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Appendix A: Scope for the development of the clinical guideline

A.1 Guideline title

Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges

A.1.1 Short title

Challenging behaviour and learning disabilities

A.1.2 The remit

The Department of Health has asked NICE to prepare a clinical guideline on 'challenging behaviour in people with learning disability.'

A.2 Clinical need for the guideline

A.2.1 Epidemiology

a) Learning disabilities are heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood.

b) 'Learning disabilities' is the widely used and accepted term in the UK. It is a term that has been used in Department of Health documents such as Valuing people (2001) and is well understood by health and social care professionals in the UK. It will therefore be used in this guideline, even though it is recognised that 'intellectual disabilities' is becoming the more widely accepted term internationally. The World Health Organisation's International statistical classification of diseases and related health problems (10th revised edition) (ICD-10) currently uses the term 'mental retardation'. The group working on ICD-11, due to be published in 2015, has proposed that it amends this to 'intellectual developmental disorders'. DSM-V, published in May 2013, replaced the DSM-IV term 'mental retardation' with 'intellectual disability'.

c) ICD-10 defines 4 degrees of learning disability: mild (an IQ of 50–69), moderate (an IQ of 35–49), severe (an IQ of 20–34) and profound (an IQ of

less than 20). These categories have been criticised on the grounds that they omit any measure of social or adaptive functioning. In addition, it has been argued that in practice IQ scores are often uncertain in people with more severe learning disabilities. It is also widely recognised that IQ scores are not fixed throughout life, so provide only an approximate guide to intellectual ability. Accordingly, many health and social care professionals object to subdividing learning disabilities because such subdivisons create labels that are then used to describe people, often inaccurately. Moreover, there are numerous different ways of subdividing learning disabilities between and within countries (for example, in the UK ‘mild’ and ‘moderate’ learning disabilities/difficulties have different meanings in education services and in health services).

d) Whatever subdivisions are used, a person with a milder degree of learning disability may need support in only some areas (for example, budgeting, planning and time management). The more severe a person’s learning disability, the more likely the person is to have very limited communication skills and a very significantly reduced ability to learn new skills. Likewise, the more severe the learning disability, the more likely the person is to need support with daily activities such as dressing, washing, eating, and mobility. It is widely agreed that it is important to treat each person as an individual, with their own specific needs, and it is recognised that a broad and detailed assessment of needs is essential. This may include assessment of communication skills, which may well be important when there is behaviour that challenges.

e) Learning disabilities are pervasive and are different from specific learning difficulties such as dyslexia, which do not affect intellectual ability.

f) Some people with learning disabilities display behaviour that challenges. ‘Behaviour that challenges’ describes actions that often result from the interaction between individual and environmental factors. It includes aggression toward others, self-injury, stereotypic behaviour (such as rocking or hand flapping), disruptive or destructive behaviour and withdrawn behaviour. It can also include violence, arson or sexual abuse, thereby bringing the person into contact with the criminal justice system. The most

widely used definition of such behaviour is ‘culturally abnormal behaviour(s) of such intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use, or result in the person being denied access to, ordinary community facilities’[a]. Such behaviours increase the likelihood that restrictive and aversive management strategies will be used and can result in people being excluded from services and from ordinary community life.

g) The terms ‘challenging behaviour’ and ‘behaviour that challenges’ are deliberately designed to remind professionals that the behaviour is a challenge to services, families and carers. Neither term is intended to be a diagnosis. The behaviour may appear in some environments and not others, and the same behaviour may be considered challenging in some settings or cultures but not in others. ‘Challenging behaviour’ or ‘behaviour that challenges’ can therefore be seen as a socially constructed concept that is the product of individual and environmental factors interacting. In order for behaviour to be considered 'challenging’, it is necessary to take account of the environment in which it is occurring, its impact on others, and the capability of the staff/carers to support the person in that environment. Nevertheless, if such behaviour has serious consequences for the person or for other people, it is likely to be considered challenging in most settings in which it occurs.

h) Behaviour that challenges is relatively common among people with learning disabilities, although the criteria used to define it affect estimates of prevalence. Prevalence rates of 5–15% have been reported in people who are in contact with educational, health or social care services for people with learning disabilities. Substantially higher rates (30-40%) are found in people with learning disabilities who live in mental health hospitals than in those who live in the community.

i) Behaviour that challenges has been found to correlate with severity of learning disabilities, with a general trend toward an increased prevalence of

[a] Emerson C. (1995) Challenging Behaviour: Analysis and intervention in people with learning difficulties. Cambridge: Cambridge University Press.

such behaviour in people with more severe learning disabilities. This is not to say that behaviour that challenges never occurs in people with mild learning disabilities, but is known to be less common among this group (although when it does occur it can bring the person into contact with the criminal justice system). People with profound and multiple learning disabilities, who often have serious physical disabilities, may not be physically able to show some behaviours that challenge but may still show self-injurious behaviour.

j) Prevalence rates for behaviour that challenges in people with learning disabilities have also been found to be sensitive to age. The highest rates are observed during late adolescence (which may result from the difficulties experienced in transitions between services), falling to lower levels in later adulthood. Increases in the number of people living longer who acquire dementia may affect this pattern in the future.

k) There are likely to be a number of underlying factors that contribute to the likelihood of behaviour that challenges for people with learning disabilities, including communication difficulties, sensory impairments, sensory processing difficulties, physical or mental health problems, emotional difficulties, neuropsychiatric disorders, pervasive developmental disorders, phenotype-related behaviours, abuse, psychological trauma and attachment difficulties.

l) Behaviour that challenges also results from environmental factors (including social, physical and emotional environmental factors). In particular, the social environment has a major effect on rates of behaviour that challenges, and if people are cared for in environments that are inadequate in some way (for example, that do not respond well to their needs because of staff knowledge, training, awareness or attitudes), behaviour that challenges is likely to develop. Carers or staff can influence the occurrence of behaviour that challenges by providing or removing social attention and by presenting or removing demands and physical objects. Many other aspects of the environment are also known to have a major effect on behaviour that challenges, for example: neglect, abuse, quality of social interaction, lack of meaningful occupation, lack of sensory input, lack of choice, excessive noise, and crowded, barren, unresponsive and unpredictable environments.

m) The factors that contribute to the likelihood of behaviour that challenges for any one person are likely to be multiple and to involve physical, emotional and social environmental factors. Thorough assessments of the person and their environment are needed and functional analyses are likely to be useful to identify the relevant factors. Interventions are typically based on a formulation of the relevant factors for each person and may involve intervening at multiple levels (including at the physical, emotional and social environmental levels).

n) Behaviour that challenges affects the quality of life of the person and their family and carers. In the most extreme instances it may become difficult to take the person out of their home and into the community. This means the person may be living in a restrictive environment. Other people may be placed in restrictive environments to live, often for years at a time.

A.2.2 Current practice

a) Medication is the most common intervention used to manage behaviour that challenges. Although it may be effective for some people, it is considered by most professionals to be overused and there is a danger that it may simply sedate the person and lead to polypharmacy. A significant proportion of the antipsychotic medication given to people with learning disabilities is for the management of behaviour that challenges.

b) Behavioural techniques (including applied behaviour analysis and positive behaviour support, as well as cognitive behavioural therapy) are the next most commonly used interventions to manage behaviour that challenges. Such interventions normally include communication assessments and intervention strategies. However, the research evidence shows that most people with learning disabilities do not receive evidence-based interventions for behaviour that challenges.

c) Families provide the majority of support for most people with learning disabilities. Outside the families, the majority of support is funded by social services (for example, support for self-care, daily living, daytime activities and respite care, specialist equipment and adaptations). Most of this support is not directly provided by social services but by independent agencies (often

not-for-profit agencies). Increasingly the support is provided through personal budgets. In addition, children, young people and adults may receive education services (such as special needs education services in mainstream schools and colleges, services in special schools or classes in further education colleges). People whose behaviour challenges may also use additional specialist health services, which tend to be provided and organised by community teams. For children and young people these services are usually embedded in Child and Adolescent Mental Health Services teams, although many families report that services from these teams are variable. For adults, the specialist services are usually provided by Community Learning Disabilities Teams. The transition from child to adult services is often badly managed, as are other transitions (for example, to services for older people). Services are often lacking for adults with a mild learning disability who may have significant behaviour that challenges but are otherwise relatively able, because they may fall outside the Fair Access to Care Services criteria used by social services and the criteria used by the NHS.

d) In terms of living situations, people with learning disabilities whose behaviour challenges may be supported at home with their families, in residential services of various kinds (including residential special schools and residential services for adults) or in homes with their own tenancies (when adults), sometimes with the support of specialist teams. Severe behaviour that challenges is a common reason for long-term placement in residential special schools, assessment and treatment units or other settings. These are often located outside the person's area, sometimes hundreds of miles away. Such services may be run by independent agencies or by the NHS.

A.3 The guideline

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

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

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

A.4 Population

A.4.1 Groups that will be covered

a) Children, young people and adults with mild, moderate, severe or profound learning disabilities and behaviour that challenges, and their families and carers.

b) Special consideration will be given with regard to a number of equality issues. Please see equality impact assessment form – scoping for further details.

A.4.2 Care setting

a) The guideline will cover the care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.

A.5 Management and support

A.5.1 Key issues that will be covered

a) Anticipating and preventing behaviour that challenges in children, young people and adults with learning disabilities, including:

- identification of those at risk of developing behaviour that challenges
- methods and tools for personal assessment (including assessment of sensory deficits, sensory processing disorders, physical health status, communication needs, emotional needs, mental health needs)
- assessment of environmental factors, including the physical environment, the social environment, parent, carers and staff attitudes, skills and staff competence
- interventions to prevent the development of behaviour that challenges.

b) Assessment of children, young people and adults with learning disabilities who have already developed behaviour that challenges, including:

- methods and tools for assessment including assessment of sensory deficits, sensory processing disorders, physical health status,

communication needs, emotional needs and mental health needs, and individual and environmental risk factors

- assessment of environmental factors, including the physical environment, the social environment, parent, carers and staff attitudes, skills and staff competence
- functional assessment (including functional analysis) and formulation
- assessment of staff/carer stress and attributes that contribute to their capacity to support the person.

c) Interventions to reduce and manage behaviour that challenges, including:

- environmental changes (including physical and social environments)
- psychosocial interventions (including a broad range of therapies, such as communication interventions, applied behaviour analysis, positive behaviour support and cognitive behavioural therapy) for the short- and long-term reduction and management of behaviour that challenges
- pharmacological interventions for the short- and long-term reduction and management of behaviour that challenges
  Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual service users.
- interventions aimed at reducing health risks and increasing an individual's understanding of their physical illness or mental health problems, and thereby possibly reducing the contribution of untreated physical illness to the development and maintenance of behaviour that challenges
- interventions aimed at potentially offending behaviour
- reactive strategies, including safe and ethical use of restrictive interventions, such as physical restraint, mechanical restraint, confinement, containment and seclusion, and the alternatives to these.

d) Training or education needed to allow health and social care professionals, paid carers and families to provide good-quality services and carry out all the above interventions if these are evidence based.

e) Transitions between services

f) Interventions and support for family and carers (including paid carers) which aim to improve the health and well-being of the family and carers

g) Strategies to engage family and carers as a resource in the design, implementation and monitoring of interventions for the person with a learning disability.

A.6 Issues that will not be covered

a) Management of coexisting conditions, unless these affect interventions, management or support for people with learning disabilities and behaviour that challenges.

A.7 Main outcomes

a) Severity, frequency and duration of the targeted behaviour that challenges.

b) Adaptive functioning, including communication skills.

c) Mental and psychological health outcomes (such as mood and anxiety).

d) Quality of life.

e) Service user and carer satisfaction.

f) Effects on carer stress and resilience.

g) Adverse effects on other people with learning disabilities.

h) Rates of seclusion.

i) Rates of manual restraint.

j) Use of psychoactive medication.

k) Premature death.

l) Rates of placement breakdown.

m) Use of inpatient placements (including out-of-area placements).

A.8 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY) but a different unit of effectiveness may be used depending on the availability of appropriate clinical and utility data for people with learning disability and behaviour that challenges. The costs considered will usually be only from an NHS and personal social services (PSS) perspective, although economic analyses will attempt to incorporate wider costs associated with the care of people with learning disabilities and behaviour that challenges if appropriate cost data are available. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

A.9 Status

A.9.1 Scope

This is the final scope.

