young person's very high risk of developing mental health problems, and the risk of changes in their home and carers (see the NICE guideline on looked-after children and young people).**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of interventions at preventing or

	treating mental health problems. In addition to the effect on the mental health problem which was the aim of the intervention (for dementia, this was cognitive function), the GC were of the view that quality of life, and community participation and meaningful occupation were particularly critical outcomes which they wished to consider in the literature. The GC noted in particular the difficulties with measuring self-reported outcomes in this population, given communication needs and cognitive impairments so there should be caution in the interpretation of these outcomes from the trials. Reported outcomes from multiple sources may be helpful (eg. teachers, parents) in addressing this issue. Additional important outcomes included problem behaviours, adaptive functioning such as communication skills, service user or carer satisfaction or experience of care, carer health and quality of life, adverse effects of interventions, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	No clinical evidence was found that met the inclusion criteria in the protocol on social and physical environmental interventions for the prevention and treatment of mental health problems.
Trade-off between net health benefits and resource use	The social and physical environment may have an important impact on the mental health of people with learning disabilities. Adaptations to the social and physical environment and related interventions are likely to have moderate resource implications for health and social care services. However, the GC expressed the view that such adaptations and interventions are necessary for the well-being of people with learning disabilities and the prevention, as well as the effective management of mental health problems; provision of such interventions and any adaptations to the social and physical environment of people with learning disabilities may bear modest costs that were deemed justifiable by the improvements in the HRQoL of people with learning disabilities, their families and carers.
Quality of evidence	Not applicable.
Other considerations	The GC decided on the basis of the outcome of the Nominal Group Technique to develop recommendations in the following areas: - involving considerations of the social and physical environment when developing care plans - ensuring that people with learning disabilities are empowered to make their own decisions, subject to their decision-making capacity, and that this should involve support to remain close to their social and support network including living where and with whom they want to and that they should be supported to do so - ensuring that the approach is centred around the person and that the needs of the family are also taken into account - engagement in meaningful personal, social and community opportunities should be supported - significant changes around living arrangements should be planned carefully and people should be adequately supported - special considerations for children such as providing positive educational environments, and if care placements are necessary, the need to avoid placement breakdown by ensuring the placement fit the needs of the person An additional contextual factor was picked up in the nominal group technique which were deemed to be important to address, and recommendations were made to incorporate these issues: - The group discussed that there are particular needs for looked after children. As such, the group used informal consensus to develop recommendations for looked after children to ensure that there is special consideration and support for these children.

	- The group also noted that there is public health guidance on looked after children (NICE, 2010) which was unable to develop specific recommendations for people on learning disabilities due to the limited evidence in this population but have noted that most of the recommendations apply to people with learning disabilities. For example, the guidance noted that it is particularly important that people with learning disabilities are offered the same interventions and support services as their counterparts in universal settings and also that all carers and practitioners who work with babies and young children should have specialist training (as part of core training) in the needs of those with learning disabilities. The guidance also makes recommendations for research on looked after children with particular needs such as learning disabilities. The GC agreed to emphasise that the person's desire to live where they want is very important. The group agreed that, due to the lack of literature on social and physical environmental interventions and other interventions, more research is required into different types of interventions or adaptations to existing interventions (including social and physical interventions) for people with mild to moderate learning disabilities. They noted that psychosocial interventions may be appropriate for people with severe or profound learning disabilities, but there is no research to support this so made a specific recommendation regarding this. The GC considered that people with more severe mental health problems might benefit from interventions related to improving their social network. As such, the group made a recommendation for future research into this area.

7.6.6 Research recommendations

9. **For people with learning disabilities, what is the clinical and cost effectiveness of social networks, or other social interventions, for improving the symptoms of severe mental health problems?**

10. **For people with mild to moderate learning disabilities, what psychosocial interventions (either adapted from those used in the non-learning disabled population or developed specifically for those with learning disabilities), are effective for the treatment of mental health problems?**

11. **For people with severe or profound learning disabilities, what is the clinical and cost effectiveness of psychosocial interventions to treat mental health problems problems?**

7.7 Review questions: In people (children, young people and adults) with learning disabilities, do occupational interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do occupational interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summaries, including the review questions and the eligibility criteria used for this section of the guideline, can be found in Table 98 and Table 99. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 98: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do occupational interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.8)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any occupational intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 99: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do occupational interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.8)
Population	People (children, young people and adults) with learning disabilities

Component	Description
	and mental health problems.
Intervention(s)	Any occupational intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

7.7.1 Clinical evidence and group consensus

No evidence was found, such as RCTs, systematic reviews, cohort or controlled before-and-after studies, the use of occupational interventions for the prevention or treatment of mental health problems in people with learning disabilities. Despite the lack of evidence, the group did not find it appropriate to consider indirect evidence for occupational interventions it was not judged a good use of time and resources. However, the group were of the view that the provision of occupational interventions was of utmost importance for people with learning disabilities and that it would be inappropriate not to include some recommendations on this area given the known benefits of employment on mental health and the importance of promoting the integration of people with learning disabilities and mental health problems into society. As such, the group decided to develop some recommendations in this area using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in the methods section in Chapter 3.

Key issues relating to occupational interventions for the prevention and treatment of mental health problems in people with learning disabilities were identified through the available literature (for example Gustafsson et al., 2009) as well as through documents such as the guide developed by the Joint Commissioning Panel for Mental Health (Joint Commissioning Panel for Mental Health, 2013) and discussions during GC meetings. These were used to generate nominal statements to be rated by the GC, which were distributed in the form of a questionnaire. Nominal statements were developed to cover a range of areas identified as important such as barriers to engaging in and maintaining involvement in occupational interventions. One example of a statement that was rated highly by the GC was ‘Adults with a learning disability who are capable of participating in meaningful work should be provided with opportunities to do so’. As all statements had moderate to high levels of agreement, and the GC were of the view that all important issues raised by GC comments could be addressed in the wording of recommendations, and as a consequence, a second round of ratings was not required. The rankings and comments were presented to the GC. Recommendations were produced on the basis of the statements, comments and group discussion. A brief summary of the process can be found in Table 100 below. A full depiction of the process can be found in Appendix U and blank copies of the questionnaires can be found within Appendix T.

Table 100: Summary of nominal group technique process followed for the development of recommendations on occupational

interventions for mental health problems in people with learning disabilities

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=15)	Level of agreement	Statements N (Total=0)	4 recommendations
High	10	High	n/a	
Moderate	5	Moderate	n/a	
Low	0	Low	n/a	

7.7.2 Economic evidence

No studies assessing the cost effectiveness of occupational interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

The National Development Team for inclusion (NDTi) research into employment support for disabled people report identified evidence suggesting that supporting individuals to access meaningful activity and employment achieves better outcomes for individuals and can be cost-effective by enabling individuals' confidence and life opportunities. This evidence did not meet inclusion criteria for the economic review undertaken for this guideline and therefore it is not presented here. In addition, the authors of the report collected national data on investment in employment support and other quantitative and qualitative evidence and concluded that the existing investment in employment support could be used to deliver much higher numbers of new or retained jobs for disabled people at significantly lower average costs than is presently being achieved, by working to evidence-based models, such as supported employment for people with learning disabilities.

7.7.3 Clinical evidence statements

- The GC agreed that occupational interventions should be based on an understanding of and tailored to the person. They agreed that adults capable of participating in meaningful work should be provided with opportunities to do so, that services should help identify potential areas of difficulty in employment and act to prevent these, and that support workers should assist in addressing any difficulties that arise. They also agreed that schools and colleges had a role to play in helping young people identify areas of strength and interest and develop work skills.
- The GC expressed support for the active encouragement of adults by support workers to find and participate in either paid or voluntary work, for information, guidance or practical support with related tasks and for support for young people to identify strengths, areas of interest and work skills at college as a preventative measure against mental health problems.

7.7.4 Economic evidence statements

No evidence on the cost effectiveness of occupational interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities is available.

There is some evidence that the existing investment in employment support in the UK could be used to deliver much higher numbers of new or retained jobs for disabled people at significantly lower average costs than is presently being achieved, by working to evidence-based models, such as supported employment for people with learning disabilities.

7.7.5 Recommendations and link to evidence

Recommendations	**55. In keeping with the preferences of the person with learning disabilities and mental health problems, all staff should support them to:** **• engage in community activities, such as going to a library or sports centre** **• access local community resources, such as those provided at day centres** **• take part in leisure activities, such as hobbies, which are meaningful to the person.** **Reasonable adjustments may be needed to do this, such as a buddy system, transport, or advising local facilities on accessibility.** **56. Actively encourage adults with learning disabilities (with or without a mental health problem) to find and participate in paid or voluntary work that is meaningful to them, if they are able.** **57. Consider providing practical support to adults with learning disabilities (with or without a mental health problem) to find paid or voluntary work, including:** **• preparing a CV** **• identifying personal strengths and interests** **• completing application forms** **• preparing for interviews** **• accompanying the person to interviews** **• completing any pre-employment checks.** **58. Health and social care services should take account of an adult or young person's sensory, physical, cognitive and communication needs and the severity of their mental health problem (if any), and consider:** **• helping them to identify and overcome any possible**

	challenges during employment • **appointing supported employment workers to provide ongoing support to adults with learning disabilities and their employers** • **providing information and guidance to potential employers about the benefits of recruiting people with learning disabilities,** • **assisting employers in making reasonable adjustments to help them to work.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of interventions at preventing or treating mental health problems. In addition to the effect on the mental health problem which was the aim of the intervention (for dementia, this was cognitive function as well as psychopathology), the GC were of the view that quality of life, and community participation and meaningful occupation were particularly critical outcomes which they wished to consider in the literature. The GC noted in particular the difficulties with measuring self-reported outcomes in this population, given communication needs and cognitive impairments so there should be caution in the interpretation of these outcomes from the trials. Reported outcomes from multiple sources may be helpful (eg. teachers, parents) in addressing this issue. Additional important outcomes included problem behaviours, adaptive functioning such as communication skills, service user or carer satisfaction or experience of care, carer health and quality of life, adverse effects of interventions, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	No clinical evidence was found that met the inclusion criteria in the protocol on occupational environmental interventions for the prevention and treatment of mental health problems.
Trade-off between net health benefits and resource use	Supporting and engaging people with learning disabilities in meaningful leisure and recreational opportunities, including paid or voluntary work, requires additional health and social care resources comprising health and social care professionals' additional time spent with people with learning disabilities, adjustments in people's community environments, and also potential appointment of specialised staff to provide continuous support and advice to people with learning disabilities that are engaged in paid or voluntary work and their employers. The GC acknowledged the barriers to employment faced by people with learning disabilities and expressed the opinion that engagement of people with learning disabilities to meaningful activities is likely to impact positively on people's HRQoL, self esteem and functional status and may indirectly contribute to the prevention and/or effective management of mental health problems and their well-being. The GC estimated that the required support by existing staff involved in the care of people with learning disabilities as well as the adjustments in people's community environments needed to enable them to engage in meaningful activities entail modest resource implications that are justifiable by the improved mental health outcomes in this population. The GC acknowledged that the appointment of supported employment workers may have more significant resource implications. On the other hand, the GC noted that there is some evidence suggesting that supporting

	disabled people to access meaningful activity and employment achieves better outcomes for individuals and can be cost-effective by enabling individuals' confidence and life opportunities. The GC also took into account evidence that the existing investment in employment support could be used to deliver much higher numbers of new or retained jobs for disabled people at significantly lower average costs than is presently being achieved, by working to evidence-based models, such as supported employment for people with learning disabilities. The GC considered that the appointment of supported employment workers is very likely to represent efficient use of resources.
Quality of evidence	Not applicable.
Other considerations	In the absence of evidence, the GC used the nominal group technique to develop recommendations on the use of occupational interventions as a way to engage individuals in meaningful activities and, ultimately, aim to prevent mental health problems and also enrich the lives of people with mental health problems and possibly manage that health problem. The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas: - actively encouraging adults to find and participant in paid or voluntary work which is meaningful to the person and provide practical support to do so - services should be arranged to provide support to people with learning disabilities in identifying possible challenges during employment, appointing supported employment workers to support them on an ongoing basis, and providing information and guidance to employers encourage them to employ people with learning disabilities and advise them on making reasonable adjustments. A number of additional contextual factors were raised during in the nominal group technique which were deemed to be important to address, and recommendations were made to incorporate these issues: - There was considerable discussion among the GC members about what constitutes a meaningful activity to people with learning disabilities. The group appreciated that what is meaningful will vary between individuals and they stressed that they should be supported and actively encouraged to engage in activities that they prefer which enrich their lives. Some examples included community participation, meaningful leisure and recreational opportunities. The GC stressed also that reasonable adjustments would be required to facilitate accessibility such as the use of buddies, assistance with transport. As a result of little high-quality research in this area, the GC agreed to recommend psychosocial interventions such as occupational interventions for people with all levels of learning disabilities (see the appropriate research recommendations).

7.8 Review questions: In people (children, young people and adults) with learning disabilities, do personal and support strategies in community and

residential settings which are aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do personal and support strategies in community and residential settings which are aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summaries, including the review questions and the eligibility criteria used for this section of the guideline, can be found in Table 101 and

Table 102. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 101: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do personal and support strategies in community and residential settings which are aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.3)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any personal and support strategy in community and residential settings.
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 102: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do personal and support strategies in community and residential settings which are aimed at treating and

Component	Description
	managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.3)
Population	People (children, young people and adults) with learning disabilities and mental health problems.
Intervention(s)	Any personal and support strategy in community and residential settings.
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

7.8.1 Clinical evidence

7.8.2 No evidence was found, such as RCTs, systematic reviews, cohort or controlled before-and-after studies, on the use of personal and support strategies in community and residential settings for the prevention or treatment of mental health problems in people with learning disabilities. Despite the lack of evidence, the group did not find it appropriate to go down the evidence hierarchy, examine indirect evidence, or conduct formal group consensus for this area as neither were judged a good use of time and resources. As the group considered that some components of personal and support strategies were considered in the evidence on psychological or exercise interventions, and that personal and support strategies would be covered to some extent by the nominal group process for adaptations to psychological interventions, or social and physical environmental interventions and occupational interventions. Economic evidence

No studies assessing the cost effectiveness of personal and support strategies in community and residential settings aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.9 Review questions: In people (children, young people and adults) with learning disabilities, do community interventions (for example, to reduce stigma or hate crimes) are aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do community interventions (for example, to reduce stigma or hate crimes) aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summaries, including the review questions and the criteria used for this section of the guideline, can be found in Table 103 and

Table 104. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 103: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do community interventions (for example, to reduce stigma or hate crimes) aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.9)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any community intervention (including those to reduce stigma or hate crimes)
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 104: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do community interventions (for example, to reduce stigma or hate crimes) aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.9)
Population	People (children, young people and adults) with learning disabilities and mental health problems.
Intervention(s)	Any community intervention (including those to reduce stigma or hate crimes).
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

7.9.1 Clinical evidence

No evidence was found, such as RCTs, systematic reviews, cohort or controlled before-and-after studies, on the use of community interventions for the prevention or treatment of mental health problems in people with learning disabilities. Despite the lack of evidence, the group did not find it appropriate to examine indirect evidence or conduct formal group consensus for this area as neither were judged a good use of time and resources (the latter would be particularly difficult given the variation and breadth of community interventions).

7.9.2 Economic evidence

No studies assessing the cost effectiveness of community interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.10 Review questions: In people (children, young people and adults) with learning disabilities, does psychoeducation aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, does psychoeducation aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summaries, including the review questions and the eligibility criteria used for this section of the guideline, can be found in Table 105 and Table 106. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 105: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do psychoeducation aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.10)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any psychoeducation intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 106: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, does psychoeducation aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.10)
Population	People (children, young people and adults) with learning disabilities and mental health problems.

Component	Description
Intervention(s)	Any psychoeducation intervention
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

7.10.1 Clinical evidence

No evidence was found, such as RCTs, systematic reviews, cohort or controlled before-and-after studies, on the use of psychoeducation interventions for the prevention or treatment of mental health problems in people with learning disabilities. Despite the lack of evidence, the group did not find it appropriate to examine indirect evidence or conduct formal group consensus for this area as neither were judged a good use of time and resources. Some components of psychoeducation were considered in the evidence on parent training and other psychological interventions.

