A realist review of interventions used to prevent and reduce the use of restrictive practices on adults with learning disabilities in NHS and independent sector settings (LEARN)

RESEARCH PROTOCOL

October 2020

This study/project is funded by the National Institute for Health Research (NIHR) [NIHR HS&DR Ref 129524]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Contents

1. FULL TITLE OF PROJECT

A realist review of interventions used to prevent and reduce the use of restrictive practices on adults with learning disabilities in NHS and independent sector settings (**LEARN**)

2. SCIENTIFIC ABSTRACT

Research question

What are the mechanisms that work to reduce the use of restrictive practices on adults with learning disabilities in NHS and independent sector settings? This includes adults with learning disabilities who also have autism or mental health co-morbidities.

Background

Despite national and international guidelines and political and public pressure to reduce and prevent the use of restrictive practices on vulnerable populations, these are still common. Restrictive practices can include the use of observation, seclusion, physical restraint, mechanical restraint, rapid tranquilisation and/or other chemical restraint (RRN, 2019). Recent data point to a significant 50% increase in the use of restrictive practices on adults with learning disabilities in English hospitals (NHS Digital, 2018). A number of interventions have been implemented in healthcare services over the last decade to address this issue - Positive Behaviour Support (PBS), Safewards, the Six Core Strategies, REsTRAIN Yourself. Despite their widespread use, there is no unifying theory that explains how or why these methods are supposed to 'work' in reducing the use of restrictive practices. This review will fill a gap in the evidence base by developing programme theories of why current interventions work and do not work in preventing and/or reducing restrictive practices with this vulnerable population.

Aims and objectives

The overall aim of this review is to gain a deeper understanding of how, why, for whom, and in what circumstances interventions used to prevent and reduce the use of restrictive practices on adults with learning disabilities are most successful.

Methods

To address these objectives, a realist review will be conducted according to RAMESES guidelines (Wong et al., 2013). The realist review will focus on 'how' interventions work and under what circumstances approaches to prevent and/or reduce restrictive practices work. We will use a realist logic of analysis to align data from 4 project phases with context mechanism outcome configurations (CMOs):

1. formulating mid-level theories in the form of CMO configurations;
2. conducting a systematic search of literature;
3. testing and refining programme theories; and
4. developing recommendations and disseminating findings.

Timelines for delivery

We estimate the project will take 22 months to complete, starting in September 2020.

Anticipated impact and dissemination

Involvement of experts by experience and other stakeholders in the review will allow for better knowledge transfer throughout. We have 2 experts by experience co-applicants leading on and engaging in dissemination of findings amongst and on behalf of carers and service users via their connections with Positive and Active Behaviour Support Scotland (PABSS), Dimensions UK, Learning

Disability England, Learning Disability Partnership Board, Restraint Reduction Network (RRN), BILD, and the Tizard Centre. Once completed, we will share the findings of our project in a number of ways through social media such as Twitter, TV and radio broadcasting, in journals, presenting at conferences and writing reports. Given the high profile nature of this issue we anticipate that there will be a need and thirst for further research in this area, policy development, media coverage and further public lobbying based upon our findings. We are well placed nationally and internationally through our current networks and reach to have significant impact and to drive information exchange opportunities.

3. BACKGROUND AND RATIONALE

3.1. Challenging behaviour and restrictive practices

Approximately 1.5 million people in the UK have a learning disability (LD) with approximately 70% of this population also on the autism spectrum (Mental Health Foundation, 2019). A learning disability begins in childhood and primarily affects learning and comprehension (and therefore intellect), whilst autism is a neurological disorder (also called Autistic Spectrum Disorder or ASD) that affects learning delays and social awareness (Connelly, 2007; BPS, 2012). In addition to ASD, individuals within a primary diagnosis of LD could have a number of other co-morbidities such as epilepsy, schizophrenia and delusional disorders, bipolar affective disorder, depressive disorder, anxiety disorders, specific phobias such as agoraphobia, obsessive compulsive disorder, dementia and personality disorders. It is estimated that approximately 40% of adults with LD also experience mental health problems; this is more than double the rate of mental health problems in the general population (Alexander et al., 2011; Mencap, 2019; McManus et al., 2009). Moreover, adults with LD and/or ASD can present with behavioural challenges that become a risk to themselves or others (Challenging Behaviour Foundation, 2018; Department of Health, 2014a; British Psychological Society, 2012; Royal College of Psychiatrists, 2018). These can include aggressive behaviour directed towards other people, self-harm, and some behaviours which are considered socially unacceptable or offending behaviours. This overlap between learning disabilities, autism, mental illness, and challenging behaviour (as shown in Figure below) point to the complex needs of these individuals and the difficulty of addressing these needs within just one service/setting.

Challenging behaviour is a result of multiple complex interactions between the person's individual needs, caregivers and staff training, and the care quality and the environment (Brosnan and Healy, 2011; NICE, 2015). The unified healthcare definition of challenging behaviour is "behaviour with such intensity, frequency and/or duration as to threaten the quality of life, and/or physical safety of the individual or others and is likely to lead to responses that are restrictive, aversive or result in exclusion reducing quality of life" (Royal College of Psychiatrists, British Psychological Society and Royal College of Speech and Language Therapists, 2007). Evidence suggests that challenging behaviour is the foremost characteristic associated with incidents of restrictive practices such restraint in LD settings (78% prevalence) (Fitzpatrick et al., n.d.) This includes restricting physical movement of the person through physical, mechanical and/or chemical restraint, limiting choice and environmental liberties, restricting accessible areas and/or isolating them from others, rapid tranquillisation and/or long-term sedation, physical abuse, placement breakdown and out-of-area placements (Royal College of Psychiatrists, British Psychological Society and Royal College of Speech and Language Therapists, 2007).

Terminology

The terms 'restrictive practices' and 'restrictive interventions' are often used interchangeably, although they are not always mutually inclusive. There is no one agreed definition of restrictive practices or interventions, but they all advocate for approaches that address a person's human rights. In this proposal, we will use the term 'restrictive practices' to focus upon practices including observation, seclusion, physical restraint, mechanical restraint, and rapid tranquilisation and other chemical restraint" (Restraint Reduction Network 2019: 159). Restrictive practices are defined here as "deliberate acts on the part of other person(s) that restrict an individual's movement, liberty and/or freedom to act independently" (Department of Health, 2014a: 14).

People who have experienced restrictive practices such as restraint describe them as frightening, traumatising, feeling like it 'broke their spirit' and have displayed after-restraint symptoms of post-traumatic stress disorder (Strout, 2010). The families, carers and staff often report frustration, physical injury, reduced quality of life and burnout from their caring roles (Hastings and Brown, 2002; Lecavalier, Leone, and Wiltz, 2006).

3.2. Positive Behaviour Support (PBS)

Challenging behaviour was historically treated as the individual's problem requiring professional help from psychiatrists and psychologists (McGill, Vanono, Clover, 2018). This implied purposeful, non-compliant and aggressive actions implicitly blaming one's character. Following repeated health service failures to protect the population's most vulnerable (incl. the Winterbourne View scandal) (Bubb, 2014), NHS and independent sector settings for people with learning disabilities and autism or mental health co-morbidities underwent a systemic change in philosophy and direction (Dunlap, Carr, and Horner, 2008; Dunlap et al., 2009). Henceforth, person-centred valued-led approaches have emerged, taking the focus off the individual's 'problematic' manifestation and onto the central independent variable – the environment in which the behaviour occurs (McGill, et al., 2018; Hastings, et al., 2002).

NICE guidance (NICE, 2015) used the term "capable environment" to endorse a set of positive behaviour support (PBS) approaches implemented in services including person-centred choices, routine and predictable environments, positive social interactions, independence and personalised routines/activities (O'Reilly et al., 2007; Brown, 1991; Department of Health, 2014a, 2014b; McLaughlin and Carr, 2005). Positive Behaviour Support (PBS) is a multi-faceted approach currently used in mental health, LD, ASD and social care settings (Gore et al., 2013). PBS informed practices are prevention focused, taking a lifespan perspective, including the individual in their care planning, with a view to improve a person's quality of life and community integration. Behavioural support interventions adopting a PBS or 'biopsychopharmacosocial' approach are currently being implemented to reduce challenging behaviours and the burden/costs associated with it, as well as to improve the patient experience, while protecting their human rights and dignity (Hext, Clarke, and Xyrichis, 2019). Research trends have followed the evolving multiple biological, pharmaceutical, psychological and social components of challenging behaviour's theoretical framework. While older research typically tackles only one component (pharmaceutical and/or psychological (Rana, Gormez, and Varghese, 2013), newer research attempts to tackle multiple root causes of challenging behaviour (McQuire et al., 2015; Niven et al., 2018; Williams and Grossett, 2011; Hewitt, Keeling, and Pearce, 2016). The focus is mainly on self-harming (Rana et al., 2013; Bethel and Beail, 2013) and/or aggression (Brosnan et al., 2011; Kitchen, Thomas, and Chester, 2014).