A.9.2 Timing

The development of the guideline recommendations will begin in July 2013.

A.10 Related NICE guidance

- Autism in adults. NICE clinical guideline 142 (2012).
- The epilepsies. NICE clinical guideline 137 (2012).
- Service user experience in adult mental health. NICE clinical guidance 136 (2011).
- Self-harm: longer-term management. NICE clinical guideline 133 (2011).
- Autism diagnosis in children and young people. NICE clinical guideline 128 (2011).
- Dementia. NICE clinical guideline 42 (2006).
- Self-harm. NICE clinical guideline 16 (2004).

A.10.1 Guidance under development

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

- Autism: the management and support of children and young people on the autism spectrum. NICE clinical guideline. Publication expected August 2013.
- Violence and aggression. NICE clinical guideline. Publication expected December 2014.

A.11 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

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

Information on the progress of the guideline will also be available from the NICE website.

Appendix B: Declarations of interests by Guideline Development Group members

With a range of practical experience relevant to behaviour that challenges in people with learning disabilities in the GDG, members were appointed because of their understanding and expertise in healthcare for people with behaviour that challenges in people with learning disabilities and support for their families and carers, including: scientific issues; health research; the delivery and receipt of healthcare, along with the work of the healthcare industry; and the role of professional organisations and organisations for people with learning disabilities and behaviour that challenges and their families and carers.

To minimise and manage any potential conflicts of interest, and to avoid any public concern that commercial or other financial interests have affected the work of the GDG and influenced guidance, members of the GDG must declare as a matter of public record any interests held by themselves or their families which fall under specified categories (see below). These categories include any relationships they have with the healthcare industries, professional organisations and organisations for people with learning disabilities and behaviour that challenges and their families/carers.

Individuals invited to join the GDG were asked to declare their interests before being appointed. To allow the management of any potential conflicts of interest that might arise during the development of the guideline, GDG members were also asked to declare their interests at each GDG meeting throughout the guideline development process. The interests of all the members of the GDG are listed below, including interests declared prior to appointment and during the guideline development process.

Categories of interest to be written in third person

- Paid employment
- Personal pecuniary interest: financial payments or other benefits from either the manufacturer or the owner of the product or service under consideration in this guideline, or the industry or sector from which the product or service comes. This includes holding a directorship or other paid position; carrying out consultancy or fee paid work; having shareholdings or other beneficial interests; receiving expenses and hospitality over and above what would be reasonably expected to attend meetings and conferences.
- Personal family interest: financial payments or other benefits from the healthcare industry that were received by a member of your family.
- Non-personal pecuniary interest: financial payments or other benefits received by the GDG member's organisation or department, but where the GDG member has not personally received payment, including fellowships and other support provided by the healthcare industry. This includes a grant or fellowship or other payment to sponsor a post, or contribute to the running costs of the department; commissioning of research or other work; contracts with, or grants from, NICE.
- Personal non-pecuniary interest: these include, but are not limited to, clear opinions or public statements you have made about Psychosis & Schizophrenia in Adults, holding office in a professional organisation or advocacy group with a direct interest in Psychosis & Schizophrenia in Adults, other reputational risks relevant to Psychosis & Schizophrenia in Adults.

Declarations of interest	
Glynis Murphy (Chair)	
Employment	Professor of Clinical Psychology & Disability, Co-Director of the Tizard Centre, University of Kent
Personal pecuniary interest	Until October 2012 I was employed (part-time) by the NHS I do conduct consultancy at times, for the NHS and sometimes for the police/lawyers (usually in relation to clients with challenging behaviour or offending behaviour), normally contracted for through the University of Kent Enterprise dept, and paid for through my University of Kent salary. I am co-editor of JARID, for which I receive a small annual payment from Wileys. Member of a CQC panel. Member of a NOMS accreditation panel.
Personal family interest	None
Non-personal pecuniary interest	I (and the Tizard Centre for which I am Co-Director) are in receipt of research grants from NIHR and elsewhere (eg charities). The Tizard Centre also runs training (undergraduate and postgraduate) for staff from Learning Disabilities services. I (and the Tizard Centre for which I am Co-Director) are in receipt of a research grant to look at the treatment of sexually abusive behaviour in young people with a learning disability.
Personal non-pecuniary interest	I have conducted research into challenging behaviour (see my CV). I chair an organisation called SOTSEC-ID which provides treatment for men with ID and sexually harmful behaviour (see www.kent.ac.uk/tizard/sotsec). This organisation also runs training for therapists. I was President of IASSIDD until 2012 and am now Immediate Past president and still involved in the running of IASSIDD (see www.iassidd.org)
Actions taken	None
Steve Pilling (Facilitator)	

Employment	Director, NCCMH
Personal pecuniary interest	None
Personal family interest	Medical research council MRC, research funding looking at Psilocibilyn. Grant from NARSAD to look at TCDS in treatment of depression
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
David Allen	
Employment	Clinical Director, Positive Response Training & Consultancy and Professor, Tizard Centre, University of Kent
Personal pecuniary interest	
Personal family interest	
Non-personal pecuniary interest	
Personal non-pecuniary interest	
Actions taken	
Katherine Andrea	
Employment	Senior Project Manager, NCCMH
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
David Branford	
Employment	Chief Pharmacist Derbyshire Healthcare Foundation NHS Trust (retired)
Personal pecuniary interest	Current -Chief Pharmacist Derbyshire Healthcare Foundation Trust Development on Guideline on Dysphagia in LD Supported by Rosemont Pharmaceuticals Opinion on Lisdexamphetamine Supported by Pharmacy management Pharmacy advisor to Castlebeck PLC Opinion on Lurasidone supported by Sunovion
Personal family interest	None
Non-personal pecuniary interest	PhD on antipsychotic drugs in learning disabilities Chairman of the English Pharmacy Board of the Royal Pharmaceutical Society

	Elected member of the College of Mental Health Pharmacy Editor of Frith Prescribing Guidelines for Adults with LD (no financial interest)
Personal non-pecuniary interest	None
Actions taken	None
Alick Bush	
Employment	Lead Psychologist, St Andrews Healthcare
Personal pecuniary interest	I am employed 0.6 wte by St Andrews Healthcare,a charity that provides inpatient care to adults with learning disabilities and autism. I provide a clinical psychology service to patients in the hospital.
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	I am the policy lead for the BPS Faculty of Learning Disabilities and as such have promoted the use of predominantly psycho-social interventions for adults who challenge services, including Positive Behaviour Support. I am the Chair of the Learning Disabilities Professional Senate- an alliance of the Professional Bodies that provide support to people with learning disabilities. Through this role I am the representative of the Professional Senate on the Learning Disability Programme Board. As a consequence, I am on a range of sub-committees and working groups that are responsible for delivering the *Transforming Care* action plan following the Winterbourne View review. This includes being a member of the Expert Advisory Group on the promotion of Positive Behaviour Support. I am co-editor of *Challenging Behaviour: a unified approach*.
Actions taken	None
Carole Buckley	
Employment	General Practitioner, The Old School Surgery
Personal pecuniary interest	Non Executive director GP Care (UK) Ltd. Private provider of NHS services to patients. Chair St Mathias holdings Ltd Practice based pharmacy offering services to residential care homes.
Personal family interest	None
Non-personal pecuniary interest	Member RCGP intellectual disability professional network. Clinical Champion for Autism by the Royal College of GPs. Joint recipient of a grant from Bristol university to

	implement focus groups for service users and carers in order to inform GP practice. Grant from the Academic Health Science Network SW to hold a conference in Taunton 19/11/14 for commissioners and providers of autism services.
Personal non-pecuniary interest	None
Actions taken	None
Vivien Cooper	
Employment	Carer representative/CEO, The Challenging Behaviour Foundation
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	Member, Transforming Care Assurance Board (formerly Winterbourne View JIB) Member, Engagement Steering Group for JI team (from June 2014 formerly Chair) Respond Steering Group for support for Winterbourne View families DH Advocacy Group DH Medication Collaborative Group, Steering Group CQC LD Advisory Group Hassiotis UCL PBS Research Group Tizard E-Pats Fellowship Steering Group Chair, CB-NSG Member, CDC Restrictive Physical Intervention Steering Group Member, DH WV Capital Funding Panel Member, LD Professional Senate Member, SSCR UCPRG Member, LD VCS Steering Group (July – November 2014) Member, Children & Young People Collaborative Steering Group
Actions taken	None

Jo Dwyer	
Employment	Clinical Specialist Occupational Therapist, Lewisham Team for Adults With Learning Disabilities, Guys and St Thomas's NHS Foundation Trust
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
David Glynn	
Employment	Health Economist, NCCMH (September 2014 onwards)
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Bronwyn Harrison	
Employment	Systematic Reviewer, NCCMH
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Angela Hassiotis	
Employment	Professor, UCL Hon Consultant Psychiatrist, Camden & Islington Foundation Trust
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	Current NIHR HTA grant on the evaluation of Positive Behaviour Support Honoraria received by Novartis for consultancy on treatments for Fragile X syndrome Other research funding (NIHR RfPB) Associate Editor of Journal of Policy and Practice in Intellectual and Developmental Disabilities Editorial Board of Advances in Mental Health Intellectual Disabilities Treasurer Faculty of the Psychiatry of Intellectual Disabilities Honoraria for lectures

Employment	Research Director, Research Autism
	Conducting a study looking at music therapy and people with a learning disability.
Personal non-pecuniary interest	I have published on challenging behaviour for some years following research carried out under my supervision
Actions taken	None
Phil Howell	
Employment	PIAS Manager and PBS Consultant, British Institute of Learning Disabilities
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Simon Jones	
Employment	Head of Behavioural Support, Care UK
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Elena Marcus	
Employment	Research Assistant, NCCMH (August 2014 onwards)
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Ifigeneia Mavranezouli	
Employment	Senior Health Economist, NCCMH
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Richard Mills	
Personal pecuniary interest	Commissioned to do work with Redbridge for training in clinical interviewing techniques for Approved Mental Health Professionals when working with individuals with Asperger's syndrome and autism.
Personal family interest	None

Non-personal pecuniary interest	Joint recipient of a grant from Bristol university to implement focus groups for service users and carers in order to inform GP practice.
Personal non-pecuniary interest	Royal Society of Medicine (RSM) International Society Autism Research (INSAR) Honorary research fellow at the department of psychology, University of Bath. Sen Research Fellow. Bond University. QLD Australia.
Actions taken	None
David Newton	
Employment	Team Manager, Adult Safeguarding Quality Assurance Team, Adult Social Care Directorate, Nottingham City Council
Personal pecuniary interest	Employed by a local authority. This employment involves liaison with local authority and local CCG contracts and commissioning groups and quality assurance. Some incidental input into local authority core contract and service specification content
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Steve Noone	
Employment	**Consultant Clinical Psychologist, Northumberland, Tyne and Wear Foundation NHS Trust**
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Cheryl Palmer	
Employment	Research Assistant, NCCMH
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Phil Perkins	
Employment	Senior Community Learning Disability Nurse for Children and Young People, Surrey and Borders Partnership NHS Foundation Trust
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None

Personal non-pecuniary interest	None
Actions taken	None
Victoria Slonims	
Employment	Senior Consultant Speech and Language Therapist; Honorary Senior Lecturer, Evelina Children's Hospital, Guy's and St Thomas' NHS Foundation Trust
Personal pecuniary interest	ADOS trainer
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Clare Taylor	
Employment	Senior Editor, NCCMH
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Craig Whittington	
Employment	Associate Director Associate Director (Clinical Effectiveness)/Senior Systematic Reviewer, NCCMH (September 2014 onwards)
Personal pecuniary interest	None
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None
Keith Wyncoll	
Employment	Carer representative
Personal pecuniary interest	Occasional trainer – The Challenging Behaviour Foundation Lay member of NHS England Patient and Public Voice Assurance Group - Specialised Commissioning
Personal family interest	None
Non-personal pecuniary interest	None
Personal non-pecuniary interest	None
Actions taken	None

Appendix C: Special advisors to the Guideline Development Group

Those who acted as advisors on specialist topics or have contributed to the process by meeting the Guideline Development Group:

- Gemma Griffiths, Bangor University
- Mieke Heyvaert, Katholieke Universiteit Leuven

Appendix D: Stakeholders who submitted comments in response to the consultation draft of the guideline

To be added post consultation.

