An evaluation of Care (Education) and treatment reviews for people with learning disabilities and autistic people (CECILIA)

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Co-Chief Investigators agree to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the relevant study regulations, GCP guidelines, and study SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the study without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

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Name Peter Langdon	**Signature**	**Date 04 Dec 2024**

Co-Chief Investigator:		
Name Karen Bunning	**Signature**	**Date 09 Dec 2024**

Sponsor:		
Name Clark Crawford	**Signature**	**Date 27 Feb 2025**

General Information This protocol describes the CECILIA study and provides information about the procedures for the study. Every care has been taken in drafting this protocol. However, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study. Problems relating to the study should be referred, in the first instance, to the Co-CIs.

This study is funded by the NIHR Health and Social Care Delivery Research Programme (NIHR158265). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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This protocol has been developed by the CECILIA Study Management Group (SMG).
For **all queries** please contact the CECILIA team through the main study email address. Any clinical queries will be directed through the Study Manager to either the Co-Chief Investigators or a Co-Investigator.

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Glossary of abbreviations

AE	Adverse Event
AIC	Akaike Information Criterion
AR	Auto-regressive
ARMA	Autoregressive, moving average
BEAR	Birmingham Environment for Academic Research
BtRS	Building the Right Support
CBF	Challenging Behaviour Foundation
C(E)TR	Care (Education) and Treatment Reviews
CI	Chief Investigator
CPA	Care Programme Approach
CTR	Care and treatment Reviews
CTU	Clinical Trials Unit
DAG	Directed Acyclic Graph
DSR	Dynamic Support Register
EbE	Expert by Experience
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
HSDR	Health and Social Care Delivery Research
HS&DR	(NIHR) Health Services and Delivery Research
iDMEC	independent Data Monitoring and Ethics Committee
ICB	Integrated Care Board
IC(E)TR	Independently Chaired Care (Education) and Treatment Reviews
ISRCTN	International Standard Randomised Controlled Study Number
LDE	Learning Disability England
LEAP	Lived Experience Advisory Panel
MA	Moving average
MCA	Mental Capacity Act
MDT	Multidisciplinary team
NAS	National Autistic Society
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PI	Principal Investigator
PPI	Patient and Public Involvement
R&D	Research and Development
RA	Research Assistant
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMF	Study Master File
SMG	Study Management Group
SSC	Study Steering Committee

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No. *(specify substantial/non-substantial)*	**Protocol version no.**	**Date issued**	**Summary of changes made since previous version**
Non substantial	1.1	27.02.2025	Signed by sponsor following REC approval.

2 Synopsis

Title	An evaluation of Care (Education) and treatment reviews for people with learning disabilities and autistic people
Acronym	CECILIA
Funder and ref.	NIHR 158265
Study design	5 work packages delivered across 4 stages: Stage 1 (Work package 1): National co-designed survey and structured interviews for those who might have difficulty accessing the survey of key groups who have received or taken part in a C(E)TR within the last 12-months. Stage 1 (Work package 2): National co-designed survey of C(E)TR workforce and health and social care professionals. Stage 2 (Work package 3): Mixed methods incorporating collection of naturalistic data from C(E)TRs and CPA meetings and semi-structured interviews with attendees. Stage 3 (Work package 4): Time-series modelling using public anonymised data about psychiatric bed utilisation by autistic people and people with learning disabilities. Stage 4 (Work package 5): Integration of qualitative and quantitative data, inclusive of our estimate of resource implications, across prior four work packages using triangulation techniques. Development of good practice guidance.
Study participants	Stage 1 (Work package 1) a) Children and adults with learning disabilities, including a subset of those with moderate to severe learning disabilities b) Autistic children and adults c) Family members d) Carers Stage 1 (Work package 2) a) C(E)TR panel members including Experts by Experience (EbE) b) Health and social care professionals Stage 2 (Work package 3) C(E)TR cases over time, to be inclusive of a) Autistic children and children with mild, moderate, and severe learning disabilities b) Autistic adults and adults with mild, moderate, and severe learning disabilities c) Inpatients from specialist assessment and treatment inpatient services, forensic inpatient services, and general inpatient mental health services

	Stage 3 (Work package 4) a) Anonymous data from (i) Assuring Transformation, and (ii) Mental Health Services datasets) about autistic inpatients and inpatients with learning disabilities Stage 4 (Work package 5) N/A
Planned sample size	Stage 1 (Work package 1) a) A minimum of 150 to a maximum of 300 people with learning disabilities and autistic people. Within this a minimum of 30 children aged 17 or younger. b) A minimum of 150 to a maximum of 300 family members and carers c) A minimum of 25 people with moderate to severe learning disabilities (in addition to those people with learning disabilities already included) Stage 1 (Work package 2) a) Overall, a minimum of 350 C(E)TR panel members, including EbE and health and social care professionals involved in C(E)TRs b) Within this, a minimum of 200 to a maximum of 400 C(E)TR panel members (Chairs, Independent Clinical Members, and EbE) c) Within this, a minimum of 150 to a maximum of 300 health and social care professionals (commissioners, social workers, advocates, paid and unpaid care staff, clinical staff including psychiatrists, nurses, psychologists, allied health professions) Stage 2 (Work package 3) (a) Overall, 20 cases over time (b) Within this, 10 adults and 10 children Stage 3 (Work package 4) a) 132 months (11 years; one aggregated observation per month) of anonymous data from (i) Assuring Transformation, and (ii) Mental Health Services datasets Stage 4 (Work package 5) N/A
Inclusion criteria	Stage 1 (Work package 1) (a) A person with a learning disability, or an autistic person, or a family member of carer of an autistic person or person with a learning disability, (b) Having received or taken part in a C(E)TR within the last 12-months including blue-light community C(E)TRs (c) Aged 5 or older (i.e. eligible to attend school at Key Stage one)

	(d) For those aged 16 years and older who lack capacity to make a decision about taking part in this research, advice indicating that they should be included from either a personal or nominate consultee (e) For those aged 15 and younger, consent from the person or organisation with parental responsibility Stage 1 (Work package 2) (a) A C(E)TR chair, clinical member, or EbE or a health or social care professional, or commissioner (b) Who has taken part in a C(E)TR within the last 12-months including blue-light community C(E)TRs Stage 2 (Work package 3) People with learning disabilities or autistic people: (a) Who are due to have at least two C(E)TRs within 15-months (b) Aged 5 or older (i.e. eligible to attend school at Key Stage one) (c) For those aged 16 and older who lack capacity to make a decision about taking part in this research, advice indicating that they should be included from either a personal or nominated consultee for inclusion (d) For those aged 15 and younger, consent from the person or organisation with parental responsibility C(E)TR panel members: (a) A chair, EbE or clinical member who is due to attend a C(E)TR for a person with a learning disability or an autistic person who is taking part in this research project. Health and social care professionals: (a) A health and social care professional who is due to attend a C(E)TR or CPA for a person with a learning disability or an autistic person who is taking part in this research project. Carers and family members: (a) A carer or family member who is due to attend a C(E)TR or CPA for someone with a learning disability or autism who is taking part in this research project. Stage 3 (Work package 4) (a) A person with a learning disability, or an autistic person, included within the Assuring Transformation and Mental Health Services datasets. Stage 4 (Work package 5) N/A
Exclusion criteria	Stage 1 (Work package 1) (a) Only having received or taken part in Independently Chaired Care (Education) and Treatment Reviews (IC(E)TRs) within the last 12-months. IC(E)TRs are only for those held within long-term segregation and are out of scope of this commissioned research study. (b) Aged younger than 5 years.

	Stage 1 (Work package 2) (a) Staff who have only taken part in Independently Chaired Care (Education) and Treatment Reviews (IC(E)TRs) within the last 12-months. IC(E)TRs are only for those held within long-term segregation and are out of scope of this commissioned research study. Stage 2 (Work package 3) (a) Aged younger than 5 years. Stage 3 (Work package 4) None. Stage 4 (Work package 5) N/A
Planned study period	36 months starting 01 Sep 2024
Aim	To undertake an evaluation of C(E)TRs using mixed methods across four stages with five work packages with children and adults with learning disabilities and autistic children and adults across a range of inpatient settings, including those in the community who receive a C(E)TR who are at risk of admission.
Objectives	To understand the experiences of all stakeholders, including people with learning disabilities and autistic people and their families, when taking part in C(E)TRs including descriptions of the barriers and facilitators to genuine participation and the use of augmentative and alternative communication, and options for improvement. To understand how C(E)TRs are being carried out in practice with a range of people with learning disabilities and autistic people across different settings, including those at risk of admission who are in the community. To understand how C(E)TRs may be changing care pathways, improving outcomes, potentially preventing admission or promoting discharge, their possible cost implications, and how this is different from existing methods for reviewing care, and to make recommendations for improvement. To publish good practice guidance inclusive of practical resources and tools for conducting C(E)TRs and outcome implementation, including how to promote inclusion and participation for people with learning disabilities and autistic people
Methodology summary	5 work packages delivered across 4 stages. Lived Experience Advisory Panels (LEAPs) will co-produce materials and actively engage throughout each stage and all work packages. Initially, we will co-develop a logic model informed by existing guidance and other literature to describe C(E)TR key activities, mechanisms of change, and outcomes. Health economics analysis will occur within Stage 1: work package 1, 2, and Stage 3: work package 4.

	Stage 1 (Work package 1) This stage is a survey using closed and open questions focused on C(E)TR experiences, including cost data. Structured interviews will take place with people with moderate-severe learning disabilities and younger children. Survey and interview questions will be informed by a logic model. Survey and interview questions will be chosen and refined collaboratively with LEAPs. Survey data will be captured on one occasion. Descriptive data will be summarised and reported. Data generated from open-ended survey questions and structured interviews will be analysed using inductive summative content analysis with emergent coding with reference to the logic model. Health economics data will be collected concerning resource use. Data concerning how C(E)TRs are being carried out for different groups will be used to define exemplar C(E)TRs. These will be combined with appropriate unit cost data to provide approximate costs of different models of providing this care. Likely changes to care pathways will also be costed to provide approximate cost implications of changes in services. Stage 1 (Work package 2) This work package is also a survey and will be a blend of closed and open questions focused on experiences of taking part within C(E)TRs, including cost data. Survey and interview questions will be informed by the logic model. Survey and interview questions will be chosen and refined collaboratively with LEAPs. Survey data will be captured on one occasion. Descriptive data will be summarised and reported. Data generated from open-ended survey questions and structured interviews will be analysed using inductive summative content analysis with emergent coding with reference to the logic model. Health economics data will be collected concerning resource use. Data will build on that obtained during work package 1 to further refine and construct exemplars of typical ways of providing C(E)TRs and potential changes to care pathways. Stage 2 (Work package 3) Data will be gathered on 20 cases over time, purposively chosen to include key sub-groups of the wider population of autistic people and people with learning disabilities. We will recruit potential participants from across England within three broad regions: (a) eastern, (b) southeastern and southwestern, and (c) midlands and northern incorporating urban and rural locations across a range of inpatient

services to ensure that our sample includes key sub-groups of the wider population of autistic people and people with learning disabilities.

Data will be captured over time from direct observation and recording of C(E)TR and CPA meetings, and interviews with those who attended these meetings. Data will be captured, and interviews will be carried out to cover approximately 60 meetings (2 C(E)TRs, and a CPA meeting per individual). We anticipate conducting up to 180 interviews in total across the 20 cases with individuals, carers and family members, C(E)TR panel members, and health and social care professionals. We will also capture demographic data, information from C(E)TR paperwork and other patient meetings, and track progress through care-pathways.

There will be two analytic approaches. The first analytic approach will be a linguistic analysis which will focus upon the: (a) Accessibility Value of Information, (b) Structure and Management of C(E)TRs, and Other Meetings and, (c) Inclusion and Communicative Participation of People with Learning Disability or Autistic People and Families or Carers. Together, this analytic approach will allow for a clear characterisation of effective and problematic communication during C(E)TRs, CPAs and other meetings.