7.10.2 Economic evidence

No studies assessing the cost effectiveness of psychoeducation aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.11 Review questions: In people (children, young people and adults) with learning disabilities, do other multidisciplinary interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do other multidisciplinary interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 107 and Table 108. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 107: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do other multidisciplinary interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.6)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any multidisciplinary interventions not covered by other review questions.
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 108: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do any other multidisciplinary interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.6)
Population	People (children, young people and adults) with learning disabilities and mental health problems.
Intervention(s)	Any multidisciplinary interventions not covered by other review questions.
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

7.11.1 Clinical evidence

No evidence was found, such as RCTs, systematic reviews, cohort or controlled before-and-after studies, on the use of any other multidisciplinary interventions for the prevention or treatment of mental health problems in people with learning disabilities. Despite the lack of evidence, the group did not find it appropriate to examine indirect evidence or conduct formal group consensus for this area as neither were judged a good use of time and resources (the later would be particularly difficult due to the variations in types of multidisciplinary interventions possible).

7.11.2 Economic evidence

No studies assessing the cost effectiveness of any other multidisciplinary interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.12 Review questions: In people (children, young people and adults) with learning disabilities, do combined interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? AND In people (children, young people and adults) with learning disabilities and mental health problems, do combined interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 109 and Table 110. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 109: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities, do combined interventions aimed at preventing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ2.7)
Population	People (children, young people and adults) with learning disabilities.
Intervention(s)	Any combined interventions.
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care

Component	Description
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

Table 110: Clinical review protocol summary for the review on the treatment and management of mental health problems

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do combined interventions aimed at treating and managing mental health problems produce benefits that outweigh possible harms when compared to an alternative approach? (RQ3.7)
Population	People (children, young people and adults) with learning disabilities and mental health problems.
Intervention(s)	Any combined interventions.
Comparison	• Treatment as usual • No treatment, placebo • Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Mental health • Community participation and meaningful occupation • Problem behaviours • Quality of life / service user and carer satisfaction / experience of care
Study design	Systematic reviews, RCTs, controlled before and after studies and cohort studies.

7.12.1 Clinical evidence

Only one study with a combined intervention was found (Heller et al., 2004). The study, which combined exercise and education compared to control, is summarised in the above section on exercise (section 7.4.1.1.1).

No other evidence was found, such as RCTs, systematic reviews, cohort or controlled before-and-after studies, on combined interventions for the prevention or treatment of mental health problems in people with learning disabilities. Despite the lack of evidence, the group did not find it appropriate to examine indirect evidence or conduct formal group consensus for this area as there are many variations in the combinations of interventions possible and neither were judged a good use of time and resources.

7.12.2 Economic evidence

No studies assessing the cost effectiveness of combined interventions aimed at preventing, treating or managing mental health problems in people with learning disabilities were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

7.12.3 Research recommendations

12. **For people with mild to moderate learning disabilities, what interventions (either adapted from those used in the non-learning disabled population or developed specifically for those with learning disabilities), are effective for the treatment of mental health problems?**

13. **For people with severe to profound learning disabilities, what is the clinical and cost effectiveness of psychosocial interventions to treat mental health problems?**

14. **For people with learning disabilities, what is the clinical and cost effectiveness of social networks, or other social interventions, for improving the symptoms of severe mental health problems?**

8 Organisation and service delivery

8.1 Introduction

It is important that services and organisations work collaboratively to ensure parity of the delivery of mental health care to individuals with learning disabilities as to those without. This includes primary care and access to mainstream services. The delivery of a coordinated care plan that is inclusive of providers, commissioners, assessors, families and the person themselves is also important, to facilitate the right support being provided at the right time.

People with learning disabilities will often, at some point in their lives, access a range of services and interventions to meet their wider, holistic needs. As discussed in chapter 4, identifying and recognising mental health problems in someone with learning disabilities can be complex, and often relies on those who know the person well to identify how they have changed. In addition, it can be difficult for learning disability services and mental health services to align, and it is therefore essential that when an individual with learning disabilities starts to experience mental health problems, access to the appropriate mental health provision is equally available. Therefore, alignment between local mental health and learning disability services should be able to demonstrate a transparent response and access to appropriate support, both in facilitating recovery and mental wellbeing, applied to the specific requirements of the individual. For example, the Green Light Toolkit (NDTi, 2013), reviewed and reissued in 2013, focuses on enabling people with learning disabilities to access mainstream mental health services.

Since 2012, following the abuse that was uncovered in 2011 at Winterbourne View private hospital, the report Transforming care: A National response to Winterbourne View Hospital (Department of Health, 2012) has sought to refocus how services are provided to people with learning disabilities and/or autism who have behaviours that challenge and/or mental health problems. The report focuses on prevention and the use of community support rather than hospital environments because they were not conducive to the recovery of people with behaviours that challenge or autism, and as a result people remained in hospital settings for prolonged periods with little opportunity for discharge. A draft service model and transformation plan was launched in 2015 led by NHS England in collaboration with the Local Government Association and the Association of Directors of Adult Social Services. This will align with the NICE service model that is currently being formulated and that will continue to address the service approaches in meeting the needs of people with learning disabilities and/or autism and behaviours that challenge. The service model will also build on the 2014 NICE guideline on challenging behaviour and learning disabilities (NICE, 2015).

For people with a learning disability who experience mental ill health, the 2015 Department of Health consultation report No voice unheard, no right ignored (Department of Health, 2015a) and the subsequent government response places more emphasis on individuals being supported through reasonable adjustments to meaningfully access mainstream mental health services wherever possible. The content of the report recommends fundamental changes to the approach in which mental health legislation is applied to people with learning disabilities and/or autism. These changes will require local NHS, local authorities and their partners to consider how mental health services will be provided in the future for the entire population, with inpatient treatment being the last resort.

The increasing focus of prevention and enablement starts with children and young people, with a greater recognition of the need to plan from a lifelong perspective. Transition from children's services is often a time of increased anxiety for parents and carers. Adolescence and young adulthood can be a significant time when mental health disorders may emerge. Building families' confidence, resources and resilience may contribute to young people's mental wellbeing.

Awareness and recognition of possible mental health disorders and appropriate referral are essential aspects of all agencies' responsibilities in their contact with young people with learning disabilities. Barriers to access and variability in resources have to be overcome. Collaborative working across agencies and long-term perspectives are well established and important principles in the care of children and adults with learning disabilities.

The new mandatory expectations of education, health and care plans for children and young people aged up to 25 provide the basis for improving the planning and coordination of care, particularly through the transition to adult services. The Department of Health and NHS England's document Future in mind (Department of Health and NHS England, 2015) focuses on the promotion, protection and improvement of children and young people's mental health without the exclusion of young people with a learning disability. Similarly to Transforming care, Future in mind identifies the need for integrating and aligning services, to improve efficiency for individual outcomes by reducing the numbers of barriers between, and gaps in, services.

Having expertise in the recognition and management of possible mental health conditions in children and young people who are accessing CAMHS can positively reinforce the effectiveness of multidisciplinary practice. Working closely in partnership with organisations to support young people's development, such as by outreaching to schools or colleges and parents through providing advice, initial support and guidance, could prevent further escalation of issues and the use of more restrictive practices for the young person in the future.

In addition, the devolution agenda, reinforced by the Care Act 2014 (UK Parliament, 2014), encourages the pooling of budgets across health and social care, designing services in co-production with people experiencing the services and providing a more personalised service through personalised budgets.

This approach may help many people and their families to receive the right support, enabling better life outcomes. However, there remains a need to facilitate the ability of individuals and their families to access assessment and support at key times. This can be a challenge because services and organisations for people with learning disabilities can be hard for individuals and their families to access within traditional services, including such services' eligibility criteria, and this may result in people slipping through the net. This can then result in a person's mental health needs being recognised at a late stage, including in a crisis-stage intervention, and a much more intensive intervention package being required.

8.2 Review question: What are the most appropriate strategies to engage and empower service users with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 111. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 111: Clinical review protocol summary for the review on strategies to engage and empower service users with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems

Component	Description
Review question	What are the most appropriate strategies to engage and empower service users with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems? (RQ 4.5)
Population	People (children, young people and adults) with learning disabilities and mental health problems Including people with genetic conditions associated with learning disabilities and mental health problems, if some of their mental health problems and needs may differ from those of people with other learning disabilities (for example, Down's syndrome, Prader–Willi syndrome, Fragile X syndrome). Special consideration will be given to groups affected by equality issues, such as black, Asian and minority ethnic groups and older adults.
Intervention(s)	Any strategy or supports to engage and empower services users in the design, implementation, and monitoring of interventions administered for a person's mental health problems.
Comparison	• Treatment as usual • No treatment • Waitlist control • Placebo (including attention control) • Any alternative intervention/strategy or approach or supports
Critical outcomes	• Mental health • Community participation and meaningful occupation • Quality of life / service user and carer satisfaction / experience of care • Problem behaviours
Study design	RCTs or systematic review of RCTs

8.2.1 Clinical evidence

One RCT (Coelho et al., 1993) identified by the Cochrane review (Balogh et al., 2008) and included in the review on service structures to support practitioners in the effective delivery of interventions used an intervention called the 'innovative intensive support services model' which involved engaging and empowering service users. In this trial, staff provided individualised functional teaching and participants were taught to recognise problem situations, accept responsibility for their behaviour and move toward autonomy. See an overview of the trial and summary of findings in section 8.4.1 below.

No additional RCTs were found which addressed this review question.

No data were available for any of the critical outcomes related to this review: mental health (of the person with learning disabilities), quality of life (service user), community participation and meaningful occupation or healthcare practitioner health and well-being.

8.2.2 Group consensus for engaging and empowering service users with learning disabilities in the design, implementation and monitoring of interventions for that person’s mental health problems

Despite the limited RCT evidence (see section 8.2.1), the group did not find it appropriate to go down the evidence hierarchy or to consider indirect evidence in this area as it was not judged a good use of time and resources. The existing systematic reviews which were found in our preliminary search, including the Balogh et al., 2008 Cochrane review on organising effective health care services for people with learning disabilities, did not identify much additional evidence relevant to this review. However, the group were of the view that it would be inappropriate not to include some guidance on engaging and empowering service users so the group decided to develop recommendations using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in Chapter 3.

Key issues in engaging and empowering service users with learning disabilities in the design, implementation and monitoring of interventions were identified from the available literature (for example Balogh et al., 2008; Oliver et al., 2005), from documents such as the Green Light Toolkit (NDTi, 2013), Transforming Care (Department of Health, 2012) and the guide from the Joint Commissioning Panel for Mental Health (Joint Commissioning Panel for Mental Health, 2013), as well as from service user focus groups and discussions during the GC meetings. These were used to generate nominal statements to be rated by the GC. These were distributed alongside nominal statements relating to the other aspects of service delivery and organisation described within this chapter. Nominal statements relating to engaging service users were designed to cover a range of areas such as the provision of information, support from family and carers and additional time taken by practitioners to thoroughly address any questions and elicit service user views. One example of a statement that was rated highly by the committee was ‘Staff members should allocate time to thoroughly explain to the person with a learning disability and a mental health problem any outcome measures that are used to monitor progress during an intervention.’

Questionnaires were distributed (round 1), and completed and returned by 11 committee members. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member’s comments in relation to the draft recommendations. A second round of ratings was not deemed necessary as all statements had reasonable levels of agreement, and it was agreed that any issues could be dealt with within the wording of the recommendations. A brief summary of the process is provided in Table 112 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used as part of the nominal group technique process can be found in appendix T.

Table 112: Summary of nominal group technique process followed for the development of recommendations on interventions to engage people with learning disabilities in the design, implementation and monitoring of interventions to treat their mental health problems

Round 1		Round 2		Resulting recommendations generated
Level of agreement	Statements N (Total=8)	Level of agreement	Statements N (Total=0)	4 recommendations
High	5	High	n/a	
Moderate	3	Moderate	n/a	
Low	0	Low	n/a	

8.2.3 Economic evidence

No studies assessing the cost effectiveness of appropriate strategies to engage and empower service users with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

8.2.4 Clinical evidence statements

- Very low quality evidence from a pilot RCT based in the US was inconclusive if a comprehensive intensive support services model (which involved encouraging participants to recognise problem situations, accept responsibility in their behaviour and move towards more autonomy) resulted in improved problem or adaptive behaviours over a standard model of service delivery; the model did result in an increased need for day programming and decrease need for more staff intensive residential programming (k=1, N=47).

8.2.4.1 Developed through formal consensus

- The GC agreed that service users and their carers should be provided with preparation time and information about what to expect, in an appropriate format, either at the time of arranging or at some point in advance of the appointment.
- The GC decided that the service user's understanding of the purpose, plan and content of the intervention should be regularly checked and communication needs held in mind at all times. They also agreed that staff members should allocate time to explain outcome measures thoroughly and provide support to complete these if necessary.
- The GC supported the involvement of families and carers in implementing and monitoring the progress of the intervention, with the permission of the service user.

8.2.5 Economic evidence statements

There is no evidence on the cost effectiveness of appropriate strategies to engage and empower service users with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems.

8.2.6 Recommendations and link to evidence

8.2.6.1 Consent, capacity and decision making

Recommendations	**59. Assess the person's capacity to make decisions throughout assessment, care and treatment for the mental health problem on a decision-by-decision basis, in accordance with the Mental Capacity Act and supporting codes of practice (see Your care). Help people make decisions by ensuring that their communication needs are met (see recommendation 61) and involving a family member, carer or care worker (as appropriate).** **60. Staff delivering care to people with learning disabilities and mental health problems should:** • **discuss the assessment process and treatment options with the person and provide information in a format and language suited to their needs, including:** o **potential benefits** o **potential side effects or disadvantages** o **the purpose of treatment** o **outcome measures** • **ensure that the person understands the purpose, plan and content of any meeting or intervention before it starts, and regularly throughout** • **address any queries or concerns that the person may have at any stage** • **allow enough time for the person to make an informed choice, or for their family members, carers or care workers to do so if the person does not have decision-making capacity.**
Relative values of different outcomes	There was no specific review on consent, capacity and decision making but this was a theme that came out of the group consensus process on assessment, organisation and service delivery, and psychological or pharmacological interventions.
Trade-off between clinical benefits and harms	Not applicable
Trade-off between net health benefits and resource use	Not applicable
Quality of evidence	Not applicable
Other considerations	While there was no specific review on consent, capacity and decision making, important issues related to consent, capacity and decision making were raised throughout the group consensus process in all other reviews and in other discussions of evidence presented to the GC. Rather than repeating considerations for each recommendation, the GC decided that there should be some overarching recommendations on this area. As a result, the group used informal consensus to agree recommendations in this

	area. In line with regulations in the Mental Capacity Act (Department of Health, 2005), the GC decided that the assessment of consent and capacity for decision making should be continually assessed throughout the assessment, care and treatment of a mental health problem. This is because it is possible that this may change over time. The GC decided on the basis of the outcome of the nominal group technique in other areas (including on assessment, organisation and service delivery, and adaptions psychological interventions) to develop recommendations in the following areas: - a person's capacity to make decisions should be supported by ensuring their communication needs are met and also to involve a family member, carer or care worker to facilitate this. - the person should be explained and understand the parts of the assessment process including the purpose, plan and content (for example, why they are being asked questions and when); this understanding should be checked regularly throughout - various treatment options should be discussed with the person to support decision making. - Information on assessment or interventions should be provided in a format that is suited to their needs and this should include purpose, potential benefits, side effects and outcome measures. - There should be enough time to consider the options and make an informed choice (if they are assessed to have capacity)

8.2.6.2 Facilitating involvement and communication with service users

Recommendations	**61. Take into account the person's communication needs and level of understanding throughout assessments, treatment and care for a mental health problem, and:** • **speak to the person directly rather than talking about or over them** • **use clear, straightforward and unambiguous language** • **assess whether communication aids or someone familiar with the person's communication methods are needed** • **make adjustments to accommodate sensory impairments** • **explain the content and purpose of every meeting or session** • **use concrete examples, visual imagery, practical demonstrations and role play to explain concepts** • **communicate at a pace that is comfortable for the person, and arrange longer or additional meetings or treatment sessions if needed** • **use different methods and formats for communication (written, visual, verbal, or a combination of these), depending on the person's preferences (see the Accessible**