Appendix E: Researchers contacted to request information about unpublished or soon-to-be published studies

Dr Ahmed
Dr Akhondzadeh
Dr Aman
Dr Amminger
Dr Amore
Dr Anderson
Dr Appleton
Dr Bagner
Dr Balthazer
Dr Bent
Dr Bilgin
Dr Braam
Dr Breau
Dr Brightman
Dr Camilleri
Dr Carr
Dr Chadwick
Dr Chan
Dr Coppola
Dr Cortesi
Dr Craft
Dr Davis
Dr Diament
Dr Dodge
Dr Durand
Dr Dykens
Dr Escalona
Professor Felce
Dr Feinberg
Dr Feldman
Dr Ferraioli
Dr Fitzgerald
Dr Gagiano
Dr Gammon
Dr Garstang
Dr Gençöz
Dr Ghanizadeh
Dr Gray
Dr Greaves
Dr Griffin
Dr Griffith
Dr Hagiliassis
Dr Hand
Dr Hardan
Dr Hassiotis
Dr Hellings
Dr Heyvaert
Dr Hollander
Dr Hudson
Dr Izmeth
Dr Jan
Dr Jocelyn
Dr Johnson
Dr Jones
Dr Kent
Dr Kirkham

Dr Kleefman
Dr Knapp
Dr Kwako
Dr Larson
Dr Lennox
Dr Leung
Dr Lindsay
Dr Lofthouse
Dr Lundqvist
Dr Lynch
Ms Iemmi
Dr Malt
Dr Marcus
Dr Martin
Dr McArthur
Dr Mcintyre
Dr McPhail
Dr Montgomery
Dr Morrissey
Dr Moss
Dr Neece
Dr Nezu
Dr Nixon
Dr O'Callaghan
Dr Oliva
Dr Owen
Dr Packman
Dr Piazza
Dr Piravej
Dr Plant
Dr Prieto-Bayard
Dr Quinsey
Dr Roberts
Dr Rojahn
Dr Roux
Dr Scahill
Dr Sallows
Dr Schuiringa
Dr Schultz
Dr Shapiro
Dr Shea
Dr Sigafoos
Dr Singer
Dr Singh
Dr Smith
Dr Snowden
Dr Sofronoff
Dr Stores
Dr Strain
Dr Synder
Dr Taffe
Dr Taylor
Dr Tonge
Dr Turk
Dr Tyrer
Dr Vaisanen
Dr Van Bellinghen
Dr Van Den Berg
Dr Vanden Borre
Dr Verbrugge
Dr Vohra
Dr Wasdell
Dr Weir
Dr White
Dr Whittingham
Dr Wiggs

Dr Wigram

Dr Wilcox

Dr Willner

Dr Wong

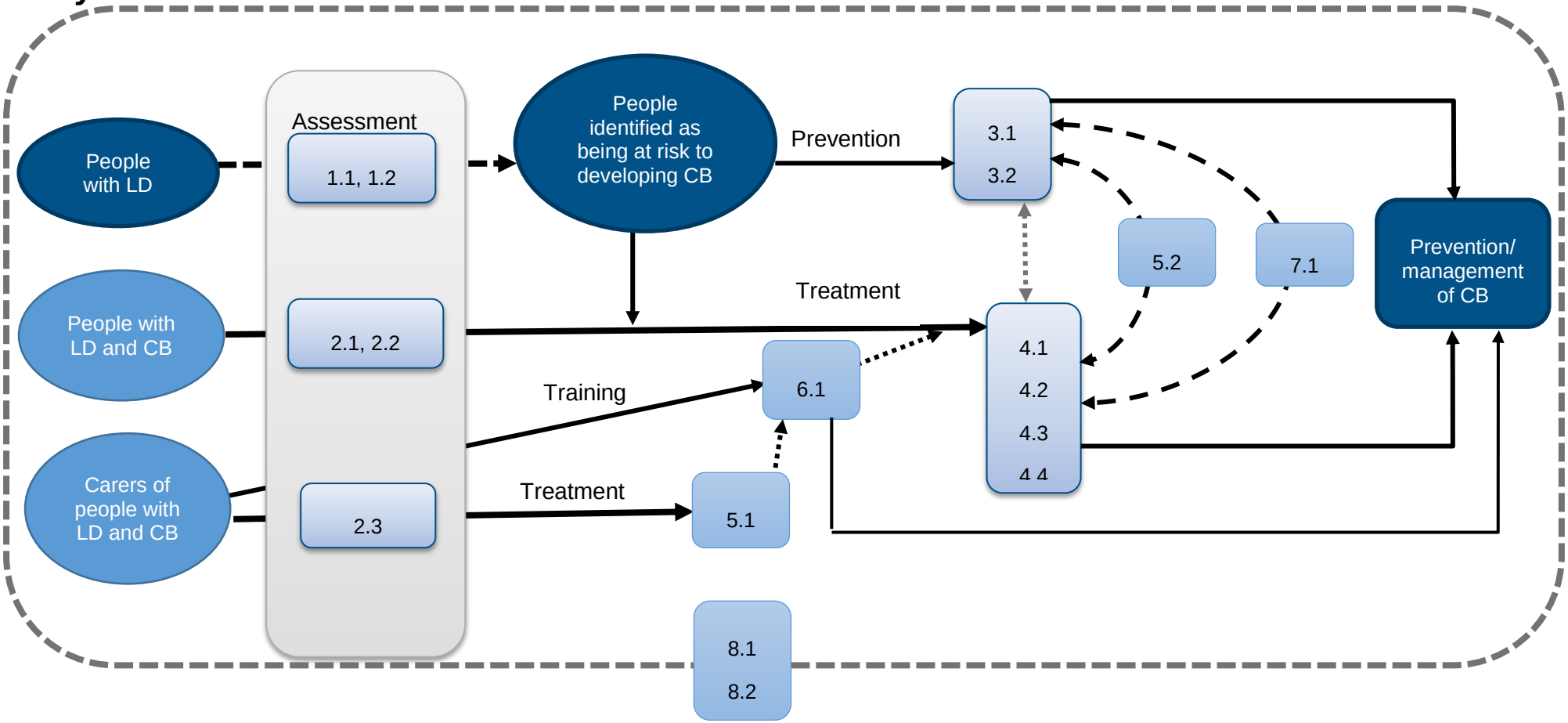
Dr Wright

Dr Yildrim

Dr Zarcone

Appendix F: Analytical framework, review questions and protocols

F.1 Analytical framework



F.2 Review questions

RQ	Review question
1.1	In people with a learning disability, what are the circumstances, risk factors and antecedents associated with the development of behaviour that challenges?
1.2	In people with a learning disability, what is the utility of methods and tools used to assess the circumstances, risk factors and antecedents associated with the development of behaviour that challenges (including assessment of sensory deficits, sensory processing disorders, physical health status, communication needs, emotional needs, mental health needs, and environmental factors)?
2.1	In people with a learning disability, what are the key components of, and the most effective structure for, an assessment of the behaviour that challenges across a range of settings? To answer this question, consideration should be given to: • methods of assessment (including functional analysis) • formal assessment tools/ psychological instruments (including risk assessment) • biological and physical health measures
2.2	In people with a learning disability and behaviour that challenges, what is the utility of methods and tools for assessment?
2.3	In carers of people with a learning disability and behaviour that challenges, what is the utility of methods used to assess and monitor their capacity to support the person? To answer this question, consideration should be given to the: • identification of appropriate carers • assessment of carers skills and capacity
3.1	In people with a learning disability, what are the benefits and potential harms of interventions (including early intervention) aimed at preventing the development of behaviour that challenges?
3.2	In people with a learning disability, and their carers, what are the benefits and potential harms of interventions aimed at reducing health risks and increasing understanding of physical illness or mental health problems in relation to the prevention or management of the behaviour that challenges?
4.1	In people with a learning disability and behaviour that challenges, what are the benefits and potential harms associated with environmental changes (including the physical and social environments) aimed at reducing and managing behaviour that challenges (including potentially offending behaviour)?
4.2	In people with a learning disability and behaviour that challenges, what are the benefits and potential harms associated with psychosocial interventions (including a broad range of therapies, such as communication interventions, applied behaviour analysis, positive behaviour support and cognitive behavioural therapy) aimed at reducing and managing behaviour that challenges (including potentially offending behaviour)?
4.3	In people with a learning disability and behaviour that challenges, what are the benefits and potential harms associated with pharmacological interventions aimed at reducing and managing behaviour that challenges (including potentially offending behaviour)?
4.4	In people with a learning disability and behaviour that challenges, what are the benefits and potential harms of 'reactive strategies' (including physical restraint, mechanical restraint, confinement, and containment and seclusion) aimed at managing behaviour that challenges?
5.1	In family and carers of people with a learning disability and behaviour that challenges, what are the benefits and potential harms of interventions aimed at improving their health and well-being?
5.2	What are the benefits and potential harms of strategies aimed at engaging the family and carers of people with a learning disability and challenging behaviour as a resource in the design, implementation and monitoring of interventions for the person with a learning

RQ	Review question
	disability and challenging behaviour?
6.1	What are the benefits and potential to allow health and social care professionals and carers to provide good-quality services and carry out evidence based interventions designed to reduce or manage behaviour that challenges in people with a learning disability?
7.1	In people with a learning disability and behaviour that challenges, what are the effective models for transition between services (for example child-adult, adult-older adult, NHS-social care/residential)? To answer this question, consideration should be given to: • the structure, design and delivery of care pathways • the nature and duration of support provided during transition.
8.1	In people with a learning disability and behaviour that challenges, what are their experiences of having a learning disability and behaviour that challenges, of access to services, and of treatment?
8.2	For the family carers of people with a learning disability and behaviour that challenges, what are their experiences of caring for people with a learning disability and behaviour that challenges, and what support is available for families, partners and carers?

F.3 Review protocols

F.3.1 Topic: Anticipation and identification

Item No.	Item	Details
1.	Review question(s) [15]*	RQ1.1: In people with a learning disability, what are the circumstances,risk factors and antecedents associated with the development of behaviour that challenges? RQ1.2: In people with a learning disability, what is the utility of methods and tools used to assess the circumstances, risk factors and antecedents associated with the development of behaviour that challenges (including assessment of sensory deficits, sensory processing disorders, physical health status, communication needs, emotional needs, environmental factors and mental health needs)?
2.	Sub-question(s)	–
3.	Searches [16]*	RQ1.1 (updates McLintock et al 2013) Major bibliographic databases: Embase (2003 to October 2014), MEDLINE/PreMEDLINE (2003 to October 2014), PsycINFO (2003 to October 2014) RQ1.2: Major bibliographic databases: Embase (inception to October 2014), MEDLINE/PreMEDLINE (inception to October 2014), PsycINFO (inception to October 2014) Note. Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published or made available in a full report. Other resources of evidence: • Reference lists of included studies • Registered stakeholders • Trial authors and drug companies • Trial registries (http://www.controlled-trials.com/ ; https://www.clinicaltrialsregister.eu) • PROSPERO (http://www.crd.york.ac.uk/Prospero/)

Item No.	Item	Details
		• Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been published in an English language journal will not be included in the review. • Note. Unpublished data will only be included where a full trial report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.
4.	Condition or domain being studied [18]*	Challenging behaviour and learning disabilities Definitions: Challenging behaviour: "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)." Learning disabilities: Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).
5.	Participants/ population [19]*	Children, young people and adults with a mild, moderate, severe or profound learning disability. Exclude coexisting conditions (unless these affect interventions, management or support for people with a learning disability and behaviour that challenges).
6.	Intervention(s), exposure(s) [20]*	Circumstances, risk factors and antecedents for challenging behaviour: Circumstance = A fact or condition connected with or relevant to an event or action Risk factor = a variable associated with an increased risk of disease/disorder Antecedent = anything that precedes another thing, especially the cause of the second thing. Methods and tools used to assess the circumstances, risk factors and antecedents associated with the development of behaviour that challenges: methods and tools for personal assessment (including assessment of sensory deficits, sensory processing disorders, physical health status, communication needs, emotional needs and mental health needs) assessment of environmental factors (including the physical environment, the social environment, parent, carers and staff