Recent research focuses mainly on reducing physical restraint, seclusion and the use of chemical/medical restraint by implementing a number of interventions including positive behavioural support plans, post-incident reviews and staff training (Allen et al., 2013; Cockerton, 2015; Whyte, 2016; Clark et al., 2017; Reeves, 2017).

3.3. Evidence regarding effectiveness of interventions used to reduce the use of restrictive practices on people with learning disabilities

We conducted a recent scoping review (March 2019, no time limit) to inform the background of this application and identify existing research in this area, using the following databases: Cochrane, Medline, NIHR, PsychINFO, PsychARTICLES, Scopus, Social Science Index, Prospero and Cinahl and the Manchester Metropolitan University Library. Search terms included "learning disability, LD, intellectual disability, ID, mental retardation, autism, autism spectrum disorder, ASD, restraint, restrictive practices, challenging behaviour, aggression, self-injury". These were combined using Boolean operators ('OR', 'AND'). We did not limit the search according to the study method due to the anticipated lack of research in this area. A total of 179 papers were found then screened by title and abstract for relevance; 62 papers' full text were then read. Studies that directly measured restraint reduction were included, whilst studies that measured only challenging behaviour reduction with no reported restrictive practices reduction outcomes were excluded, leaving six papers in total, two systematic reviews and four primary research papers.

Williams & Grossett (2011) implemented a three-part 'Organisational Behaviour Management' restraint reduction plan in a residential setting housing 925 people with LD over a 17-month period. Within this timeframe, the number of behaviour plans doubled seeing mechanical restraint reduce by approximately 80%. Authors denote establishing organizational goals, providing restraint alternative consultation, and implementing monthly individual reports on all/any practices contributed to the reduction of restraint. Additionally, the recruitment of multi-disciplined behavioural analysts to improve behaviour training with staff ensured basic competencies. The nature of this individualised approach means whilst effects are significant there is limited generalisability. Additionally, with no cross comparison of settings there is limited evidence this implementation would work outside of this specific facility.

Allen and colleagues (2011) explored Positive Behaviour Support (PBS) as the primary clinical approach used to reduce restrictive practices on adults with LDs. They collated monthly data from eleven specialist LD services who used PBS over a seven-year period. Results showed an overall reduction of approximately 73%. However, reductions in physical restraint varied across acute and long-stay settings during this timeframe and other forms of restrictive practices increased, such as seclusion and/or medication.

Gaskin and colleagues (2013) conducted a systematic review and quantitative synthesis of initiatives to reduce seclusion, physical and mechanical restraints on people with LD. The initiatives included (though not exhaustively): precedents of aggressive behaviour and verbal and non-verbal diffusions (Allen, et al., 1997); behavioural support plans and medication at bedtime (Allen et al., 1997); service users choices of which staff member(s) to care for them (Jensen et al., 2012); fixed time releases (Luiselli, 2006); service users' designing their own schedules (Luiselli and Waldstein, 1994); alternative sensory reinforcements (Greenhalgh et al., 2011); relaxation methods (Obi, 1997); and mindfulness (Singh et al., 2009). Based on the 14 studies included, they established a 79% reduction in frequency and 28% decrease in duration of restrictive practices targeting agitation and aggression. There was a 71% reduction in restraint for self-harming behaviours but no results noted for duration. Follow up was only conducted in 2 of the 14 studies therefore long term efficacy is largely unknown.

Riding (2016) explored the impact of a reducing restraint programme implemented over 12 months within a secure LD unit, as a response to the National 'Positive and Safe Program' (Gov UK, 2014). The programme had three components: implementing the 'Safewards' model of conflict and containment (Bowers, et. al., 2014); integrating PBS principles (e.g. skills development, empowerment and person-centred approaches); and monitoring, reporting and reviewing the implementation of the programme every month for a 12 month period. Completion of the programme saw the elimination of prone and mechanical restraint, a 42% reduction in general restraint use, a 42% reduction in seclusion and a 52% reduction in chemical restraint. Although effective, authors denoted it was "impossible" to identify what parts of the intervention were responsible for the success.

Hayvaert and colleagues (2014a; 2014b) conducted a two-part systematic review of qualitative studies exploring experiences (2014b) and a meta-analysis (2014a) of the effectiveness of interventions to reduce the use of restraint for challenging behaviour with people with LDs. The meta-analysis (Hayvaert et al., 2014a) included 59 single case experiments with varying restraint types including: mechanical, response blocking, prone restraint, physical restraint, seclusions, and restrictive protective clothing. Their meta-analysis concluded that interventions were highly effective in decreasing challenging behaviour and that challenging behaviour reduction was linked with restraint reduction. However, the qualitative review (Hayvaert et al., 2014b) emphasized controversial uses of restrictive practices due to ethical issues leading to counter effective results.

3.4. Evidence explaining why this research is needed now

There is now an emerging political and public pressure to reduce and prevent the use of restrictive practices globally (Wilson et al., 2018; Søndenaa, Dragsten, and Whittington, 2015). National guidance specifies restraint may be used on rare occasions where all de-escalation techniques have failed to eliminate immediate danger or harm to life however, de-escalation, prevention and person-centred therapeutic approaches tackling the root cause of challenging behaviour should be the first course of action (Department of Health 2014a; NICE, 2015; Restraint Reduction Network, 2019; Care Quality Commission, 2019). Despite this, recent statistics indicate a significant increase of restraint used on adults with LD in English hospitals (NHS Digital, 2018). As a result, the government is being urged to explore in detail the context and reasons for such dramatic increases (Mencap, 2018).

We are currently conducting a systematic review of eterterffectiveness of interventions to minimise or reduce the use of restraint on people with LD or people with LD and autism or mental health co-morbidities. Whilst this is not complete to report at this stage, it is clear from our initial scoping review that there is some evidence of the effectiveness of interventions in reducing the use of restrictive practices on people with LD, but this is highly variable and limited. Furthermore, there is no evidence or clear indications why these did or did not work. This realist methodology therefore provides a road map for developing theory to understand how interventions work, namely that "causal outcomes follow from mechanisms acting in contexts" (Pawson and Tilly, 1997: 58). Put more simply, interventions occur in specific contexts. The mechanisms at work are, in turn, dependent on that context. As such, Context-Mechanism-Outcome configurations are central to Pawson and Tilley's explanation of 'scientific realism' evaluation (1997) and Pawson's further developments of a realist review methodology (Pawson, 2002; Pawson et al., 2005; Wong et al., 2012). This will provide a useful framework for developing theory that incorporates but extends current knowledge and research in the field.

This review will fill a gap in the evidence by developing programme theories of why interventions work and do not work in preventing and/or reducing the use of restrictive practices on adults with LD in a variety of NHS and independent sector inpatient and community or residential settings. Specifically, we are interested in uncovering how context influences programme specific theories to guide policy, practice and future research in this area. Interventions reducing challenging behaviour, rather than restrictive practices tend to dominate the research in this area (McGill et al, 2014; Hayvaert et al., 2014a; McQuire et al., 2015; Niven et al., 2018; Hewitt et al., 2016). The assumption that a reduction in challenging behaviour is directly linked to a reduction in restrictive practices is yet to be evidenced.

A particular issue is the complex co-dependent relationship between challenging behaviour and restrictive practices – challenging behaviour triggers the use of restrictive practices, but restrictive practices can also trigger escalating challenging behaviour (Challenging Behavior Foundation, 2018; Hayvaert et al., 2014a). Fitzpatrick and colleagues have submitted a protocol to the international prospective register of systematic reviews exploring if there is an evidence base that supports elements of Positive Behaviour Support (PBS) to reduce the need for restrictive physical practices for people with intellectual disabilities and ASD. This study might offer some insight into these causal mechanisms; however, the results will be limited to evidence based on quantitative studies only, with no single-case designs, reporting solely on outcomes related to elements of PBS as defined by Gore et al's. (2013) multicomponent framework model for defining PBS, and only looking at physical restraint.