	Information Standard for guidance on ensuring people with learning disabilities receive information in formats they can understand)regularly check the person's understanding • **summarise and explain the conclusions of every meeting or session** • **check that the person has communicated what they wanted.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of strategy or supports to engage and empower services users in the design, implementation, and monitoring of interventions administered for a person's mental health problems. In addition to the effect on the mental health problem, the GC considered community participation and meaningful occupation, quality of life / experience of care, and the effect on problem behaviour to be particularly critical outcomes which they wished to examine in the literature. Additional important outcomes included adaptive functioning including communication skills (this may be most relevant to common mental health disorders), carer health and quality of life, adverse events, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	There was limited evidence available from only one RCT on service models which involved an attempt to engaging and empowering service users. The study used a model which provided individualised functional teaching and participants were taught to recognise problem situations, accept responsibility for their behaviour and move toward autonomy. The study was inconclusive if a comprehensive intensive support services model (which involved encouraging participants to recognise problem situations, accept responsibility in their behaviour and move towards more autonomy) resulted in improved problem or adaptive behaviours over a standard model of service delivery but did result in an increased need for day programming and decrease need for more staff intensive residential programming. However, it is difficult to isolate the effects of this multiple component intervention.
Trade-off between net health benefits and resource use	There may be some modest resource implications associated with effective communication between people with learning disabilities and a mental health problem and health and social care staff working with them. The GC expressed the view that effective communication is essential for the effective care of service users and that the benefits from effective communication between staff and service users far outweigh any associated costs. Additionally the GC viewed this in part as an important aspect of making reasonable adjustments in line with relevant legislation.
Quality of evidence	The evidence from the one study which considered engaging and empowering service users within a multiple-component intervention was very low quality due to risk of bias, indirectness (the study is an American population for which service structures are quite different than the UK), and imprecision (largely due to its small size).
Other considerations	The GC decided to conduct formal group consensus in this area because of the lack of evidence and the importance of guidance in this area. The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas: - In the preparation of service users about what they should expect in their interactions with services. - Ensuring that explanations and discussions are clear, and that the

	service user can participate fully in such discussions as a result. - In facilitating service user involvement by involving other people known to and trusted by the service user. A number of contextual factors were picked up in the discussions of the nominal group technique: - The service user focus groups raised the issue of how they are addressed by professionals on numerous occasions, with reports of people talking over them and feeling disrespected and finding it more difficult to engage with professionals as a result. - A lack of accessible information was raised as a significant problem in the service user focus groups, with GP appointments and inpatient admissions used as examples of times that it would be helpful and less daunting to have information about what to expect - The need for preparation time so that they can express themselves adequately was raised as an issue by the service user focus groups - The communication skills of professionals were considered to be of utmost importance to all aspects of interactions with service users and were agreed to be a key training consideration - Communication needs vary from person to person and should be individualised as per understanding of the individual gained through a comprehensive assessment. - Professionals should be aiming to work alongside service users in all areas of their work and this requires clear communication and adaptations to working practices.

8.2.6.3 Improving the experience of care

Recommendations	**62. Use this guideline with:** • **the NICE guidelines on service user experience in adult mental health and patient experience in adult NHS services, to improve the experience of care for adults with learning disabilities and mental health problems** • **recommendations for improving the experience of care for children and young people with mental health problems in relevant NICE guidance (see alcohol-use disorders, antisocial behaviour and conduct disorders, attention deficit hyperactivity disorder, autism, depression, eating disorders, obsessive-compulsive disorder, post-traumatic stress disorder, psychosis and schizophrenia, self-harm – long-term management, self-harm – short-term management and social anxiety disorder)** • **the NICE guideline on challenging behaviour and learning disabilities if relevant.**
Relative values of different outcomes	There was no specific review on improving the experience of care but this was an area addressed through the focus group work, and qualitative outcomes on service user experience were extracted from any included studies addressing other review questions, if reported.
Trade-off between clinical benefits and harms	Not applicable

Trade-off between net health benefits and resource use	Not applicable
Quality of evidence	Not applicable
Other considerations	The GC took into account the recommendations in the Service User Experience in Adult Mental Health (NICE, 2011) and Patient Experience in Adult NHS Services (NICE, 2012b), and the recommendations in the existing guidelines relevant to children. The GC decided that while they did not wish to replicate the recommendations from these guidelines, they wished to draw attention to the recommendations in both these guidelines. This was, in part, to emphasise that much of the experience of a mental health problem is common to all people with a mental health problem irrespective of whether they have learning disabilities. The GC also noted the importance of using this guideline alongside the recommendations in the guideline on challenging behaviour and learning disabilities (NICE, 2015) as people with learning disabilities who present with challenging behaviour may have an underlying mental health problem, or may be at risk of developing a mental health problem.

8.3 Review question: What are the most appropriate strategies to engaging the family and staff/advocate of people with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 113. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 113: Clinical review protocol summary for the review on strategies to engage the family and staff/advocate of people with learning disabilities in the design, implementation and monitoring of interventions

Component	Description
Review question	What are the most appropriate strategies to engaging the family and staff/advocate of people with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems? (RQ 4.4)
Population	Family and staff or advocates of people with learning disabilities and a mental health problem.
Intervention(s)	Any strategy or supports to engage family and staff/advocate in design, implementation, and monitoring of interventions administered for a person's mental health problems.
Comparison	• Treatment as usual • No treatment • Waitlist control • Placebo (including attention control)

Component	Description
	• Any alternative intervention/strategy or approach or supports
Critical outcomes	• Mental health • Community participation and meaningful occupation • Family or staff/advocate health and quality of life • Problem behaviours • Quality of life
Study design	RCTs or systematic review of RCTs

8.3.1 Clinical evidence and group consensus for engaging family and staff/advocates of people with a learning disability in the design, implementation and monitoring of interventions for that person's mental health problem

No RCTs were found on strategies to engage the family and staff/advocate of people with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems.

Despite the limited RCT evidence, the group did not find it appropriate to go down the evidence hierarchy or to consider indirect evidence in this area as it was not judged a good use of time and resources. The existing systematic reviews which were found in our preliminary search, including the Balogh et al., 2008 Cochrane review on organising effective health care services for people with learning disabilities, did not identify much additional evidence relevant to this review. However, the group were of the view that it would be inappropriate not to include some guidance on engaging family and staff/advocates of people with learning disabilities so the group decided to develop recommendations using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in Chapter 3.

Key issues in engaging family and staff/advocates in implementation and monitoring of interventions were identified from the available literature (for example Oliver et al., 2005), from documents such as the Francis Report (Francis, 2013), Transforming Care (Department of Health, 2012), the CORE competencies frameworks (Roth et al., 2011) and the guide from the Joint Commissioning Panel for Mental Health (Joint Commissioning Panel for Mental Health, 2013), as well as from discussions during the GC meetings. These were used to generate nominal statements to be rated by the GC. These were distributed alongside nominal statements relating to the other aspects of service delivery and organisation described within this chapter. Nominal statements relating to engaging family and staff/advocates were designed to cover a range of areas such the provision of information and attendance of family members and staff or advocates at intervention sessions. One example of a statement that was rated highly by the committee was 'Family members or carers of people with a learning disability and a mental health problem should be provided with information about support and interventions in an appropriate language and format, including NICE's 'Information for the Public'.

Questionnaires were distributed (round 1), and completed and returned by 11 committee members. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member's comments in relation to the draft recommendations. A second round of ratings was not deemed necessary as it was agreed by the GC that all important issues raised in the GC comments could be addressed in the wording of recommendations. A brief summary of the process is provided in Table 114 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used as part of the nominal group technique process can be found in appendix T.

Table 114: Summary of nominal group technique process followed for the development of recommendations on engaging family and staff/advocates of people with a learning disability in the design, implementation and monitoring of interventions for that person's mental health problem

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=8)	Level of agreement	Statements N (Total=0)	3 recommendations
High	5	High	n/a	
Moderate	2	Moderate	n/a	
Low	1	Low	n/a	

8.3.2Economic evidence

No studies assessing the cost effectiveness of appropriate strategies to engage the family and staff/advocate of people with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

8.3.3 Clinical evidence statements (developed through formal consensus)

- The GC agreed that it would be helpful to consult family members, carers and staff to help inform the design of interventions for mental health problems, with permission if possible and that family members and carers should be provided with information about support and interventions in an appropriate language and format such as NICE's 'Information for the Public'.
- The GC decided that consultation should be offered to families and carers during the implementation of interventions, and that these individuals should be encouraged to become actively involved in the implementation of interventions. The GC expressed moderate support for family members and carers to attend sessions so that they can provide opinions on the progress and acceptability of interventions. The GC did not agree that families and carers should be encouraged to adopt a co-therapist role, or that input relating to the progress and acceptability of interventions should be sought from these individuals via post.

8.3.4 Economic evidence statements

No evidence on the cost effectiveness of appropriate strategies to engage the family and staff/advocate of people with learning disabilities in the design, implementation and monitoring of interventions for that person's mental health problems is available.

8.3.5 Recommendations and link to evidence

8.3.5.1 Involving family members, carers and care workers

Recommendations	**63. Encourage and support family members, carers and care workers (as appropriate) to be actively involved throughout the assessment, care and treatment of the person's mental health problem, apart from in exceptional circumstances when an adult or young person with decision-making capacity has said that they do not want their family members, carers or care workers involved.** **64. Give family members, carers and care workers (as appropriate) information about support and interventions in a suitable format and language, including NICE's 'Information for the public'.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of strategy or supports to engage family and staff/advocate in design, implementation, and monitoring of interventions administered for a person's mental health problems. In addition to the effect on the person's mental health problem, the GC considered community participation and meaningful occupation, quality of life / experience of care, and the effect on problem behaviour to be particularly critical outcomes which they wished to examine in the literature. Additional important outcomes included adaptive functioning including communication skills (this may be most relevant to common mental health disorders), carer health and quality of life, adverse events, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	No evidence was found meeting the inclusion criteria in the protocol on the involvement of family members, carers and care workers, however this was a theme that arose repeatedly during GC discussions and therefore nominal group technique was used to develop principles. A number of authors, as well as professional and carer members of the GC and service users involved in the focus groups, identified potential clinical benefits of family and carer involvement. These included improved engagement with assessment and intervention, more consistent implementation of interventions and potentially improved clinical outcomes. Potential risks arise in cases where family relationships are strained, or abusive. Additionally the assumption of potential benefits of family and carer involvement must be balanced with the right of the service user to have a choice over who is involved and to what extent.
Trade-off between net health benefits and resource use	Encouraging family members, carers and care workers to be actively involved in the care of a person with learning disabilities and a mental health problem and providing them with information about support and interventions might entail minor resource implications. In any case, the GC considered that any resource implications would be probably offset by provision of more effective care and of improved outcomes associated with the additional support provided to the service users by their family members, carers and care workers.
Quality of evidence	Not applicable
Other considerations	The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas:

	- On the principle that it is typically beneficial to involve family and carers where this is feasible - On the most fruitful way to accomplish this A number of contextual factors were picked up in the nominal group technique again: - The GC discussed the Frazer guidelines, following concerns raised by a carer representative that the service user should make the decision over whether family and carers are involved in assessment and intervention. - Involvement can be at all stages and can include attendance at sessions, implementation of interventions at home with consultation from clinicians and input into the progress of interventions. - In order for family and carers to be actively involved they need to be provided with the right information, and in an appropriate format (such as NICE’s ‘Information for the Public’) - A carer representative raised the issue that information alone is insufficient, and that skills training would be beneficial. This consideration has been included in the recommendations relating to training.

8.4 Review question: What are the most appropriate service structures, training and supervision to support practitioners in the effective delivery of interventions for people (children, young people and adults) with learning disabilities and mental health problems?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 115. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 115: Clinical review protocol summary for the review on service structures, training and supervision to support practitioners in the effective delivery of interventions for people (children, young people and adults) with learning disabilities and mental health problems

Component	Description
Review question	What are the most appropriate service structures, training and supervision to support practitioners in the effective delivery of interventions for people (children, young people and adults) with learning disabilities and mental health problems? (RQ 4.6)
Population	Healthcare practitioners involved in delivering interventions to people (children, young people and adults) with learning disabilities and mental health problems
Intervention(s)	Any service structure, training or supervision programme, including: • Assertive Community Treatment (ACT) • Care management training • Care pathway and outcome-based service models • Case management (including intensive case management)

Component	Description
	• Clinical networks providing specialist input • Community learning disabilities teams • Coordination approaches (that is, the care programme approach) • Crisis resolution teams • Early intervention teams (for psychosis) • Green light toolkit • Improving Access to Psychological Therapies (IAPT) • Learning Disabilities Child and Adolescent Mental Health Service (CAMHS) • Outreach/inreach services (including assertive outreach teams and prison inreach services) • Sure start • Staff skills development and training routed in a care pathway-based service delivery and competencies framework
Comparison	• Treatment as usual • No treatment • Waitlist control • Placebo (including attention control) • Any alternative staff training or education programme
Critical outcomes	• Healthcare practitioner health and well-being • Mental health (of people with learning disabilities) • Community participation and meaningful occupation • Quality of life / service user and carer satisfaction / experience of care • Problem behaviours
Study design	RCTs or systematic review of RCTs

8.4.1Clinical evidence

A Cochrane review (Balogh et al., 2008) on the organisation healthcare services for people with learning disabilities was identified and formed the basis for this review, with permission from the publishers, John Wiley and Sons, and with assistance from the Effective Practice and Organisation of Care Cochrane Review Group (Sasha Shepherd, email communication, August 2015; and Daniela Gonçalves Bradley, email communication, November 2015). Relevant data from this review was considered and analysed according to the strategy set out in the guideline review protocol. While the review was not specifically focused on services for mental health, all papers which were identified and included were focused on mental health. The Cochrane review had other study inclusion criteria which were different including the inclusion of borderline learning disabilities and other study designs. As a result, the results from Balogh 2008 have been partially included and updated. The individual papers were also further assessed for quality on additional measures related to risk of bias and other aspects of GRADE (see Chapter 3 Methods used to develop this guideline).

After applying the inclusion criteria of this review, 3 of the RCTs (N=97) which were identified and included in the Cochrane review fit the inclusion criteria for this review, specifically related to service structures to support practitioners in the effective delivery of interventions: Martin et al. (2005), Oliver et al. (2005) and Coelho et al. (1993). No additional more recent papers were identified.

No studies were identified on training and supervision to support practitioners in effective delivery of interventions.

An overview of the trials included can be found in Table 116. Further information about both included and excluded studies can be found in Appendix M.

8.4.1.1 Assertive community treatment (ACT) versus standard community treatment

There were 2 RCTs (N=50) which met the eligibility criteria for this review: Martin et al. (2005) and Oliver et al. (2005).

Summary of findings for this comparison can be found in

Table 117.

The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The assertive community treatment model which was used in the study involved input from a Community Psychiatric Nurse (CPN) and a clinical psychologist or Occupational Therapist, one of whom took on the role of Case Coordinator, providing as many contacts as were required per week; the standard model involved an assessment package with input from one member of the multi-professional specialist service (usually a CPN) with contact no more than once per week to monitor mental health state and ensure compliance with treatment.

While 1 study (Martin et al., 2005) explicitly excluded those with challenging behaviour (including only those diagnosed with a psychiatric disorder), the other included people with either challenging behaviour or a diagnosed psychiatric disorder, or both (Oliver 2005).

The studies included adults with mild to moderate learning disabilities.

No data were available for any of the critical outcomes of mental health (of the person with learning disabilities), problem behaviours, healthcare practitioner health and well-being, community participation and meaningful occupation.

8.4.1.2 Innovative intensive support services model versus standard model

One RCT (N=47) met the eligibility criteria for this review: Coelho et al. (1993).

Summary of findings for this comparison can be found in Table 118. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O

The innovative intensive support services model which was used in the study consisted of contact with the service user twice per week, with staff taking on a care coordination and advocacy role, care planning in collaboration with the service user, support to improve social and adaptive functioning and reduce maladaptive behaviours, the identification of measurable goals with the service user, consultation and support to other involved staff, access to 24-hour crisis support, medication monitoring and brief individual psychotherapy (manager to participant ratio from 1:7 to 1:10). The standard model involved direct case management by the community mental health team including direct treatment services, counselling, advocacy, individual program plan development and coordination, monitoring of treatment plans and services (direct contact with services from once per month to once per quarter; manager to participant ratio 1:35).