Item No.	Item	Details
		attitudes, skills and staff competence)
7.	Comparator(s)/ control [21]*	N/A
8.	Types of study to be included initially [22]*	RQ1.1: Any RQ1.2: Any Excluded studies that did not use instruments in English, to ensure greatest applicability to the UK.
9.	Context [23]*	Care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.
10.	Primary/Critical outcomes [24]*	RQ1.1: Correlation between risk factor and challenging behaviour RQ1.2: Clinical utility (including sensitivity and specificity) Definitions Clinical utility: the instrument should be feasible and implementable in a routine clinical care, especially primary care. The instrument should contribute to the identification of further assessment needs and inform decisions about referral to other services. Psychometric data: The instrument should have established reliability and validity. Psychometric properties of instruments that meet inclusion criteria will be evaluated according to the following criteria: Reliability • Inter-rater reliability – correlation between two raters (r ≥0.70) = relatively reliable. • Test-retest reliability – stability of the instrument as shown by the correlation between test scores in the same group of participants across two different times (r ≥0.70) = relatively reliable. • Internal consistency – the extent to which items measure a single construct (r ≥0.70 or α ≥0.50; k≥0.40) = relatively reliable. Validity ● Criterion validity – minimum r = 0.50 (or some suggest 0.30 to 0.40 is more reasonable). Criterion validity refers to the degree to which there is a relationship between the instrument and some other established standard of the measure of interest. There are two subtypes of criterion validity: (1) predictive validity (extent to which instrument scores are correlated with performance on some future criterion) and (2) concurrent validity (extent to which instrument scores are correlated with performance on a related criterion at the same time point). ● Construct validity r ≥0.50 or discrimination index = 0.3 to 0.7. Construct validity refers to the degree to which the instrument measures the construct. Construct validity includes two subtypes: (1) discriminant validity (degree to which the instrument differentiates between constructs that are different, such as cases and controls) and (2) convergent validity (correlation between

Item No.	Item	Details
		constructs that are similar).
11.	Secondary/Important, but not critical outcomes [25]*	N/A
12.	Data extraction (selection and coding) [26]*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. Data to be extracted:
13.	Risk of bias (quality) assessment [27]*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist.
14.	Strategy for data synthesis [28]*	RQ1.1 Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. RQ1.2: We will conduct pooled diagnostic accuracy meta-analyses on the sensitivity and specificity of methods and tools to assess the circumstances, risk factors and antecedents associated with the development of behaviour that challenges in people with a learning disability (dependent on available data). In the absence of adequate date, a narrative review of methods and tools to assess the circumstances,risk factors and antecedents will be conducted and guided by available evidence, current practice and GDG consensus (for example, the clinical utility of the tool and psychometric data evaluating its reliability and validity). If existing reviews are found, the review team with advice from the Guideline Development Group (GDG) will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations.

Item No.	Item	Details
15.	Analysis of subgroups or subsets [29] (including sensitivity analyses)	Subgroups include: Population: Children and young people; adults. Degree of learning disability: mild (an IQ of 50–69), moderate (an IQ of 35–49), severe (an IQ of 20–34) and profound (an IQ of less than 20). Form of challenging behaviour: Self-injurious behaviour (includes head-banging, scratching, pulling, eye poking, picking, grinding teeth, eating non-foodstuffs) Aggressive behaviour toward others (includes biting and scratching, hitting, pinching, grabbing, hair pulling, throwing objects, verbal abuse, screaming, spitting). Stereotyped behaviour (including repetitive movements, rocking, repetitive speech and repetitive manipulation of objects). Non-person directed behaviour (includes damage to property, hyperactivity, stealing, inappropriate sexualised behaviour, destruction of clothing, incontinence, lack of awareness of danger, withdrawal).

F.3.2 Topic: Monitoring and assessment

Item No.	Item	Details
1.	Review question(s) [15]*	RQ2.1: In people with a learning disability, what are the key components of, and the most effective structure for, an assessment of the behaviour that challenges across a range of settings? To answer this question, consideration should be given to: methods of assessment (including functional analysis) formal assessment tools/ psychological instruments (including risk assessment) biological and physical health measures RQ2.2: In people with a learning disability and behaviour that challenges, what is the utility of methods and tools for assessment? RQ2.3: In carers of people with a learning disability and behaviour that challenges, what is the utility of methods used to assess and monitor their capacity to support the person? To answer this question, consideration should be given to the: identification of appropriate carers assessment of carers skills and capacity
2.	Sub-question(s)	RQ#:
3.	Searches [16]*	RQ2.1: N/A; GDG consensus-based

Item No.	Item	Details
		RQ2.2, 2.3: Major bibliographic databases: Embase (inception to October 2014), MEDLINE/PreMEDLINE (inception to October 2014), PsycINFO (inception to October 2014) Note. Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published or made available in a full report. Other resources of evidence: • Reference lists of included studies • Registered stakeholders • Trial authors and drug companies • Trial registries (http://www.controlled-trials.com/ ; https://www.clinicaltrialsregister.eu) • PROSPERO (http://www.crd.york.ac.uk/Prospero/) • Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been published in an English language journal will not be included in the review. Note. Unpublished data will only be included where a full trial report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.
4.	Condition or domain being studied [18]*	Challenging behaviour and learning disabilities. Definitions: Challenging behaviour: "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)." Learning disabilities: Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).

Item No.	Item	Details
5.	Participants/ population [19]*	Children, young people and adults with a mild, moderate, severe or profound learning disability and their family carer and paid carers. Carers of people (children, young people and adults) with a learning disability and behaviour that challenges. The term 'carers' encompasses both family carers and paid carers. Definitions: • Family carer: ○ Has personal experience of caring for one or more persons with CBLD who is a family member; ○ Has personal contact with a family member who has CBLD, even though that individual may not reside in the family home; ○ Is not paid to have a personal, continuous relationship with a person with CBLD. ○ Not all family carers may be related by blood, but choose to support a person with a learning disability in the way described above. [Adapted from Ward, C. (2001). Family matters: counting families in. London: Department of Health.]' • Paid carer: ○ Is paid to care for one or more persons with CBLD. Exclude coexisting conditions (unless these affect interventions, management or support for people with a learning disability and behaviour that challenges).
6.	Intervention(s), exposure(s) [20]*	RQ2.1: Assessment of the behaviour that challenges RQ2.2: Methods and tools for assessment (including assessment of sensory deficits, sensory processing disorders, physical health status, communication needs, emotional needs, individual, environmental risk factors and mental health needs) Assessment of environmental factors (including the physical environment, the social environment, parent, carers and staff attitudes, skills and staff competence) RQ2.3: Methods used to assess and monitor family carers and paid carers capacity to support the person with a learning disability and behaviour that challenges
7.	Comparator(s)/ control [21]*	N/A
8.	Types of study to be included initially [22]*	RQ2.1: N/A; GDG consensus-based

Item No.	Item	Details
		RQ2.2: Any RQ2.3: Any Excluded studies that did not use instruments in English, to ensure greatest applicability to the UK.
9.	Context [23]*	Care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.
10.	Primary/Critical outcomes [24]*	RQ2.1: Clinical utility (including key components of, and the most effective structure for, an assessment of the behaviour that challenges across a range of settings) RQ2.2: Clinical utility (including sensitivity and specificity, utility and reliability) RQ2.3: Clinical utility (including sensitivity and specificity, utility and reliability) Definitions: • Clinical utility: the instrument should be feasible and implementable in a routine clinical care, especially primary care. The instrument should contribute to the identification of further assessment needs and inform decisions about referral to other services. • Psychometric data: The instrument should have established reliability and validity. • Psychometric properties of instruments that meet inclusion criteria will be evaluated according to the following criteria: • Reliability • Inter-rater reliability – correlation between two raters (r ≥0.70) = relatively reliable. • Test-retest reliability – stability of the instrument as shown by the correlation between test scores in the same group of participants across two different times (r ≥0.70) = relatively reliable. • Internal consistency – the extent to which items measure a single construct (r ≥0.70 or α ≥0.50; k≥0.40) = relatively reliable. • Validity • Criterion validity – minimum r = 0.50 (or some suggest 0.30 to 0.40 is more reasonable). • Criterion validity refers to the degree to which there is a relationship between the instrument and some other established standard of the measure of interest. There are two subtypes of criterion validity: (1) predictive validity (extent to which instrument scores are correlated with performance on some future criterion) and (2) concurrent validity (extent to which instrument scores

Item No.	Item	Details
		are correlated with performance on a related criterion at the same time point). • Construct validity r ≥0.50 or discrimination index = 0.3 to 0.7. Construct validity refers to the degree to which the instrument measures the construct. Construct validity includes two subtypes: (1) discriminant validity (degree to which the instrument differentiates between constructs that are different, such as cases and controls) and (2) convergent validity (correlation between constructs that are similar).
11.	Secondary/Important, but not critical outcomes [25]*	N/A
12.	Data extraction (selection and coding) [26]*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. Data to be extracted:
13.	Risk of bias (quality) assessment [27]*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist.
14.	Strategy for data synthesis [28]*	RQ2.1: The GDG will use a consensus-based approach to identify the key components of an effective assessment. RQ2.2-2.3: We will conduct pooled diagnostic accuracy meta-analyses on the sensitivity and specificity of methods and tools for assessment of people with challenging behaviour and a learning disability (dependent on available data). In the absence of adequate date, a narrative review of assessment methods and tools will be conducted and guided by a pre-defined list of consensus-based criteria (for example, the clinical utility of the tool and psychometric data evaluating its reliability and validity).
15.	Analysis of subgroups or subsets [29] (including sensitivity analyses)	Subgroups include: • Population: Children and young people; adults • Degree of learning disability: mild (an IQ of 50–69), moderate (an IQ of 35–49), severe (an IQ of 20–34) and profound (an IQ of less than 20). Form of challenging behaviour:

Item No.	Item	Details
		• Self-injurious behaviour (includes head-banging, scratching, pulling, eye poking, picking, grinding teeth, eating non-foodstuffs) • Aggressive behaviour toward others (includes biting and scratching, hitting, pinching, grabbing, hair pulling, throwing objects, verbal abuse, screaming, spitting). • Stereotyped behaviour (including repetitive movements, rocking, repetitive speech and repetitive manipulation of objects). • Non-person directed behaviour (includes damage to property, hyperactivity, stealing, inappropriate sexualised behaviour, destruction of clothing, incontinence, lack of awareness of danger, withdrawal).

F.3.3 Topic: Prevention Interventions

Item No.	Item	Details
1.	Review question(s) [15]*	RQ3.1: In people with a learning disability, what are the benefits and potential harms of interventions (including early intervention) aimed at preventing the development of behaviour that challenges? RQ3.2: In people with a learning disability, and their carers, what are the benefits and potential harms of interventions aimed at reducing health risks and increasing understanding of physical illness or mental health problems in relation to the prevention or management of the behaviour that challenges?
2.	Sub-question(s)	RQ#:
3.	Searches [16]*	RQ3.1,3.2: RCTs: Major bibliographic databases: CENTRAL (inception to October 2014), CINAHL (inception to October 2014), Embase (inception to October 2014), MEDLINE/PreMEDLINE (inception to October 2014), PsycINFO (inception to October 2014) Topic databases: AEI (inception to October 2014), ASSIA (inception to October 2014), BEI (inception to October 2014), ERIC (inception to October 2014), IBSS (inception to October 2014), SSCI (inception to October 2014), Sociological Abstracts (inception to October 2014), Social Services Abstracts (inception to October 2014) Systematic reviews of RCTs: Major bibliographic databases CDSR (1999 to October 2014), DARE (1999 to October 2014), CINAHL (1999 to October 2014), Embase (1999 to October 2014), MEDLINE/PreMEDLINE (1999 to October 2014), PsycINFO (1999 to October 2014)

Item No.	Item	Details
		Topic databases: AEI (1999 to October 2014), ASSIA (1999 to October 2014), BEI (1999 to October 2014), ERIC (1999 to October 2014), IBSS (1999 to October 2014), SSCI (1999 to October 2014), Sociological Abstracts (1999 to October 2014), Social Services Abstracts (1999 to October 2014) Note. Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published or made available in a full report. Other resources of evidence: • Reference lists of included studies • Registered stakeholders • Trial authors and drug companies • Trial registries (http://www.controlled-trials.com/ ; https://www.clinicaltrialsregister.eu) • PROSPERO (http://www.crd.york.ac.uk/Prospero/) • Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been published in an English language journal will not be included in the review. Note. Unpublished data will only be included where a full trial report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.