The second analytic approach will be a temporal pathway model developed using a mixed methods grounded theory approach from transcripts of participant interviews and our documentary review describing how the C(E)TR process unfolds over time for the 20 cases. The development of a C(E)TR pathway model will allow us to understand how the C(E)TR process unfolds over time from the personal accounts of the participants themselves, whilst taking into account contributory contextual and environmental factors

Stage 3 (Work package 4)

Anonymous data will be obtained from the Assuring Transformation and Mental Health Services datasets. Both of these datasets are published monthly. The Assuring Transformation dataset details the number of autistic inpatients and inpatients with learning disabilities over time. The Mental Health Services dataset details psychiatric bed utilisation by people with learning disabilities and autistic people. Combining both datasets, we anticipate having data for 132 months (11 years).

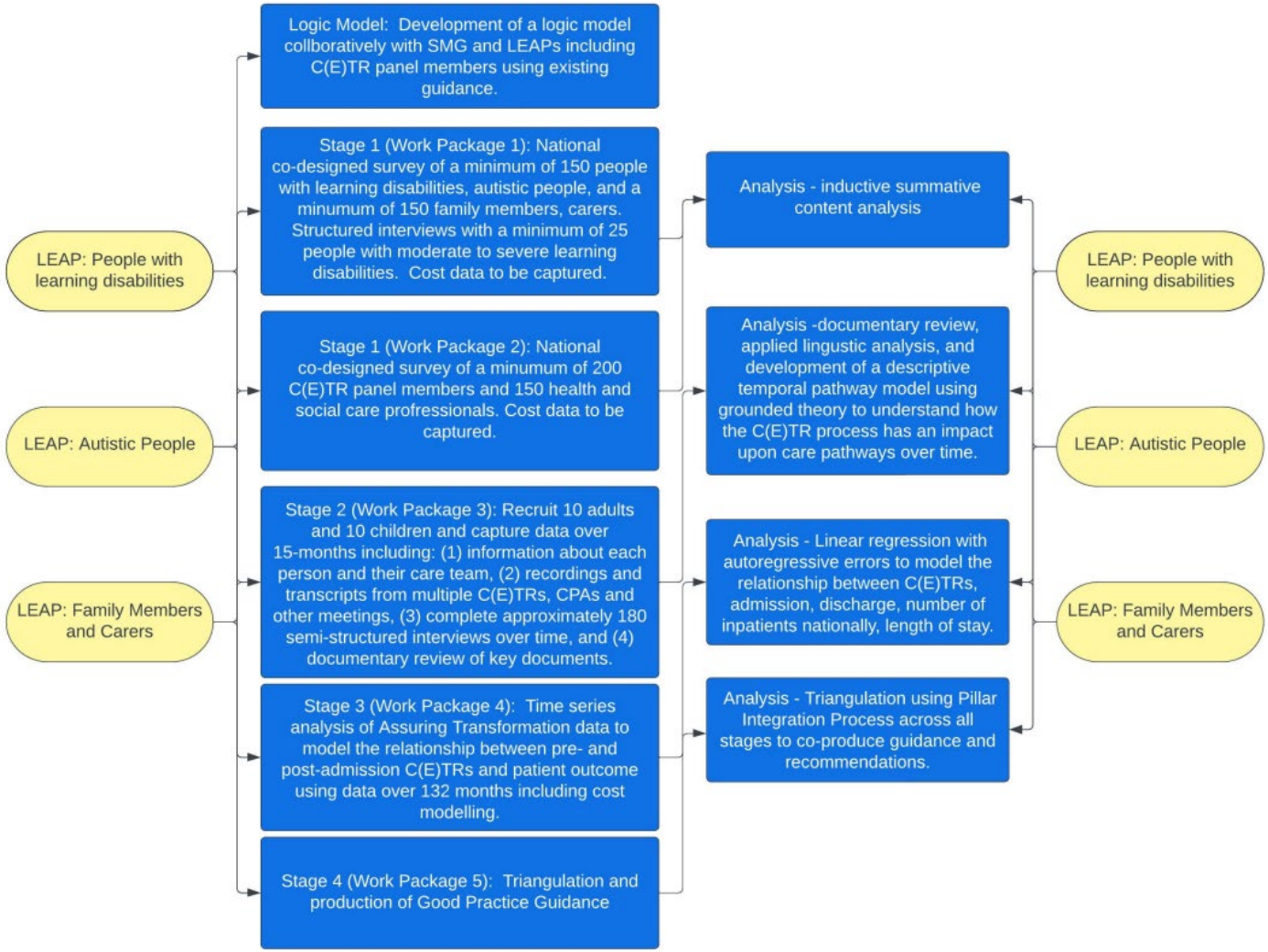
A Directed Acyclic Graph (DAG) will be created to map assumptions about the causal pathways between C(E)TRs, the number of inpatients over time and additional predictors. The DAG will be created in consultation with stakeholders and informed by the C(E)TR logic model, to determine a minimum adjustment set of potential predictors.

Ordinary regression will be fitted initially, and corresponding residuals checked to determine if the anticipated autoregressive structure is present. If present, generalized least squares regression with auto-regressive (AR) errors

	will be used to model relationships between the explanatory and outcome variables over time. Further health economics analysis will involve using information from the time-series modelling to inform estimates of the potential cost implications of C(E)TRs. From Stage 1, we will have estimates of the indicative costs of C(E)TRs and how this might vary across different people. We would also have information on typical effects on care pathways, and associated costs. Using time-series modelling we aim to show the relationship between C(E)TRs, inpatient stays, and other variables. Costs can be applied to inpatient stays, potential confounding factors, and C(E)TRs themselves to explore what effects C(E)TRs might be having on NHS and care costs. Stage 4 (Work package 5) Quantitative and qualitative data from the prior four work packages, inclusive of our estimate of resource implications, will be integrated using triangulation techniques. The findings will be used to inform the context of our good practice guidance for C(E)TRs, outlining best practice for maximising participation for people with learning disabilities and autistic people and their families/carers, as well as EbEs, how to implement C(E)TR outcomes effectively to maximise progression along care pathways, and guidance to overcome barriers. This process will also inform a final version of a logic model for C(E)TRs as a key project output.

3 Study summary and schema

3.1 Study overview



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3.2 Project timetable

Frequency	Project Management
Monthly	Project Team Meetings
Monthly	Study Management Group
≈ every 6 months (6 meetings)	Study Steering Committee – to be held jointly with the OptiCaT (optimising community C(E)TRs through understanding the experience of people with intellectual disability and autistic people and investigating their impact on care) project led by Rory Sheehan and Afia Ali
≈ every 4 months (11 meetings)	LEAP – Autistic People
≈ every 4 months (11 meetings)	LEAP – People with Learning Disabilities
≈ every 4 months (11 meetings)	LEAP – Family Members and Carers
Month(s)	**Activity and Milestones**
-3 to 2	Finalise protocol, Stage 1 ethics application, and recruit staff.
0 to 2	Finalise logic model. Finalise Stage 1 survey questions and structured interview questions.
3 to 10	Stage 1 (Work Package 1 and 2): survey and structured interviews.
9 to 11	Stage 1 (Work Package 1 and 2): analysis.
9 to 10	Finalise Stage 2 (Work Package 3) semi-structured interviews. Stage 2 (Work Package 3) ethics application.
10 to 24	Stage 2 (Work Package 3): recordings and observations of C(E)TRs, semi-structured interviews – development of temporal pathway model.
21 to 27	Stage 3 (Work Package 4): data download, cleaning, and analysis.
24 to 27	Stage 2 (Work Package 3): analysis.
28 to 31	Stage 4 (Work Package 5): triangulation of findings across Stages 1 to 3.
32 to 36	Development of good practice guidance together with LEAPs and submission of final report.
>36	Dissemination conferences, podcasts, peer review journal outputs

3.3 Study lay summary

Aims

In this research project, we will determine whether Care (Education) and Treatment Reviews are helpful for people with learning disabilities and autistic people and their families.

Background

Care (Education) and Treatment Reviews were started in 2014 to help get autistic people and people with learning disabilities out of psychiatric hospitals and to prevent their admission to psychiatric hospitals. Care (Education) and Treatment Reviews involve an independent panel including an Expert by Experience, a clinician, and a commissioner who is responsible for paying for an individual's care. The autistic person or the person with learning disability and their family also attend the meeting. The focus of a Care (Education) and Treatment Review is to either prevent a person from being admitted to a psychiatric hospital in the first place, or to help someone who is already in hospital, get out. They do this by trying to work out ways to overcome barriers that might be stopping someone from leaving hospital. However, we do not know if Care (Education) and Treatment Reviews stop people from being admitted to a psychiatric hospital in the first place, or help people already in hospital get out.

Method

Our project has four stages.

In Stage 1 we will work with the members of our Lived Experience Advisory Panels to co-produce survey questions. We will design surveys for people with learning disabilities and autistic people, families and carers, Care (Education) and Treatment Reviews panel members, and health and social care professionals to complete. We will share these surveys with as many people as we can nationally. We will make adjustments so that people with learning disabilities can take part in our surveys. We know that individuals with moderate to severe learning disabilities and younger children will not be able to complete the surveys and so we will use other ways to gather their views and experiences. We will also try to work out how much it costs to have a Care (Education) and Treatment Review .

Within Stage 2, we will find out how patients in hospital are doing over time, by attending Care (Education) and Treatment Reviews, CPA, and other patient meetings. We will ask people, including people with moderate and severe learning disabilities to take part in some interviews with us, ensuring we adapt the interview process, so it is accessible. We will use the information from these interviews to work out whether Care (Education) and Treatment Reviews are helping people and making things better.

In Stage 3, we will look at the anonymous data that is collected by the NHS about everyone with a learning disability or autism who is admitted to hospital. We will work out what sorts of things helped them and what sorts of things did not help them get out of hospital. We think we will have data that covers over 11 years.

Within our final stage, Stage 4, we will bring together all of the information we have collected from the different stages of the research to work out what it tells us. We will use the information along with input from our Lived Experience Advisory Panel members to co-produce and share reports and information about what we have found out. We will also co- develop and publish good practice guidance for doing Care (Education) and Treatment Reviews and make sure our guidance is shared in different ways and to different people who need it.

Patient/public involvement

We have partnered with Learning Disability England, the National Autistic Society, and the Challenging Behaviour Foundation who will each lead one of our three Lived Experience Advisory Panels: (1) people with learning disabilities, (2) autistic people, and (3) carers and family members. We will have regular meetings with each Lived Experience Advisory Panel to make sure we they can provide input throughout the study. They will help us to design the surveys and interviews, interpret our findings, share the findings and co-produce and publish our good practice guidance in different formats for different target audiences. Each advisory panel will meet separately but we will bring them together once a year to benefit from their combined input.

Our project has been developed collaboratively with Learning Disability England, the National Autistic Society, and the Challenging Behaviour Foundation who all have experience of being involved within Care (Education) and Treatment Reviews. Learning Disability England, the National Autistic Society, and the Challenging Behaviour Foundation will be core members of our study management and study steering committees. Further, a nurse with significant learning disability and autism experience, Expert-by-Experience, and Care (Education) and Treatment Review panel chair is a co-researcher. A carer of a man with severe learning disability is also a co-researcher.

Dissemination

We will work with our Lived Experience Advisory Panel members to co-produce a communication plan to ensure that our findings are shared with the people who can and should use them. We expect information to be produced in different formats. We will place information about our study on Learning Disability England, the National Autistic Society, and the Challenging Behaviour Foundation websites and within their newsletters. We will develop accessible videos about our study and our findings and share them with wide audiences and through many networks. We will hold joint dissemination events following the completion of this project to reach as many people as possible. We will also have specific events to showcase our good practice guidance.