The studies included adults with mild to moderate learning disabilities.

No data were available for any of the critical outcomes of mental health (of the person with learning disabilities), healthcare practitioner health and well-being, community participation and meaningful occupation or quality of life (service user).

Table 116: Study information table for trials included in the analysis of service structures, training and supervision to support practitioners in the effective delivery of interventions for people (children, young people and adults) with learning disabilities and mental health problems

	Assertive community treatment (ACT) versus standard community treatment	Innovative intensive support services model versus standard model
Total no. of studies (N¹)	2 (50)	1 (47)
Study ID	(1) Martin 2005, (2) Oliver 2005	Coelho 1993
Country	(1, 2) UK	US
Diagnosis/degree of learning disabilities	(1, 2) Mild or moderate	Mild-moderate (63% mild, 37% moderate)
Age (mean)	(1) 45 (2) 40.5	34
Sex (% female)	(1) 50% (2) 57%	40
Ethnicity (% white)	(1) 80% (20% were Afro-Caribbean (2) 70% English, Scottish or Welsh ethnicity, 30% 'other' white, Black Caribbean, Indian and Pakistani ethnicity	Not reported
IQ (mean)	(1, 2) Not reported	Not reported
Living arrangements	(1) 45% supported housing, 30% familial home, 25% independently (2) 47% in 24 hour staff community, 23% <24 hour staffed or un-staffed community homes and 30% with family in owner occupied or rented housing from local authority	67% had never resided in an institution, 22% had resided in an institution for 11 years or more
Coexisting conditions	(1) 5 had epilepsy, no treatments reported (2) Not reported	Not reported
Targeted behaviour	(1) Psychiatric disorder[2] (2) Psychiatric disorder/mental health problems or challenging behaviour (or both)[3]	DSM-III-R (DSM-III Revised) diagnosis of mental illness or behavioural complications concerning mental illness[4]
Treatment length	(1) At least 4 weeks (aim was 1 year; outcomes in paper after 6 months) (2) 3 months	Unclear
Intervention (mean dose; mg/day)	ACT (increased frequency of contact): (1) Treatment from a single source, to increase functioning and assist in symptom management. Services provided in the community by CPN with	Innovative intensive support services model for people with MR and mental illness – same as standard treatment, but greater direct contact with services in their natural environment; direct

	Assertive community treatment (ACT) versus standard community treatment	**Innovative intensive support services model versus standard model**
	additional input from professional specialist service involving 2 members of staff offering as many contacts as required per week (usually more than 1) and 1 allocated as case coordinator (1 member was a CPN and another a clinical psychologist or occupational therapist providing intensive intervention); weekly team meetings to discuss progress (2) Received more than 1 visit per week from anyone professional	contact with services on average twice per week; 1 manager per 7-10 participants. Staff provided individualised functional teaching; participants were taught to recognise problem situations, accept responsibility for their behaviour and move toward autonomy; involve unification of agency services with joint networking, consultation and problem solving
Comparison	Standard community treatment: assessment package and involvement with one member of the multi-professional specialist service (usually a CPN) with contact no more than once per week to monitor mental health state and ensure compliance with treatment.	Standard model of service delivery including direct case management by the community mental health team including direct treatment services, counselling, advocacy, individual program plan development and coordination, monitoring of treatment plans and services - direct contact with services once per month or once per quarter; 1 manager per 35 participants

Notes.

[1] Number randomised.

[2] Based on ICD-10 criteria; those with challenging behaviour or with severe mental health problems requiring immediate intensive treatment were excluded.

[3] At least 20% of participants in each group did not appear to have a diagnosed mental health problem (ICD-10 criteria).

[4] Including changed sleep patterns, eating habits, emotional affect, mood/motivation or increased confused thinking.

Table 117: Summary of findings table for the analysis of assertive community treatment (ACT) versus standard community treatment for people (children, young people and adults) with learning disabilities and mental health problems

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with standard community treatment	Risk difference with Assertive community treatment
Mental health (service user) - not reported	-	-			
Healthcare practitioner health and well-being - not reported	-	-			
Quality of life follow up: range 13 weeks to 26 weeks	50 (2 RCTs)	⊕⊕◯◯ LOW [1,2]	-	-	SMD 0.2 fewer (0.75 fewer to 0.36 more)
Community participation and meaningful occupation - not reported	-	-			
Problem behaviours - not reported	-	-			
Global assessment of function (symptomatology) (Adaptive functioning including communication skills) follow up: range 13 weeks to 26 weeks	50 (2 RCTs)	⊕⊕◯◯ LOW [1,2]	-	The mean global assessment of function (symptomatology) was 65.2	MD 0.76 fewer (6.07 fewer to 4.55 more)
Global assessment of function (Disability) (Adaptive functioning including communication skills) follow up: range 13 weeks to 26 weeks	50 (2 RCTs)	⊕⊕◯◯ LOW [1,2]	-	The mean global assessment of function (Disability) was 64.6	MD 1.05 more (4.05 fewer to 6.16 more)
Carer uplift/burden follow up: range 13 weeks to 26 weeks	50 (2 RCTs)	⊕◯◯◯ VERY LOW [1,3,4]	-	The mean carer uplift/burden was not reported	MD 0.03 more (3.48 fewer to 3.54 more)

Note

1. Risk of performance bias.

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with standard community treatment	Risk difference with Assertive community treatment

2. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
3. I-squared = 36% and may represent moderate heterogeneity.
4. Confidence intervals cross two minimally important differences. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

Table 118: Summary of findings table for the analysis of innovative intensive support services model versus standard model for people (children, young people and adults) with learning disabilities and mental health problems

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with standard model of service delivery	Risk difference with Active treatment case management model
Mental health (service user) - not reported	-	-			
Healthcare practitioner health and well-being - not reported	-	-			
Quality of life (service user) - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Maladaptive behaviour (Problem behaviour) assessed with: AAMD maladaptive behaviour scale follow up: 3 years	46 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	-	The mean maladaptive behaviour was 53	MD 12.91 fewer (27.37 fewer to 1.55 more)
Adaptive behaviour (Adaptive functioning including communication skills)	46 (1 RCT)	⊕◯◯◯ VERY LOW	-	The mean adaptive behaviour was 201.3	MD 10.56 more (6.77 fewer to 27.89 more)

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with standard model of service delivery	Risk difference with Active treatment case management model
assessed with: AAMD Adaptive behaviour scale follow up: 3 years		[1,2,3]			
Move to more staff intensive residential programming (Need for out-of-area specialist or secure placement) follow up: 3 years	46 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,4]	RR 0.25 (0.03 to 2.07)	Study population	
				174 per 1000	130 fewer per 1000 (169 fewer to 186 more)
Move to more staff intensive day programming (Need for out-of-area specialist or secure placement) follow up: 3 weeks	46 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,4]	RR 0.20 (0.01 to 3.95)	Study population	
				87 per 1000	70 fewer per 1000 (86 fewer to 257 more)

Note

1. Risk of selection, performance and detection bias
2. American study so service structures less applicable to UK population
3. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).
4. Confidence intervals cross two minimally important differences. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).

AAMD = American Association for Mental Deficiency

8.4.2 Group consensus for service structures, training and supervision to support practitioners in the effective delivery of interventions for people (children, young people and adults) with learning disabilities and mental health problems

Despite the limited RCT evidence (see section 8.5.1), the group did not find it appropriate to go down the evidence hierarchy or to consider indirect evidence in this area as it was not judged a good use of time and resources. The existing systematic reviews which were found in our preliminary search, including the Balogh et al., 2008 Cochrane review on organising effective health care services for people with learning disabilities, did not identify much additional evidence relevant to this review. However, the group were of the view that it would be inappropriate not to include some guidance on service structures, training and supervision so the group decided to develop recommendations using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in chapter 3.

Key issues in developing service structures, training and supervision to support practitioners in the effective delivery of interventions for people with learning disabilities and mental health problems were identified from the available literature (for example Brock, 2015; Salvador-Carulla, 2015). Policy documents including the Francis Report (Francis, 2013), Transforming care (Department of Health, 2012), the BPS CORE Competence Frameworks for supervision of psychological therapies (Roth & Pilling, 2007) and the guide developed by the Joint Commissioning Panel for Mental Health(Joint Commissioning Panel for Mental Health, 2013) were also consulted, as well as feedback from service user focus groups and discussions during the GC meetings. These were used to generate nominal statements to be rated by the GC, which were then distributed alongside nominal statements relating to the other aspects of service delivery and organisation described within this chapter. Nominal statements relating to engaging service users were designed to cover a range of areas such as location of services, competencies required of staff who work with this population and supervision. One example of a statement that was rated highly by the committee was: ‘Services for people with a learning disability and a mental health problem should be delivered flexibly, taking into account the person’s needs (including financial considerations, mobility needs or any anxieties about travel)’.

Questionnaires were distributed (round 1), and completed and returned by 11 committee members. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member’s comments in relation to the draft recommendations. A second round of ratings was completed in order to further clarify comments from the GC and issues raised during the first round of ratings. A brief summary of the process is provided in Table 119 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used as part of the nominal group technique process can be found in appendix T.

Table 119: Summary of nominal group technique process followed for the development of recommendations on service structures, training and supervision to support practitioners in the effective delivery of interventions for people (children, young people and adults) with learning disabilities and mental health problems

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=15)	Level of agreement	Statements N (Total=5)	3 recommendations
High	10	High	4	
Moderate	3	Moderate	1	
Low	2	Low	0	

8.4.3 Economic evidence

No studies assessing the cost effectiveness of appropriate service structures, training and supervision to support practitioners in the effective delivery of interventions for people with learning disabilities and mental health problems were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

8.4.4 Clinical evidence statements

8.4.4.1

- Low and very low quality evidence from 2 pilot RCTs in the UK show no difference between assertive community treatment and standard in community treatment in terms of quality of life, adaptive functioning (measured as global symptomology or function) or carer uplift/burden (k=2, N=50).
- Very low quality evidence from a pilot RCT based in the US was inconclusive if a comprehensive intensive support services model resulted in improved problem or adaptive behaviours over a standard model of service delivery; the model did result in an increased need for staff intensive day programming and decrease need for more staff intensive residential programming (k=1, N=47).

8.4.4.2 Developed through formal consensus

- The GC agreed that intensive support at home and community settings for those with severe mental health problems could be beneficial, and that different services should work closely to facilitate joined-up service provision. The GC expressed moderate support for co-location of different services to facilitate joined-up service provision.
- The GC decided that learning disability specialists should be employed within generic inpatient mental health settings and that specific dedicated beds should be available for those who require acute admission. The GC did not agree that dedicated beds within generic inpatient mental health settings for those requiring acute admission.
- The GC agreed that specialist learning disabilities services should be able to offer a broad range of psychological interventions for common and severe mental health problems, and that it is the responsibility for both mainstream mental health services and key workers to ensure that the mainstream service

is fully informed about the nature and impact of the person's mental health problems. The GC expressed support for people with mild learning disabilities to be treated by specialists within generic mental health services to prevent people 'falling between the gaps'.

- The GC decided that guidance and supervision from a specialist should be provided for those working with people with learning disabilities without specialist training, and that these staff should receive training in the needs and presentations of people with learning disabilities and mental health problems. The GC expressed agreement on the importance of both mainstream mental health and psychological treatment services having the competence to treat people with learning disabilities, calling upon specialist support if needed.

8.4.5 Economic evidence statements

No evidence on the cost effectiveness of appropriate service structures, training and supervision to support practitioners in the effective delivery of interventions for people with learning disabilities and mental health problems is available.

8.5 Review question: In people (children, young people and adults) with learning disabilities and mental health problems, do interventions aimed at improving accessibility of services (for example, by removing barriers) produce benefits that outweigh possible harms when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 120. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H

Table 120: Clinical review protocol summary for the review on improving accessibility of services

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, do interventions aimed at improving accessibility of services (e.g., by removing barriers) produce benefits that outweigh possible harms when compared to an alternative approach? (RQ4.1)
Population	People (children, young people and adults) with learning disabilities and mental health problems Including people with genetic conditions associated with learning disabilities and mental health problems, if some of their mental health problems and needs may differ from those of people with other learning disabilities (for example, Down's syndrome, Prader–Willi syndrome, Fragile X syndrome). Special consideration will be given to groups affected by equality issues, such as black, Asian and minority ethnic groups and older adults.
Intervention(s)	Any intervention aimed at improving accessibility to services (for example, by removing barriers).
Comparison	• Any alternative intervention/strategy or approach or supports
Critical outcomes	• Mental health

Component	Description
	• Community participation and meaningful occupation • Quality of life / service user and carer satisfaction / experience of care • Problem behaviours
Study design	RCTs or systematic review of RCTs

8.5.1 Clinical evidence

One RCT (N=1) was found on improving accessibility of services for people with learning disabilities and mental health problems: Raghavan et al. (2009).This paper (which includes young people) does not meet the inclusion criteria for the Cochrane review which is restricted to adults only.

An overview of the trials included can be found in Table 121. Further information about both included and excluded studies can be found in Appendix M.

Summary of findings can be found in Table 122. The full GRADE evidence profiles and associated forest plots can be found in Appendices N and O.

The paper combined the results of all degree of learning disabilities so it was not possible to examine the results by degree.

The trial screened participants for inclusion using the Reiss Screen for Maladaptive Behaviour; those considered to have either had a mental health problem or a challenging behaviour on this scale were included in the study.

No data were available for the critical outcomes of problem behaviours or community participation and meaningful occupation.

Table 121: Study information table for trials included in the analysis of specialist liaison worker model versus no liaison worker for young people and adults with learning disabilities and mental health problem

	Specialist liaison worker model versus no liaison worker
Total no. of studies (N^1)	1 (30)
Study ID	Raghavan 2009
Country	UK
Diagnosis/degree of learning disabilities	Mixed (38.5% mild, 30.8% moderate, 30.8% severe)
Age (mean)	18 (range: 13-25)
Sex (% female)	Not reported
Ethnicity (% white)	0 (88.5% Pakistani and 11.5% Bangladeshi)
IQ (mean)	Not reported
Living arrangements	Not reported
Coexisting conditions/treatments	7 had challenging behaviour 1 autism 2 Down’s syndrome 1 cerebral palsy 2 Joubert's syndrome 4 epilepsy * All participants were also receiving services from professionals for challenging behaviour and/or mental

	Specialist liaison worker model versus no liaison worker
	health problems
Targeted behaviour	Mental health problems and/or challenging behaviour[2]
Treatment length (weeks)	39
Intervention (mean dose; mg/day)	Use of a liaison worker to help participants and their families find out about available services and help them make contact and receive required services including: • liaison once per fortnight or more, if required with families through home visits, phone (&keeping detailed records • discussing families' concerns and working on types of help required for the person & family • reflecting on families' issues/problems and working on ways to move forward • exploring services available to them • liaising with agencies, teams & individuals who provide services, making them aware of individual's needs& discussing how they can help the individual • communicating information back to the family and helping them get in touch with services • checking to see whether families acted on advice given by the liaison worker or whether services could bridge gaps • explore other possibilities.
Comparison	No liaison worker
Notes. [1] Number randomised. [2] Screened with Reiss Screen for Maladaptive behaviour before inclusion but only 4 had a diagnosis of challenging behaviour.	