4.	Condition or domain being studied [18]*	Challenging behaviour and learning disabilities
		
		Definitions:
		• Challenging behaviour:
		  ○ "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)."
		• Learning disabilities:
		  ○ Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70),

Item No.	Item	Details
		significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).
5.	Participants/ population [19]*	Children, young people and adults with a mild, moderate, severe or profound learning disability. Exclude coexisting conditions (unless these affect interventions, management or support for people with a learning disability and behaviour that challenges). If some, but not all, of a study's participants are eligible for our review, we will ask the study authors for disaggregated data. If we are unable to obtain the appropriate disaggregated data, then we will include a study only if: i) the majority of the study participants are eligible or participants are eligible on average (e.g. the average IQ < 70) and; ii) the GDG feel that the study's overall quality and directness is applicable to the review question.
6.	Intervention(s), exposure(s) [20]*	Categorisation of intervention based on participants risk: • Universal prevention intervention: Inclusion of people with a learning disability that have not been identified on the basis of increased risk. • Selective prevention intervention: Inclusion of people with a learning disability was done of the basis of risk factors (e.g. biological, psychological, environmental or social) or a screening instrument based on risk factor research. • Indicated prevention (IP) intervention: Inclusion of people with a learning disability was done of the basis of high risk with minimal but detectable signs or symptoms foreshadowing the development of behaviour that challenges, but who do not meet criteria for behaviour problems at the current time. RQ 3.1: Psychosocial; Pharmacological; Environmental; Complex interventions (e.g. Combined psychological and pharmacological interventions) RQ3.2: Interventions aimed at reducing health risks and increasing an individual's and carers understanding of that persons physical illness or mental health problems, and thereby possibly reducing the contribution of untreated physical illness to the development and maintenance of behaviour that challenges. Excluded Interventions Studies including participants exhibiting clinical significant behaviour that challenges. Studies evaluating the process of interventions rather than outcomes (for example, uptake of programme)

Item No.	Item	Details
7.	Comparator(s)/ control [21]*	Treatment as usual No treatment, waitlist control, attention control Any alternative prevention intervention
8.	Types of study to be included initially [22]*	RCTs and systematic reviews of RCTs. Crossover randomised trials will be included only if data from the first phase is available. In the first instance, only data from RCTs or systematic reviews of RCTs will be included. If the GDG consider the RCT evidence to be limited in terms of quality, directness or quantity, the range of included studies will be expanded to systematic reviews of non-randomised studies (i.e. controlled before-after studies, interrupted time-series, small-n studies, observational studies). Such reviews will only be included if the review team and GDG agree that the systematic review of non-randomised studies is of adequate quality, completeness, and applicability to the NHS and to the scope of the guideline.
9.	Context [23]*	Care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.
10.	Primary/Critical outcomes [24]*	RQ3.1 Behaviour that challenges (Severity, frequency and duration) Adaptive functioning, including communication skills. Quality of life. Service user and carer satisfaction. RQ3.2 Behaviour that challenges (Severity, frequency and duration) Adaptive functioning, including communication skills. Quality of life. Mental and psychological health outcomes (such as mood and anxiety). Physical health outcomes Service user and carer understanding of health risks Service user and carer satisfaction. Premature death.
11.	Secondary/Important, but not critical outcomes [25]*	RQ3.1 Mental and psychological health outcomes (such as mood and anxiety).

Item No.	Item	Details
		Effects on carer stress and resilience. Adverse effects on other people with a learning disability. Rates of seclusion. Rates of manual restraint. Use of psychoactive medication. Premature death. Rates of placement breakdown. Use of inpatient placements (including out-of-area placements). RQ3.2 Effects on carer stress and resilience. Adverse effects on other people with a learning disability. Rates of seclusion. Rates of manual restraint. Use of psychoactive medication. Rates of placement breakdown. Use of inpatient placements (including out-of-area placements).
12.	Data extraction (selection and coding) [26]*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. Data to be extracted: Study characteristics (Study ID, Year, Intervention/comparison, Context or Setting, Recruitment location , Randomised N, Diagnosis, Target Behaviour, IQ Cut-off, Run In/ Washout, Inclusion/exclusion criteria, Group assignment [number of groups, randomisation, N cluster], Demographics [age, sex, race, IQ, etc], Funding, Publication type, References, Risk of bias [Sequence generation, Allocation concealment, Blinding, Missing outcome data, Selective outcome reporting])

Item No.	Item	Details
		Comparisons (N, N post-treatment, N follow up, Intervention, Target group, Dose type, Dose, Frequency, Duration) Outcomes (Outcome type, Outcome name, Data type, Rater, Weeks post-randomisation, Time point – phase, Outcome data [e.g., mean, SD, N, events]).
13.	Risk of bias (quality) assessment [27]*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
14.	Strategy for data synthesis [28]*	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the Guideline Development Group (GDG) will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations. Repeated observations on participants: If studies reports results for several periods of follow-up (e.g. 4 weeks, 12 weeks and 26 weeks post treatment) the longest follow-up from each study shall be utilised in analyses. If the GDG feel that periods of follow-up are sufficiently distanced by time, we shall consider defining several different outcomes, based on different periods of follow-up, and to perform separate analyses (e.g. short-term, medium-term and long-term follow-up). Method of dealing with missing data Because imputation of missing data in order to perform a full ITT analysis is controversial, only the results for available participants will be analysed in meta-analysis. However, for dichotomous outcomes a sensitivity analyses will be carried out whereby missing data will be imputed according to worst case scenario. Outcomes from the sensitivity analysis will only be presented if the ITT analysis differs significantly from the available case analysis. GRADE methods Whilst considering all of the below, our decisions will be based a greater amount on those studies that carry the greatest weight within the outcome. If weight is distributed equally, all studies shall be considered equally. Risk of bias: mark down 1 ROB if a single study demonstrates a crucial limitation for one criterion or some limitations for multiple,

Item No.	Item	Details
		OR if risk of bias across multiple studies is at moderate ROB; mark down 2 if there is a crucial limitation for one or more criteria within a study OR if risk of bias across multiple studies is at high ROB. Inconsistency: mark down 1 if I2 > 40%; mark down 2 if I2 > 75%. We shall also consider the variability in point estimates, overlap of CI and P-value (<0.05) in our decision. Indirectness:review applicability of intervention, population and comparison. Consider down grading if >33% of population is not relevant, if the intervention is not aimed primarily at reducing the targeted behaviour that challenges, or if the comparison may reduce our confidence in the effect. Imprecision: mark down 1 if optimal information size is not met with multiple studies (Guyatt, 2011); mark down 2 if optimal information size is not met with a single study. Publication bias: Where possible, use funnel plots to determine the presence of publication bias. If this is not possible, and we have a strong suspicion that publication bias is present, mark down a maximum of 1.
15.	Analysis of subgroups or subsets [29] (including sensitivity analyses)	Subgroups include: • Population: Children and young people; adults • Degree of learning disability: mild (an IQ of 50–69), moderate (an IQ of 35–49), severe (an IQ of 20–34) and profound (an IQ of less than 20). • Form of challenging behaviour: • Self-injurious behaviour (includes head-banging, scratching, pulling, eye poking, picking, grinding teeth, eating non-foodstuffs) • Aggressive behaviour toward others (includes biting and scratching, hitting, pinching, grabbing, hair pulling, throwing objects, verbal abuse, screaming, spitting). • Stereotyped behaviour (including repetitive movements, rocking, repetitive speech and repetitive manipulation of objects). • Non-person directed behaviour (includes damage to property, hyperactivity, stealing, inappropriate sexualised behaviour, destruction of clothing, incontinence, lack of awareness of danger, withdrawal). Sensitivity analyses: • Exclude RCT studies with <10 participants per arm

F.3.4 Topic: Treatment interventions/ management strategies

Item No.	Item	Details

Item No.	Item	Details
1.	Review question(s) [15]*	RQ4.1: In people with a learning disability and behaviour that challenges, what are the benefits and potential harms associated with environmental changes (including the physical and social environments) aimed at reducing and managing behaviour that challengesb? RQ4.2:In people with a learning disability and behaviour that challenges, what are the benefits and potential harms associated with psychosocial interventions (including a broad range of therapies, such as communication interventions, applied behaviour analysis, positive behaviour support and cognitive behavioural therapy) aimed at reducing and managing behaviour that challenges2? RQ4.3: In people with a learning disability and behaviour that challenges, what are the benefits and potential harms associated with pharmacological interventions aimed at reducing and managing behaviour that challenges2? RQ4.4: In people with a learning disability and behaviour that challenges, what are the benefits and potential harms of 'reactive strategies' (including physical restraint, mechanical restraint, confinement, and containment and seclusion) aimed at managing behaviour that challenges2?
2.	Sub-question(s)	RQ#:
3.	Searches [16]*	RQ4.1, 4.2, 4.3, 4.4 RCT: Major bibliographic databases: CENTRAL (inception to October 2014), CINAHL (inception to October 2014), Embase (inception to October 2014), MEDLINE/PreMEDLINE (inception to October 2014), PsycINFO (inception to October 2014) Topic databases: AEI (inception to October 2014), ASSIA (inception to October 2014), BEI (inception to October 2014), ERIC (inception to October 2014), IBSS (inception to October 2014), SSCI (inception to October 2014), Sociological Abstracts (inception to October 2014), Social Services Abstracts (inception to October 2014) Systematic reviews of RCTs: Major bibliographic databases

[b]Including potentially offending behaviour

Item No.	Item	Details
		CDSR (1999 to October 2014), DARE (1999 to October 2014), CINAHL (1999 to October 2014), Embase (1999 to October 2014), MEDLINE/PreMEDLINE (1999 to October 2014), PsycINFO (1999 to October 2014) Topic databases: AEI (1999 to October 2014), ASSIA (1999 to October 2014), BEI (1999 to October 2014), ERIC (1999 to October 2014), IBSS (1999 to October 2014), SSCI (1999 to October 2014), Sociological Abstracts (1999 to October 2014), Social Services Abstracts (1999 to October 2014) Note. Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published or made available in a full report. Other resources of evidence: • Reference lists of included studies • Registered stakeholders • Trial authors and drug companies • Trial registries (http://www.controlled-trials.com/ ; https://www.clinicaltrialsregister.eu) • PROSPERO (http://www.crd.york.ac.uk/Prospero/) • Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been published in an English language journal will not be included in the review. Note. Unpublished data will only be included where a full trial report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.
4.	Condition or domain being studied [18]*	Challenging behaviour and learning disabilities Definitions: • Challenging behaviour: ○ "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is

Item No.	Item	Details
		likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)." • Learning disabilities: ○ Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).
5.	Participants/ population [19]*	Children, young people and adults with a mild, moderate, severe or profound learning disability and behaviour that challenges. Exclude coexisting conditions (unless these affect interventions, management or support for people with a learning disability and behaviour that challenges). If some, but not all, of a study's participants are eligible for our review, we will ask the study authors for disaggregated data. If we are unable to obtain the appropriate disaggregated data, then we will include a study only if: i) the majority of the study participants are eligible or participants are eligible on average (e.g. the average IQ < 70) and; ii) the GDG feel that the study's overall quality and directness is applicable to the review question.
6.	Intervention(s), exposure(s) [20]*	Included interventions RQ4.1: Environmental changes (including the physical and social environments) RQ4.2: Psychosocial interventions (including a broad range of therapies, such as communication interventions, applied behaviour analysis, positive behaviour support and cognitive behavioural therapy) RQ4.3: Pharmacological interventions RQ4.4: 'Reactive strategies' (including physical restraint, mechanical restraint, confinement, and containment and seclusion) Excluded interventions Intervention that are not targeted at reducing/ managing behaviour that challenges. Studies evaluating the process of interventions rather than outcomes (for example, uptake of programme)
7.	Comparator(s)/ control [21]*	Treatment as usual No treatment, placebo, waitlist control, attention control

Item No.	Item	Details
		Any alternative management strategy
8.	Types of study to be included initially [22]*	RCTs and systematic reviews of RCTs. Crossover randomised trials will be included only if data from the first phase is available. In the first instance, only data from RCTs or systematic reviews of RCTs will be included. If the GDG consider the RCT evidence to be limited in terms of quality, directness or quantity, the range of included studies will be expanded to systematic reviews of non-randomised studies (i.e. controlled before-after studies, interrupted time-series, small-n studies, observational studies). Such reviews will only be included if the review team and GDG agree that the systematic review of non randomised studies is of adequate quality, completeness, and applicability to the NHS and to the scope of the guideline.
9.	Context [23]*	Care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.
10.	Primary/Critical outcomes [24]*	RQ4.1-4.3: Targeted behaviour that challenges* (Severity, frequency and duration) Adaptive functioning, including communication skills. Quality of life. Service user and carer satisfaction. Adverse events (for 4.3 only including sedation/solemnence/drowsiness, weight outcomes, prolactin level outcomes, seizures, study discontinuation due to adverse events, study discontinuation due to other reasons). RQ4.4: Targeted behaviour that challenges (Severity, frequency and duration) Rates of manual restraint. Rates of seclusion. Quality of life. Service user and carer satisfaction. *Including offending behaviour
11.	Secondary/Important, but not critical outcomes [25]*	RQ4.1-4.3: Mental and psychological health outcomes (such as mood and anxiety). Effects on carer stress and resilience.