We will add to the evidence by understanding the complexity of implementing the range of behavioural support approaches to reduce restrictive practices within complex healthcare settings. The realist review will be informed by a systematic review of effectiveness that the team is currently conducting.

4. AIMS AND OBJECTIVES

Pawson (2002) sketches out a method for a 'realist review'. A realist review utilises a 'generative' approach to causation whereby it is not 'programmes' that work but instead the underlying reasons or resources that they offer subjects that generate change.

The overall aim of this review is to gain a deeper understanding of what is currently known about how, why, for whom, and in what circumstances interventions to prevent and reduce the use of restrictive practices on adults with learning disabilities are most successful.

Objectives:

- To use a theory-driven approach to identify the main factors which influence the success or failure of interventions implemented in NHS and independent sector settings with the view to prevent and/or reduce the use of restrictive practices on people with LD;
- To develop a set of refined programme theories of causal mechanisms and contextual factors linked to short-term, medium-term and long-term outcomes

- To produce recommendations to inform future research, policy and practice and disseminate key mechanisms
- To use extensive consultation with stakeholders to inform theory development, theory testing and recommendations

5. RESEARCH PLAN / METHODS

5.1. Review approach

To understand how and why programmes to prevent and/or reduce restrictive practices used on people with LD in NHS and independent sector settings work, we will undertake a realist review and synthesis of literature (Pawson et al., 2005). Health interventions do not operate *in silo*, but within complex systems, interacting with personal, interpersonal and environmental variables outside of the programme (Pawson et al., 2005; Connelly, 2007) and, by using a realist approach, one can explore how these interactions impact on the success of a programme. This is realised by identifying and explaining relationships between context (C), mechanism (M) and outcome (O). The basic principle of the realist review method involves starting with a 'rough initial theory', then conducting a systematic but targeted review of literature to 'test' this rough theory, and, finally, re-articulate this in light of the current evidence base (note, this might happen over several iterations until the review reaches 'theory saturation' (Pawson and Tilley, 1997). In realist reviews, theories are articulated in the form of Context-Mechanism-Outcome configurations (CMOs). Identifying the CMOs within a programme enables a better understanding of how, why, for whom, and in what context the programme realises its intended and unintended outcomes in the short, medium and long term.

The realist review is an evidence building, theory-driven and interpretative approach (Pawson, 2006). The basic principle of the realist review method involves starting with a 'rough initial theory', then conducting a systematic but targeted review of literature to 'test' this rough theory, and, finally, re-articulate the 'rough initial theory' in light of the current evidence base. Following the realist methodology, the 'rough initial theory' will take the form of context-mechanism-outcome configurations and begin the identification of middle-range theories underlying the reduction of the use of restrictive practices.

We have chosen this approach as it is appropriate in dealing with complexity and heterogeneity in study setting, context and design (Pawson et al., 2005), which are characteristics present in the literature we will be reviewing. Interventions implemented to deal with and responses to challenging behaviour, i.e. restrictive practices, are usually complex and commonly delivered in an inconsistent way due to differences in socio-ecological variables that cannot be fully controlled (Williams and Grossett, 2011). We believe that understanding context is key in explaining why current prevention programmes are not consistent in reducing the use of restrictive practices in LD settings. Another advantage of the realist review approach is that it supports various forms of evidence, with equal importance given to quantitative, qualitative and mixed methods studies (Wong et al., 2012), including grey literature that is usually excluded from more traditional reviews. This gives us the possibility to evaluate underlying theories rather than focusing solely on specific outcome measures.

This realist synthesis will be conducted according to ***RAMESES*** guidelines (Wong et al., 2013), and will include four main sequential but iterative phases over 22 months:

- (1) formulating mid-level theories in the form of CMO configurations;
- (2) conducting a systematic search of literature;
- (3) testing and refining programme theories; and

- (4) developing recommendations and disseminating findings.

5.2. Theoretical framework

The review will develop and test a mid-level theory, which will be an explanatory account of how interventions work through the application of (but not exclusive to) theories underpinning behavioural interventions. We recognise, however, the complexity of the interplay between LD, ASD and mental health problems in this population and that our attention needs to span across diagnoses and settings to develop an appropriate theoretical framework. Including a significant stakeholder and expert by experience consultation component within the review will help us carefully consider these complexities and identify or refine candidate theories.

5.3. Review strategy

Our review will be using the accepted four phases of realist synthesis (Pawson, 2006).

5.3.1. Phase I: Formulating mid-level theories in the form of CMO configurations

This phase will involve developing the 'rough initial theory(ies)' that will underpin the rest of the realist review.

Developing CMOs will involve:

- Extensive consultation with a range of experts and stakeholders
- A scoping review of the underpinning academic literature (e.g. policy documents, commentaries, letters, reviews and editorials) that helps us explain the impact and responses to challenging behaviour, including theories underlying behavioural interventions.

Due to the current Covid-19 situation, consultation with stakeholders will now take a more workshop based (online) approach with stages of consultation, CMO development, and reviewing current theories. Stakeholders will include academics, practitioners, service users and carers, commissioners and service providers, members of advocacy groups and charities, and other experts in areas relevant to developing the emerging programme theories.

Step 1: Initial Theory of Change (October 2020):

Dr Szifris will lead a Theory of Change (ToC) workshop with a small number of stakeholders and the wider research team to develop an initial understanding of how specific outcomes are achieved (***<u>Stakeholder workshop #1</u>***). This will include a mapping of a range of possible CMOs and/or mechanisms that relate to the desired outcomes.

Step 2: Developing CMOs and engaging with literature (October-November 2020)

Outcomes of the ToC workshop will be developed into a framework of CMOs that that will provide a framework to map the theoretical and conceptual landscape of restrictive practices used on people with LD as a response to challenging behaviour. These will then analysed in reference to the wider literature, policy documentation and other commentaries.

Step 3: Wider stakeholder engagement (November-January 2020)

Having developed clear CMOs, the research team will engage with the wider stakeholder group to discuss and refine the initial theory. With the current COVID related situation, we anticipate engaging with the wider stakeholder group online during this period and therefore suggest a staged workshop approach with small numbers of participants (5-7) as opposed to a single, wider workshop including 15-20 individuals. Short (1-2 hour) workshops will be held with each of the following groups separately (***<u>Stakeholder workshops #2</u>***)

- Experts by experience (people with lived experience of LD, ASD)
- Experts by experience (carers/family of people with lived experience of LD, ASD)
- Professionals working in the field, commissioners and policy makers (members of the Advisory Panel)
- Academic experts (research team and their connections)

To be noted that, with regards to experts by experience groups (EEGs) involving people with lived experience, we have established connections with three distinct groups: one for people within forensic settings (led by Thompson); one for people in community settings (led by Ridley); and one from Learning Disability England (LDE) (led by Bourlet). With the current COVID situation in mind, we are mindful of the implications and appropriateness of working with these sub-groups online.

Completing Step 3 will result in articulating a small number of CMOs (3-5) that reflect genuine mid-level theory (i.e. neither too specific nor too abstract but which reflects the broader behaviours and interventions in which the research is interested).

Step 4: Finalising CMOs (January 2021)

The research team will finalise the CMOs for testing following the consultation period. A final meeting with the research team, advisory panel, and experts by experience will be used to agree the final working of the initial CMOs for testing (***<u>Stakeholders workshop #3</u>***).

<u>Expected outputs from Phase</u> <u>*1*</u>: (1) identification of programme theories expressed as CMO configurations to be tested and refined in Phase 3; and (2) submission of the realist review protocol for open access publication

5.3.2. Phase II: Conducting a systematic search of literature

Having developed a rough initial theory in the form of CMOs, the next stage of a realist review involves systematically searching for and sifting through evidence that would assist us in understanding the accuracy of our rough CMOs. In line with the iterative nature of realist synthesis methods (Pawson et al., 2004, 2005), we will finalise the search strategy upon consultation with stakeholders (e.g. members of the advisory panel, experts by experience groups) (***<u>Stakeholders workshop #4</u>***) and the wider research team. This will involve refining study selection criteria, search terms, search syntax and choices of databases. The team acknowledges that adherence to the protocol may change during the systematic review process due to the complexity of managing literature of varying methodologies and the nature of the evidence. Any deviations from the planned protocol will be recorded in the final report.

This phase will involve the following five steps:

Step 1: Study selection criteria

The PICO (Population, Intervention, Comparison, Outcome) framework (Schardt et al., 2007) will be used to inform the search strategy and study selection criteria.