Table 122: Summary of findings table for the analysis of specialist liaison worker model versus no liaison worker for young people and adults with learning disabilities and mental health problem

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with no liaison worker	**Risk difference with Liaison worker model**
Mental health assessed with: Strength and difficulties questionnaire (SDQ) follow up: 39 weeks	30 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	-	SMD 1.12 SD lower (1.95 lower to 0.29 lower)
Quality of life (service user) - not reported	-	-			
Community participation and meaningful occupation - not reported	-	-			
Problem behaviours - not reported	-	-			
Carer quality of life - physical assessed with: SF12-physical	30 (1 RCT)	⊕◯◯◯ VERY LOW [1,2]	-	-	SMD 0.8 lower (1.6 lower to 0)

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with no liaison worker	**Risk difference with Liaison worker model**
follow up: 39 weeks					
Care quality of life - mental assessed with: SF12-mental follow up: 39 weeks	30 (1 RCT)	⊕◯◯◯ VERY LOW[1,3]	-	-	SMD 0.26 fewer (1.03 fewer to 0.51 more)
Carer mental health assessed with: General health questionnaire (GHQ30) follow up: 39 weeks	30 (1 RCT)	⊕◯◯◯ VERY LOW[1,3]	-	-	SMD 0.11 fewer (0.88 fewer to 0.66 more)
Note 1. Risk of selective outcome, performance, and detection bias 2. Confidence intervals cross one minimally important difference. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes). 3. Confidence intervals cross two minimally important differences. Sample size less than optimal information size (<400 for continuous outcomes or <300 events for dichotomous outcomes).					

8.5.2 Group consensus for improving accessibility of services for people with a learning disability and a mental health problem

Despite the limited RCT evidence (see section 8.5.1), the group did not find it appropriate to go down the evidence hierarchy or to consider indirect evidence in this area as it was not judged a good use of time and resources. The existing systematic reviews which were found in our preliminary search, including the Balogh et al., 2008 Cochrane review on organising effective health care services for people with learning disabilities, did not identify much additional evidence relevant to this review. However, the group were of the view that it would be inappropriate not to include some guidance on improving accessibility of services so the group decided to develop recommendations in this area using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in Chapter 3.

Key issues in improving accessibility of services for this population were identified from the available literature (for example Balogh et al., 2008), including as the Green Light Toolkit (NDTi, 2013), Transforming Care (Department of Health, 2012), and (Joint Commissioning Panel for Mental Health, 2013), as well as from discussions during the GC meetings. These were used to generate nominal statements to be rated by the GC. These were distributed alongside nominal statements relating to the other aspects of service delivery and organisation described within this chapter. Nominal statements relating to accessibility were designed to cover a range of factors that can impede or facilitate access including flexibility of service delivery, cultural sensitivity and good communication. One example of a statement that was rated highly by the committee was ‘Services for people with a learning disability and a mental health problem should be delivered flexibly, taking into account the person’s needs (including financial considerations, mobility needs or any anxieties about travel)’.

Questionnaires were distributed completed and returned by 11 committee members. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member's comments in relation to the draft recommendations. A second round of ratings was not deemed necessary as it was agreed by the GC that all important issues raised in the GC comments could be addressed in the wording of recommendations. All statements were used to draft recommendations. A brief summary of the process is provided in Table 123 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used as part of the nominal group technique process can be found in appendix T.

Table 123: Summary of nominal group technique process followed for the development of recommendations on improving accessibility of services for people with mental health problems and learning disabilities

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=5)	Level of agreement	Statements N (Total=0)	2 recommendations
High	5	High	n/a	
Moderate	0	Moderate	n/a	
Low	0	Low	n/a	

8.5.3 Economic evidence

No studies assessing the cost effectiveness of interventions aimed at improving accessibility of services for people with learning disabilities and mental health problems were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

8.5.4 Clinical evidence statements

- Very low quality evidence from a pilot RCT conducted in a Bangladeshi and Pakistani subpopulation in the UK demonstrated that use of a liaison worker improves contact with services and may improve mental health in young people and young adults with learning disabilities and a mental health problem; it is less clear if there is an impact on quality of life or mental health of their carers (k=1, N=30).

8.5.4.1 Developed through formal consensus

- The GC were of the view that services should be delivered flexibly and take into account the person's needs, provide care outside of the clinical environment if necessary, consider whether communication difficulties are a factor where someone is struggling to access a service, should be accessible to people from all cultural backgrounds and accommodate service-user preferences for workers of a particular gender or cultural background where possible.

8.5.5 Economic evidence statements

No evidence on the cost effectiveness of interventions aimed at improving accessibility of services for people with learning disabilities and mental health problems is available.

8.6 Review question: In people (children, young people and adults) with learning disabilities and mental health problems, what are the effective models or support for transition between services (for example, young person to adult, adult to older adult, NHS to social care/residential)?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 124. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 124: Clinical review protocol summary for the review on effective models or support for transition between services

Component	Description
Review question	In people (children, young people and adults) with learning disabilities and mental health problems, what are the effective models or supports for transition between services (for example, young person to adult, adult to older adult, NHS to social care/residential)? (RQ 4.2)
Population	People (children, young people and adults) with learning disabilities and mental health problems Including people with genetic conditions associated with learning disabilities and mental health problems, if some of their mental health problems and needs may differ from those of people with other learning disabilities (for example, Down's syndrome, Prader–Willi syndrome, Fragile X syndrome). Special consideration will be given to groups affected by equality issues, such as black, Asian and minority ethnic groups and older adults.
Intervention(s)	Any model or supports for transitioning between services
Comparison	• Treatment as usual • No treatment • Waitlist control • Placebo (including attention control) • Any alternative model for transition
Critical outcomes	• Mental health • Community participation and meaningful occupation • Quality of life / service user and carer satisfaction / experience of care • Problem behaviours
Study design	RCTs or systematic review of RCTs

8.6.1 Clinical evidence and group consensus for providing effective support for transition between services

No RCTs were found on effective models or support for transition between services for people with learning disabilities and mental health problems.

Despite no RCT evidence in this area, the group did not find it appropriate to go down the evidence hierarchy or to consider indirect evidence in this area as it was not judged a good use of time and resources. The existing systematic reviews which were found in our preliminary search, including the Balogh et al., 2008 Cochrane review on organising effective health care services for people with learning disabilities, did not identify much additional evidence relevant to this review. However, the group were of the view that it would be inappropriate not to include some guidance on providing effective support for transition between services so the group decided to develop recommendations using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in Chapter 3.

Key issues in providing effective support for transition in this population were identified from the available literature (for example Balogh et al., 2008), from documents including the Transforming Care (Department of Health, 2012), the guide from the Joint Commissioning Panel for Mental Health (Joint Commissioning Panel for Mental Health, 2013) and the Francis Report (Francis, 2013), as well as from discussions during the GC meetings. These were used to generate nominal statements to be rated by the GC. These were distributed alongside nominal statements relating to the other aspects of service delivery and organisation described within this chapter. Nominal statements relating to transition were designed to cover a range of areas such as ensuring continuity of care and where responsibility should lie for the transmission of information. One example of a statement that was rated highly by the committee was ‘The person with a learning disability and a mental health problem and their families and carers should be involved in the planning of transitions’.

Questionnaires were distributed, and completed and returned by 11 committee members. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member’s comments in relation to the draft recommendations. A single statement was included in a second round of ratings, however it was agreed by the GC that all other important issues raised in the GC comments could be addressed in the drafting of the recommendations. A brief summary of the process is provided in Table 125 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used as part of the nominal group technique process can be found in appendix T.

Table 125: Summary of nominal group technique process followed for the development of recommendations on providing effective support for transition between services for people with mental health problems and learning disabilities

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=14)	Level of agreement	Statements N (Total=1)	2 recommendations
High	11	High	1	
Moderate	3	Moderate	0	
Low	0	Low	0	

8.6.2 Economic evidence

No studies assessing the cost effectiveness of models or support for transition between services for people with learning disabilities and mental health problems were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

8.6.3 Clinical evidence statements (developed through formal consensus)

- The GC agreed that people with learning disabilities admitted to hospital for physical health problems should receive additional support at admission and discharge and that the referring or discharging organisation should ensure that the person's records are transmitted and any safeguarding concerns communicated in a timely fashion. The GC expressed moderate support for the need for a referral to be accepted by the service accepting care before a service-user is discharged, and that it should be the responsibility of the organisation accepting care to ensure that they have received the person's records.
- The GC decided that transitions should be planned as far as possible in advance and involve the person and their family or carers, that the transition should be as smooth as possible, include a joint meeting with both incoming and outgoing staff during the transition period, should consider any special requirements that may assist with a smooth transition and should ensure that the person feels adequately supported throughout.
- In children and young people the GC agreed that those looked after within the care system should receive additional support during transitions and that CAMHS staff should provide advice and facilitate transitions for young people within educational settings.

8.6.4 Economic evidence statements

No evidence on the cost effectiveness of models or support for transition between services for people with learning disabilities and mental health problems is available.

8.7 Review question: What is the best approach with regard to the coordination and communication with key persons and services in the life of the person with learning disabilities and mental health problems?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 126. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 126: Clinical review protocol summary for the review on coordination and communication with key persons and services in the life of the person with learning disabilities and mental health problems

Component	Description
Review question	What is the best approach with regard to the coordination and communication with key persons and services in the life of the person with learning disabilities and mental health problems? (RQ 4.3)
Population	Key persons and services involved in the life of the person with learning disabilities and mental health problems including family members, healthcare practitioners and other staff.

Component	Description
Intervention(s)	Any approach or supports to improve coordination and communication with key persons and services.
Comparison	• Treatment as usual • No treatment • Waitlist control • Placebo (including attention control) • Any alternative intervention/strategy or approach or supports
Critical outcomes	• Mental health • Community participation and meaningful occupation • Quality of life / service user and carer satisfaction / experience of care • Health and quality of life of key persons involved • Problem behaviours
Study design	RCTs or systematic review of RCTs

8.7.1 Clinical evidence

One RCT (Coelho et al., 1993) identified by the Cochrane review (Balogh et al., 2008) and included in the review on service structures to support practitioners in the effective delivery of interventions used the ‘innovative intensive support services model’ which involved improving coordination and communication with key persons and services. The model used in the study aimed to unify agency services with joint networking, consultation and problem solving. See the overview of the trial and summary of findings in 8.4.1 above.

No additional RCTs were found which addressed this review question.

No data were available for any of the critical outcomes related to this review: mental health (of the person with learning disabilities), quality of life (service user), community participation and meaningful occupation or healthcare practitioner health and well-being.

8.7.2 Group consensus for improving coordination and communication with key persons and services in the life of the person with a learning disability and a mental health problem

Despite the limited RCT evidence (see section 8.7.1), limited RCT evidence (see section 8.2.1), the group did not find it appropriate to go down the evidence hierarchy or to consider indirect evidence in this area as it was not judged a good use of time and resources. The existing systematic reviews which were found in our preliminary search, including the Balogh et al., 2008 Cochrane review on organising effective health care services for people with learning disabilities, did not identify much additional evidence relevant to this review. However, the group were of the view that it would be inappropriate not to include some guidance on coordination and communication with key persons and services so the group decided to develop recommendations using the modified nominal group technique. The method of the nominal group technique used in this guideline is described in Chapter 3.

Key issues in improving coordination and communication with key people and services were identified from the available literature (for example Balogh et al., 2008), from documents such as the Green Light Toolkit (NDTi, 2013), and the guide from the Joint Commissioning Panel for Mental Health (Joint Commissioning Panel for Mental Health, 2013), as well as from discussions during the GC meetings and service user focus-group feedback. These were used to generate nominal statements to be rated by the GC. Nominal statements relating to improving coordination and communication were designed to cover a range of areas such as the use of key workers and provision of accessible information. One example of a statement that was rated highly by the committee was 'For people with a learning disability and a mental health problem, a proactive approach should be taken to the sharing of information with key people and services, in line with local procedures and with the permission of the person with a learning disability and a mental health problem'.

Questionnaires were distributed, and completed and returned by 11 committee members. Percentage consensus values were calculated, and comments collated, for each statement. The rankings and comments were then presented to the GC members and used to inform a discussion of the issues raised by member's comments in relation to the draft recommendations. A second round of ratings was not deemed necessary as it was agreed by the GC that all important issues raised in the GC comments could be addressed in the wording of recommendations. A brief summary of the process is provided in Table 127 below. The full list of statements and ratings can be found in appendix U whilst blank copies of the questionnaires used as part of the nominal group technique process can be found in appendix T.

Table 127: Summary of nominal group technique process followed for the development of recommendations on improving coordination and communication with key persons and services in the life of the person with mental health problems and learning disabilities

Round 1		**Round 2**		**Resulting recommendations generated**
Level of agreement	Statements N (Total=9)	Level of agreement	Statements N (Total=0)	3 recommendations
High	7	High	n/a	
Moderate	2	Moderate	n/a	
Low	0	Low	n/a	

8.7.3 Economic evidence

No studies assessing the cost effectiveness of approaches with regard to the coordination and communication with key persons and services in the life of a person with learning disabilities and mental health problems were identified by the systematic search of the economic literature undertaken for this guideline. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

8.7.4 Clinical evidence statements

- Very low quality evidence from a pilot RCT based in the US was inconclusive on comprehensive intensive support services model (with a focus on unifying agency services with joint networking, consultation and problem solving) which resulted in improved problem or adaptive behaviours over a standard model of service delivery; the model did result in an increased need for day programming and decrease need for more staff intensive residential programming (k=1, N=47).

8.7.4.1 Developed through formal consensus

- The GC supported the appointment of a key worker for the service-user to coordinate all aspects of care and facilitate clear communication between all people and services involved in the service-user's care.
- The GC agreed that all involved agencies should ensure that they communicate clearly, in a timely fashion and in an agreed format with each other and with the service user, family and carers.
- The GC agreed that services should take a proactive approach to information sharing, within the boundaries of local procedures and with the person's permission, that each person or service involved in the service-user's care should clarify their own role and familiarise themselves with each other's roles, and that clarity on this point is crucial to manage safeguarding concerns and risk. The GC expressed support for the requirement for staff to familiarise themselves with the working practices of each key person or service involved in the service-user's care.

8.7.5 Economic evidence statements

There is no evidence on the cost effectiveness of approaches with regard to the coordination and communication with key persons and services in the life of a person with learning disabilities and mental health problems.

8.8 Recommendations and link to evidence

8.8.1 Organising effective care, service structure, transition between services and accessibility of services

Recommendations	
	65. A designated leadership team of healthcare professionals, educational staff, social care practitioners and health and local authority commissioners should develop and implement care pathways in collaboration with people with learning disabilities and mental health problems and their family members, carers or care workers (as appropriate). **66. The designated leadership team should ensure that care pathways:** • **provide a person-centred integrated programme of care** • **are negotiable, workable and understandable for people with learning disabilities and mental health problems, their family members, carers or care workers, and staff** • **are accessible and acceptable to people using the services** • **are responsive to the needs and abilities of people using the services.** **67. The designated leadership team should ensure that care pathways:** • **cover all health, social care, support and education services,**

	and define the roles and responsibilities of each service
	- **have designated staff who are responsible for coordinating:**
	  o **how people are involved with a care pathway**
	  o **transition between services within and across different care pathways**
	- **maintain consistency of care**
	- **have protocols for sharing information:**
	  o **with all services, including those not covered by the care pathway**
	  o **with the person with learning disabilities and a mental health problem and their family members, carers or care workers (as appropriate)**
	  o **with other staff (including GPs) involved in the person's care**
	- **are focused on outcomes (including measures of quality, service user experience and harm)**
	- **establish clear links (including access and entry points) to other care pathways (including those for physical health problems).**
	68. The designated leadership team should ensure that young people with learning disabilities and mental health problems have in place plans that address their health, social, educational and recreational needs, as part of their transition to adult services and adulthood. This planning should start when young people are aged 14 and follow the NICE guideline on transition from children's to adults' services
	69. The designated leadership team, together with health and social care providers, should ensure that care pathways:
	- **provide access to all NICE-recommended interventions for mental health problems**
	- **clearly state the responsibilities of specialist learning disabilities and specialist mental health services to ensure people's needs are met.**
	70. For people with learning disabilities who need acute inpatient treatment for a serious mental illness, provide treatment:
	- **within a locally available service *and***
	- **with staff who are skilled and knowledgeable in the care and treatment of mental health problems in people with learning**

	disabilities
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of models for service delivery (service structure), transitions between services, or interventions to improve accessibility. In addition to the effect on the mental health problem, the group considered community participation and meaningful occupation, quality of life / experience of care, and the effect on problem behaviour to be particularly critical outcomes which they wished to examine in the literature. Additional important outcomes included adaptive functioning including communication skills (this may be most relevant to common mental health disorders), carer health and quality of life, adverse events, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	**Service structures** The GC noted the scarcity of studies on service structures for people with learning disabilities and mental health problems, with only 3 trials covering 2 types of interventions. The group noted that there appeared to be very little difference between assertive community treatment (ACT) and standard community treatment on all outcomes from studies based in the UK. The authors reported that part of the reason why there was no difference between groups was likely to have been because of the difficulty in defining assertive community treatment. They also noted that the intervention and standard community treatment may have been too similar in content. One study considered an innovative intensive support services model which involved multiple components in the intervention. While the intervention appeared to reduce the need for staff intensive residential programming or day programming, the effects on the effects of the intervention on problem or adaptive behaviour are less clear. Furthermore, given the multiple component of the intervention, it is difficult to isolate which component is effecting the outcome. **Transition between services** No evidence meeting the inclusion criteria in the protocol was found on effective transition between services. See discussion in Other considerations below. **Accessibility of services** The GC noted the scarcity of studies on improving accessibility of services for people with learning disabilities and mental health problems. The only RCT which reported on improving access to services reported that the use of a liaison worker appeared to improve the frequency of contacts with services compared to a control group. Qualitative outcomes from focus groups were also reported by the study which showed that both the individuals and families/carers of those who had the assistance of a liaison worker felt better equipped to access mental health services while those in the control group felt they had continuing difficulties in obtaining help they needed. This fed into the development of nominal statements. The study reported that mental health as measured on the strength and difficulties questionnaire was improved with the use of a liaison worker over the control group but there was little certainty in this result. In terms of carer outcomes, carer quality of life was very uncertain. Carer mental health on the General Health Questionnaire was again very uncertain.