Item No.	Item	Details
		Adverse effects on other people with a learning disability. Rates of seclusion. Rates of manual restraint. Use of psychoactive medication. Premature death. Rates of placement breakdown. Use of inpatient placements (including out-of-area placements). RQ4.4: Mental and psychological health outcomes (such as mood and anxiety). Adaptive functioning, including communication skills. Effects on carer stress and resilience. Adverse effects on other people with a learning disability. Use of psychoactive medication. Premature death. Rates of placement breakdown. Use of inpatient placements (including out-of-area placements).
12.	Data extraction (selection and coding) [26]*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. Data to be extracted: Study characteristics (Study ID, Year, Intervention/comparison, Context or Setting, Recruitment location , Randomised N, Diagnosis, Target Behaviour, IQ Cut-off, Run In/ Washout, Inclusion/exclusion criteria, Group assignment [number of groups, randomisation, N cluster], Demographics [age, sex, race, IQ, etc], Funding, Publication type, References, Risk of bias [Sequence generation, Allocation concealment, Blinding, Missing outcome data, Selective outcome reporting])

Item No.	Item	Details
		Comparisons (N, N post-treatment, N follow up, Intervention, Target group, Dose type, Dose, Frequency, Duration) Outcomes (Outcome type, Outcome name, Data type, Rater, Weeks post-randomisation, Time point – phase, Outcome data [e.g., mean, SD, N, events]).
13.	Risk of bias (quality) assessment [27]*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
14.	Strategy for data synthesis [28]*	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the Guideline Development Group (GDG) will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations. Repeated observations on participants: If studies reports results for several periods of follow-up (e.g. 4 weeks, 12 weeks and 26 weeks post treatment) the longest follow-up from each study shall be utilised in analyses. If the GDG feel that periods of follow-up are sufficiently distanced by time, we shall consider defining several different outcomes, based on different periods of follow-up, and to perform separate analyses (e.g. short-term, medium-term and long-term follow-up). Method of dealing with missing data Because imputation of missing data in order to perform a full ITT analysis is controversial, only the results for available participants will be analysed in meta-analysis. However, for dichotomous outcomes a sensitivity analyses will be carried out whereby missing data will be imputed according to worst case scenario. Outcomes from the sensitivity analysis will only be presented if the ITT analysis differs significantly from the available case analysis. GRADE methods Whilst considering all of the below, our decisions will be based a greater amount on those studies that carry the greatest weight within the outcome. If weight is distributed equally, all studies shall be considered equally. Risk of bias: mark down 1 ROB if a single study demonstrates a crucial limitation for one criterion or some limitations for multiple, OR if risk of bias across multiple studies is at moderate ROB; mark down 2 if there is a crucial limitation for one or more criteria

Item No.	Item	Details
		within a study OR if risk of bias across multiple studies is at high ROB. Inconsistency: mark down 1 if I2 > 40%; mark down 2 if I2 > 75%. We shall also consider the variability in point estimates, overlap of CI and P-value (<0.05) in our decision. Indirectness: review applicability of intervention, population and comparison. Consider down grading if >33% of population is not relevant, if the intervention is not aimed primarily at reducing the targeted behaviour that challenges, or if the comparison may reduce our confidence in the effect. Imprecision: mark down 1 if optimal information size is not met with multiple studies (Guyatt, 2011); mark down 2 if optimal information size is not met with a single study. Publication bias: Where possible, use funnel plots to determine the presence of publication bias. If this is not possible, and we have a strong suspicion that publication bias is present, mark down a maximum of 1.
15.	Analysis of subgroups or subsets [29] (including sensitivity analyses)	Subgroups include: Population: Children and young people; adults Degree of learning disability: mild (an IQ of 50–69), moderate (an IQ of 35–49), severe (an IQ of 20–34) and profound (an IQ of less than 20). Form of challenging behaviour: Self-injurious behaviour (includes head-banging, scratching, pulling, eye poking, picking, grinding teeth, eating non-foodstuffs) Aggressive behaviour toward others (includes biting and scratching, hitting, pinching, grabbing, hair pulling, throwing objects, verbal abuse, screaming, spitting). Stereotyped behaviour (including repetitive movements, rocking, repetitive speech and repetitive manipulation of objects). Non-person directed behaviour (includes damage to property, hyperactivity, stealing, inappropriate sexualised behaviour, destruction of clothing, incontinence, lack of awareness of danger, withdrawal). Sensitivity analyses: Exclude RCT studies with <10 participants per arm

F.3.5 Topic: Interventions for family and carers

Item No.	Item	Details
1.	Review question(s) [15]*	RQ5.1: In family and carers of people with a learning disability and behaviour that challenges, what are the benefits and potential harms of interventions aimed at improving their health and well-being? RQ5.2: What are the benefits and potential harms of strategies aimed at engaging the family and carers of people with a learning

Item No.	Item	Details
		disability and challenging behaviour as a resource in the design, implementation and monitoring of interventions for the person with a learning disability and challenging behaviour?
2.	Sub-question(s)	RQ#:
3.	Searches [16]*	RQ5.1, 5.2 RCT: Major bibliographic databases: CENTRAL (inception to October 2014), CINAHL (inception to October 2014), Embase (inception to October 2014), MEDLINE/PreMEDLINE (inception to October 2014), PsycINFO (inception to October 2014) Topic databases: AEI (inception to October 2014), ASSIA (inception to October 2014), BEI (inception to October 2014), ERIC (inception to October 2014), IBSS (inception to October 2014), SSCI (inception to October 2014), Sociological Abstracts (inception to October 2014), Social Services Abstracts (inception to October 2014) Systematic reviews of RCTs: Major bibliographic databases CDSR (1999 to October 2014), DARE (1999 to October 2014), CINAHL (1999 to October 2014), Embase (1999 to October 2014), MEDLINE/PreMEDLINE (1999 to October 2014), PsycINFO (1999 to October 2014) Topic databases: AEI (1999 to October 2014), ASSIA (1999 to October 2014), BEI (1999 to October 2014), ERIC (1999 to October 2014), IBSS (1999 to October 2014), SSCI (1999 to October 2014), Sociological Abstracts (1999 to October 2014), Social Services Abstracts (1999 to October 2014) Note. Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published or made available in a full report. Other resources of evidence: • Reference lists of included studies • Registered stakeholders • Trial authors and drug companies

Item No.	Item	Details
		• Trial registries (http://www.controlled-trials.com/ ; https://www.clinicaltrialsregister.eu) • PROSPERO (http://www.crd.york.ac.uk/Prospero/) • Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been published in an English language journal will not be included in the review. Note. Unpublished data will only be included where a full trial report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.
4.	Condition or domain being studied [18]*	Challenging behaviour and learning disabilities. Definitions: • Challenging behaviour: ○ "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)." • Learning disabilities: ○ Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).
5.	Participants/ population [19]*	Family and carers of children, young people or adults with a mild, moderate, severe or profound learning disability and behaviour that challenges. The term 'carers' encompasses both family carers and paid carers. Definitions: • Family carer: ○ Has personal experience of caring for one or more persons with CBLD who is a family member; ○ Has personal contact with a family member who has CBLD, even though that individual may not reside in the family home; ○ Is not paid to have a personal, continuous relationship with a person with CBLD. ○ Not all family carers may be related by blood, but choose to support a person with a learning disability in the way described above. [Adapted from Ward, C. (2001). Family matters: counting families in. London: Department of Health.]' • Paid carer:

Item No.	Item	Details
		○ Is paid to care for one or more persons with CBLD. Exclude family and carers of people with coexisting conditions (unless these affect interventions, management or support for family and carers of people with a learning disability and behaviour that challenges).
6.	Intervention(s), exposure(s) [20]*	Included interventions All interventions targeted at improving health and well-being of family and carers Excluded Interventions Interventions targeted at improving health and well-being of children, young people or adults with a learning disability and behaviour that challenges. Studies evaluating the process of interventions rather than outcomes (for example, uptake of programme)
7.	Comparator(s)/ control [21]*	Treatment as usual No treatment, waitlist control, attention control Any alternative management strategy
8.	Types of study to be included initially [22]*	RCTs and systematic reviews of RCTs. Crossover randomised trials will be included only if data from the first phase is available. In the first instance, only data from RCTs or systematic reviews of RCTs will be included. If the GDG consider the RCT evidence to be limited in terms of quality, directness or quantity, the range of included studies will be expanded to systematic reviews of non-randomised studies (i.e. controlled before-after studies, interrupted time-series, small-n studies, observational studies). Such reviews will only be included if the review team and GDG agree that the systematic review of non-randomised studies is of adequate quality, completeness, and applicability to the NHS and to the scope of the guideline. If no evidence is identified, formal methods of consensus shall be employed to ensure maximum transparency where possible.
9.	Context [23]*	Care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.
10.	Primary/Critical outcomes [24]*	RQ5.1 Family and carer quality of life. Family and carer mental and psychological health outcomes (such as mood and anxiety).

Item No.	Item	Details
		Family and carer stress and resilience. Family and carer satisfaction. RQ5.2 Severity, frequency and duration of the targeted behaviour that challenges. Quality of life. Family and carer stress and resilience. Use of inpatient placements (including out-of-area placements). Service user and carer satisfaction.
11.	Secondary/Important, but not critical outcomes [25]*	RQ5.1 Severity, frequency and duration of the targeted behaviour that challenges. Adaptive functioning, including communication skills. Mental and psychological health outcomes (such as mood and anxiety). Quality of life Adverse effects on other people with a learning disability. Rates of seclusion. Rates of manual restraint. Use of psychoactive medication. Premature death. Rates of placement breakdown. Use of inpatient placements (including out-of-area placements). RQ5.2 Adaptive functioning, including communication skills. Family and carer mental and psychological health outcomes (such as mood and anxiety). Mental and psychological health outcomes (such as mood and anxiety). Quality of life Adverse effects on other people with a learning disability. Rates of seclusion. Rates of manual restraint. Use of psychoactive medication.

Item No.	Item	Details
		Premature death. Rates of placement breakdown.
12.	Data extraction (selection and coding) [26]*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. Data to be extracted: Study characteristics (Study ID, Year, Intervention/comparison, Context or Setting, Recruitment location , Randomised N, Diagnosis, Target Behaviour, IQ Cut-off, Run In/ Washout, Inclusion/exclusion criteria, Group assignment [number of groups, randomisation, N cluster], Demographics [age, sex, race, IQ, etc], Funding, Publication type, References, Risk of bias [Sequence generation, Allocation concealment, Blinding, Missing outcome data, Selective outcome reporting]) Comparisons (N, N post-treatment, N follow up, Intervention, Target group, Dose type, Dose, Frequency, Duration) Outcomes (Outcome type, Outcome name, Data type, Rater, Weeks post-randomisation, Time point – phase, Outcome data [e.g., mean, SD, N, events]).
13.	Risk of bias (quality) assessment [27]*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
14.	Strategy for data synthesis [28]*	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the Guideline Development Group (GDG) will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations.