4 Background and rationale for the current study

Care (Education) and Treatment Reviews (C(E)TRs) were introduced due to the challenges with implementing Transforming Care for people with learning disabilities and autistic people [1]. This national strategy was launched due to concern about the quality of care and the abuse of people with learning disabilities and autistic people within psychiatric hospitals aired repeatedly on the BBC Panaroma and Channel 4 Dispatches programmes, most recently in 2023 [2]. A key goal of Transforming Care [1], and later developed policy, Building the Right Support (BtRS), [3] was to reduce inpatient numbers by increasing admission avoidance and discharge, and C(E)TRs were seen as one of the key mechanisms of change. The aim of C(E)TRs was, “to bring a person-centred and individualised approach to ensuring that the care and treatment and differing support needs of the person and their families are met, and that barriers to progress are challenged and overcome” [p.10;

4]. While there is evidence that the number of people with learning disabilities and autistic people within psychiatric hospital beds has reduced since 2015, the BtRS target of a 35 to 50% reduction in inpatient numbers was not met [5]. Within the long-term plan, NHS England [6] recommitted to reduce the number of people with learning disabilities and autistic people who are within psychiatric hospital beds; the targets set are to decrease inpatient numbers to less than 50% of the numbers in 2015, and that for every 1 million people in the population, there should be no more than 30 adults and 15 children with learning disability and/or autism within a psychiatric hospital by 2024. The BtRS action plan includes a commitment to ensuring that all people with learning disability and autistic people receive high quality support, including those who are in psychiatric hospitals, while working towards timely discharge [7]. Further, the government has considered giving C(E)TRs a statutory role within the planned revisions to the Mental Health Act, such that the outcomes of C(E)TRs must be considered within the statutory care and treatment plan and any deviation from C(E)TR recommendations must be justified [8]. However, there is little to no evidence that C(E)TRs have led to a reduction in the number of people with learning disabilities and autistic people within psychiatric hospitals.

The Public Accounts Committee [9] stated that C(E)TRs are the main mechanism for reducing the number of people in hospital and expressed concern that they were not working as intended. C(E)TRs are undertaken by an independent panel comprised of an Expert by Experience (EbE), a clinician, and the commissioner who chairs the meeting and is also responsible for funding an individual's care. The autistic person or the person with learning disability and their family also attend the meeting. C(E)TRs can take place in the community with someone who is identified as at risk of admission to hospital, or in hospital, after someone has been admitted. After admission, C(E)TRs initially take place within six weeks, and then take place every three months for children, every six months for adults within non-secure services, and every twelve months for adults in secure services. However, C(E)TRs can be requested at any time by an individual, their family, the commissioner, an advocate, or the clinicians supporting the person. For those in the community at risk of admission, the primary aim of a community C(E)TR is to undertake a review of care to determine whether a person's needs could be better met in a community setting, as opposed to hospital, with additional support. Admission to hospital should be a last resort and only happen when remaining in the community will place the individual and others at significant risk of harm. For those who are admitted, the focus of a C(E)TR is to determine whether someone needs to remain in hospital for continuing care, and to identify barriers to discharge and develop solutions to these barriers.

However, there is also little evidence regarding whether C(E)TRs are associated with positive outcomes for people with learning disabilities and/or autistic people. Clark [10] undertook a survey of experts by experience, clinical advisors, commissioners, individuals and their families about the implementation and effectiveness of C(E)TRs. The findings indicated that while people with learning disabilities and families were positive about C(E)TRs, there were concerns about C(E)TR outcomes not being actioned or monitored, a view that the process was a paper exercise only, and concerns about a lack of key staff engagement, including community staff. Recommendations made were: to ensure that family members are included, C(E)TRs should be combined with the Care Programme Approach (CPA), key staff should attend (e.g., responsible clinician), and communication during meetings should support the engagement of people with learning disabilities. While not the focus of this commissioned call, similar and other concerns have been noted about Independent C(E)TRs for people within long-term segregation [11]. Independent C(E)TRs are different from C(E)TRs as they review the care given to autistic people and people with a learning disability who are in long-term

segregation within hospital. They have an independent chair and a Mental Health Act reviewer and are not the focus of the current commissioned call.

Recently, we made use of time-series modelling to examine data collected by NHS Digital about psychiatric hospital admission and discharges for people with learning disabilities and autistic people from 2013 to 2021 [5]. We reported that pre-admission C(E)TRs, represented as a ratio of those who received one to those who did not receive one, were associated with increased admissions over time. Post-admission C(E)TRs, also represented as a ratio of those who had received one relative to those who had not received one, were associated with increased discharges over time. C(E)TRs were not related to the total number of inpatients within hospital over time. Relatively recently, NHS England [12] have updated their C(E)TR policy, outlining the relationship with the Dynamic Support Registers (DSRs). DSRs are local systems that are intended to be used to identify those at risk of admission to hospital, used to triage that risk, and should be used to trigger C(E)TRs prior to admission. However, there is little information about how well both C(E)TRs and DSRs are working, and to date, there has been no systematic evaluation of C(E)TRs investigating their effectiveness in reducing the number of people with learning disabilities and autistic people in hospital. Further, there are no data about the cost implications of C(E)TRs.

People with learning disabilities and autistic people are at increased risk of developing mental illness and/or behaviour that challenges, relative to the general population [13-15], which may be associated with psychiatric hospital admission. Concerns have been raised about the appropriateness of these admissions, excessive lengths of stay, and actual abuse leading to a drive to reduce the use of inpatient admission [16, 17]. Improving the lives of people with learning disabilities and autistic people is a national priority, and while this group are more likely to develop mental illness and behaviours that challenge, they are also likely to die prematurely with a substantial number of these deaths being avoidable had good quality care been given [18]. For those who die prematurely, difficulties with care planning and recognising need, inappropriate accommodation, carers not feeling listened to, and difficulties following the Mental Capacity Act 2005, were cited as contributory factors [18]. Good communication contributes to positive health outcomes for all [19], but communication is difficult for many people with learning disabilities and autistic people, and adaptations are required [20, 21]. As a consequence, C(E)TRs, which aim to review care and improve outcomes for a very vulnerable population, if effective in the way intended, could lead to substantial health and social care improvements for people with learning disabilities and autistic people by improving support and reducing inappropriate psychiatric hospital admission.

5 Study aim, objectives and research questions

5.1 Aim

To undertake an evaluation of C(E)TRs using mixed methods across four stages with five work packages with children and adults with learning disabilities and autistic children and adults across a range of inpatient settings, including those in the community who receive a C(E)TR who are at risk of admission

5.2 Objectives

1. To understand the experiences of all stakeholders, including people with learning disabilities and autistic people and their families, when taking part in C(E)TRs including

descriptions of the barriers and facilitators to genuine participation and the use of augmentative and alternative communication, and options for improvement.

2. To understand how C(E)TRs are being carried out in practice with a range of people with learning disabilities and autistic people across different settings, including those at risk of admission who are in the community.
3. To understand how C(E)TRs may be changing care pathways, improving outcomes, potentially preventing admission or promoting discharge, their possible cost implications, and how this is different from existing methods for reviewing care, and to make recommendations for improvement.
4. To publish good practice guidance inclusive of practical resources and tools for conducting C(E)TRs and outcome implementation, including how to promote inclusion and participation for people with learning disabilities and autistic people

5.3 Research questions

1. What are the experiences of people with learning disabilities and autistic people, families, C(E)TR panel members and a range of health and social care professionals when taking part in C(E)TRs?
2. How are experts by experience being included and supported to take part in C(E)TRs? What are the barriers and facilitators to participation and how can their participation be promoted?
3. How are C(E)TRs being carried out in practice with different groups (e.g., children, adults, autistic adults without learning disabilities) and in different settings (e.g., assessment and treatment units, secure units, acute mental health wards, inpatient units for children)?
4. What impact do C(E)TRs have upon care-pathways, and how are recommendations and outcomes implemented and monitored?
5. What barriers and facilitators to discharge are identified by C(E)TRs and how are they overcome or addressed by care teams?
6. How are C(E)TRs different, similar to, or integrated with existing methods for reviewing care (e.g., Care Programme Approach, Child Protection Conferences, Extraordinary Care Review Meetings)?
7. How are C(E)TRs structured and managed to support inclusion, and what adjustments and supports aid participation (e.g., augmentative and alternative communication) of people with learning disabilities and autistic people, and how can these be improved?
8. Is there evidence that people with learning disabilities and autistic people who are receiving a C(E)TR are being empowered as a consequence of C(E)TRs? What are the barriers and facilitators to empowerment and how can this be promoted?
9. Is there a relationship between the skill mix of a C(E)TR panel and the recommendations or outcomes made and are they implemented and how?
10. Are C(E)TRs associated with reducing inpatient numbers and what effect do they have on costs?
11. What are likely resource implications of C(E)TR and how might they differ between different types of individuals?

6 Study design and data collection methods overview

This research has four stages comprising five work packages using mixed methods. Lived Experience Advisory Panels (LEAPs) will co-produce study materials and will be actively engaged throughout

each stage and all work packages. Initially, we will co-develop a logic model informed by existing guidance and other literature to describe C(E)TR key activities, mechanisms of change, and outcomes which will be used to inform the choice of survey and interview questions and analysis within Stages 1 and 2, the analytic strategy within Stage 3, and the data triangulation within Stage 4. Our logic model will be developed in collaboration with our Lived Experience Advisory Panels (LEAPs) and the Study Management Group inclusive of C(E)TR panel members. We will also seek direct feedback from lead staff in NHS England who lead C(E)TR policy.

Within Stage 1, national surveys (co-produced with our LEAPs) will be circulated to people with learning disabilities and autistic people, including children and young people, families and carers, C(E)TR panel members, and health and social care professionals. Surveys will ask about their experiences of taking part in C(E)TRs and also gather data to inform estimates of the likely cost of undertaking C(E)TRS. We will use adapted methods, led by our expert partners and with LEAP input to capture the voice of younger children and those with moderate-severe learning disabilities and those with associated communication difficulties including children and young people whose views and experiences are often not collected.

Within Stage 2, we will attend C(E)TRs, and CPA meetings to track individual progress over time, collect naturalistic data from the meetings, and undertake semi-structured interviews with attendees. We will undertake a linguistic analysis of our data to determine the relative contributions of different individuals to the decision-making process, and we will develop a descriptive temporal pathway model of C(E)TRs process over time and determine how C(E)TRs affect care pathways.

In Stage 3, we will model relationships between C(E)TRs and numbers of admissions, discharges, total number of inpatients, types of inpatient service, consider cost-implications and length of stay over time using anonymised data available from NHS Digital for children and adults.

Within our final stage, Stage 4, we will combine our quantitative and qualitative data to generate conclusions and develop and publish good practice guidance and practical resources and tools (e.g., videos, easy to read checklists, guides to promote good communication) for C(E)TRs including outlining best practice for maximising participation and engagement

6.2 Risk assessment

We will complete a formal risk assessment before the study commences, which will include:

- The known and potential risks and benefits
- How the risk will be minimised/managed

A copy of the study risk assessment may be requested from the Study Manager. The risk assessment will be used to determine the focus of monitoring activity.

We anticipate that this is a low-risk study. The research is observational, and no interventions will be implemented outside of the treatment as usual within services. Involvement in the study is voluntary, and informed consent will be obtained prior to any data collection with participants.

7 Site and Investigator selection

Stage 1 (Work Package 1 and Work Package 2)

Recruitment will take place across all NHS Trusts, private sector psychiatric hospitals, and social care organisations including local authorities, in England. We will ask NHS Trusts to share information with NHS patients, carers, and staff without having to formally confirm capacity and capability nor appoint a Principal Investigator due to the nature of our study which is a non-interventional survey and therefore low risk. This would enable us to rapidly recruit participants and include as many NHS Trusts as possible within Stage 1 without delay.