<u>Population</u>: adult (>18 years old) males and females with a primary diagnosis of learning disabilities, who may also have a secondary diagnosis of autism or mental health problems; staff, services or carers that provide support to this specific population.

- A Learning Disability (LD) is a “significant reduced ability to understand new or complex information, to learn new skills (impaired intelligence), with a reduced ability to cope independently (impaired social functioning), which started before adulthood” (Care Quality

Commission, 2019). Mild LDs score an IQ of 50-70, moderate 35-50, severe 20-35 and profound less than 20 (World Health Organisation, 2019).

- Adults with LD and on the autistic spectrum (autism/autistic spectrum disorder) will also be included. Autism or Autistic Spectrum Disorder (ASD) is a complex neural disorder affecting development, usually diagnosed in childhood, with persistent impairment in social interaction, relationships, arousal impairments, verbal and non-verbal communication, and restricted/repetitive behaviours (DSM-5, 2013).
- Adults with LD and a mental health diagnosis will also be included. The search will include (but not exclusive to) mental health problems such as schizophrenia, bipolar disorder, depression, anxiety disorders, specific phobias, agoraphobia, obsessive compulsive disorder and dementia – problems which have been identified as common in adults with LD.

Intervention: Any programmes or discreet interventions designed to prevent or reduce the use of restrictive practices. Examples of multi-component/complex interventions include: the Safewards model (Bowers et al., 2014) and the RAID and Positive Behaviour Support (PBS) approaches developed in the UK (Gore et al., 2013), the Engagement model (Borckardt et al., 2007) and the Six Core Strategies (Huckshorn, 2005) and the 'No Force First' (Ashcraft and Anthony, 2008; Ashcraft, Bloss, and Anthony, 2012) developed in the US. Examples of 'simple'/discreet interventions include: staff training and de-escalation, debriefing, staff education and e-learning; review (post incident), sensory modulation (environmental), risk assessment (MAS-M, Broset, DASA), data analysis and text mining; joint crisis plans, open doors policy, behavioural/non-pharmacological interventions, Methodical Work Approach (MWA), clozapine, Relational Neurobehavioral Approach (RNA), recovery-based practice, rapid restraint analysis (RRA), post-seclusion counselling.

Comparison: Other interventions or treatment as usual.

Outcomes: The national and international consensus – whether in policy, guidelines or the literature – is that there is an urgent need to minimise the use of restrictive practices on vulnerable people with LD. A reduction in restrictive practices will therefore be a candidate primary outcome for this review. We will include all types of restrictive practices, duration, frequency and intensity. Examples include: all forms of restraint, seclusion, observation, segregation, rapid tranquilization and other types of coercive medication (IM, PRN), restriction by default, clinical holding, blanket rules/restrictions. However, caution will be used when selecting outcomes to avoid outcome reporting bias. Authors of included papers will be contacted if it is unclear whether significant and non-significant restrictive practices minimisation outcomes were recorded.

The review process will encompass an iterative identification of outcomes that are important to stakeholders, in particular service users and carers. Other candidate outcomes will include: service users' safety (including incidents of aggression; self-harm; injury); service user and carer satisfaction with the service; staff attitudes; staff safety, burnout, stress.

The full inclusion and exclusion criteria will be fully defined following the initial scoping review and the stakeholder consultation.

We will include all published and grey evidence of any study design including single case studies, RCTs, quasi-experiments and observational studies looking at the impact of any interventions implemented to address challenging behaviour and restrictive practices. We anticipate mixed-method studies and qualitative studies will provide evidence of facilitators and barriers to the implementation and success of such interventions. This will include participants' views and experiences of preventative or reduction interventions.

Step 2: Identifying the literature

The search strategy will be developed with the help of a clinical librarian, with input from the project team and stakeholders to identify relevant published and unpublished evidence. We will also consult search strategies from previous relevant reviews. A comprehensive overall search be will used to search the following databases from 2000-onwards to ensure relatively recent, but sufficient evidence: Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, Education Resources Information Centre, MEDLINE, PsycINFO, PubMed and Web of Science.

Searching for grey and unpublished literature

Supplementary searches will be used to search for grey and unpublished literature. We will conduct a broad search on Open Grey (http://www.opengrey.eu/), Grey Literature Report (http://www.greylit.org), World Health Organisation (http://www.who.int/en/) and Google. We will attempt to identify any evidence from as many sources as possible. That includes asking EEG and AP members to identify any known literature and useful websites and organisations to contact. The results from these methods of searching will be saved to record the source data (URL, organisation or expert), the date found/contacted and the references identified via that method.

In addition to searching reference lists of eligible evidence identified through electronic database searching, a purposive and iterative approach will be employed following the CLUSTER (Citations, Lead Authors, Unpublished materials, Scholar searches, Theories, Early Examples and Related Projects) methodology (Booth et al., 2013) as illustrated in Table 1. This approach will involve identifying the 'key pearl citations' (i.e. key evidence in the topic area) to identify additional relevant outputs that may include 'sibling' studies (i.e. evidence from the same study – for example, qualitative studies associated with an RCT) or 'kinship' studies (i.e. theoretically associated) that inform contextual elements. This method overcomes one of the limitations of database searching by aiming to identify additional evidence linked with a study of interest, instead of potential evidence simply using the same terminology.

Table 1. The CLUSTER approach

Element	**Search procedure**	**Sources**
Citations	Identify at least one 'key pearl' through consensus with review team	Preliminary searches of databases and grey literature
Lead authors	Check reference list of 'key pearl', conduct lead author search	Full text of 'key pearl', search of reference management collection, Google (e.g. institutional repository, author publication webpage)
Unpublished materials	Make contact with lead author	Email
Scholar searches	Citation searches on 'key pearl' and other relevant studies. Conduct search of 'project name'	Web of Science/Google Scholar
Theories	Follow up 'key pearl' and other cluster documents for citations of theory. Recheck for mention of theory in titles/abstracts/keywords, iterative	Full text of 'key pearl', search of reference management collection, databases

	searches for theory in combination with condition of interest	
Early examples	Follow up key pearl citation and other cluster documents for citations to project antecedents and related projects	Full text of 'key pearl'
Related projects	Conduct named project and citation searches for relevant projects identified from cluster documents, seek cross case comparisons by combining project name/identifier for cluster with project name/identifiers for other relevant projects	Web of Science/Google Scholar, databases

Electronic search results will be imported into a reference manager and duplicates deleted. Materials from other sources will be manually recorded in the same file.

Step 3: Screening process

The results of the database searching and selection process will be reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA; Moher et al., 2009). Two reviewers will independently screen all titles and abstracts for potentially identify relevant evidence. Then full-text versions of potentially relevant evidence will be assessed for inclusion using the eligibility criteria. Disagreements will be resolved by discussion with a third reviewer where necessary. The reasons for exclusions at full-text level will be recorded following the PRISMA flowchart.

Step 4: Quality assessment

The methodological quality of included evidence will be assessed using appropriate tools based on study design. For example, Critical Appraisal Skills Programme (CASP, 2013) will be used to assess qualitative studies, mixed-methods studies will be assessed using the Mixed Methods Appraisal Tool (MMAT) and grey literature will be assessed using the Authority, Accuracy, Coverage, Objectivity, Date, Significance (AACODS) checklist (Tyndall, 2010). The appraisal of evidence will be assessed by one reviewer and independently verified by a second reviewer. Any disagreements will be resolved through consensus and if necessary, a third reviewer will be consulted for arbitration. Studies will not be excluded by their methodological quality as evidence in realist reviews is based on what knowledge they bring, we are however, conducting quality assessment to ensure transparency (Kastner et al., 2011).

Step 5: Data extraction

Selected studies meeting the full criteria will be read twice before data extraction onto bespoke data extraction forms (developed based on the content of the programme theories that emerge from Phase 1) in order to collate the evidence on CMOs. The stakeholders and wider research team will inform the data extraction strategy as it is anticipated data extraction will differ based on the type of evidence, content of CMOs and the underlying review question. We will conduct a workshop with key members of the RMG, AP and EEGs to agree on components to be extracted for the realist review (***Stakeholders workshop #5***).