Item No.	Item	Details
		Repeated observations on participants: If studies reports results for several periods of follow-up (e.g. 4 weeks, 12 weeks and 26 weeks post treatment) the longest follow-up from each study shall be utilised in analyses. If the GDG feel that periods of follow-up are sufficiently distanced by time, we shall consider defining several different outcomes, based on different periods of follow-up, and to perform separate analyses (e.g. short-term, medium-term and long-term follow-up). Method of dealing with missing data Because imputation of missing data in order to perform a full ITT analysis is controversial, only the results for available participants will be analysed in meta-analysis. However, for dichotomous outcomes a sensitivity analyses will be carried out whereby missing data will be imputed according to worst case scenario. Outcomes from the sensitivity analysis will only be presented if the ITT analysis differs significantly from the available case analysis. GRADE methods Whilst considering all of the below, our decisions will be based a greater amount on those studies that carry the greatest weight within the outcome. If weight is distributed equally, all studies shall be considered equally. Risk of bias: mark down 1 ROB if a single study demonstrates a crucial limitation for one criterion or somelimitations for multiple, OR if risk of bias across multiple studies is at moderate ROB; mark down 2 if there is a crucial limitation for one or more criteria within a study OR if risk of bias across multiple studies is at high ROB. Inconsistency: mark down 1 if I2 > 40%; mark down 2 if I2 > 75%. We shall also consider the variability in point estimates, overlap of CI and P-value (<0.05) in our decision. Indirectness: review applicability of intervention, population and comparison. Consider down grading if >33% of population is not relevant, if the intervention is not aimed primarily at reducing the targeted behaviour that challenges, or if the comparison may reduce our confidence in the effect. Imprecision: mark down 1 if optimal information size is not met with multiple studies (Guyatt, 2011); mark down 2 if optimal information size is not met with a single study. Publication bias: Where possible, use funnel plots to determine the presence of publication bias. If this is not possible, and we have a strong suspicion that publication bias is present, mark down a maximum of 1.
15.	Analysis of subgroups or subsets [29] (including sensitivity analyses)	Subgroups include: Population: Family carers, paid carers. Definitions: • Family carer:

Item No.	Item	Details
		○ Has personal experience of caring for one or more persons with CBLD who is a family member; ○ Has personal contact with a family member who has CBLD, even though that individual may not reside in the family home; ○ Is not paid to have a personal, continuous relationship with a person with CBLD. ○ Not all family carers may be related by blood, but choose to support a person with a learning disability in the way described above. [Adapted from Ward, C. (2001). Family matters: counting families in. London: Department of Health.]' • Paid carer: ○ Is paid to care for one or more persons with CBLD. Sensitivity analyses: Exclude RCT studies with <10 participants per arm

F.3.6 Topic: Training or education

Item No.	Item	Details
1.	Review question(s) [15]*	RQ6.1: What are the benefits and potential harms of training and education programmes to allow health and social care professionals and carers to provide good-quality services and carry out evidence based interventions designed to reduce or manage behaviour that challenges in people with a learning disability?
2.	Sub-question(s)	RQ#:
3.	Searches [16]*	RCT: Major bibliographic databases: CENTRAL (inception to October 2014), CINAHL (inception to October 2014), Embase (inception to October 2014), MEDLINE/PreMEDLINE (inception to October 2014), PsycINFO (inception to October 2014) Topic databases: AEI (inception to October 2014), ASSIA (inception to October 2014), BEI (inception to October 2014), ERIC (inception to October 2014), IBSS (inception to October 2014), SSCI (inception to October 2014), Sociological Abstracts (inception to October 2014), Social Services Abstracts (inception to October 2014) Systematic reviews of RCTs: Major bibliographic databases CDSR (1999 to October 2014), DARE (1999 to October 2014), CINAHL (1999 to October 2014), Embase (1999 to October 2014),

Item No.	Item	Details
		MEDLINE/PreMEDLINE (1999 to October 2014), PsycINFO (1999 to October 2014) Topic databases: AEI (1999 to October 2014), ASSIA (1999 to October 2014), BEI (1999 to October 2014), ERIC (1999 to October 2014), IBSS (1999 to October 2014), SSCI (1999 to October 2014), Sociological Abstracts (1999 to October 2014), Social Services Abstracts (1999 to October 2014) Note. Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published or made available in a full report. Other resources of evidence: • Reference lists of included studies • Registered stakeholders • Trial authors and drug companies • Trial registries (http://www.controlled-trials.com/ ; https://www.clinicaltrialsregister.eu) • PROSPERO (http://www.crd.york.ac.uk/Prospero/) • Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been published in an English language journal will not be included in the review. Note. Unpublished data will only be included where a full trial report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.
4.	Condition or domain being studied [18]*	Challenging behaviour and learning disabilities Definitions: • Challenging behaviour: ○ "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)." • Learning disabilities:

Item No.	Item	Details
		○ Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).
5.	Participants/ population [19]*	Health and social care professionals, and carers of children, young people or adults with a mild, moderate, severe or profound learning disability and behaviour that challenges. The term 'carers' encompasses both family carers and paid carers. Definitions: • Family carer: ○ Has personal experience of caring for one or more persons with CBLD who is a family member; ○ Has personal contact with a family member who has CBLD, even though that individual may not reside in the family home; ○ Is not paid to have a personal, continuous relationship with a person with CBLD. ○ Not all family carers may be related by blood, but choose to support a person with a learning disability in the way described above. [Adapted from Ward, C. (2001). Family matters: counting families in. London: Department of Health.]' • Paid carer: ○ Is paid to care for one or more persons with CBLD. Exclude coexisting conditions (unless these affect interventions, management or support for people with a learning disability and behaviour that challenges).
6.	Intervention(s), exposure(s) [20]*	Included interventions Training and education programs to allow health and social care professionals and carers provide good-quality services and carry out evidence based interventions targeted at the reduction or management of behaviour that challenges. Excluded interventions Training or education programs not targeted at the reduction or management of behaviour that challenges.
7.	Comparator(s)/ control [21]*	Treatment as usual No treatment, waitlist control, attention control Any alternative management strategy
8.	Types of study to be included initially [22]*	RCTs and systematic reviews of RCTs. Crossover randomised trials will be included only if data from the first phase is available.

Item No.	Item	Details
		In the first instance, only data from RCTs or systematic reviews of RCTs will be included. If the GDG consider the RCT evidence to be limited in terms of quality, directness or quantity, the range of included studies will be expanded to systematic reviews of non-randomised studies (i.e. controlled before-after studies, interrupted time-series, small-n studies, observational studies). Such reviews will only be included if the review team and GDG agree that the systematic review of non randomised studies is of adequate quality, completeness, and applicability to the NHS and to the scope of the guideline.
9.	Context [23]*	Care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.
10.	Primary/Critical outcomes [24]*	Severity, frequency and duration of the targeted behaviour that challenges. Effects on carer stress and resilience. Quality of life. Fidelity (using validated measures only) Service user and carer satisfaction.
11.	Secondary/Important, but not critical outcomes [25]*	Adaptive functioning, including communication skills. Mental and psychological health outcomes (such as mood and anxiety). Adverse effects on other people with a learning disability. Rates of seclusion. Rates of manual restraint. Use of psychoactive medication. Premature death. Rates of placement breakdown. Use of inpatient placements (including out-of-area placements).
12.	Data extraction (selection and coding) [26]*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG. Data to be extracted:

Item No.	Item	Details
		Study characteristics (Study ID, Year, Intervention/comparison, Context or Setting, Recruitment location , Randomised N, Diagnosis, Target Behaviour, IQ Cut-off, Run In/ Washout, Inclusion/exclusion criteria, Group assignment [number of groups, randomisation, N cluster], Demographics [age, sex, race, IQ, etc], Funding, Publication type, References, Risk of bias [Sequence generation, Allocation concealment, Blinding, Missing outcome data, Selective outcome reporting]) Comparisons (N, N post-treatment, N follow up, Intervention, Target group, Dose type, Dose, Frequency, Duration) Outcomes (Outcome type, Outcome name, Data type, Rater, Weeks post-randomisation, Time point – phase, Outcome data [e.g., mean, SD, N, events]).
13.	Risk of bias (quality) assessment [27]*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
14.	Strategy for data synthesis [28]*	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the Guideline Development Group (GDG) will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations. Repeated observations on participants: If studies reports results for several periods of follow-up (e.g. 4 weeks, 12 weeks and 26 weeks post treatment) the longest follow-up from each study shall be utilised in analyses. If the GDG feel that periods of follow-up are sufficiently distanced by time, we shall consider defining several different outcomes, based on different periods of follow-up, and to perform separate analyses (e.g. short-term, medium-term and long-term follow-up). Repeated observations on participants: If studies reports results for several periods of follow-up (e.g. 4 weeks, 12 weeks and 26 weeks post treatment) the longest follow-up from each study shall be utilised in analyses. If the GDG feel that periods of follow-up are sufficiently distanced by time, we shall consider defining several different outcomes, based on different periods of follow-up, and to perform separate analyses (e.g. short-term, medium-term and long-term follow-up).

Item No.	Item	Details
		Method of dealing with missing data Because imputation of missing data in order to perform a full ITT analysis is controversial, only the results for available participants will be analysed in meta-analysis. However, for dichotomous outcomes a sensitivity analyses will be carried out whereby missing data will be imputed according to worst case scenario. Outcomes from the sensitivity analysis will only be presented if the ITT analysis differs significantly from the available case analysis. GRADE methods Whilst considering all of the below, our decisions will be based a greater amount on those studies that carry the greatest weight within the outcome. If weight is distributed equally, all studies shall be considered equally. Risk of bias: mark down 1 ROB if a single study demonstrates a crucial limitation for one criterion or some limitations for multiple, OR if risk of bias across multiple studies is at moderate ROB; mark down 2 if there is a crucial limitation for one or more criteria within a study OR if risk of bias across multiple studies is at high ROB. Inconsistency: mark down 1 if I2 > 40%; mark down 2 if I2 > 75%. We shall also consider the variability in point estimates, overlap of CI and P-value (<0.05) in our decision. Indirectness: review applicability of intervention, population and comparison. Consider down grading if >33% of population is not relevant, if the intervention is not aimed primarily at reducing the targeted behaviour that challenges, or if the comparison may reduce our confidence in the effect. Imprecision: mark down 1 if optimal information size is not met with multiple studies (Guyatt, 2011); mark down 2 if optimal information size is not met with a single study. Publication bias: Where possible, use funnel plots to determine the presence of publication bias. If this is not possible, and we have a strong suspicion that publication bias is present, mark down a maximum of 1.
15.	Analysis of subgroups or subsets [29] (including sensitivity analyses)	Subgroups include: Population: Health and social care professionals, family carers, paid carers. Sensitivity analyses: Exclude RCT studies with <10 participants per arm

F.3.7 Topic: Organisation and delivery of care

Item No.	Item	Details

Item No.	Item	Details
1.	Review question(s) [15]*	RQ7.1: In people with a learning disability and behaviour that challenges, what are the effective models for transition between services (for example child-adult, adult-older adult, NHS-social care/residential)? To answer this question, consideration should be given to: the structure, design and delivery of care pathways the nature and duration of support provided during transition
2.	Sub-question(s)	RQ#:
3.	Searches [16]*	RCT: Major bibliographic databases: CENTRAL (inception to October 2014), CINAHL (inception to October 2014), Embase (inception to October 2014), MEDLINE/PreMEDLINE (inception to October 2014), PsycINFO (inception to October 2014) Topic databases: AEI (inception to October 2014), ASSIA (inception to October 2014), BEI (inception to October 2014), ERIC (inception to October 2014), IBSS (inception to October 2014), SSCI (inception to October 2014), Sociological Abstracts (inception to October 2014), Social Services Abstracts (inception to October 2014) Systematic reviews of RCTs: Major bibliographic databases CDSR (1999 to October 2014), DARE (1999 to October 2014), CINAHL (1999 to October 2014), Embase (1999 to October 2014), MEDLINE/PreMEDLINE (1999 to October 2014), PsycINFO (1999 to October 2014) Topic databases: AEI (1999 to October 2014), ASSIA (1999 to October 2014), BEI (1999 to October 2014), ERIC (1999 to October 2014), IBSS (1999 to October 2014), SSCI (1999 to October 2014), Sociological Abstracts (1999 to October 2014), Social Services Abstracts (1999 to October 2014) Note. Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published or made available in a full report. Other resources of evidence: • Reference lists of included studies • Registered stakeholders

Item No.	Item	Details
		• Trial authors and drug companies • Trial registries (http://www.controlled-trials.com/ ; https://www.clinicaltrialsregister.eu) • PROSPERO (http://www.crd.york.ac.uk/Prospero/) • Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been published in an English language journal will not be included in the review. Note. Unpublished data will only be included where a full trial report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.

4.	Condition or domain being studied [18]*	Challenging behaviour and learning disabilities.
		
		Definitions:
		• Challenging behaviour:
		  ○ "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)."
		• Learning disabilities:
		  ○ Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).

5.	Participants/ population [19]*	Children, young people and adults with a mild, moderate, severe or profound learning disability and behaviour that challenges Exclude coexisting conditions (unless these affect interventions, management or support for people with a learning disability and behaviour that challenges).
6.	Intervention(s), exposure(s) [20]*	Models for transition between services
7.	Comparator(s)/ control [21]*	Treatment as usual No treatment, waitlist control, attention control Any alternative management strategy
8.	Types of study to be	RCTs and systematic reviews of RCTs.