	The GC considered the importance of having support in place for practitioners to deliver effective interventions in the form of service structures, training and supervision; of having clear pathways of transition; and having clear pathways of support to access services, However, they appreciated that having service structures in place may be considered a harm if it limits individual choice.
Trade-off between net health benefits and resource use	The GC acknowledged the considerable resource implications of establishing person-centred integrated programmes of care across all health and social care services and support and education providers or people with learning disabilities and mental health problems. However, they expressed the view that formalising and integrating care pathways for people with learning disabilities and mental health problems, including transition between and within services, would enable more effective delivery of care and better outcomes for service users, reducing, at the same time, the high variation in care costs resulting from provision of ineffective and poorly coordinated care. The GC also noted the response of the Department of Health to the Winterbourne report (Transforming Care) and the emphasis given to the need for personalised care and support planning for people with learning disabilities. The GC estimated that the additional healthcare resources required to ensure acute inpatient care of people with learning disabilities and a severe mental health problem in a local setting are modest and comprise the presence of staff with skills and knowledge in the care and treatment of people with learning disabilities in the setting. The GC expressed the opinion that locally provided acute inpatient care is beneficial to the service users and their carers in terms of clinical outcomes and accessibility and may ultimately lead to a reduction in total care costs, since it is expected to result in more effective, integrated delivery of care. The GC noted that the Department of Health, in response to the Winterbourne report (Transforming care), has published guidance highlighting the need for people with learning disabilities to have access to the support and services they need locally, where possible, near family and friends. The GC expressed the view that providing local services for the acute treatment of severe mental health problems in this population entails also an equality issue: people with severe mental health problems who have also learning disabilities should have access to locally available mental health inpatient settings, the same way as people with severe mental health problems but without learning disabilities have. Finally, the GC expressed the opinion that improving access to NICE-recommended interventions for the treatment and management of mental health problems in people with learning disabilities will ensure efficient use of resources and enhance equality within the services.
Quality of evidence	**Service structures** The overall quality of the evidence on service structures was low and very low. The studies were all quite small with wide confidence intervals in the estimates so many outcomes were downgraded as imprecise. The trial on innovative intensive support services model was considered to be indirect since it was based in the US where services are very different; the group also noted that the study was quite old, as well. **Accessibility of services** The overall quality of the evidence on improving accessibility was very low quality evidence. The one RCT addressing this question was considered to have risk of bias and was a pilot RCT with very few patients so may not

	have the adequate power to show a difference in outcomes between groups (this was reflected in the wide confidence intervals for most outcomes, resulting in low precision). The GC noted that the intervention in the study considered was designed for a specific subpopulation in the UK (from a Pakistani and Bangladeshi community). As a result, particular aspects of the intervention may be only culturally applicable to this subpopulation and a similar intervention may not have the same effect in another populations in the UK.
Other considerations	**Service structures** The GC noted that the existing trials in this area were conducted because a post-hoc analysis of UK based trial of ACT (the UK700) suggested that ACT may be useful in people with borderline IQ. They noted that the positive effects of ACT in the UK have not been shown in most UK trials. The GC also noted that this may be because the American trials are in psychosis where the ‘standard care’ is viewed to be of a poorer quality to that provided in the UK so a difference between the intervention and control groups may be exaggerated. Furthermore, both the authors and the GC noted that the reason why no difference was shown between ACT and control may be because the standard care in the trials may have been quite good as both were conducted in areas that have relatively good services. The GC decided to conduct formal group consensus in this area because of the lack of evidence and the importance of guidance in this area. On the basis of the outcome of the nominal group technique, the GC developed recommendations on service delivery in areas including: - intensive support at home and community settings for those with severe mental health problems, and that different services should work closely to facilitate joined-up service provision - learning disability specialists should be employed in generic inpatient mental health settings and that dedicated beds should be available for those who require acute admission - learning disabilities services should be able to offer a broad range of psychological interventions - people with mild learning disabilities should not fall between the gaps between services and general mental health services should be able to deliver services tailored to people with learning disabilities A number of additional contextual factors were picked up in the nominal group technique: - there should be a leadership team that is responsible for establishing and developing care pathways for people with learning disabilities and mental health problems - services should be person-centred and accessible (with information communicated clearly with the person and their family member, carer or care worker) - care pathways and services need to support the use of a broad range of psychological interventions. When discussing coordination and communication with key persons (see 7.9 1.2 below), the GC considered that in addition to taking a proactive approach to information sharing between services, that there should be protocols for sharing information with other involved staff, in particular GPs. **Transition between services** The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas:

- decisions about transitions should be made in collaboration with people with learning disabilities and their family members, carers and care workers (the group appreciated this was important, in general, and was not specific to transitions)
- ensuring designated staff are responsible for coordinating transitions between services
- roles and responsibilities of all services involved needs to be clearly defined and understood by each service involved (again, the group appreciated this was important in general and was not specific to transitions)
- ensuring consistency of care for people, including during any transition (again the group appreciated this was important in general and was not specific to transitions)
- ensuring that the planning for service transition is done as far as possible in advance, including/in particular for people moving into adult services should involve health, social, education, recreational and development planning

The group also noted that NICE social care guidance was in development related to transition between services. In particular, the group noted the social care guideline on children to adult services which has published recently (NICE, 2016). They also noted the work on transitioning between inpatient mental health settings and community or care home settings.

Accessibility of services

The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas:

- services should be delivered flexibly and take into account the person’s needs
- care should be provided outside of the clinical environment if necessary
- consider whether communication difficulties are a factor where someone is struggling to access a service
- services should be accessible to people from all cultural backgrounds and accommodate service-user preferences for workers of a particular gender or cultural background where possible.

A number of additional contextual factors were picked up in the nominal group technique:

- inpatient services should be locally available, as much as possible.
- care pathways should ensure that NICE-recommended interventions are made available for people with learning disabilities and mental health problems.

As a result of very little high-quality evidence, the GC agreed to make recommendations for future research. As they were particularly concerned about people with mild learning disabilities falling between the gaps in services since they are often not treated within a learning disabilities service future research will be useful in informing whether people with mild learning disabilities should be treated within a generic mental health setting that included support from learning disabilities specialists, or within a specialist learning disabilities mental health service. The treatment of psychosis in these patients was seen as a particular area of poor quality currently so this was considered an area to focus research.

8.8.2 Staff coordination and communication

Recommendations	**71. Staff working with people with learning disabilities and mental health problems should ensure they are fully informed about:** • **the nature and degree of the learning disabilities** • the nature and severity of the mental health problem, and any physical health problems**.** **72. All people with learning disabilities and a serious mental illness should have a key worker who:** • **coordinates all aspects of care, including safeguarding concerns and risk management** • **helps services communicate with the person and their family members, carers or care workers (as appropriate) clearly and promptly, in a format and language suited to the person's needs and preferences** • **monitors the implementation of the care plan and its outcomes.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of models for service delivery (service structure). In addition to the effect on the mental health problem, the group considered community participation and meaningful occupation, quality of life / experience of care, and the effect on problem behaviour to be particularly critical outcomes which they wished to examine in the literature. Additional important outcomes included adaptive functioning including communication skills (this may be most relevant to common mental health disorders), carer health and quality of life, adverse events, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending.
Trade-off between clinical benefits and harms	Very little evidence was found on improving coordination and communication. The evidence was limited to one study on service models which involved an attempt to unify agency services with joint networking, consulting and problem solving. The study was inconclusive if a comprehensive intensive support services model (which involved encouraging participants to recognise problem situations, accept responsibility in their behaviour and move towards more autonomy) resulted in improved problem or adaptive behaviours over a standard model of service delivery but did result in an increased need for day programming and decrease need for more staff intensive residential programming. However it is difficult to isolate the effects of this multiple component intervention.
Trade-off between net health benefits and resource use	There are costs associated with the appointment of a key worker involved in the care and monitoring of a person with learning disabilities and a serious mental illness. However, co-ordination of care by a key worker for people with a serious mental illness is standard practice, although a key worker may not always be designated to people with learning disabilities and a serious mental illness. The GC expressed the view that this might raise equality issues as not designating a key worker to people with learning disabilities and a serious mental illness would be discriminatory against this population.

	The GC expressed the view that costs incurred by the appointment of a key worker involved in the care of people with learning disabilities and serious mental illness, in cases where a key worker has not been already designated, are offset by better outcomes for service users, their family and carers as well as cost-savings resulting from efficient coordination and use of existing resources.
Quality of evidence	The evidence from the one study which considered communication and coordination within a multiple-component intervention was very low quality due to risk of bias, indirectness (the study is an American population for which service structures are quite different than the UK), and imprecision (largely due to its small size).
Other considerations	The GC decided to conduct formal group consensus in this area because of the lack of evidence and the importance of guidance in this area. The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas: - a key worker to be appointed to coordinate all aspects of care and facilitate clear communication between all people and services involved in the service-user's care. - all involved agencies should ensure that they communicate clearly, in a timely fashion and in an agreed format with each other and with the service user, family and carers - information sharing - staff working with people should be informed of the nature and degree of the person's learning disabilities, the impact of the mental health problem and any other physical problems. A number of additional contextual factors were picked up in the nominal group technique: - in particular, that there should be information sharing protocols within systems (see 7.9.17.9.1)

8.8.3 Staff training and supervision

Recommendations	**73. Health, social care and education services should train all staff who may come into contact with people with learning disabilities to be aware:** • **that people with learning disabilities are at increased risk of mental health problems** • **that mental health problems may develop and present in different ways from people without learning disabilities, and the usual signs or symptoms may not be observable or reportable** • **that people with learning disabilities can develop mental health problems for the same reasons as people without learning disabilities (for example, because of financial worries, bereavement or relationship difficulties)** • **that mental health problems are commonly overlooked in people with learning disabilities** • **where to refer people with learning disabilities and**

	suspected mental health problems. **74. Health and social care services should ensure that staff who deliver interventions for people with learning disabilities and mental health problems are competent, and that they:** • **receive regular high-quality supervision** • **deliver interventions based on relevant manuals, if available** • **evaluate adherence to interventions** • **take part in the monitoring of their practice (for example, by using video and audio recording, external audit and scrutiny).** **75. Health and social care staff who deliver interventions for people with learning disabilities and mental health problems should consider using routine sessional outcome measures.**
Relative values of different outcomes	The GC discussed the importance and relevance of various outcomes in the evidence when assessing the effectiveness of models for service delivery (service structure). In addition to the effect on the mental health problem, the group considered community participation and meaningful occupation, quality of life / experience of care, and the effect on problem behaviour to be particularly critical outcomes which they wished to examine in the literature. Additional important outcomes included adaptive functioning including communication skills (this may be most relevant to common mental health disorders), carer health and quality of life, adverse events, rates of placement breakdown (including out-of-area placements or rates of restrictive interventions), psychiatric hospital admissions (including length of stay or other outcomes related to admission), as well as offending or re-offending..
Trade-off between clinical benefits and harms	No evidence meeting the inclusion criteria in the protocol was found on staff training and supervision to support practitioners in the effective delivery of interventions.
Trade-off between net health benefits and resource use	Training and supervising health and social care staff working with people with learning disabilities and a mental health problem is likely to incur significant costs. Nevertheless, the GC expressed the view that care and support of people with learning disabilities by trained and supervised staff will more likely lead to better and more timely identification and management of mental health problems, and that the associated benefits to service users, their family and carers will outweigh training and supervision costs. Furthermore, the GC noted that the Department of Health, in response to the Winterbourne report (Transforming care), acknowledged the importance of appropriate training and continuous support for staff working with people with learning disabilities, so that staff obtains the skills and the knowledge that will enable them to provide appropriate and effective care to people with learning disabilities. Staff that has received no or poor training, as well as under-supported staff, has been shown to provide poor quality of care with bad outcomes for service users, indicating that training and supervision of staff working with people with learning disabilities represents an efficient use of resources.
Quality of evidence	Not applicable.

Other considerations	The GC decided to conduct formal group consensus in this area because of the lack of evidence and the importance of guidance in this area. The GC decided on the basis of the outcome of the nominal group technique to develop recommendations in the following areas: - guidance and supervision from a specialist should be provided for those working with people with learning disabilities without specialist training, and that these staff should receive training in the needs and presentations of people with learning disabilities and mental health problems. - both mainstream mental health and psychological treatment services should have the competence to treat people with learning disabilities, calling upon specialist support if needed A number of additional contextual factors were picked up in the nominal group technique: - all those who came into contact with people with learning disabilities should be aware of a number of things about people with mental health problems and that they may present differently; they also must know where to refer people who they suspect as having a mental health problem. This was also highlighted when discussing the identification of potential mental health problems in people with learning disabilities; the group considered that most people in regular contact with people need to be aware of the potential for mental health problems in this group and that these are often overlooked (or attributed to physical health problems [diagnostic overshadowing]). - Discussions from other nominal group processes (such as case identification, assessment, and adaptations to psychological interventions) have contributed to recommendations on staff training and supervision.

8.8.4 Research recommendations

15. **For people with mild learning disabilities, what is the clinical and cost effectiveness of delivering treatment for psychosis within a learning disabilities service, compared with a generic mental health service (including with support from learning disabilities specialists)?**

16. **For people with mild learning disabilities, what is the clinical and cost effectiveness of delivering treatment for mental health conditions other than psychosis within a learning disabilities service, compared with a generic mental health service including with support from learning disabilities specialists?**

9 Family carer and staff interventions

9.1 Introduction

9.1.1 Family carers

The vast majority of children, and over one third of adults with a learning disability known to social services in England (Hatton, 2014), live with family carers. Even when people with learning disabilities do not live with family carers, various family members are typically involved in their lives and may provide care and support. Family members will also have known their relative for a long time, and may be in a good position to notice changes in mental health and behaviour. Family carers are also more likely to directly experience the impact of their relative's mental health problems and be in a position to identify and influence the course of any mental health problems.

Population-based data from the UK suggest that mothers of children with a learning disability are 2-3 times more likely to experience concerning levels of stress and mental health problems themselves compared to other parents (Totsika, 2011). These problems in maternal mental health emerge early – at least by the time that their child with a learning disability is 5 years of age (Totsika et al., 2011). Although fewer data are available, fathers of children with a learning disability also report increased levels of mental health problems compared to other men (MacDonald, 2010). In addition to reduced well-being, parents of children with a learning disability report poorer physical health (Eisenhower et al., 2013). Data relating to sibling well-being in families of children with a learning disability are less clear, although there is probably a small increased risk of psychological problems in the siblings of children with a learning disability (Hastings, 2014a).

The putative impact of caring can also be life-long, with many family carers continuing to support their relative with learning disability for several decades (Heller et al., 2007). Family caregivers, including parents and siblings, continue to report poor outcomes when they are caring for adults with learning disability (Seltzer, 2011).