We will request that the HRA indicate in their approval letter that: (1) a Principal Investigator is not necessary at each site, and (2) sites are not required to formally confirm capacity and capability to deliver the study. The reason for this is we are only asking NHS Trusts to share information about our survey with potentially eligible participants and staff.

The study will be carried out at the University of Birmingham, the University of Kent and the University of East Anglia under the supervision of the Co-Chief Investigators (Langdon and Bunning). Fully trained research staff at each university will be responsible for recruitment and all data collection.

Occasionally during the course of the study, amendments may be made to the study documentation, required approvals obtained, and the latest approved versions will be added to the Site File.

Stage 2 (Work Package 3)

Recruitment will take place across all NHS Trusts in England and private sector psychiatric hospitals in England. A PI will be identified within each site. A Site Delegation Log and Roles and Responsibilities document will be completed, and full contact details will be recorded for all Sites. A Site File, containing all relevant study documents will be prepared. Once all study documentation is in place and a Site Initiation Visit has been completed, recruitment of participants into the study will begin.

The study will be carried out at the University of Birmingham, the University of Kent and the University of East Anglia under the supervision of the Co-Chief Investigators (Langdon and Bunning). research staff at each university will be responsible for recruitment and all data collection.

Occasionally during the course of the study, amendments may be made to the study documentation, required approvals obtained, and the latest approved versions will be added to the Site File.

Stage 3 (Work Package 4), and Stage 4 (Work Package 5)

N/A as using anonymous data from the Assuring Transformation and Mental Health Services datasets (stage 3) and integrating quantitative and qualitative data from the prior work packages (stage 4).

8 Participant selection

Stage 1 (Work Package 1)

The survey sample will include key sub-groups of the population of autistic people, people with learning disabilities, and their carers and family members. We will ensure this by explicitly sampling younger and older autistic people and younger and older people with learning disabilities nationally

who are receiving a service from a variety of services including inpatient and community services, forensic services, services for children and adolescents, acute and non-specialist services, and community learning disabilities teams. We will capture data about protected characteristics including the nature and degree of disability, ethnicity, age, and sex, and if needed, revise our recruitment strategy to help ensure that our final sample includes participants from key sub-groups.

Children aged 5 and above (eligible for entry to school Key Stage 1) will be included because evidence suggests rarely very young autistic children or children with learning disabilities are at risk of admission or are admitted to a specialist psychiatric hospital. We anticipate that younger children will be unable to complete the survey and will make use of a highly structured approach to capture their voice when possible. We need to include the full range of individuals that may have experience of a C(E)TR, and will intentionally sample from ethnically diverse regions (e.g., urban areas with large diverse communities) to help ensure that our sample is suitable to examine associations with ethnicity. Our materials will be available in different languages and our interviews can be completed with a translator.

We will make appropriate adaptations to meet the communication needs of people with learning disabilities or autistic people (e.g., easier-to-read text, pictorial prompts, having a supporter present, embedded text to speech reader, manual signing) including offering people the option of completing the survey together with a researcher either online or in person. We will include a version for older children and young people which can be completed with additional support. It is likely the case that some older children and teenagers with mild learning disabilities will be able to complete an online version of our survey with limited support. However, this will likely not be the case for some, including younger children. For this group, who are not able to complete a survey, we will also offer the option of completing a Talking Mats® interview instead. For those with no or limited vision, further adaptations will be made (e.g., visually enhanced rating scale with optional tactile markers for completion in person, and/or embedded text-to-speech functions for online completion).

Running in parallel with the surveys, we will complete structured interviews with a minimum of 25 people with learning disabilities and autistic people who have moderate to severe learning disabilities including children and adolescents with moderate to severe learning disabilities. These participants will be in addition to the minimum of 150 people with learning disabilities or autistic people who will complete our survey. Those with moderate to severe learning disabilities are likely unable to take part in our survey except through the participation of their carers. To capture their voice directly, we will make use of augmentative and alternative communication methods to support the communication of participants as appropriate to their needs, such as Talking Mats® (www.talkingmats.com) and manual sign support (https://makaton.org). These participants are likely to lack capacity to make a decision about whether they wish to take part in our survey.

Stage 1 (Work Package 2)

The sample will include key sub-groups of the C(E)TR workforce and health and social care professionals. We will recruit participants from both urban and rural areas within England across the full range of professionals who are involved in C(E)TRs. This includes paid and unpaid care staff along with professional staff and Experts by Experience (EbEs). We will capture data about protected characteristics including disability, ethnicity, age, and sex. If needed, the recruitment strategy will be revised to ensure that our final sample contains sufficient data from key sub-groups. If required, our materials will be translated and associated costs have been included. We will provide participants

with the option to complete the survey with a researcher, which may be helpful for EbEs, and will help ensure full participation.

Stage 2 (Work Package 3)

We will recruit potential participants from across England within three broad regions: (a) eastern, (b) southeastern and southwestern, and (c) midlands and northern incorporating urban and rural locations across a range of inpatient services to ensure that our sample includes key sub-groups of the wider population of autistic people and people with learning disabilities.

Cases will be purposively chosen to include key sub-groups of the wider population of autistic people and people with learning disabilities. Our sample will be inclusive of (1) children and adults, (2) autistic children and adults, and children and adults with learning disabilities including those with mild, moderate and severe learning disabilities, and (3) those from specialist assessment and treatment inpatient services, forensic services, and generic inpatient mental health services for both children and adults. We will collect data on protected characteristics including disability, sex, and ethnicity. We will make use of translators and translation as needed, and an associated budget has been included.

Stage 3 (Work Package 4)

We will access anonymous data about autistic inpatients and inpatients with learning disabilities from (i) Assuring Transformation, and (ii) Mental Health Services datasets. These data are freely available from NHS Digital and are fully anonymised.

Stage 4 (Work Package 5)

This final stage will make use of data drawn from all aforementioned Stages.

8.1 Eligibility criteria

Participants across all stages and work packages are eligible if they meet the following work package-specific inclusion criteria, and the work package-specific exclusion criteria do not apply. All queries about participant eligibility should be directed to the Study Manager.

Stage 1 (Work Package 1)

Inclusion criteria:

1. A person with a learning disability, or an autistic person, or a family member or carer of an autistic person or person with a learning disability
2. Having received or taken part in a C(E)TR within the last 12-months including blue-light C(E)TRs
3. Aged 5 or older (i.e. eligible to attend school at Key Stage one)
4. For those aged 16 years and older who lack capacity to make a decision about taking part in this research, advice indicating that they should be included from either a personal or nominate consultee

5. For those aged 15 and younger, consent from the person or organisation with parental responsibility

Exclusion criteria:

1. Only having received or taken part in Independently Chaired Care (Education) and Treatment Reviews (IC(E)TRs) within the last 12-months. IC(E)TRs are only for those held within long-term segregation and are out of scope
2. Aged younger than 5 years

Stage 1 (Work Package 2)

Inclusion criteria:

1. A C(E)TR chair, clinical member, or EbE or a health or social care professional, or commissioner
2. Who has taken part in a C(E)TR within the last 12-months including blue-light C(E)TRs.

Exclusion criteria:

1. Staff who have only taken part in Independently Chaired Care (Education) and Treatment Reviews (IC(E)TRs) within the last 12-months. IC(E)TRs are only for those held within long-term segregation and are out of scope

Stage 2 (Work Package 3)

Inclusion criteria:

People with learning disabilities or autistic people:

1. Who are due to have at least two C(E)TRs within 15-months
2. Aged 5 or older (i.e. eligible to attend school at Key Stage one)
3. For those aged 16 and older who lack capacity to make a decision about taking part in this research, advice indicating that they should be included from either a personal or nominate consultee
4. For those aged 5 years and older, but aged 15 years or younger, consent from the person or organisation with parental responsibility

C(E)TR panel members:

1. A chair, EbE or clinical member who is due to attend a C(E)TR for a person with a learning disability or an autistic person who is taking part in this research project

Health and social care professions:

1. A health and social care profession who is due to attend a C(E)TR or CPA for a person with a learning disability or an autistic person who is taking part in this research project

Carers and family members:

1. A carer or family member who is due to attend a C(E)TR or CPA for someone with a learning disability or autism who is taking part in this research project

Exclusion criteria:

People with learning disabilities or autistic people:

1. Aged younger than 5 years.

Stage 3 (Work Package 4)

Inclusion criteria:

1. A person with a learning disability, or an autistic person, included within the Assuring Transformation and Mental Health Services datasets.

Exclusion criteria:

None.

Stage 4 (Work Package 5)

N/A

9 Recruitment, Screening and registration

9.1 Identification of Services

Stage 1 (Work Package 1 and 2)

NHS Trusts, social care providers, private sector hospitals and services in England providing mental health and learning disabilities services to those with autism and/or learning disabilities will be eligible for inclusion.

Stage 2 (Work Package 3)

NHS Trusts and private sector hospitals in England providing inpatient psychiatric care to autistic people and people with learning disabilities will be eligible for inclusion.

Stage 3 (Work package 4) and Stage 4 (Work Package 5)

N/A

9.2 Identification of Participants

Stage 1 (Work Package 1)

Participants will be approached via posters, social media postings, emails, and text messages. Such information about how to take part will be disseminated through Integrated Care Boards, Provider Collaboratives, commissioners, NHS Trusts, local authorities, and social care providers nationally, including inpatient services and community teams. Further information about our survey will be shared by the National Autistic Society, Challenging Behaviour Foundation, and Learning Disability

England directly with and through networks of carers, family members, and people with learning disabilities, and autistic people. Younger child participants will be identified via an item in the parent/carer survey asking if they would be comfortable being contacted about potential data collection from the child who has received a C(E)TR that they are completing the survey about – with various options of how such data collection can occur to meet the individual communication needs of the child (including full survey, shorter version of the survey, or Talking Mats® interview).

Stage 1 (Work Package 2)

Participants will be approached via posters, social media postings, emails, and text messages. Such information about how to take part will be disseminated through Integrated Care Boards, Provider Collaboratives, commissioners, NHS Trusts, local authorities, and social care providers nationally, including inpatient services and community teams and NHS England. Our survey will also be promoted by the National Autistic Society, Challenging Behaviour Foundation, and Learning Disability England including through relevant professional networks.

Stage 2 (Work Package 3)

We will disseminate information about our study to Integrated Care Boards, Provider Collaboratives, private sector hospitals, commissioners, NHS Trusts, local authorities and social care providers nationally. Our research will also be promoted by the National Autistic Society, Challenging Behaviour Foundation, and Learning Disability England to help ensure maximum reach. We will then work directly with services that express interest to identify potential cases.

Stage 3 (Work Package 4)

We will access anonymous data from (i) Assuring Transformation, and (ii) Mental Health Services datasets. These data are freely available for download from NHS Digital and currently within the public domain.

Stage 4 (Work Package 5)

N/A

9.3 Approach logs

Stage 1 (Work Package 1 and 2), Stage 3 (Work Package 4), and Stage 4 (Work Package 5)

N/A

Stage 2 (Work Package 3)

The research team and sites will maintain approach logs of people with learning disabilities or autistic people, C(E)TR panel members, health and social care professionals, and carers and family members approached to take part in an interview within each case, including those who decline to take part.

9.4 Recruitment rates

Stage 1 (Work Package 1)

For surveys, we aim to recruit a minimum of 150 people with learning disabilities or autistic people up to a maximum of 300. Within this we aim to recruit a minimum of 30 children aged 17 or younger, who will provide data in a manner best suited to meet their individual communication needs (including full survey, shorter version of the survey, or Talking Mats® interview). We also aim to recruit a minimum of 150 family members/carers up to a maximum of 300. We will ensure the sample includes key sub-groups: children and young people, adults, those who are at risk of admission to hospital, and those currently within different hospital settings (e.g., acute ward, inpatient forensic services, psychiatric intensive care unit, specialist inpatient mental health services).