In conjunction with the data extraction forms, we will extract study aims, methods used and characteristics of the population from all eligible evidence. This will include but not be limited to:

publication characteristics (e.g. country of data), study design (e.g. review, observational, cohort, qualitative studies), type of interventions, context of intervention, mechanisms generated, descriptions of all outcomes and author interpretations (e.g. any theories or mechanisms postulated by study authors) that explain the outcomes of interventions. Data will be extracted independently by one reviewer and checked for accuracy by second reviewer. Any disagreements will be resolved through consensus and a third reviewer will consult where necessary. Data from multiple related publications of single studies will be extracted and reported as a single reference. We will attempt to contact corresponding authors for missing data, where possible.

The extracted data will be tabulated to summarise studies and allow evidence to be meticulously mapped against the initial programme theories. This will also allow the identification of any new programme theories.

Expected outputs from Phase 2: (1) eligible evidence to test and refine the initial CMOs; and (2) developed data extraction forms for different types of evidence and content of CMOs.

5.3.3. Phase III: Testing and refining programme theories

The analytical task is in aligning the extracted evidence in relation according to the relationships between Mechanisms (e.g. underlying processes and structures), Contexts (e.g. diagnoses, setting, organisational configurations), and Outcomes (i.e. intended and unintended consequences and impact) with the initial programme theories. Rycroft-Malone et. al. (2012) have developed an approach to synthesis which builds on Pawson's work (2006) and the principles of realist enquiry, including the following steps:

1. organisation of extracted information into evidence tables representing the different bodies of literature;
2. theming by individual reviewers across the evidence tables to identify demi-regularities (reoccurring patterns);
3. comparison of reviewers' themes and linking agreed demi-regularities seeking confirming and disconfirming evidence;
4. refinement or development of new explanatory middle-range theories expressed as CMO configurations

Realist synthesis is a time consuming and resource intensive phase within the project, as it will involve individual reflection, team discussion and further consultation with key stakeholders, e.g. practitioners, policy makers, charity workers and experts by experience (people with lived experience and carers). The view of stakeholders will be sought via a follow up workshops (***Stakeholders workshop #6***). This will include in-depth discussion of the findings to develop and confirm the resultant hypotheses. These will act as synthesised statements of findings around which a narrative can be developed summarising the nature of the context, mechanism and outcome links, and the characteristics of the evidence underpinning them. We are hoping to be able to organise face to face workshops where we present our findings and we validate them by consulting with key experts, but smaller online workshops will be considered as an alternative if the situation regarding social isolation/COVID does not improve by that time. A refined set of hypotheses with accompanying evidence-based narrative will be produced.

We will also re-visit eligible evidence, extracted data and perform additional searches, if there are any unanticipated development of new explanatory middle-range theories during the synthesis stage.

Expected outputs from Phase III: (1) an evidence-based framework indicating what works for whom and in what context in relation to reducing the use of restrictive practices on people with learning disabilities and autism or mental health co-morbidities.

5.3.4. Phase IV: Developing recommendations and disseminating findings

A final stakeholder consultation will take place to help produce recommendations for policy and practice (***Stakeholder workshop #7***). There is a possibility of limited evidence for any proposed theory, thus recommendations could also highlight the strength of evidence in this area. This project might highlight theories, interventions or mechanisms that need to be tested with further, more robust research, e.g. randomised trials (cluster, stepped wedge).

We will finalise the project by holding a ***knowledge mobilisation event*** open to a wide range of key stakeholders, academics, practitioners, people with lived experience, policy makers, commissioners, to present the results and emerging recommendations and identify possible barriers to the adoption and implementation of evidence-based findings.

Expected outputs from Phase IV: (1) refined/actionable recommendations; (2) realist review final report; and (3) paper to be submitted in open access peer reviewed journal.

6. DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

6.1. What do you intend to produce from your research?

Using involvement of stakeholders in the review as outlined will allow for better knowledge transfer throughout. To increase the visibility and impact of the research, we will disseminate findings through knowledge exchange with stakeholders and policy makers using social media (Twitter, Blogs, Podcasts), publications in peer-reviewed journals, conference presentations, and formal and informal reports.

We will produce a ***final report*** identifying main factors that influence the success or failure of interventions implemented in NHS and independent sector settings. This will enrich the current theoretical body of knowledge adding contextual causation of the success and/or failure of interventions to minimise restrictive practices. The report will include case studies to illustrate examples and make findings real and accessible to healthcare professionals. It will also identify areas for future research and make recommendations for policy and practice. An ***executive summary*** of the full report, suitable to be used as a stand-alone report for professional health cares, will be produced. This will include a set of refined programme theories of causal mechanisms and contextual factors linked to outcomes. This can be used as a practical guide for healthcare managers, providers and staff to predict desired outcomes within their settings. Additionally, a ***lay summary*** (easy read accessible in different formats) will be developed with the aid of people with LD to make findings accessible to service users and their families. This will include images, illustrations and widgets to aid comprehension.

We will present findings at regional, national and international relevant conferences. For example, Transforming Care of People with LD conference, Improving the Use of Interventions and Practice Conference, Restraint Reduction Network Conference, RPsyc Faculty of Intellectual Disability Conference and the International Conference on Learning Disabilities, the National Convention for People with Learning Disabilities, the International Association for the Scientific Study of Intellectual Disabilities (IASSID) and the British Institute of Learning Disabilities (BILD)'s annual conferences). Presentations will be available as ***conference papers*** and ***posters*** and shared using ***social media***

platforms (Twitter, Blogs, Podcasts). We will develop an ***interactive poster*** to link people to YouTube and Vimeo videos of research findings and policy and practice implications.

Two ***peer reviewed papers*** will be submitted for publication, a review protocol and a findings paper. Our publication strategy focuses on service user publications and peer-reviewed, high impact academic journals (e.g. Learning Disability Practice, Journal of Intellectual Disabilities and Offending Behaviour, Journal of Adult Protection, Journal of Applied Research in Intellectual Disabilities), as well as practitioner magazines to reach grassroots care deliverers. To ensure maximum reach costs we will include open access publication of findings. Finally, we will produce ***a paper*** based on the findings for the Equalities and Human Rights Commission.

6.2. How will you inform and engage patients, NHS and the wider population about your work?

Stakeholder engagement is central to the way we conduct research and facilitated by the approach and methods we use. For this project, stakeholder engagement will take place throughout the duration of the review. This depth of engagement should increase the significance, accessibility and relevance of the findings. Stakeholders (including the research team, practitioners, steering group, experts by experience and policy makers) will be encouraged to disseminate findings through their local and national networks including Manchester Metropolitan's existing links with mental health NHS trusts, Learning Disability Partnership Boards, community adult learning disability services and health and social care commissioners across Greater Manchester, the Care Quality Commission, the Restraint Reduction Network, The British Institute of Learning Disabilities (BILD), Positive and Active Behaviour Support Scotland (PABSS), Dimensions UK, the Tizard Centre, and regional and national self-advocacy and family networks. MMU's MetroPolits think tank (https://mcrmetropolis.uk/) will help with access to and engaging effectively with policy makers.

A final, national dissemination event will invite researchers, stakeholders, including experts by experience and support groups and healthcare professionals to engage with evidence and discussion of restrictive practices on people with LD or people with LD and ASD or comorbid mental health needs. The event 'Improving the Quality of Care of People with LD - Best Practice Interventions to Reduce the Use of Restrictive Practices' will be a certified Continued Professional Development event for healthcare professionals. This event will be advertised through the NHS internal communications, care homes and private hospitals, in practitioner journals and via social media. To ensure maximum impact we will also draw upon the team's media and broadcasting expertise. Key note presentations will be video captured and disseminated through social media (You Tube, Vimeo and blogs) to maximise access for those who cannot attend and for impact in the medium/long term. In addition, video and audio podcasts of the findings will be similarly produced and disseminated to maximise public access.

Service providers and commissioners will be provided with the reports listed above and the video/podcast links to disseminate through their internal communications (e.g. bulletins, e-mail updates, intranet). The findings will also be designed into an interactive poster with a QR code directly linking audiences to the YouTube and Vimeo videos where they can stream research findings and the policy and practice implications live to computers and hand-held devices. The poster will be taken to the local, regional and national conferences noted above and disseminated trough all social media platforms. In February 2018, BBC One Breakfast reported on the alarming use of restraint practices in LD settings. On completion of the project, we will approach the BBC to do a follow up interview based on our research findings.

6.3. How will your outputs enter our health and care system or society as a whole?

Our aim is to use the results from the review to inform future policy, research and practice in the development and implementation of more effective and appropriate interventions to minimise the use of restrictive practices on people with learning disabilities and autism or mental health comorbidities. The research team, advisory panel and experts by experience groups will share findings through their networks and promote change beyond the end of the project.