Family carers' health and well-being is affected by a multitude of factors including lack of support from or battles with services and professionals (Griffith & Hastings, 2014), stigma experienced within society (Werner, 2015), socio-economic deprivation (Emerson, 2003a), and cultural factors (Hatton, 2002). However, carer health and well-being is also directly related to the behavioural and emotional well-being of the individual with learning disability receiving care: increased mental health problems in children and adults with learning disabilities predict poorer carer outcomes over time (Esbensen & Benson, 2006; Hastings, 2006). In addition, siblings in families of individuals with learning disabilities have lower levels of well-being themselves when their brother or sister with learning disability has higher levels of behavioural and emotional problems (Hastings, 2014a).

In summary, the existing evidence suggests that family members of children and adults with learning disabilities have health and well-being needs in their own right that may be related to the demands of caring and especially when their relative has mental health problems (Esbensen, 2011).

There is a further reason for considering the evidence for how best to intervene to improve the health and well-being of family members of people with a learning disability and mental health problems. Several studies have shown that the well-being of family members has an impact over time on the behavioural and emotional health of both children and adults with learning disability (Neece, 2012; Zeedyk, 2015). There is also some preliminary evidence to suggest that sibling well-being can influence the behavioural and emotional health of children with disabilities over time (Hastings, 2014b). Therefore, it is possible that targeting parental and other family members' well-being in intervention could have an indirect positive effect on the mental health of children and adults with learning disabilities themselves.

A note of caution is also warranted at this point. Given the tendency to ask negatively-phrased questions about the impact of caregiving on the family members of individuals with learning disability, it is easy to think that problematic outcomes for family members are predominant. Certainly, research and the direct experience of families suggest that family members can face some real challenges and these may affect their health and well-being. However, population-based data in the UK suggested that the majority of mothers of children with learning disability did not report elevated levels of mental health problems (Totsika, 2011). In addition, parents (Hastings, 2002b) and siblings (Hastings, 2014a) also identify the positive aspects of living with and caring for a person with learning disability. There is even some suggestion that positive mental health may not differ between mothers of children with learning disability and other mothers (Totsika, 2011).

9.1.2 Staff working in learning disability settings

Many individuals, especially adults, with a learning disability live in settings where they are supported at least for some of the time by paid staff. Although staff experience work-related stress, it is not clear if their level of work stress and related outcomes such as burnout are any higher than other workers (Skirrow & Hatton, 2007). However, as with family carers, there is some evidence that staff working with children and adults with learning disability experience higher levels of work stress and burnout if they are in settings where they support individuals who have behavioural or emotional difficulties (Devereux et al., 2009; Hastings, 2002a). Therefore, staff may need specific interventions to improve their work-related well-being.

As with family carer well-being, it is also possible that improving staff well-being will affect mental health and other outcomes for individuals with a learning disability. Although of generally poor methodological quality, there is evidence that directly intervening to improve staff well-being is associated with observed reductions in problem behaviour and improvements in skills for adults with learning disability (Singh, 2006), and increased positive interactions between staff and people with learning disability (Rose et al., 1998). Staff reporting higher levels of work stress or burnout are also more likely to consider leaving their job (Kozak, 2013). Staff turnover is likely to affect the quality and consistency of care and support for people with learning disability, and changes in staffing and other disruptions to care are some of the most common life events for adults with a learning disability associated with negative effects on their well-being (Hulbert-Williams et al., 2014). This accumulated evidence suggests that targeting staff well-being in interventions may be indirectly beneficial for the mental health of people with learning disabilities as well as directly beneficial for staff.

A short note of caution is also needed when considering research on the work-related well-being of staff in learning disability services. Although they may face significant work stress, like family members staff also report positive perceptions and experiences related to their work with people with learning disability and the impact of people with a learning disability on their lives (Lunsky, 2014). At present, research on this topic is in its infancy and we understand little about whether promoting staff positive perceptions may improve their work-related well-being or the quality of care and support provided for people with a learning disability.

9.2 In family carers and staff caring for people (children, young people and adults) with learning disabilities and mental health problems, which interventions, training and support improve the health and well-being of the family and staff as well as that of the person with learning disabilities when compared to an alternative approach?

The review protocol summary, including the review question and the eligibility criteria used for this section of the guideline, can be found in Table 128. A complete list of review questions and review protocols can be found in Appendix F; further information about the search strategy can be found in Appendix H.

Table 128: Clinical review protocol summary for the review on the prevention of mental health problems

Component	Description
Review question	In family carers and staff caring for people (children, young people and adults) with learning disabilities and mental health problems, which interventions, training and support improve the health and well-being of the family and staff as well as that of the person with learning disabilities when compared to an alternative approach? (RQ 5.1)
Population	Family carers and staff caring for people (children, young people and adults) with learning disabilities and mental health problems. This includes family carers and staff caring for people with genetic conditions associated with learning disabilities and mental health problems, if some of their mental health problems and needs may differ from those of people with other learning disabilities (for example, Down’s syndrome, Prader–Willi syndrome, Fragile X syndrome). Special consideration will be given to groups affected by equality issues, such as black, Asian and minority ethnic groups and older adults.
Intervention(s)	Any intervention, training or support with the aim of improving health and wellbeing of family carers and staff caring for people with learning disabilities and mental health problems including: • Acceptance and Commitment Therapy • Cognitive behaviour therapy (CBT) • Mindfulness • Stress inoculation training • Supported communication including Intensive Interaction, Augmented and Alternative Communication (AAC), Picture Exchange, Communication System (PECS), Individualised Sensory Environment (ISE)
Comparison	• Placebo / no intervention

Component	Description
	• Any of the other interventions (that is, head-to-head trials)
Critical outcomes	• Carer health and quality of life / carer satisfaction • Relationship between carer and person being cared for (measured by observational measures of staff support of expressed emotion on the relationship)
Study design	RCTs and systematic reviews of RCTs

9.2.1 Clinical evidence

There were no RCTs which focused on interventions, training or support in the family carers or staff caring for people with learning disabilities that also had mental health problems. The review completed for the NICE guideline on behaviour that challenges (NICE, 2015) which focused on interventions for family carers and staff of people with learning disabilities, in general, was adopted for this guideline as indirect evidence. This is because the GC believed this constituted the best available evidence, rather than going down the evidence hierarchy or conducting formal group consensus, which in the GC's view would not be a good use of time and resources. Most studies focused on the use of interventions for the health and well-being of family carers. The only studies which were identified which focused on interventions for the health and well-being of staff were on the use of a mindfulness intervention (see 9.2.1.4 below).

9.2.1.1 Interventions informed by cognitive behavioural principles for family carers of people with a learning disability versus any control

There were 9 RCTs (N=774) that met the eligibility criteria for this review: Feinberg 2014 (Feinberg et al., 2014), Gammon 1991 (Gammon & Rose, 1991), Greaves 1997 (Greaves, 1997), Kirkham 1990 (Kirkham & Schilling, 1990), Nixon 1993 (Nixon & Singer, 1993), Schultz 1993 (Schultz et al., 1993), Singer 1988 (Singer et al., 1988), Singer 1989 (Singer et al., 1989) and Wong 2010 (Wong & Poon, 2010).

All studies considered interventions for family carers and most studies included used a different type of intervention based on cognitive behavioural principles except for the two studies which used the Coping Skills Training Program, An overview of the trials included in the analysis can be found in Table 129. Further information about both included and excluded studies, as well as all forest plots can be found in the challenging behaviour guideline (NICE, 2015).

Of the 9 eligible studies, 7 (N=610) included sufficient data to be included in a meta-analysis and 2 (N=79) included critical outcome data that could not be included in a meta-analysis because of the way the data had been reported (Gammon 1991; Greaves 1997); a brief narrative synthesis is therefore given to assess how the findings compare with those in the meta-analyses. Greaves 1997 was a 3-armed trial (N=54); for the purposes of this review only the experimental and no treatment control group were utilised (N=37). Greaves 1997 (N=37) reported that the cognitive behavioural intervention (Coping Skills Training Program) was more effective than no-treatment control in reducing stress. Conversely, Gammon 1991 (n = 42) reported no overall effect of the cognitive behavioural intervention (Rational-Emotive Parent Education Program), when compared with control, on dimensions of parental stress at the end of the intervention.

Summary of findings can be found in Table 130. The full GRADE evidence profiles can be found in Appendix N.

No data were available for the critical outcomes of family or carer satisfaction.

Table 129: Study information table for trials included in the analysis of interventions informed by cognitive behavioural principles for family carers of people with a learning disability any control

	Interventions informed by cognitive behavioural principles versus any control
Total no. of studies (N[1])	9 (774)
Study ID	(1) Gammon 1991[2] (2) Greaves 1997[2,3] (3) Feinberg 2014 (4) Kirkham 1990 (5) Nixon 1993 (6) Schultz 1993 (7) Singer 1988 (8) Singer 1989 (9) Wong 2010
Country	(1, 3, 4, 5, 6, 7, 8) USA (2, 9) Australia
Diagnosis	(1, 4, 7, 8, 9) Developmental disability (2) Down’s syndrome (3) Autism (5, 6) Learning disability
Carer type	(1-9) family carer
Carer age (mean)	(1, 3, 4, 6, 9) 34-47 (2, 5, 7, 8) Not reported
Carer sex (% female)	(1, 2, 3, 4, 5, 9) 95-100 (7) Not reported (6, 8) 50-65
Carer ethnicity (% white)	(1, 2, 5, 6, 7, 8) Not reported (3) 44 (4) 92 (9) 0
Treatment length (weeks)	(1, 2, 3, 4, 7, 9) 8-10 (5, 6) 5-6 (8) 16
Intervention	(1, 8) Coping Skills Training Program (2) Rational-Emotive Parent Education Program (3) Problem-solving education (4) Life-skills intervention training (5) Cognitive restructuring treatment programme (6) Caring for Parent Caregivers (7) Stress management training (9) CBT
Comparison	(1, 2, 6) No treatment (3, 4, 7, 8) Treatment as usual (5, 9) Waitlist

Note.
[1] Number randomised. [2] Data not reported in a meta-analysable format; findings are described narratively. [3] 3-armed trial;

	Interventions informed by cognitive behavioural principles versus any control
only intervention and no treatment control arms utilised.	

Table 130: Summary of findings table for the review of interventions informed by cognitive behavioural principles for family carers of people with a learning disability versus any control

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with any control	**Risk difference with Cognitive behavioural intervention**
Carer health and well-being (depression) - post-treatment	428 (5 RCTs)	⨁◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.35 fewer (0.54 fewer to 0.15 fewer)
Carer health and well-being (depression) - follow-up follow up: range 46 to 104 weeks to	130 (2 RCTs)	⨁◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.41 fewer (0.79 fewer to 0.04 fewer)
Carer health and well-being (clinically depressed) - post-treatment	111 (1 RCT)	⨁◯◯◯ VERY LOW [1,2,4]	RR 0.25 (0.08 to 0.84)	Study population	
				224 per 1000	168 fewer per 1000 (206 fewer to 36 fewer)
Carer health and well-being (anxiety, trait) - post-treatment	68 (2 RCTs)	⨁◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.5 fewer (1.03 fewer to 0.03 more)
Carer health and well-being (anxiety, state) - post-treatment	36 (1 RCT)	⨁◯◯◯ VERY LOW [2,4,5]	-	-	SMD 0.46 fewer (1.12 fewer to 0.2 more)
Carer health and well-being (mental ill health) - post-treatment	58 (1 RCT)	⨁◯◯◯ VERY LOW [2,4,5]	-	-	SMD 2.19 fewer (2.85 fewer to 1.53 fewer)
Carer health and well-being (quality of life) - post-treatment	58 (1 RCT)	⨁◯◯◯ VERY LOW [2,4,5]	-	-	SMD 0.87 more (0.33 more to 1.41 more)
Carer health and well-being (stress) - post-treatment	384 (3 RCTs)	⨁◯◯◯ VERY LOW [1,2,3,6]	-	-	SMD 0.45 fewer (0.78 fewer to 0.12 fewer)
Carer health and well-being (stress) - follow-up follow up: mean 104 weeks	76 (1 RCT)	⨁◯◯◯ VERY LOW [2,4,5]	-	-	SMD 0.43 fewer (0.9 fewer to 0.05 more)
Carer health and well-being (clinically stressed) - post-treatment	111 (1 RCT)	⨁◯◯◯ VERY LOW [2,4,5]	RR 0.13 (0.03 to 0.53)	Study population	
				293 per 1000	255 fewer per 1000 (284 fewer to 138 fewer)

Note

1. Most information is from studies at moderate risk of bias
2. Population not family carers of people with learning disabilities with no mental health problems.
3. Optimal information size not met

				Anticipated absolute effects	
Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Risk with any control	Risk difference with Cognitive behavioural intervention
4. Optimal information size not met; small, single study 5. Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect 6. $I^2 > 40\%$					

9.2.1.2 Psychosocial support for parents of children with a learning disability versus any control

There was 1 RCT (N=80) that met the eligibility criteria for this review: Davis 1991 (Davis & Rushton, 1991).

The paper used a home-based, family focused counselling scheme (Parent Advisor Scheme) for parents of children with a learning disability which involved psychosocial support in the form of a respectful negotiated partnership aimed to facilitate parental and family adaptation. An overview of this trial can be found in Table 131. Further information about both included and excluded studies, as well as all forest plots can be found in the challenging behaviour guideline (NICE, 2015).

Summary of findings can be found in Table 132. The full GRADE evidence profiles can be found in Appendix N.

No data were available for the critical outcomes of family and carer quality of life, mental and psychological health, and satisfaction.

9.2.1.3 Psychoeducation for parents of children with a learning disability versus any control

There were 2 RCTs (N=180) that met the eligibility criteria for this review and were included in a meta-analysis: Bilgin 2009 (Bilgin & Gozum, 2009), Yildirim 2013 (Yildirim et al., 2013).

Both papers used psychoeducation interventions for mothers of children with a learning disability. One paper used an information booklet followed by a 60 minute interactive lecture including information about the needs of intellectually disabled children and about how to provide appropriate care and cope with stress associated with caring for an intellectually disabled child (Bilgin 2009). The other study considered a group psychosocial educational program which was conducted once per week over four weeks; this involved a pre-interview to determine the type of support the mothers needed and the intervention consisted of developing an understanding of the needs of intellectually disabled children, communication techniques including communication with family and coping with stress, problem-solving methods, through role-play, question and answer format, and homework (Yildirim 2013).An overview of the trials included can be found in Table 131. Further information about both included and excluded studies, as well as all forest plots can be found in the challenging behaviour guideline (NICE, 2015).

Summary of findings can be found in Table 133. The full GRADE evidence profiles can be found in Appendix N.

No data were available for the critical outcomes of family and carer quality of life, and satisfaction.

Table 131: Study information table for trials included in the meta-analysis of psychosocial support and psychoeducation for parents of children with a learning disability versus any control

	Psychosocial support versus any control	Psychoeducation versus any control
Total no. of studies (N[1])	1 (80)	2 (180)
Study ID	Davis 1991	(1) Bilgin 2009 (2) Yildirim 2013
Country	UK	Turkey
Diagnosis	Learning disability	Learning disability
Carer age (mean)	33	(1) 34 (2) 42
Carer sex (% female)	100	(1, 2) 100
Carer ethnicity (% white)	65	Not reported
Treatment length (weeks)	66	(1) 1 (2) 4
Intervention	Parent Advisor Scheme	(1) Interactive education sessions (2) Psychosocial education programme
Comparison	Treatment as usual	(1) Waitlist (2) Treatment as usual
Note. [1] Number randomised.		