Running in parallel with the surveys, we will complete structured interviews with a minimum of 25 people with learning disabilities and autistic people who have moderate to severe learning disabilities, including children and adolescents with moderate to severe learning disabilities. These participants will be in addition to the minimum of 150 people with learning disabilities or autistic people who will complete the surveys.

Stage 1 (Work Package 2)

A minimum of 350 C(E)TR panel members, including EbE and health and social care professionals involved in C(E)TRs will be surveyed. A minimum of 200 C(E)TR panel members (Chairs, Independent Clinical Members, and EbE) up to a maximum of 400, and a minimum of 150 health and social care professionals (commissioners, social workers, advocates, paid and unpaid care staff, clinical staff – psychiatrists, nurses, psychologists, allied health professions) up to a maximum of 300 will be recruited.

Stage 2 (Work Package 3)

Overall, 20 case over time. Within this, 10 adults and 10 children.

Stage 3 (Work Package 4)

Combining both datasets, we anticipate having data for 132 months (11 years).

Stage 4 (Work Package 5)

N/A

9.5 Informed consent

All participants will be provided with information about the research and encouraged to ask any questions or request any additional information from the research team to assist them making an informed decision of whether to take part. All informed consent will be documented on consent

forms; it will not be possible to proceed further within research processes (e.g., start a survey or begin an interview) without first indicating informed consent.

It is the responsibility of whoever is conducting data collection to assess capacity to consent, and all the research staff undertaking such tasks will have relevant knowledge and experience to undertake such assessments. For those participants who are judged to lack capacity to make a decision about whether they wish to take part in our survey, advice will be sought from a personal or nominated consultee in accordance with the Mental Capacity Act, 2005. For those aged 15 and younger, consent for their inclusion will be sought from the person(s) or organisation with parental responsibility while assent will be sought from the child for their inclusion. In some instances, clear assent might not be possible due to the child's degree of learning disability. Those involved in direct data collection will remain vigilant to signs of discomfort and unwillingness to take part, taking a cautious approach to ending data collection if there are any indications of discomfort or unwillingness. Advice will be sought about the nature of communication from someone who knows an individual well (e.g., parents, carers). This will also happen for those aged 16 years and older who are judged to lack capacity to make a decision about whether they wish to take part in this research project.

Stage 1 (Work Package 1)

Participants completing the survey independently will have first received the Participant Information Sheet to consider whether they want to take part in the research. Participants will not be given a specific time frame within which to make a decision about taking part – but the opportunity to take part will not extend beyond the time frame for Stage one. Those who indicate that they wish to proceed without needing further information to make a decision will be permitted to proceed.

Participants will express interest in taking part via an expression of interest form, including preferences around how they would like to complete the survey. The research team will then send/arrange access to the survey. An online Consent Form will be presented ahead of the survey questions – it will not be possible to proceed to completing the survey without first providing consent. Researcher contact details will be provided in case the participants have any questions and/or would like any additional information.

Participants can also get in touch with the research team directly to access support in completing the survey if this would be preferable to completing the online form in standard text. Additional options are (i) text to speech reader, (ii) easier-to-read text, (iii) having someone present to provide support, (iv) manual sign support, and (v) translation into languages other than English.

Potential child participants will have been identified via an item in the parent/carer survey asking if they would be comfortable being contacted about potential data collection from the child who has received a C(E)TR that they are completing the survey about. It would then be discussed with the parent/carer what would be the most suitable format for the child to provide data – including completing the full survey, a shorter version of the survey, or a Talking Mats® interview. The additional format options detailed above (e.g., text to speech reader, easier-to-read text, additional support from parent or carer) will also be considered. The focus will be on being guided by the family/child to adapt communication to meet the needs of the child, so that their voice can be included within the research. For those aged 15 or younger, parental consent for them to participate will be sought. Assent will also be sought from the child prior to any data collection. We anticipate using a Talking Mat® with all younger children and some older children and young people.

However, it is likely to be the case that some teenagers with mild learning disabilities will be able to complete our survey with minimal adaptations and additional support.

Interviews with participants with moderate to severe learning disabilities will always utilise Talking Mats® methodology. For those aged 16 years and older who lack capacity to make a decision about taking part in this research, agreement for them to participate will be sought from either a personal or nominate consultee. After affirmative consultee advice, or consent from the person(s) with parental responsibility, the researcher will contact the supporter (relative, friend, carer) of the person with moderate to severe learning disabilities to arrange a mutually convenient date, time and place to meet to conduct a Talking Mats® interview. At the appointed time, the researcher and participant will settle in a place preferred by the participant. The researcher will present the mat to be used and place yes-no picture symbols at each of the top corners of the mat. The participant's attention will be drawn to the yes-no symbols through gesture and words. The researcher will offer picture symbols to the participant and asks them to indicate yes or no to each item. The items are: doing a Talking Mat®; being videoed; taking a photograph of the completed mat. The researcher will record the participant's completed assent/dissent mat by taking a photograph. Having already sought advice from someone who understands an individual's communication well (e.g., parent or carer), researchers will be acute to any signs of dissent (e.g., increased rates of challenging behaviour and/or crying) and discontinue.

Stage 1 (Work Package 2)

Participants completing the survey independently will have first received the Participant Information Sheet to consider whether they want to take part in the research. Participants will not be given a specific time frame within which to make a decision about taking part – but the opportunity to take part will not extend beyond the time frame for Stage one.

Participants will express interest in taking part via an expression of interest form, including preferences around how they would like to complete the survey. The research team will then send/arrange access to the survey. An online Consent Form will be presented ahead of the survey questions – it will not be possible to proceed to completing the survey without first providing consent. Researcher contact details will be provided in case the participants have any questions and/or would like any additional information.

Participants can also get in touch with the research team directly to access support in completing the survey if this would be preferable to completing the online form in standard text. Additional options are (i) text to speech reader, (ii) easier-to-read text, (iii) having someone present to provide support, (iv) manual sign support, and (v) translation into languages other than English.

Stage 2 (Work Package 3)

Participants (people with learning disabilities or autistic people, C(E)TR panel members, health and social care professionals, and carers and family members) asked to take part in an interview or direct observation/recording will have first received the Participant Information Sheet to consider whether they want to take part in the research. Participants will not be given a specific time frame within which to make a decision about taking part – but the opportunity to take part will not extend beyond the time frame for Stage two. Researcher contact details will be provided in case the participants have any questions and/or would like any additional information. If they choose to take part, they will be asked to sign a consent form; nobody who has capacity to consent will be interviewed or meetings recorded without first providing consent.

It is the responsibility of whoever is conducting data collection to assess capacity to consent, all the research staff undertaking such tasks will have relevant knowledge and experience to undertake such assessments. For those aged 16 years and older who lack capacity to make a decision about taking part in this research, agreement for them to participate will be sought from either a personal or nominate consultee. For those aged 15 and younger, consent will be sought from the person(s) or organisation with parental responsibility.

We will make use of appropriately adapted methods to complete our interviews. For C(E)TR panel members, and health and social care professionals, we anticipate making minimal adaptations to our interview processes (e.g., simplified questions). For autistic people and those with learning disabilities, we will make use of the full range of appropriate adaptations having consulted with parents and carers, or someone else who knows the individual very well. These adaptations can include simplified questions, having a carer or supporter present, use of Makaton, and the use of a Talking Mat®. Our interview methods will be responsive to individual need and designed to maximise participation.

Stage 3 (Work Package 4)

The Assuring Transformation and Mental Health Services datasets are publicly available anonymous datasets; participant consent is not possible or required.

Stage 4 (Work Package 5)

N/A

9.6 Registration

The CECILIA study will be registered with the ISRCTN database.

10 Withdrawal

We respect the right of every participant to refuse to participate in the study, or to stop at any point in the survey or interview, without giving reasons. Similarly, participants, parents, and consultees have the right to withdraw their data or the data of the person they support at any time from the point of giving consent and up to the point at which data analysis begins without giving reasons and without having any adverse effect on services received by them, their family member, or in the case of paid carers and professionals, on their employment.

Participants will be given details of and access to the online study withdrawal form in debrief information. Participants who consent and subsequently want to withdraw should complete the online study withdrawal form. The online study withdrawal form can also be completed by others on behalf of participants (e.g., those providing support). Participants/supportive people may also contact the research team in other ways to ask to withdraw (e.g., by email or phone). In this case, the research team would go through the online study withdrawal form with the participant/supportive person, completing this on their behalf (e.g., completing during a phone conversation). Any queries relating to potential withdrawal of a participant should be forwarded to the Study Manager.

If any participant wishes to stop, or refuses to answer a question, that will be respected. If a participant becomes distressed during data collection (single occasion data capture) the session will be stopped immediately without any implications to that participant. Attempts will be made to ascertain the reason for distress in collaboration with others (e.g., carers, parents, consultees) as required. Participants will have the option to request data deletion prior to the completion of our analysis. For children and young people, and those who lack capacity to make a decision about taking part in our study, researchers will be acute to any signs of dissent (e.g., increased rates of challenging behaviour and/or crying) and discontinue having previously sought advice about communication from someone who knows them well. Following this, further advice will be sought from those with either parental responsibility, in the case of participants aged 15 years or younger, or from consultees, for those aged 16 and older who have been judged to lack capacity to make a decision about taking part in this study.

11 Study procedures

Stage 1 (Work Package 1)

Potential survey participants will have been approached with research information as described in Section 9. Potential participants will have been provided with an information sheet about the study, with which to decide about whether they would like to take part in the research. They will also be encouraged to contact the research team if they have any additional questions or would like any further information to make an informed decision of whether to take part in the research. Interested participants will be given options of how they would prefer to complete the survey, including independently online or receiving support to complete the survey. Options for support include: (i) text to speech reader, (ii) easier-to-read text, (iii) having someone present to provide support, (iv) manual sign support and (v) translation into languages other than English.

When expressing a preference about how to complete the survey, participants will provide identifiable contact details. These will include their name, and contact details including postal address, email address, and phone number as per their preference of how they would like us to contact them. The primary rationale for the surveys not being anonymous is to guard against fraudulent responses (e.g., ineligible people completing the survey purely to receive the voucher). By having a small amount of contact with participants between them expressing interest and completing the survey we have a greater chance of identifying fraudulent responses. A secondary rationale is that we need identifiable personal data to fulfil our duty of care and safeguarding obligations (e.g., if a disclosure was made within a survey, we would not be able to act on this if we did not know personal information). Additionally, to send participant vouchers, we need to know their name and address.

Potential child participants will have been identified via an item in the parent/carer survey asking if they would be comfortable being contacted about potential data collection from the child who has received a C(E)TR that they are completing the survey about. It would then be discussed with the parent/carer what would be the most suitable format for the child to provide data – including completing the full survey, a shorter version of the survey, or a Talking Mats® interview. The additional format options detailed above (e.g., text to speech reader, easier-to-read text, additional support from parent or carer) will also be considered. The focus will be on being guided by the

family/child to adapt communication to meet the needs of the child, so that their voice can be included within the research.

Having received expressions of interest we will arrange for participants to complete the survey in accordance with their preferences (e.g., sending them a link to complete independently or providing desired support to complete the survey). We will capture survey data on a single occasion where possible. The online surveys will be a blend of closed and open questions focused upon experiences of taking part within C(E)TRs, how they were carried out, the interface with dynamic support registers, perceived barriers and facilitators to participation, and the adjustments and supports made to support participation and empowerment along with any changes made to mental health services received. We will make use of augmentative and alternative communication methods with younger children, and specifically, we will complete Talking Mats® interviews. These will focus upon the experience of being admitted to hospital, if this occurred, and their experience of taking part in a C(E)TR, if they were included. We recognise that younger children are unlikely to have been included within C(E)TRs, but they may have communicated their wishes; for example, they may have indicated that they wish to leave hospital and return home, and we will aim to attempt to capture their voice about their experiences. The survey and interview questions will be further chosen and refined collaboratively with our LEAPs. For health economic analysis, we will also include questions to describe resources typically required to provide C(E)TRs and changes to the care pathway.