6.4. What further funding or support will be required if this research is successful (e.g. from NIHR, other Government departments, charity or industry)?

We will endeavour to seek further funding from the NIHR to conduct feasibility work based on our findings and to explore approaches to implementation through Health Foundation monies. There will also be opportunities to seek funding for PhD studentships and KTP monies.

6.5. What are the possible barriers for further research, development, adoption and implementation?

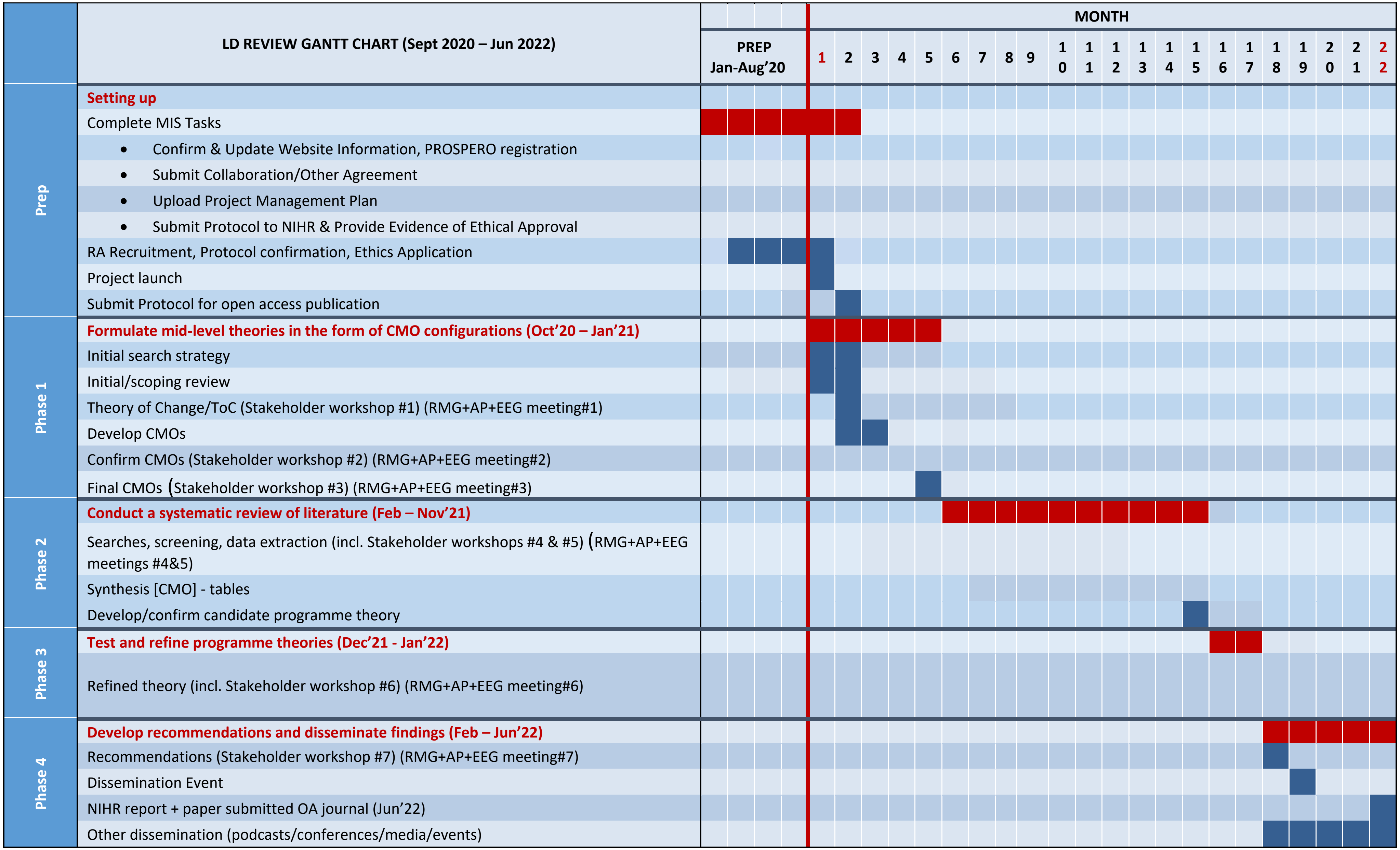
The current restructuring of services where people with LD access care, as well as the significant funding cuts to service providers in this area will be a challenge. A key element in stakeholder engagement events will therefore be to engage a wider and influential audience with the research findings and proactively facilitate a two-way conversation about barriers to implementation and how these can be overcome. These discussions will be integrated into the Vimeo and YouTube audio and visual podcasts with suggestions of how to overcome any foreseeable obstacles.

6.6. What do you think the impact of your research will be and for whom?

It is expected that the results (1) would raise awareness of harmful restrictive practices; (2) would highlight what, for whom, and in what circumstances interventions work to prevent restrictive practices; and/or (3) would highlight a lack of evidence and suggest the direction of future research in this area. We would also expect to further inform guidelines for organisations and professionals about how to reduce the use of restrictive practices with people with learning disabilities. A reduction in the use of such practices would improve the lives of people with learning disabilities and reduce the negative consequences associated with restrictive practices, for service users, staff, and services in general.

7. PROJECT/RESEARCH TIMETABLE

We estimate the project will take 22 months to complete (01.09.2020 – 30.06.2022). See Gantt chart below for an outline of the research timetable:



	LD REVIEW GANTT CHART (Sept 2020 – Jun 2022)	MONTH																									
		PREP Jan-Aug'20				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Prep	**Setting up**																										
	Complete MIS Tasks	🟥	🟥	🟥	🟥	🟥	🟥																				
	• Confirm & Update Website Information, PROSPERO registration																										
	• Submit Collaboration/Other Agreement																										
	• Upload Project Management Plan																										
	• Submit Protocol to NIHR & Provide Evidence of Ethical Approval																										
	RA Recruitment, Protocol confirmation, Ethics Application		🟦	🟦	🟦	🟦																					
	Project launch					🟦																					
	Submit Protocol for open access publication						🟦																				
Phase 1	**Formulate mid-level theories in the form of CMO configurations (Oct'20 – Jan'21)**					🟥	🟥	🟥	🟥	🟥																	
	Initial search strategy					🟦	🟦																				
	Initial/scoping review					🟦	🟦																				
	Theory of Change/ToC (Stakeholder workshop #1) (RMG+AP+EEG meeting#1)						🟦																				
	Develop CMOs						🟦	🟦																			
	Confirm CMOs (Stakeholder workshop #2) (RMG+AP+EEG meeting#2)																										
	Final CMOs (Stakeholder workshop #3) (RMG+AP+EEG meeting#3)									🟦																	
Phase 2	**Conduct a systematic review of literature (Feb – Nov'21)**										🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥	🟥							
	Searches, screening, data extraction (incl. Stakeholder workshops #4 & #5) (RMG+AP+EEG meetings #4&5)																										
	Synthesis [CMO] - tables																										
	Develop/confirm candidate programme theory																			🟦							
Phase 3	**Test and refine programme theories (Dec'21 - Jan'22)**																				🟥	🟥					
	Refined theory (incl. Stakeholder workshop #6) (RMG+AP+EEG meeting#6)																										
Phase 4	**Develop recommendations and disseminate findings (Feb – Jun'22)**																						🟥	🟥	🟥	🟥	🟥
	Recommendations (Stakeholder workshop #7) (RMG+AP+EEG meeting#7)																						🟦				
	Dissemination Event																							🟦			
	NIHR report + paper submitted OA journal (Jun'22)																										🟦
	Other dissemination (podcasts/conferences/media/events)																						🟦	🟦	🟦	🟦	🟦

8. ETHICS / REGULATORY APPROVALS

Ethical and governance approvals will be sought from Manchester Metropolitan University. For clarification, as discussions with members of the Advisory Group and the Experts by Experience Groups (EEGs) will not be recorded and will only guide the scope of the review, formulation of the research questions, inclusion/exclusion criteria, and development of the CMOs, these will not be considered primary data collection.

9. PATIENT AND PUBLIC INVOLVEMENT (PPI)

Experts by experience including service users and carers are integral to the development and conduct of this realist review. Our PPI strategy was co-created following consultation with Michaela Thomson from the Specialist Learning Disability Division (SpLDD) team within a mental health trust in the North West of England, and Beth Morrison, an expert by experience (carer). In January 2018 we were awarded £350 from the Research Design Service to consult with members of two established service user (SU) groups within an forensic LD hospital in the NW of England. The research team were invited to one of the group meetings to discuss the topic and proposed research. Issues with regards to restrictive practices were discussed. Following consultation with this group to inform this work, we were able to shape the proposal to address a number of issues including the constitution of advisory groups, terminologies used, the extent of restrictive practices and the need for safety and advice regarding accessible information. The proposal was designed accordingly.