Table 132: Summary of findings table for the review of psychosocial support for parents of children with a learning disability versus any control

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with any control	Risk difference with Psychosocial support interventions
Carer health and well-being (stress) - post-treatment	28 (1 RCT)	⊕○○○ VERY LOW [1,2,3]	-	-	SMD 1.21 fewer (2.04 fewer to 0.39 fewer)

Note
1. Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect
2. Population not family carers of people with learning disabilities with no mental health problems.
3. Optimal information size not met; small, single study

Table 133: Summary of findings table for the review of psychoeducation for parents of children with a learning disability versus any control

Outcomes	№ of	Quality of	Relative	Anticipated absolute effects

	participants (studies) Follow-up	the evidence (GRADE)	effect (95% CI)	Risk with any control	Risk difference with Psychoeducation
Carer health and well-being (depression) - follow-up follow up: mean 4 weeks	75 (1 RCT)	⊕◯◯◯ VERY LOW[1,2,3]	-	-	SMD 0.84 fewer (1.31 fewer to 0.36 fewer)
Carer health and well-being (burnout) - follow-up follow up: mean 8 weeks	90 (1 RCT)	⊕◯◯◯ VERY LOW[1,2,3]	-	-	SMD 0.35 fewer (0.77 fewer to 0.06 more)

Note

1. Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect
2. Population not family carers of people with learning disabilities with no mental health problems.
3. Optimal information size not met; small, single study

9.2.1.4 Mindfulness versus any control for family carers and staff working with people with a learning disability

There were 3 RCTs (N=240) that met the eligibility criteria for this review and were included in a meta-analysis: Bethay 2013 (Bethay et al., 2013), McConachie 2014 (McConachie et al., 2014), Neece 2014 (Neece, 2014). An overview of the trials can be found in Table 134. Further information about both included and excluded studies, as well as all forest plots can be found in the challenging behaviour guideline (NICE, 2015).

There were 2 studies which considered mindfulness interventions for staff (Bethay et al., 2013) (McConachie et al., 2014) and one for parents (Neece, 2014). One paper for staff used ACT and applied behaviour analysis over 6 weeks which started with a mindfulness based exercise and a focus on mindfulness throughout the intervention (Bethay et al., 2013). Another paper used an Acceptance and Mindfulness Workshop, also based on ACT, followed by a refresher session after 6 weeks (McConachie et al., 2014). The paper for family carers used an intervention called mindfulness-based stress reduction including regular weekly sessions, a daylong medication retreat, and home practice.

Summary of findings for the outcome for staff can be found in Table 135 and the outcome for family carers can be found in Table 136. The full GRADE evidence profiles can be found in Appendix N

The study on family carers did not report a measure of variance so the findings are described narratively . Parent depression and distress decreased in the intervention group from baseline and increased after treatment in the control group from baseline. Satisfaction with life increased in both groups but the increase was larger in the intervention group.

No data were available for the critical outcomes of family and carer quality of life.

Table 134: Study information table for trials included in the analysis of mindfulness interventions for family carers and staff working with people with a learning disability versus any control

	Mindfulness versus any control
Total no. of studies (N[1])	2 (240)
Study ID	(1) Bethay 2013 (2) McConachie 2014 (3) Neece 2014[2]
Country	(1, 3) USA (2) UK
Diagnosis	(1,2) Learning disability (3) Developmental disability
Carer type	(1,2) staff (3) family carer (parent)
Carer age (mean)	(1) 38 (2) 43 (3) 35
Carer sex (% female)	(1) 77 (2) 26 (3) Not reported
Carer ethnicity (% white)	(1) 50 (2, 3) Not reported
Treatment length (weeks)	(1) 3 (2) 6 (3) 8
Intervention	(1) Mindfulness and acceptance-based work stress reduction intervention + applied behaviour analysis (2) Acceptance and Mindfulness Workshop (3) Mindfulness-based stress reduction
Comparison	(1) Treatment as usual/ applied behaviour analysis (2, 3) Waitlist

Note.
[1] Number randomised. [2] Data not reported in a meta-analysable format; findings are described narratively.

Table 135: Summary of findings table for the review of mindfulness versus any control for staff working with people with a learning disability

Outcomes	**№ of participants (studies) Follow-up**	**Quality of the evidence (GRADE)**	**Relative effect (95% CI)**	**Anticipated absolute effects**	
				Risk with any control	**Risk difference with Mindfulness interventions**
Carer health and well-being (mental well being) - post-treatment	120 (1 RCT)	⊕◯◯◯ VERY LOW[1,2,3]	-	-	SMD 0.17 more (0.19 fewer to 0.53 more)
Carer health and well-being (mental well being) - follow-up follow up: mean 6 weeks	120 (1 RCT)	⊕◯◯◯ VERY LOW[1,2,3]	-	-	SMD 0.28 more (0.08 fewer to 0.64 more)
Carer health and well-being (mental ill health) - post-treatment	154 (2 RCTs)	⊕◯◯◯ VERY LOW[2,3,4,5]	-	-	SMD 0.54 fewer (1.06 fewer to 0.02 fewer)
Carer health and well-being (mental ill	154 (2 RCTs)	⊕◯◯◯ VERY LOW	-	-	SMD 0.24 fewer (0.72 fewer to 0.24

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with any control	Risk difference with Mindfulness interventions
health) - follow-up follow up: range 6-13 weeks to		[2,3,4,5]			more)
Carer health and well-being (stress) - post-treatment	120 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.17 more (0.19 fewer to 0.53 more)
Carer health and well-being (stress) - follow-up follow up: mean 6 weeks	120 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.05 fewer (0.41 fewer to 0.31 more)
Carer health and well-being (burnout) - post-treatment	34 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.18 fewer (0.86 fewer to 0.49 more)
Carer health and well-being (burnout) - follow-up follow up: mean 13 weeks	34 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	-	-	SMD 0.08 fewer (0.76 fewer to 0.59 more)

Note

1. Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect
2. Population not family carers of people with learning disabilities with no mental health problems.
3. Optimal information size not met; small, single study
4. Most information is from studies at moderate risk of bias
5. $I^2 > 40\%$

Table 136: Summary of findings table for the review of mindfulness versus any control for parents working with children with a learning disability

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Impact
Carer health and well-being (mental well-being) - post-treatment assessed with: CES-D Total depression score follow up: 8 weeks	46 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	Parent depression appeared to decrease in the intervention group from baseline (from 17.86 to 11.67) and increase after treatment in the control group from baseline (from 17.53 to 22.0). (no variance reported)
Carer health and well-being (mental ill health) - post-treatment assessed with: PSI Parental Distress Subscale follow up: 8 weeks	46 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	Parent distress appeared to decrease in the intervention group from baseline (from 35.17 to 31.72) and also in the control group from baseline (from 38.28 to 37.61). However, the control group appeared to have higher distress at baseline. (no variance reported)
Carer health and well-being (satisfaction with life) - post-treatment (Satisfaction with Life	46 (1 RCT)	⊕◯◯◯ VERY LOW [1,2,3]	Satisfaction with life appeared to increase in both groups but the increased appeared larger in the intervention group (19.8 to 24.65 in the intervention group vs from

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Impact
Total Score) follow up: 8 weeks			18.41 to 19.42 in the control group). (no variance reported)
Note 1. Risk of selection, selective outcomes bias. 2. Population not family carers of people with learning disabilities with no mental health problems. 3. Optimal information size not met; small, single study			

9.2.2 Economic evidence

No studies assessing the cost effectiveness of interventions, training and support for family carers and staff caring for people with learning disabilities and mental health problems were identified by the systematic search of the economic literature undertaken for this guideline. The economic review completed for the NICE guideline on behaviour that challenges (NICE, 2015) which focused on interventions for family carers and staff of people with learning disabilities and behaviour that challenges did not identify any economic evidence either. Details on the methods used for the systematic search of the economic literature are described in Chapter 3.

9.2.3 Clinical evidence statements

9.2.3.1 Interventions informed by cognitive behavioural principles versus any control for family carers

- Very low-quality evidence from 5 studies (N=428) suggested that interventions informed by cognitive behavioural principles are more effective than the control in reducing depression in family carers at the end of the intervention. At up to 2 years’ follow-up, the intervention was similarly effective, but the evidence was from 2 studies (N=130) and graded as low quality.
- Very low-quality evidence from single studies with 111 participants at most, suggested that interventions informed by cognitive behavioural principles had a positive impact on other mental and psychological outcomes, quality of life and stress when compared with control.
- 2 trials could not be included in the meta-analysis (N=79). Greaves 1997 (N=37) reported that the intervention was more effective than no-treatment control in reducing stress. Conversely, Gammon 1991 (n = 42) reported no overall effect of the intervention, when compared with control, on dimensions of parental stress at the end of the intervention.

9.2.3.2 Psychosocial support versus any control for parents

- Very low-quality evidence from a single study (N=28) suggested that psychosocial support was more effective than control in reducing stress in parents of children with learning disabilities at end of the intervention.

9.2.3.3 Psychoeducation versus any control for parents

- Very low-quality evidence from single studies (N=75-90) suggested that psychoeducation was more effective than control in reducing depression and burnout in parents of children with learning disabilities at 4 to 8 weeks' follow-up.

9.2.3.4 Mindfulness versus any control for staff

- Very low-quality evidence from up to 2 studies (N=154) demonstrated some benefit in improving mental ill health of a mindfulness intervention in staff working with people with a mental health problems when compared with control at the end of the intervention, but was inconclusive regarding mental wellbeing, stress and burnout.

9.2.3.5 Mindfulness versus any control for parents

- Very low-quality evidence from up to 1 studies (N=46) demonstrated some benefit in improving mental ill health (both depression and distress) and satisfaction with life of a mindfulness intervention in parents of children with learning disabilities when compared with control at the end of the intervention.

9.2.4 Economic evidence statements

No economic evidence on interventions for interventions, training and support for family carers and staff caring for people with learning disabilities and mental health problems is available.

9.3 Recommendations and link to evidence

9.3.1 Interventions, training and support to improve the health and well-being of the family and staff as well as that of the person with learning disabilities

Recommendations	**76. Advise family members and carers about their right to the following and how to get them:** • **a formal assessment of their own needs (including their physical and mental health)** • **short breaks and other respite care.** **77. When providing support to family members (including siblings) and carers:** • **recognise the potential impact of living with or caring for a person with learning disabilities and a mental health problem** • **explain how to access:** o **family advocacy** o **family support and information groups** o **disability-specific support groups for family members or carers** • **provide skills training and emotional support, or information about how to access these, to help them take part in and**

	support interventions for the person with learning disabilities and a mental health problem. **78. If a family member or carer also has an identified mental health problem, offer:** • **interventions in line with the NICE guidelines on specific mental health problems (see mental health and behavioural conditions on the NICE website) or** • **referral to a mental health professional who can provide interventions in line with NICE guidelines.**
Relative values of different outcomes	The GC agreed that the following outcomes were critical: carer health and quality of life, carer satisfaction, relationship between carer and person being cared for (measured by observational measures of staff support of expressed emotion on the relationship).
Trade-off between clinical benefits and harms	The GC agreed that based on the available data there was reasonable evidence that some interventions for families and carers can have important benefits. While the data was not specific to people caring for family members with mental health problems, the GC were of the view that it was reasonable to infer from the evidence that interventions to support the family carers may be beneficial for them. Most studies were for family carers and only two studies were on the use of interventions for staff working with people with learning disabilities. All interventions appeared to show some benefit over placebo and no harms were reported within the studies. - Interventions informed by cognitive behavioural principles were effective at reducing depressive symptoms, stress and improving quality of life over control; the interventions may also be effective at reducing anxiety symptoms but the results for this were less clear. - Psychosocial support appears to be effective at reducing stress in parents of children with learning disabilities over control and psychoeducation was effective at reducing depressive symptoms and burnout in a similar populations; however, the studies comprising of this evidence were small in both number and size. - Mindfulness appears it may be more effective at improving mental well-being and reducing mental ill health in staff over control but it is less clear that it reduces stress and burnout in this population over control. Mindfulness appears to be more effective at reducing depressive symptoms and improving satisfaction with life in parents of children with learning disabilities but this was based on a small study. As the studies did not compare interventions with each other, it was not possible to draw conclusions about one intervention over another. While the studies reported no harms, the GC did not consider that interventions to improve health and well-being in family carers or staff would be likely to have adverse effects. The GC also agreed by informal consensus to make a recommendation that all parents and carers should be made aware of and offered a formal assessment of their own needs. (Although this is a statutory requirement for all services there was concern amongst the GC that some family members were not aware of this). Although there was evidence for the treatment of depression only, the GC agreed that it was important that those with identified mental health problems should be offered interventions in line with existing NICE guideline on mental health and behavioural conditions or should be referred to someone who can provide these interventions.
Trade-off between net health benefits	The GC acknowledged that provision of interventions for families and carers has some resource implications. However, they expressed the opinion that

and resource use	effective interventions for families and carers are likely value for money since they improve outcomes for families and carers and may consequently reduce healthcare resource utilisation associated with mental and psychological health problems experienced by families and carers, including depression and anxiety.
Quality of evidence	All of the outcomes from the evidence were very low quality. As the population in the studies was not in family carers or staff caring for people who had a mental health problem, it was downgraded as being an indirect population. The majority of the evidence was also downgraded because of risk of bias and small sample sizes. However, despite the limitations in the quality of evidence, support should offered to carers, if this is needed, and that they should be aware of the support that is available to them. The carers on the GC considered that it was essential that carers know what type of support is available to them.
Other considerations	The GC also noted that, from their experience, parent training is likely to have a positive benefit on the health of the parents as well and that the parent outcomes from the evidence on parent training supports this. However, parent outcomes were not extracted and quality assessed to be considered by the group. The GC considered that research on the use of interventions to improve the health and quality of life of family carers and staff caring for people with learning disabilities who also have mental health problems is needed.

9.3.2 Research recommendations

17. **What is the clinical and cost effectiveness of interventions for the health and well-being of family carers and staff caring for people with learning disabilities and mental health problems?**

10 Abbreviations

ABS	Adaptive Behaviour Scale
ACT	Acceptance and Commitment Training
ADHD	attention deficit hyperactivity disorder
AGREE	Appraisal of Guidelines for Research and Evaluation Instrument
ASD	autism spectrum disorder
AUC	area under the curve
BDI-II	Beck Depression Inventory
BILD	British Institute for Learning Disabilities
CBT	cognitive behavioural therapy
CDSR	Cochrane Database of Systematic Reviews
CENTRAL	Cochrane Central Register of Controlled Trials
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CPN	community psychiatric nurse
DARE	Cochrane Database of Abstracts of Reviews of Effects
DASH-II	Diagnostic Assessment for the Severely Handicapped-II
DBC-P	Developmental Behaviour Checklist
DMR	Dementia Questionnaire for Persons with Mental Retardation
DSM(-III, -IV, -5, -R, -TR)	Diagnostic and Statistical Manual of Mental Disorders (3rd edition, 4th edition, 5th edition, Revised, Text Revision)
DSQIID	Dementia Screening Questionnaire for Individuals with Intellectual Disabilities
Embase	Excerpta Medica Database
GAD	generalised anxiety disorder
GC	Guideline Committee
GDS(-CS, -LD)	Glasgow Depression Scale (for People with a Learning Disability, Carer Supplement)
GP	general practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HCR-20	Historical, Clinical, Risk Management-20
HIRU	Health Information Research Unit
HTA	Health Technology Assessment
ICD-10	International Statistical Classification of Diseases and Related Health Problems - 10th revised edition
IQ	intelligence quotient
IU	international unit
k	number of studies (K=Kappa statistics)
MEDLINE	Medical Literature Analysis and Retrieval System Online
M-iCBT	Manualised individual Cognitive Behavioural Therapy
n	number of participants
N	total number of participants
n/a	not applicable
NCCMH	National Collaborating Centre for Mental Health
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OCD	obsessive–compulsive disorder
ODD	oppositional defiant disorder
OIS	optimal information size
OR	odds ratio
P-AID	Psychopathology Checklists for Adults with Intellectual Disabilities
PAS-ADD	Psychiatric Assessment Schedule for Adults with Developmental Disabilities
PCL-R	Psychopathy Checklist – Revised
PICO	Population, Intervention, Comparison and Outcome

PIMRA	Psychopathology Inventory for Mentally Retarded Adults
PsycINFO	Psychological Information Database
PTSD	post-traumatic stress disorder
QALY	quality-adjusted life year
RCT	randomised controlled trial
ROC	receiver operator characteristic
RQ	review question
RR	risk ratio
SD	standard deviation
SDQ	Strengths and Difficulties Questionnaire
SE	standard error
SIB	Severe Impairment Battery
SMD	standardised mean difference
TAU	treatment as usual
VRAG	Violence Risk Appraisal Guide
WISC-R	Weschler Intelligence Scale for Children-Revised
XLMR	X-linked mental retardation

11 References

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