After completing the survey, participants will be shown a debrief sheet in the same manner that they have chosen to complete the survey e.g., text-to-speech reader, easier-to read text. This will detail their right to withdraw data and include a link to the online withdrawal form.

Additional interviews with participants with moderate to severe learning disabilities will make use of augmentative and alternative communication methods to support the communication of participants as appropriate to their needs, such as Talking Mats® (www.talkingmats.com) and manual sign support (https://makaton.org) to aid processing and decision-making, including visually enhanced rating scales with optional tactile markers for those with no to limited vision. Before the visit we will collect some background information from participants and carers to generate a communication profile which can be used to support the interview.

Talking Mats® uses questions that can be answered on a 3-point rating scale with picture symbols that are used to represent the topics, options, and the rating scale. Further, and to cater for the diverse communication needs of our participants, we will make use of the “easy on the i” image library which was developed by services for people with learning disabilities within Leeds and York Partnership NHS Foundation Trust and are available for use free of charge when using Talking Mats®. These pictures are coloured line drawings with text displayed above the image. The choice of image, topics, options, and ratings scales will be discussed and considered within our LEAPs. Each Talking Mat® is represented by a topic card, for example, “My Treatment” and a 3-point picture-based semantic rating scale is used representing good-ok-bad. Option cards associated with the topic are presented one by one to the participant who is invited to place each card within proximity to their preferred rating.

Interviews will take place in the participant’s setting. The Interviewer will sit at a table - ideally adjacent to the participant depending upon their needs. Talking Mat® symbol wallets will be placed to the outside of the interviewer to minimise distractions for the participant. The process is videoed with a video camera set up on tripod angled towards where the Talking Mat® will be carried out. The view should include both participant and interviewer as well as the Talking Mat® on the tabletop, and once completed, a digital photograph is taken of the completed Talking Mat®. An

effectiveness rating tool is used across five domains to ensure that the participant's answers have been correctly understood [22]. We are very experienced with the use of these methods within research.

After consultee advice in the affirmative, Talking Mats® methodology will be used to determine assent/dissent from the person with moderate to severe learning disabilities (see Section 9.5). For those who confirm assent, the interview will then take place. Afterward, consultees will be shown a debrief sheet. This will detail their right to withdraw data and include a link to the online withdrawal form

Stage 1 (Work Package 2)

Potential survey participants will have been approached with research information as described in Section 9. Potential participants will have been provided with an information sheet about the study, with which to decide about whether they would like to take part in the research. They will also be encouraged to contact the research team if they have any additional questions or would like any further information to make an informed decision about whether to take part in the research. Interested participants will be given options of how they would prefer to complete the survey, including independently online or receiving support to complete the survey. Options for support include: (i) text to speech reader, (ii) easier-to-read text, (iii) having someone present to provide support, (iv) manual sign support , and (v) translation into languages other than English.

When expressing a preference of how to complete the survey, participants will provide identifiable contact details. These will include their name, and contact details including postal address, email address, and phone number as per their preference of how they would like us to contact them. The primary rationale for the surveys not being anonymous is to guard against fraudulent responses e.g., ineligible people completing the survey purely to receive the voucher. By having a small amount of contact with participants between them expressing interest and completing the survey we have a greater chance of identifying fraudulent responses. A secondary rationale is that we need identifiable personal data to fulfil our duty of care and safeguarding obligations e.g., if a disclosure was made within a survey, we would not be able to act on this if we did not know personal information. Additionally, to send participant vouchers, we need to know their name and address.

Having received expressions of interest we will arrange for participants to complete the survey in accordance with their preferences (e.g., sending them a link to complete independently or providing desired support to complete the survey). We will capture data on a single occasion. Our online surveys will be a blend of closed and open questions focused upon experiences of taking part within C(E)TRs, how they were carried out, views regarding how the skill mix may relate to outcomes, how EbE are included and supported, perceived barriers and facilitators to participation, how C(E)TRs are integrated within existing methods and the adjustments and supports made to support participation and empowerment of people with learning disabilities and autistic people. For health economic analysis, we will also include questions to describe resources typically required to provide C(E)TRs and changes to the care pathway.

After completing the survey, participants will be shown a debrief sheet in the same manner that they have chosen to complete the survey e.g., text-to-speech reader, easier-to read text. This will detail their right to withdraw data and include a link to the online withdrawal form.

Stage 2 (Work Package 3)

Potential cases will have been approached with research information as described in Section 9. Multiple types of data about each case will be captured over time from a mixture of direct observation and recording of C(E)TR and CPA meetings, and interviews with those who attended these meetings. We will capture the following data:

(a) Information about the individual, including demographic data, and details of their hospital admission(s) and care team
(b) Audio/video recordings (where possible) and transcripts from multiple C(E)TRs, CPAs, and other patient meetings to track participant progress within their care pathway
(c) Semi-structured interviews with participants following each meeting. These will include C(E)TR panel chairs, clinical members, advocates, responsible clinicians, other health and social care staff, along with the individual and their family members or carers. As already described, we will make use of adapted methods to provide inclusion, participation, and data capture (e.g., Talking Mats® with children and those with moderate to severe learning disabilities). Data will be captured, and interviews will be carried out to cover approximately 60 meetings (2 C(E)TRs, and a CPA meeting per individual). We anticipate conducting up to 180 interviews in total across the 20 cases with individuals, carers and family members, C(E)TR panel members, and health and social care professionals
(d) Data extracted from a documentary review of C(E)TR paperwork including the completed Key Line of Enquiry document and associated workbooks for panel members, EbEs, and C(E)TR planners completed by individuals themselves, along with CPA paperwork and minutes and documents of other relevant patient meetings (e.g., MDT meetings, extraordinary patient meetings)

At the end of Stage 2, approximately 15 months after initial case recruitment, participants will be shown a debrief form. This will detail their right to withdraw data and include a link to the online withdrawal form.

Stage 3 (Work Package 4)

Data from the publicly available anonymous Assuring Transformation and Mental Health Services datasets will be downloaded from NHS Digital.

The monthly Assuring Transformation data set details the number of autistic inpatients and inpatients with learning disabilities over time published by NHS Digital from 2015 onwards. This anonymised national dataset reports the number of pre-admission and post-admission C(E)TRs completed each month, along with other data detailing information about an inpatient's care pathway (e.g., use of advocacy, type of inpatient service, planned discharge date, length of stay, family involvement in care, local authority involvement in care). The Assuring Transformation dataset reports data about the use of inpatient beds specifically commissioned for use by autistic people or people with a learning disability.

Additional anonymised data about psychiatric bed utilisation by people with learning disabilities and autistic people is available from the Mental Health Services Data Set which is also published on a monthly basis by NHS Digital and will be downloaded and included. This data set is wider and includes information about the use of psychiatric beds by people with learning disabilities or autistic

people that are not specifically commissioned for use by this population (e.g., autistic people or people with learning disabilities on a general psychiatric ward).

Stage 4 (Work Package 5)

Quantitative and qualitative data from the prior four work packages, inclusive of our estimate of resource implications, will be integrated using triangulation techniques [50]. We are experienced with these methods [51]. The findings will be used to inform the context of our good practice guidance for C(E)TRs, outlining best practice for maximising participation for people with learning disabilities and autistic people and their families/carers, as well as EbEs, how to implement C(E)TR outcomes effectively to maximise progression along care pathways, and guidance to overcome barriers. This analysis will also inform a final version of a logic model for C(E)TRs as a key project output.

11.1 Participant voucher payments

All participants completing a survey or interviewed in work package 1, 2 and 3 and will receive a £20 high-street voucher for taking part.

12 Safety reporting

There are no expected adverse or serious adverse events related to research procedures noting that this study is non-interventional. The NHS REC will be asked to approve that unrelated adverse and serious adverse events should not be recorded for this study. Serious adverse events that are judged to be related will be reported to the NHS REC.

However, should any member of the research team become concerned at any point about the well-being or safety of a participant, or a child involved in the study, study staff will follow a study-specific Standard Operating Procedure for dealing with harm which will be explained to participants during the consent process and highlighted explicitly in participant information sheets.

13 Statistical considerations

13.1 Sample size

Stage 1 (Work Package 1)

A minimum of 150 people with learning disabilities and autistic people (inclusive of 30 children and young people), and a minimum of 150 carers and/or family members will complete the survey or Talking Mat®; this sample size is considered sufficient to allow for the capture of the diversity of experiences and voices from different people with learning disabilities, autistic people, and their carers and family members. The additional 25 Talking Mats® interviews will supplement the survey

data with direct experiences from children and adults with more severe learning disabilities. Assuming a sample size of 150, if 50% of respondents endorse our outcomes in one direction (e.g., satisfied with C(E)TRs, agree that C(E)TRs improved care pathways) then the 95% CI would cover a range [42%, 58%] that will give a good degree of precision for interpretation in terms of meaning for practice and policy.

Stage 1 (Work Package 2)

A minimum of 350 participants was considered sufficient to allow for the capture of enough data to reflect the diversity of experiences and voices amongst C(E)TR panel members, and health and social care professionals. Based upon a sample size of 350, if we consider 50% respondents endorse our outcomes in one direction (e.g., satisfied with C(E)TRs, agree that C(E)TRs improved care pathways) then the 95% CI would cover a range [42%, 58%] that will give a good degree of precision for interpretation in terms of meaning for practice and policy.

Stage 2 (Work Package 3)

A sample size of 20 cases has been selected to ensure we are able to identify common patterns within the data whilst also keeping the analytical process manageable in line with the planned timeframe and resources requested. Sample sizes in the development of temporal pathway models using grounded theory do tend to be relatively small given the depth of analysis required. It is generally accepted that a sample size of at least 15 participants is required to achieve saturation of the data in the development of temporal pathway models and a key strength of grounded theory is its ability for future modification in response to additional data [26-28].

Stage 3 (Work Package 4)

Sample size estimates from previous literature relating to time series analyses recommend 50-100 time points and that the number of parameters estimated does not exceed the number of time points [46, 47]. Similarly, recommendations regarding multiple linear regression using ordinary least squares suggest 15:1, for every 15 observations, one parameter can be estimated [48]. We created a Monte Carlo simulation to quantify the power to detect the overall trend in the time series model with one of the key parameters of interest, number in contact with services, based on data from Langdon et al. [5]. The simulation used 5000 iterations and calculated the proportion of p-values less than or equal to 0.05 (alpha level), indicating that we had over 80% power to detect both effects (84% and approaching 100%).

Stage 4 (Work Package 5)

N/A

13.2 Missing data

Detail of procedures for dealing with missing data will be described in the Statistical Analysis Plan (SAP).

13.3 Procedures for reporting deviation(s) from the original Statistical Analysis Plan

Any deviations from the original SAP will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

14 Analysis

Stage 1 (Work Package 1)

Survey Statistical Analysis

Descriptive data will be summarised and reported as frequencies and percentages, means and standard deviations, or medians and interquartile ranges as appropriate. Data generated from our open-ended survey questions and structured interviews will be analysed using inductive summative content analysis with emergent coding with reference to our logic model to: (a) consider the experiences of people with learning disabilities and autistic people, families and carers when taking part in C(E)TRs, (b) how C(E)TRs are being carried out with different groups (e.g., children, adults) and in different settings (e.g., different types of inpatient units and the community), (c) the types of adjustments and supports that are used to aid participation, (d) whether there is any evidence that people with learning disabilities and autistic people are being empowered due to taking part in C(E)TRs, (e) whether there are any barriers and facilitators to empowerment, and (f) perceived impact upon care pathway. This analytic approach is appropriate for this context as it can be used with different types of data and will allow the inferential study of responses, their systematic coding and thematic alignment [23-25].