Two experts by experience have agreed to be co-applicants and contribute to all project phases, including developing and delivering a dissemination and impact strategy. The experts by experience will be leading the consultation with the Experts by Experience Groups (EEGs): one established for service users and one for carers. The term ‘service user’ is used in this application, but the experts by experience will be choosing themselves how they would like to be called for this project. To represent the service users’ perspective, one expert by experience has agreed to act as ‘research buddy’ and to be involved throughout the duration of the project. Gary Bourlet is an LD expert by experience and is the co-founder of *Learning Disability England* who work to make life better for people learning disabilities by informing policy, supporting best practices, and supporting research. Gary has actively campaigned for the human rights for people with LDs for the last 33 years. His advocacy has reached significant political and public impact. To represent and drive the carers’ perspective, the mother and carer of Calum, who has epilepsy and learning disabilities and has been traumatised by the use of physical restraint, has agreed to be a co-applicant. She has been lobbying against the use of restraint and seclusion on vulnerable children and her petition has been successful in influencing policy at national and international level. With the support of the research team (Chapman, the RA) and one key member of the advisory panel (AP) (Jinks), the two experts by experience will be leading the EEG meetings, to discuss elements of review and help with theory development and validation and will sit on the AP. Feedback from these EEG meetings will be discussed during the Research Management Group (RGM) and Advisory Panel (AP) meetings.

Additionally, one of the co-applicants, Mrs Thomson, who is a practitioner with extensive research and PPI experience, will consult with two other service user groups established within a specialist LD forensic unit, to capture the views of people with LD who have experienced institutionalised care and feedback to the RGM and AP their input regarding key components of the review.

In developing this application, the experts by experience have helped the research team shape the project and the writing of the lay summary and they will ensure throughout that project information and summary findings are accessible to and comprehensive for the needs of service users, carers and the public. They will be involved in dissemination events and video/audio podcasts.

10. PROJECT MANAGEMENT

We have developed a management plan to ensure the project aims and deliverables are completed in line with the project approved protocol and Gantt chart. Manchester Metropolitan University will be the sponsor for the study. The project will be conducted by staff experienced in research into learning disability, mental health, restrictive practices and research synthesis. The research assistant (AT) will be supervised by the Chief Investigator (JD) and the project manager/Co-CI (AH), via weekly meetings and ongoing contact, when necessary. JD and AH have successfully worked together on projects and in supervising staff. JD has managed a number of large funded projects successfully.

The ***Research Management Group (RMG)*** includes the CI, all co-investigators and the research assistant and will be responsible for managing progress and delivering the project milestones. JD will chair the RMG meetings which will be held face to face or virtual, to plan work, review progress against milestones, and troubleshoot any problems. Virtual meetings will be more cost effective and provide flexibility to boost engagement throughout the duration of the project, especially in light of the COVID pandemic restrictions. All team members will attend the RMG meetings which will take place at key time points during the project, as indicated in the Gantt chart. The CI will send regular updates to the RMG to inform these meetings. The CI and nominated members of the RMG (JR and MC) will support the experts by experience leads.

An external multi-disciplinary ***Advisory Panel (AP)*** has been established to oversee the project and support key strands of the proposed work (as outlined in the project design and Gantt chart). The AP includes the CI, the project manager/co-CI, a PPI representative, and key stakeholders from relevant organisations such as: The Tizard Centre, The British Institute of Learning Disabilities (BILD), Restraint Reduction Network (RRN), Positive & Active Behaviour Support Scotland (PABSS), Mersey Care NHS FT, Challenging Behaviour Foundation, Positive and Active Behaviour Support Scotland, Care Quality Commission, NHS England, Dimensions UK. The AP meetings will be co-chaired by the CI, co-CI and one PPI representative (rotating responsibilities). Key stakeholders have been approached to participate in this project as members of the advisory panel (AP). The following have agreed to be part of the AP:

- Mr Andrew Brown, Nurse consultant ASD specialist in forensic settings, Mersey Care NHS FT
- Dr Arun Chidambaram, Deputy Medical Director, Mersey Care NHS FT
- Mr Ben Higgins, CEO, British Institute of Learning Disabilities (BILD)
- Mrs Charlotte Jinks, Voyage Care, charity providing support specialist support for over 3,500 people with learning disabilities and complex needs
- Prof Chris Hatton, Department of Social Care and Social Work, MMU. Policy and research in health inequalities experienced by people with learning disabilities
- Mrs Kate Sanger, Trustee advisor to CBF and Positive and Active Behaviour Support Scotland (PABSS)
- Mr Gavin Harding, Learning Disability Adviser for Learning Disability Programme, NHS England
- Mrs Maggie Graham, Development Manager for Learning Disability and Autism Programme, NHS England
- Mrs Samantha Clark, Chief Executive and co-founder Learning Disability England (LDE)
- Mrs Sarah Leitch, Director of Development at BILD & RRN
- Dr Theresa Joyce, Clinical Psychologist and National Professional Advisor on Learning Disabilities, CQC
- Mrs Viv Cooper, CEO, Challenging Behaviour Foundation (CBF)

Collectively their expertise will complement the project team. Members of the AP will attend meetings at key time points during the project, as indicated in the Gantt chart.

In addition, dedicated independent ***Experts by Experience Groups (EEGs)*** including service users and carers have be developed to oversee the project and support key strands of the proposed work. We have established connections with four distinct groups, as follows:

- EEG1 - Carer Group, led by Morrison (PPI co-applicant)
- EEG2 - Forensic Group, led by Thompson (co-applicant)
- EEG3 - Community group, led by Chapman/Ridley (co-applicants)
- EEG4 - Learning Disability England (LDE) members group, led by Bourlet (PPI co-applicant)

The EEGs will be supported by the RMG and the project RA and will convene at key time points during the project, as indicated in the Gantt chart. With the current COVID situation in mind, we are mindful of the implications and appropriateness of working with these sub-groups online.

11. PROJECT TEAM/RESEARCH EXPERTISE

The research team has significant clinical and methodical expertise and an international reputation for our work related to restraint reduction, mental health, learning disabilities, and challenging behaviour.

Prof Joy Duxbury (JD) – Chief Investigator (CI) (20%FTE) – Expert restrictive practices and mental health. Responsible for overall project and budgetary management (strategic and research direction for the project); chairing the advisory panel (AP) and research management group (RMG); supervise RA; delivery of final report. JD is a professor of Mental Health within the Faculty of Health, Psychology and Social Care at Manchester Met. She is the chair of the European Research Group on Violence in Psychiatry (EViPRG) and the Restraint Reduction Network, UK. She contributed to the Department of Health, Minimising Restrictive Practices Guidance and was a member of the NICE Guidelines on Violence and Aggression: the Short Term Management of Violent and Physically Threatening Behaviour in Mental Health and Community Settings (2014). JD has published in the area of minimising restrictive practices for over twenty years and has extensive experience of successfully delivering funded research from the NIHR, Ministry of Justice, the Youth Justice Board and the Health Foundation.

Dr Alina Haines (AH) – Co-CI (operational aspects of the project/day to day project management); second reviewer (20%FTE). Responsible for co-managing project with JD, stakeholder consultation events, acting as a second reviewer, attending all RMG and AP meetings, organise with the RA all dissemination events. AH is a Research Fellow in Mental Health and Coercion at MMU with extensive experience relating to forensic settings, vulnerable populations, project management and research methodology. She has successfully delivered research projects in a wide range of settings, including acute and mental health wards, forensic hospitals, prisons and police custody.

Anthony Tsang (AT) - Project RA, main reviewer (100%FTE), contributing to all components of the project, including impact and dissemination. He has a background in psychology including an MRes in research methodology. Anthony has experience in a range of research methodologies including conducting focus groups, interviews and evidence syntheses. He is a Cochrane Review author and has worked on systematic reviews covering a wide range of topics including mental health, respiratory care and social care. He has led a realist review of self-management in bronchiectasis and a meta-analysis synthesising literature between clinical voice-hearers and distress.