Item No.	Item	Details
	included initially [22]*	Crossover randomised trials will be included only if data from the first phase is available. In the first instance, only data from RCTs or systematic reviews of RCTs will be included. If the GDG consider the RCT evidence to be limited in terms of quality, directness or quantity, the range of included studies will be expanded to systematic reviews of non-randomised studies (i.e. controlled before-after studies, interrupted time-series, small-n studies, observational studies). Such reviews will only be included if the review team and GDG agree that the systematic review of non randomised studies is of adequate quality, completeness, and applicability to the NHS and to the scope of the guideline.
9.	Context [23]*	Transition between services (for example child-adult, adult-older adult, NHS-social care/residential)
10.	Primary/Critical outcomes [24]*	Severity, frequency and duration of the targeted behaviour that challenges. Quality of life. Rates of placement breakdown. Use of inpatient placements (including out-of-area placements). Effects on carer stress and resilience. Service user and carer satisfaction.
11.	Secondary/Important, but not critical outcomes [25]*	Adaptive functioning, including communication skills. Mental and psychological health outcomes (such as mood and anxiety). Adverse effects on other people with a learning disability. Rates of seclusion. Rates of manual restraint. Use of psychoactive medication. Premature death.
12.	Data extraction (selection and coding) [26]*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG.

Item No.	Item	Details
		Data to be extracted: Study characteristics (Study ID, Year, Intervention/comparison, Context or Setting, Recruitment location , Randomised N, Diagnosis, Target Behaviour, IQ Cut-off, Run In/ Washout, Inclusion/exclusion criteria, Group assignment [number of groups, randomisation, N cluster], Demographics [age, sex, race, IQ, etc], Funding, Publication type, References, Risk of bias [Sequence generation, Allocation concealment, Blinding, Missing outcome data, Selective outcome reporting]) Comparisons (N, N post-treatment, N follow up, Intervention, Target group, Dose type, Dose, Frequency, Duration) Outcomes (Outcome type, Outcome name, Data type, Rater, Weeks post-randomisation, Time point – phase, Outcome data [e.g., mean, SD, N, events]).
13.	Risk of bias (quality) assessment [27]*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist. The quality of evidence for each outcome will be assessed using the GRADE approach.
14.	Strategy for data synthesis [28]*	Where appropriate, meta-analysis using a random-effects model will be used to combine results from similar studies. Alternatively, a narrative synthesis will be used. If existing reviews are found, the review team with advice from the Guideline Development Group (GDG) will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations.
15.	Analysis of subgroups or subsets [29] (including sensitivity analyses)	Subgroups include: Population: Children and young people; adults Degree of learning disability: mild (an IQ of 50–69), moderate (an IQ of 35–49), severe (an IQ of 20–34) and profound (an IQ of less than 20). Form of challenging behaviour: Self-injurious behaviour (includes head-banging, scratching, pulling, eye poking, picking, grinding teeth, eating non-foodstuffs, Aggressive behaviour toward others (includes biting and scratching, hitting, pinching, grabbing, hair pulling, throwing objects, verbal abuse, screaming, spitting). Stereotyped behaviour (including repetitive movements, rocking, repetitive speech and repetitive manipulation of objects). Non-person directed behaviour (includes damage to property, hyperactivity, stealing, inappropriate sexualised behaviour,

Item No.	Item	Details
		destruction of clothing, incontinence, lack of awareness of danger, withdrawal).

F.3.8 Topic: Experience of care

Item No.	Item	Details
1.	Review question(s)*	RQ8.1: In people with a learning disability and behaviour that challenges, what are their experiences of having a learning disability and behaviour that challenges, of access to services, and of treatment? RQ8.2: For the family carers of people with a learning disability and behaviour that challenges, what are their experiences of caring for people with a learning disability and behaviour that challenges, and what support is available for families, partners and carers?
2.	Sub-question(s)	N/A
3.	Searches*	Q8.1, 8.2 Major bibliographic databases CINAHL (1999 to October 2014), Embase (1999 to October 2014), MEDLINE/PreMEDLINE (1999 to October 2014), PsycINFO (1999 to October 2014) Topic databases: AEI (1999 to October 2014), ASSIA (1999 to October 2014), BEI (1999 to October 2014), ERIC (1999 to October 2014), IBSS (1999 to October 2014), SSCI (1999 to October 2014), Sociological Abstracts (1999 to October 2014), Social Services Abstracts (1999 to October 2014) Other resources of evidence: • Reference lists of included studies • PROSPERO (http://www.crd.york.ac.uk/Prospero/) • Conference abstracts will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in full. • Non-English language papers (with English abstracts) will be assessed for eligibility and potentially eligible studies will be checked to determine if they have been published in an English language journal. Studies that have not been

Item No.	Item	Details
		published in an English language journal will not be included in the review. Note. Unpublished data will only be included where a full study report is available with sufficient detail to properly assess the risk of bias. Authors of unpublished evidence will be asked for permission to use such data, and will be informed that summary data from the study and the study's characteristics will be published in the full guideline.
4.	Condition or domain being studied	Challenging behaviour and learning disabilities Definitions: • Challenging behaviour: ○ "Culturally abnormal behaviour(s) of such an intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities (Emerson, 1995)." • Learning disabilities: ○ Heterogeneous conditions, but are defined by 3 core criteria: lower intellectual ability (usually defined as an IQ of less than 70), significant impairment of social or adaptive functioning and onset in childhood. This corresponds to 'mental retardation' as described in the major taxonomies DSM IV (APA 1994) and ICD 10 (WHO, 1992).
5.	Perspective	RQ8.1 People with a learning disability and behaviour that challenges RQ8.2 Family carer of people with a learning disability and behaviour that challenges. Definition of family carer: Has personal experienceof caring for one or more persons with CBLD who is a family member; Has personal contact with a family member who has CBLD, even though that individual may not reside in the family home; Is not paid to have a personal, continuous relationship with a person with CBLD. Not all family carers may be related by blood, but choose to support a person with a learning disability in the way described above. [Adapted from Ward, C. (2001). Family matters: counting families in. London: Department of Health.]'
6.	Phenomenon of interest	RQ8.1 The individuals experiences of i) having a learning disability and behaviour that challenges, ii) of access to services, andiii) of treatment. RQ8.2: The family carers experiences of i) caring for people with a learning disability and behaviour that challenges, ii) the support available.

Item No.	Item	Details
7.	Comparison	• Usual care • No intervention.
8.	Types of study to be included initially	Systematic reviews and qualitative research.
9.	Setting	Care and shared care provided or commissioned by health and social care, in whatever care setting the person resides.
10.	Primary outcome/ Evaluation	RQ8.1 Experience of having a learning disability and behaviour that challenges Experience of access to services Experience of treatment RQ8.2 Experience of caring for people with a learning disability and behaviour that challenges Experience of the support available
11.	Data extraction (selection and coding)*	Citations from each search will be downloaded into EndNote and duplicates removed. Records will then be screened against the eligibility criteria of the review. The unfiltered search results will be saved and retained for future potential re-analysis. All primary-level studies included after the first scan of citations will be acquired in full and re-evaluated for eligibility at the time they are being entered into a study database (standardised template created in Microsoft Excel). Eligibility will be confirmed by at least one member of the Guideline Development Group (GDG). The GDG are experts in the topic and/or research methodology. Two researchers will extract data into the study database, comparing a sample of each other's work for reliability. Discrepancies or difficulties with coding will be resolved through discussion with members of the GDG.
12.	Risk of bias (quality) assessment*	The quality of individual studies will be assessed using the appropriate NICE quality assessment checklist.
13.	Strategy for data synthesis*	Thematic synthesis will be used. If existing reviews are found, the review team with advice from the Guideline Development Group (GDG) will assess their quality, completeness, and applicability to the NHS and to the scope of the guideline. If the GDG agree that a systematic review appropriately addresses a review question, we will search for studies conducted or published since the review was conducted, and the GDG will assess if any additional studies could affect the conclusions of the previous review. If new studies could change the conclusions, we will update the review and conduct a new analysis. If new studies could not change the conclusions of an existing review, the GDG will use the existing review to inform their recommendations.

Item No.	Item	Details
14.	Analysis of subgroups or subsets	N/A

Appendix G: Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

G.1 Preventing the development of behaviour that challenges in children aged under 5 years with a learning disability

Can positive behaviour support provided for children aged under 5 years with a learning disability reduce the risk of developing behaviour that challenges?

G.1.1 Why this is important

Behaviour that challenges is common in children with a learning disability and can have a considerable impact on them and their family members or carers. It is a common reason for residential placement with associated high costs. Positive behaviour support aims to reduce behaviour that challenges and increase quality of life through teaching new skills and adjusting the environment to promote positive behaviour changes. Early intervention with children at risk of developing behaviour that challenges offers an opportunity to significantly enhance their life and that of their family members or carers.

The question should be addressed by a programme of research that includes:

- developing interventions to prevent the onset of behaviour that challenges in children aged under 5 years at risk of behaviour that challenges
- testing the feasibility of the formal evaluation of the interventions in a randomised controlled trial
- testing the clinical and cost effectiveness of the interventions in a large scale randomised controlled trial with long-term follow up
- testing the implementation of the interventions in routine care.

G.2 Interventions to reduce the frequency and extent of moderate to severe behaviour that challenges

Are applied behavioural analysis interventions and antipsychotic medication, or a combination of these, effective in reducing the frequency and severity of behaviour that challenges in adults with a learning disability?

G.2.1 Why this is important

Behaviour that challenges is common in adults with a learning disability and can have a considerable impact on them and their family members or carers. It is also a common reason for hospital or residential placement. There is limited evidence for the effectiveness of either applied behavioural analysis or antipsychotic medication, or a combination of these. Little is known about which people respond best to which interventions or about the duration of the interventions. There is considerable evidence of the over use of medication and of limited skills and competence in delivering behavioural interventions.

The question should be addressed by a programme of research evaluating these interventions that includes:

- developing a protocol for the assessment of moderate to severe behaviour that challenges that:

  - characterises the nature and function of the behaviour
  - assesses all coexisting problems that may contribute to the behaviour developing or being maintained
- developing protocols for delivering and monitoring the interventions to be tested (including how any currently provided interventions will be stopped)
- testing the feasibility of the formal evaluation of the interventions in a randomised controlled trial (in particular, recruitment)
- testing the comparative clinical effectiveness (including moderators and mediators) and cost effectiveness of the interventions in a large-scale randomised controlled trial.

G.3 Locally accessible residential care

Does providing care where people live compared with out-of-area placement lead to improvements in both the clinical and cost effectiveness of care for people with a learning disability and behaviour that challenges?

G.3.1 Why this is important

Many out-of-area care placements for people with a learning disability and behaviour that challenges are a long way from their home. This can have a considerable impact, limiting a family member or carer's ability to care for the person and leading to poorer outcomes and increased costs. It is widely recognised that locally accessible residential placements would be beneficial and reduce costs but there is no strong empirical evidence to support this.

The question should be addressed by a programme of research that includes:

- a needs assessment and the care costs of a representative national consecutive cohort of 250 people who have been placed in out-of-area care in a 2-year period
- developing standards for a range of support programmes designed to meet people's needs, which would provide detailed information on:
  - the needs to be meet
  - the nature of the residential environments
  - the support, including specialist staff, needed
- testing the clinical and cost effectiveness of 'close to home' residential placements that meet the developed standards (compared with consecutive cohorts in out-of-area placements)
- establishing a national register of people who need out-of-area placement.

G.4 Factors associated with sustained, high-quality residential care

What factors (including service management, staff composition, training and supervision, and the content of care and support) are associated with sustained high-quality residential care for people with a learning disability and behaviour that challenges?

G.4.1 Why this is important

The quality of residential care for people with a learning disability and behaviour that challenges remains an issue of national concern. Reviews (most recently of Winterbourne View Hospital) have identified failings in care. Although recommendations have been made this has not led to a significant and sustained improvement in care. It is important to understand how improvement can be maintained.

The question should be addressed by a programme of research that includes:

- a systematic review of the factors associated with sustained and beneficial change in health and social care organisations
- designing service-level interventions to support the implementation of these factors
- testing the clinical and cost effectiveness of sustainable service-level interventions in a randomised controlled trial of residential units that are identified as performing poorly or well (the follow-up period should be for a minimum of 3 years after the implementation of the intervention).