For the health economics analysis concerning resource use, the data from this Work Package will yield descriptions of how C(E)TRs are being carried out for different groups. These will be used to define exemplar C(E)TRs which will be combined with appropriate unit cost data to provide approximate costs of different models of providing this care. Additionally, likely changes to care pathways can also be costed to provide approximate cost implications of changes in services.

Talking Mats® data

A Talking Mat® will be considered completed if participants are able to make valid placements of stimuli relevant to the given topic area. A discrete-response coding system will be devised for the current study to verify the validity of children's responses. Researchers will view videos of participants one Talking Mat® at a time. Placements will be recorded for each stimulus presented and a confidence rating of high or low will then be made based on an estimation of the validity of the child's response. The observed position of stimuli on a mat following a participant's response will be used to code placements (i.e., the area/column depicting stimuli that is favoured/experienced frequently, or not liked/seldom experienced, or partially liked/experienced). Low confidence ratings will be made if placements appear motivated by acquiescence; are contrary to other communications (e.g., the child or adult says "don't like" and places the item in the highly preferred column); where the child is highly distracted (e.g., placement appears non-intentional), or where placements appear motivated by a sensory stimulation function (e.g., lining items up to create a visually reinforcing display). High confidence will be assumed and rated in the absence of these low confidence indicators.

A second observer will view videos from a randomly selected 50% of participants, in each case coding at least 50% of Talking Mats® from the interview and covering all categories of Talking Mat® from the study overall. Inter-rater reliability (based on both placements and confidence ratings) will be calculated and reported as a percentage (total agreements divided by total agreements plus total disagreements × 100). In addition, the second observer (a Talking Mats® trainer), will complete the Effectiveness Framework of Functional Communication (EFFC) [22] for each mat in their sample. This tool is commonly used in Talking Mats® research and provides five 0–4-point ratings concerning quality of communicative interactions based on the behaviour of both the speaker (child or adult) and listener (researcher). A score below 12 of 20 would be considered insecure and excluded from the dataset.

Researchers will review transcripts in detail and analyse these using a thematic approach [24, 44] in relation to each mat, across all participants. Transcriptions will be analysed alongside stimuli placement records to support an integration of both data sources and help further explore the manner in which children use the mat and perceive the topic area. Analysis involves comparing what is understood about the participant's views, what (and how) views are expressed by the participant during the visit, and how the participant is supported to influence interactions and events using whatever skills they have.

Stage 1 (Work Package 2)

Descriptive data will be summarised and reported as frequencies and percentages, means and standard deviations, or medians and interquartile ranges as appropriate. Data generated from our open-ended survey questions and structured interviews will be analysed using inductive summative content analysis with emergent coding informed by our logic model. The will allow for consideration of: (a) the experiences of C(E)TR panel member, and health and social care professionals when taking part in C(E)TRs, (b) how EbEs are being included and supported to take part in C(E)TRs and the associated barriers and facilitators to their participation, (c) how C(E)TRs are being carried out with different groups (e.g., children or adults) in different settings (e.g., community or inpatient), (d) perceived impact upon care-pathways, (e) barriers and facilitators to discharge as identified by C(E)TRs and how they may be overcome or promoted, (f) how C(E)TRs are different or similar to other patient meetings, (g) how C(E)TRs are structured or managed to promote inclusion and the adjustments that are made for autistic people and people with learning disabilities, and (h) whether there is evidence that people with learning disabilities and autistic people are being empowered due to C(E)TRs, and whether there are any associated empowerment barriers or facilitators. This analytic approach is appropriate for this context as it can be used with different types of data and will allow the inferential study of responses, their systematic coding and thematic alignment [23- 25].

For the health economics analysis, data collected within Work Package 2 will complement that collected in Work Package 1 to further refine and construct exemplars of typical ways of providing C(E)TRs and potential changes to care pathways. We will use appropriate unit costs to approximate costs for these and to explore scenarios as to what effect C(E)TRs may have on resource use and costs; likely changes to care pathways can be costed to provide approximate cost implications of changes in services.

Stage 2 (Work Package 3)

The analysis of Work Package 3 data is comprised of two related strands:

Linguistic analysis

The first analysis approach used in Work Package 3 will be a linguistic analysis which will encompass the following:

Accessibility Value of Information

This will involve an analysis of the cognitive and linguistic load of information provided to both people with learning disabilities, or autistic people, and/or family members or carers using data generated from meeting documentation (e.g., agendas, shared documents), and audio/video footage of information given by panel members in the form of monologues, during periods when the person with learning disability, or the autistic person, and family members or carers are present. First, the analysis will involve a review of the documentation to extract data about key characteristics including format (number of pages, type of document – Word, PowerPoint), images (pictures and symbols including source), typography (font point type, size and style), and layout (organisational devices such as bullet points and numbering, use of headings and subheadings, and use of colour). We have previously used this analytic strategy for documents that have been prepared for use for people with communication difficulties [29]. Second, the linguistic features of documents and oral monologue segments of our recordings will be analysed. Monologues are defined as incidents of information sharing by C(E)TR panel members or professionals during the meeting. Recordings will be reviewed to identify monologue segments [30] and the associated transcript and recording will be used to identify the segment boundaries. The linguistic features to be analysed include language at both the word and sentence level to capture the quantity of textual information and syntactic complexity, lexical diversity using type-token ratio to reveal word variability, content word attributes of concreteness, familiarity, and imageability [29]. This will be achieved using automated linguistic analysis using the open-source software, Coh-metrix [31]. This analysis will yield both quantitative and qualitative data for an evaluation of the accessibility value of both written and verbal information during C(E)TRs.

Structure and Management of C(E)TRs, and Other Meetings

The video recordings of meetings will be reviewed and analysed using a bespoke checklist to capture the salient features of meetings developed in collaboration with our LEAPs and informed by the C(E)TR logic model. It is envisaged that this will include data about the number of persons present, meeting duration, number and length of breaks, agenda items and time allocation per item, formats for supporting documentation (e.g., documents shared before and during the meeting), devices used to manage the meeting (e.g., chair mediation of turns and directions to named participants). We will also look to capture detailed resource use data from our participants to help estimate costs with greater precision.

Inclusion and Communicative Participation of People with Learning Disability or Autistic People and Families or Carers:

There are two components to this analysis:

1. Inclusive and Exclusive Interaction: the recordings of C(E)TRs and additional meetings will be reviewed to identify segments where inclusive and exclusive interaction occurs and their time duration. Exclusive interaction is communication between members of a meeting other than the person with a learning disability, the autistic person, and/or family member or carer that consists of discussion about the person with a learning disability or the autistic person in some way (e.g., talking over their heads). Inclusive interaction is communication

(verbal or non-verbal) directed towards or initiated by a person with learning disability or an autistic person and/or family member or carer [32]. Transcripts will be segmented [30] and the analysis will yield information about the proportion of inclusive and exclusive communication during meetings when the person with a learning disability or the autistic person and/or the carer or family member is present

2. Natural Language Sampling and Structural-Functional Linguistic Analysis: natural language sampling will be used to determine the participation of people with learning disabilities, autistic people and/or carers or family members in discussions during meetings; this method has been used with spontaneous language in natural contexts [33] and multi-party meetings [34] and 10 to 20 minute samples are considered adequate to extract reliable data [35, 36]. To determine communicative participation during C(E)TRs, structural-functional linguistic analysis will be completed. A sampling matrix will be used to capture conversation when the person with learning disabilities or the autistic person and/or their family member or carer are present. The sampled conversation will be coded using a framework to determine:
    (a) The range of communicative modalities in use (spoken words, manual signs, gesture, pictures, communication aid) to determine whether reasonable adjustments and communication supports are being used
    (b) The distribution of communicative turns and conversational units (defined as separate clauses), the ratio of conversational units to communicative turns, indicating the length, content, and complexity of turns occupied by different persons to evidence the communicative participation of the person with learning disability or the autistic person and their carer or family member relative to other people present (e.g., C(E)TR Chairs, EbE, or clinicians)
    (c) The distribution of initiations and their function (i.e., linguistic move type: requestive/directive, prompt, statement) and responses and their functions (i.e., linguistic move type: answer, repetition, acknowledgement) or the absence of a response.

    This will provide information about the interactional balance amongst the participants during the meeting, and the communicative experience of people with learning disabilities, or autistic people, and their carers or family members, relative to other people present. Up to 30% of data will be extracted and rated by a second independent rater and agreement statistics calculated. A lag sequential analysis [37] will also be completed on our sampled conversations to identify patterns of communicator behaviours and contingencies within the interactions [38, 39]. First, two-event sequences within the transcribed interaction will be identified which typically consist of an initiation followed by a response and are called adjacency pairs. Second, the simple probability of different linguistic move types will be calculated to determine which types are favoured by each communicator during an interaction and in relation to each other. Third, transitional probabilities will be calculated which will determine which transitions occur between any two interlocutors. Finally, the data will be summarised using state transition matrices.

Together, this analytic approach will allow for a clear characterisation of effective and problematic communication during C(E)TRs, CPAs and other meetings that can be used to make clear recommendations for improving communication and participation within our good practice guidance.

<u>Temporary pathway model</u>

The second analysis approach used in Work Package 3 will be a temporary pathway model developed using a mixed methods grounded theory approach [40, 41] from transcripts of participant interviews and our documentary review describing how the C(E)TR process unfolds over time for the 20 cases. Data gathered from meeting transcripts, linguistic analysis, and supplementary documentation will be utilised to further develop and refine the model informed by the C(E)TR logic model. The application of the core logic and procedures of grounded theory (e.g., description, conceptual ordering, and theorizing) has moved beyond its traditional conceptualisation of pure theory generation in recent years and has since been developed to have a much wider, flexible, and creative approach to analysing data grounded in the accounts of the participants, as was the original intention of Strauss and Corbin [40]. The development of descriptive temporal pathway models using this analysis is a novel approach but has been successfully applied in other areas such as forensic psychology [42] and critical care [43] to aid treatment provision and clinical practice.

The development of a C(E)TR pathway model will thus allow us to understand how the C(E)TR process unfolds over time from the personal accounts of the participants themselves, whilst taking into account contributory contextual and environmental factors. Grounded Theory will be employed to analyse participant care pathway narratives across three key review events (i.e., 2 consecutive C(E)TRs and 1 interim review event such as a CPA). Data will be broken down into conceptual components (open coding) and these components arranged into categories (axial coding). The relationships between the categories will be identified (selective or theoretical coding) and chronologically ordered culminating in a preliminary model of the C(E)TR process which is grounded in data from individuals, families, carers, and key professionals. The preliminary model will then be refined and developed using secondary sources pertaining to file review information (i.e., information about the individual, including demographic and background information) and recordings from the two consecutive C(E)TRs and a key interim review meeting to identify contributory contextual and environmental factors relevant to progression along the care pathway (e.g., Ministry of Justice restrictions, risk assessments).

The resulting temporal model will provide a clear, yet detailed, account of the current operation of C(E)TRs in context from the narratives of the individuals concerned and key persons supporting them, documenting the contributory roles of the contextual, psycho-social, and environmental factors within individual care pathways. It will be sufficiently developed to document similarities between individuals, whilst sensitive enough to allow for heterogeneity, thus allowing us to identify factors which facilitate or hinder progression along the care pathway with a focus upon the impact C(E)TRs are potentially having upon care pathways.