Beth Morrison (BM) – Patient and Public Involvement Lead 1, Expert by Experience (carer) (10%FTE). With the help of the research team (Chapman and the RA), BM will organise and co-chair the EEG (carers) meetings, provide feedback to the RMG and AP, attend the AP meetings and 50% of the RMG meetings. BM will have a key role in supporting the dissemination and impact strategy, with a focus on carer dissemination, attending the events and participating in the video/audio podcasts.

BM is an expert by experience. She is the mother and carer of her son Calum, who has epilepsy and LS and has been traumatised by the use of physical restraint. BM has been lobbying against the use of restraint and seclusion on vulnerable children and her petition has been successful in influencing policy at national and international level. In June 2016, after the United Nations Convention for the Rights of the Child (UNCRC)'s 72nd session in Geneva, recommendations were made to abolish all methods of restraint against children for disciplinary purposes in all institutional settings, and ban the use of any technique designed to inflict pain on children.

Gary Bourlet (GB) - Patient and Public Involvement Lead 2 – Expert by Experience (service user) (10%FTE). Gary will mirror Beth's role, but with the expert by experience service user group. GB is an LD expert by experience and is the co-founder of '*Learning Disability England',* who work to make life better for people with LDs by informing policy, best practice guidance, and participating in research. GB was the founder and president of the '*People First Movement'* in the UK in 1984 and has actively campaigned for the human rights for people with LDs for the last 33 years. His advocacy has had political and public impact leading to a 10-part BBC documentary called '*Life Of Our Own*,' about the lives of people with LDs. He has also wrote for *the Guardian* and made regular appearances on Chanel 4. GB is a regular keynote speaker at national and international conferences giving presentations in Brussels on '*The European Year of Disabled People*' that led to him being a European representative on the United Nations Panel in Alaska. Gary partners with various day centres, schools and colleges delivering leadership training for people with LDs. He has also been a part of '*The Learning Disability Partnership Board'* to promote the objectives of the Department of Health's '*Valuing People*' document. Gary's exemplary work had led to a large social media following of over 2000 followers.

Michaela Thomson (MT) – Research Practitioner, Patient and Public Involvement Lead 3 (LD specialist services) (5%FTE). MT, who has extensive research and PPI experience, will access two service user groups established within a specialist LD forensic unit: The 'Media Crew' and 'The Service User Involvement Group'. MT will aim to capture the views of people with LD who have experienced institutionalised care and provide feedback to the RGM and AP. MT has worked in Learning Disabilities service for over 25 years in varying roles. She has extensive experience of undertaking qualitative research within the Trust, resulting in publications on the subject of views and experiences of service users with learning disabilities and autism spectrum disorder.

Prof John Baker (JB) – Expert in restrictive practices and systematic reviews of behavioural interventions (5%FTE). JB will contribute to the development and refinement of programme theory (by attending RMG and AP meetings), contribute to writing the final report and peer reviewed publications. JB is a chair in mental health nursing at the University of Leeds. His research specialises in reducing coercive and restrictive practices. He has used a range of methods from qualitative studies to complex trials. The good practice manuals which he developed have been evaluated, cited as examples of good practice, and influenced clinical practice in the UK and abroad. The training package for patients, service users and carers to promote research awareness and understanding has been cited by the MHRN and NICE as an exemplar of good practice. JB is currently leading on 2 NIHR funded evidence syntheses of interventions to reduce restrictive practices in acute mental health settings, and children and adolescents institutional settings.

Dr Peter Baker (PB) – Expert LD, challenging behaviour and mental health (5%FTE). PB will contribute to programme theory development and dissemination/impact. PB is senior lecturer at the Tizard Centre, University of Kent, and a Chartered Clinical Psychologist. He has worked in the NHS for over 35 years, most of that time as a clinical psychologist where he led one of the country's longest established specialist support and intervention services for people with LDs who present challenging behaviour. He is a senior lecturer at the Tizard Centre and is also a Board Certified Behaviour Analyst

(BACB-D) and Associate Fellow of the British Psychological Society. He has authored many papers, journal articles, book chapters and pamphlets as well as being on the working groups for the recent NHS Protect Meeting Needs & Reducing Distress guidance and the original unified approach guidance. During his time in the NHS PB developed a BILD accredited physical intervention teaching programme (PBS Sussex) which was delivered to over 2000 care staff. He is the senior editor of the International Journal of Positive Behavioural Support. PB is also a member of the project management group at the Sharland Foundation Developmental Disabilities ABA Research and Impact Network.

Dr Melanie Chapman (MC) – Expert LD, systematic reviews, public involvement (5%FTE). MC will have a key role in developing and validating programme theory, advise regarding the conduct of the realist review and support the experts by experience (BM, GB) with the review and dissemination strategy. MC has published expensively in the area of LD with over twenty years of disability research experience in academic, health and social care settings, including reviews on the diagnosis of epilepsy and mindfulness. She is committed to public and patient engagement in research and was a forum facilitator for the North West People in Research Forum 2012-2015. MC is the current PI on Greater Manchester Growing Older with Learning Disabilities partnership research project which has set up and is supporting a team of older people with LDs to carry out research into social isolation amongst their peers (£100K, Ambition for Ageing, National Lottery Community Fund). MC's previous partnership research projects include 'Being Warm Being Happy' research into how to support people with learning disabilities to keep warm at home and advocacy support for people with LDs.

Dr Kirstine Szifris (KS) – Specialist in realist reviews (20%FTE). KS will have a leading role regarding the realist review methodology and will be the key advisor regarding the conduct of the review. She will also provide a 1-day training to experts by experience and members of the RMG and AP, to improve members' understanding of the realist review methodology. KC will also contribute to the writing of the final report and the peer reviewed publication. Dr. Szifris is a Senior Research Associate at the Policy Evaluation and Research Unit (PERU) at Manchester Metropolitan University. As part of an interdisciplinary team, Kirstine has experience in a range of methodologies. In particular, she has led on a realist review of prison education, conducted meta-analyses, and run a pilot Randomised Controlled Trial in a prison education department. Her methodological expertise lies in mixed-methods research and theory development.

James Ridley (JR) – Expert LD, Positive Behaviour Support, policy impact (5%FTE). JR will contribute to the development and refining of programme theory (by attending RMG and AP meetings), contribute to writing the final report and peer reviewed publications, and to impact events. JR is a Senior Lecturer, Pre-registration Nursing (Learning Disability) who has worked with health and social care services since 1992, qualifying as a Registered Nurse in 2004. He has devoted his career to the care of people with LDs and has a passion for supporting people with the label of "Challenging Behaviour". He is successful in presenting at regional, national and international conferences where restrictive practice reduction and practice of "Positive Behavioural Support" continue to be points of discussion for practitioners. Externally JR is a specialist clinical advisor for the Care Quality Commission, and NHS England. He is on the panel of the British Institute of LD Accreditation, which is nationally recognised as a good practice tool for benchmarking restrictive practice education. JR has recently co-authored national guidelines on training standards in minimising restrictive practices on policy impact. JR is also an active member of the North West LD Network and the North West PBS Network. He will play a key role in the support of disseminating the findings of this project through his networks and advisory roles.

12. SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK

Success will be monitored on a monthly basis and will be closely linked to the delivery of milestones indicated in the Gantt chart. At each RMG meeting a review of progress in relation to milestones will be held and solutions identified.

There is a risk that the conclusions emerging from the review will not be sufficiently robust to avoid the risk of bias, given that the majority of studies we anticipate will be observational and single case studies. An assessment of the quality/risk of bias of the evidence base will be conducted and the results incorporated in the synthesis/conclusions. Similarly, there is the risk that the evidence will not be sufficient to support the emerging theory. In this case, we will highlight theories or mechanisms that need to be tested with further, more robust research, e.g. randomised trials. In engaging service users and carers in the theory development stages of the realist review, we recognise that this can be challenging. We have a number of strategies in place to address this. Firstly, we will organise training to improve awareness and understanding regarding the realist review methodology. Secondly, we are using existing service users and carers groups which will support those who are less familiar with research. The research team have already made contact with members of PABSS, Dimensions UK, and the service users groups within SpLDD who are supportive of the research agenda and methodology.

Finally, we acknowledge that the realist review requires time and commitment from stakeholders. Our research team is well connected with key organisations in this area and given the importance of this agenda we feel we have attracted key and highly motivated co-applicants and members to the AP and EEG. Furthermore, given the size of the team and the various groups, any unexpected problems with availability can be managed and shared accordingly.

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This study/project is funded by the National Institute for Health Research (NIHR) [NIHR HS&DR Ref 129524]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.