Grounded theory is the most appropriate analytic method for developing temporal pathway models because it allows the model to be grounded in the accounts of the participants themselves (service user, family member or carer, professional) and offers insight, enhances understanding, and provides a meaningful guide to action; in this case via the production of what will be a pictorial temporal model describing the pathway followed by participants immediately before, during, and after two consecutive C(E)TRs. Other qualitative analytical approaches do not allow for the development of related categories ordered temporally which are grounded in the data, nor do they allow for the process of constant iteration inherent to grounded theory. For instance, thematic analysis [24, 44] would lead to mutually exclusive themes or patterns within a data set, but would not allow for the contextual or causal relationships between those themes nor for a temporal sequence of events. Conversely, although interpretative phenomenological analysis does allow for an in-depth analysis of the lived experiences of a group of individuals, this approach requires very small sample sizes (usually three to five) which would limit the identification of common patterns in

the data, and would not allow for the integration of external contextual or environmental factors over time which we wish to capture. Additionally, these other approaches do not allow for the incorporation of secondary data, whereas grounded theory has been successfully used with secondary data in the context of large data sets across multiple sites [43, 45]. As a consequence, our chosen analytic approach will enable us to address our objectives robustly.

Reliability checks will be employed throughout the analytical process to ensure strong levels of accuracy and reliability. For interview data, inter-rater reliability checks will be conducted during the first stage of open coding using two independent raters to assess the reliability and validity of the open coding process. Second, reliability checks will be conducted during the axial and theoretical coding stages of the analysis. The analytic process for each step will be reviewed until agreement is reached by the researchers and independent raters on the categories identified and the relationships between them.

Stage 3 (Work Package 4)

Given our sample size, we will take a pragmatic approach, consulting with stakeholders and informed by the C(E)TR logic model, to determine a minimum adjustment set of potential predictors by creating a Directed Acyclic Graph (DAG) that maps out our assumptions about the causal pathways between C(E)TRs, the number of inpatients over time and additional predictors [49]. This process is designed to ensure that additional variables that may have an influence on the direct relationship (e.g., confounders, mediators, and moderators) between C(E)TRs and the number of inpatients over time are considered, and adjusted for, if required. This would likely include models determining the relationship between use of C(E)TRs and admissions, discharges, and number of inpatients over time, along with type of inpatient service (e.g., mental health, forensic, adult, child), length of stay, age, diagnosis of learning disability, autism, or both, use of advocacy, discharge location, length of stay over time and other key factors.

Information from the time-series modelling will be used to inform estimates of the potential cost implications of C(E)TRs. From Stage 1, we will have estimates of the indicative costs of C(E)TRs and how this might vary across different people. We would also have information on typical effects on care pathways, and associated costs. Using time-series modelling we aim to show the relationship between C(E)TRs, inpatient stays, and other variables. Costs can be applied to inpatient stays, potential confounding factors, and C(E)TRs themselves to explore what effects C(E)TRs might be having on NHS and care costs. If relationships are found between C(E)TRs and these predictors, then we can estimate the potential resource implications of these changes. Estimates could also be produced by different patient groups (e.g., adults compared to children). Where data indicate, we could also model 'what if' scenarios such as how much would C(E)TRs need to reduce inpatient stays to offset their cost. However, it should be noted that we do not intend to carry out an economic evaluation to determine if C(E)TRs represent a cost-effective service as we will not have patient related outcomes in terms of changes in health or other relevant outcomes related to the use of C(E)TRs in a manner that will allow for this type of analysis.

We have previously completed similar work [5]. Ordinary linear regression will be fitted initially, and corresponding residuals checked to determine if the anticipated autoregressive structure is present by examining autocorrelation- and partial-autocorrelation function plots. If present, generalized least squares regression with auto-regressive [AR] errors will be used to model relationships between the explanatory and outcome variables over time. A model with AR errors assumes outcome observations are linearly dependent on the previous time points and correlated errors are

explicitly factored into the model structure. The 'order' of the autoregressive lags defines the number of previous time points which the outcome depends upon. It may be that different error structures are required after inspection of autocorrelation plots, such as moving average (MA) or ARMA (autoregressive, moving average), but AR will be assumed in the first instance. Model selection of best fitting model will be decided based on the Akaike Information Criterion (AIC) fit index (lower AIC values indicating improvements in model fit). Within our models, we will be able to estimate the nature of the relationship between C(E)TRs, other explanatory variables (e.g., use of advocacy, family involvement) and the number of inpatients over time.

Stage 4 (Work Package 5)

At the point of completing our analysis of our individual work packages, we will make use of "following a thread" which involves following a research question and theme from one dataset across datasets during our analysis to create a multi-faceted understanding of our findings based upon both qualitative and quantitative data [52]. We will also make use of a "mixed method matrix" examining both quantitative and qualitative data about participants within Stage 3 as we will have data on individual cases [53]. A mixed method matrix is a powerful tool because it allows for the integration of qualitative and quantitative data about a participant. The focus of this analysis is upon the similarities and differences between different types of data about the participant, while looking for patterns across all participants.

Following the completion of the analysis of our work packages, we will make use of four sequential stages of the Pillar Integration Process to triangulate and display our findings [54] using co-design together with our LEAPs. These stages involve:

1. Listing: this involves listing quantitative data and categories, and qualitative codes and categories within a joint display
2. Matching: following listing, matching involves matching qualitative codes and quantitative data leading to refining and organising the categories. The patterns, including similarities and dissonance between qualitative and quantitative data are displayed
3. Checking: this involves checking the data within the display to ensure that rows are matched appropriately
4. Pillar building: the final central column of the display is completed by considering the findings from the listing, matching, and checking stages

Together with our LEAPs, we will generate inferences about the patterns or themes that have emerged and their associated explanation. All the findings at this stage will be viewed together to help generate a narrative incorporating both the qualitative and quantitative findings across all Stages of this project. The resulting integrated findings will be used to develop good practice guidance for completing C(E)TRs and inform a final version of the C(E)TR logic model.

15 Data Management

Physical data

Physical data is paper copies of surveys (work package 1 and 2), audio recordings saved on audio recording devices (work package 1 and 3), video recordings saved on video recording devices (work package 1 and 3), photos saved on photo taking devices (work package 1), and copies of confidential minutes from patient meetings (e.g., CPA meetings) (work package 3).

Physical copies of data will be returned to the respective University (University of Birmingham, University of East Anglia, University of Kent) office of the person collecting physical data as soon as possible, ideally on the same day that physical data are created/obtained. Where this is not possible, data will be stored securely (e.g., in a locked room/cabinet in homes of those who obtained the data such as research assistants) until this is done. Once in the office, physical data will be stored in locked filing cabinets in lockable offices, and only members of the research team will have access to these data. Identifiable data will be stored separately from non-identifiable data.

If questionnaires are posted to the participants, they will be returned in freepost envelopes to the CECILIA study team. Questionnaires will only contain a unique identifier per participant. No other identifiable information will be recorded on the questionnaires.

Physical data will be converted into electronic data as soon as possible. Audio recordings, video recording and photographs will be transferred into appropriate electronic storage locations as described below. Once this has been done, the physical copy of such data (e.g., saved video recording on device) will be deleted. Survey data will be entered onto a secure bespoke database. The completeness and accuracy of physical→electronic survey data input will be checked by an independent member of the research team (i.e., not the person who entered the data). Once accuracy has been confirmed, physical copies of surveys will be destroyed.

Electronic data

Electronic data are electronic records of surveys (workpackage 1 and 2), audio recordings (workpackage 1 and 3), video recordings (workpackage 1 and 3), and photos (workpackage 1). Additionally, anonymous public datasets will be downloaded within work package 4.

Online versions of survey data will be stored on Qualtrics and downloaded weekly. The downloads will be securely stored in a study-specific folder on University of Birmingham, University of East Anglia, and University of Kent servers, only accessible to research team members. Once data collection has been completed for any given part of the study, the data collected online will be transferred to the secure bespoke database with the data entered from physical versions of the questionnaires.

Access to the database will be via username and password and restricted to appropriately trained personnel only. The database will be housed on local servers at the University of Birmingham, University of East Anglia, and University of Kent in accordance with all appropriate legislation. Identifiable data will be password protected and stored separately from non-identifiable data.

Wherever possible data will be validated at point of entry, thereby reducing the opportunity for missing or unexpected data. All changes made to the data will be recorded and visible via an audit log within the database.

Interviews will be recorded on encrypted audio-recorders or on the online platform being used (e.g., Teams, Zoom, Whatsapp) and stored on password protected computers at the University of Birmingham, University of East Anglia, and University of Kent. Any transcripts will be fully pseudonymised.

A data sharing agreement will be developed to confirm arrangements around how data will be shared, transferred, stored, and accessed across the University of Birmingham, University of East Anglia, and University of Kent. Once data capture has completed, data will be stored at the University of Birmingham within a secure network location.

A data management plan will be developed to outline the details of how data will be collected, transferred, stored, and accessed by the team.

16 Protocol/GCP non-compliance

The Co-chief Investigators should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice in writing to the ethics committee and sponsor as soon as they become aware of it.

17 End of Study definition

The end of the study is defined as the date of publication of the good practice guidance for C(E)TRs, expected to be approximately September 2027.

The sponsor must notify the HRA of the end of the study within 90 days of its completion or within 15 days if the study is terminated early.

18 Archiving

The Study Master File (SMF) will contain all essential study documents. At the end of the study all data and documents stored by the University of East Anglia and the University of Kent will be transferred to the University of Birmingham and filed within the SMF. The SMF will be archived following University of Birmingham protocols for 10 years. The SMF will be archived within a secure network location.

Additionally, for Stage 2 (Work Package 3) sites will archive data for their individual cases. Costs are included in the SoECAT to cover this.

19 Regulatory Considerations

19.1 Ethical and governance approval

Stage 1 described within this protocol will receive a favourable ethical opinion from an NHS Research Ethics Committee, and approval from the Health Research Authority (due to the involvement of NHS services). Stage 2 will receive a separate favourable ethical opinion from an NHS Research Ethics Committee, and approval from the Health Research Authority (again, due to the involvement of NHS services).

19.2 Data Protection

The research team will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained, or if abusive practice is disclosed that researchers would have a duty to report. Data will be stored in

a secure manner and will be registered in accordance with the Data Protection legislation (in accordance with GDPR). Participants will always be identified using a unique PIN. The key to identification will be stored separately and securely to the research data to safeguard individual identities. It will not be possible to identify individuals or settings in published results.

All data will be pseudonymised as quickly as possible after data collection. This means all direct and indirect identifiers will be removed from the research data we hold and will be replaced with a participant number. Research team members directly involved in data collection and input will have access to participants' personal data. Access to the database that is created will be via username and password and restricted to appropriately trained personnel only.

As sponsor of this study, Coventry and Warwickshire Partnership NHS Trust will be the data controller, along with The University of Birmingham, the University of East Anglia, and the University of Kent.

19.3 Indemnity

NHS Indemnity Scheme for negligent harm will apply.

19.4 Study sponsorship

Coventry and Warwickshire Partnership NHS Trust will act as Sponsor for study.

19.5 Funding

The study is funded by National Institute for Health and Care Research: Health and Social Care Delivery Research (HSDR) programme (Ref NIHR 158265).

20 Study management

20.1 LEAPs (Lived Experience Advisory Panels)

PPI is central to this project. We will establish three Lived Experience Advisory Panels (LEAPs):

1. Autistic people – led by the National Autistic Society
2. People with learning disabilities – led by Learning Disability England
3. Carers and family members – led by the Challenging Behaviour Foundation.

The lead from each of these three groups will be a member of the Study Management Group and will share governance responsibility with the wider researcher team. Each LEAP will provide strategic advice and contribute towards the development of our logic model, study documentation, and participant information sheets, and act as consultation groups for survey content and questions, interview questions, and the analysis and interpretation of our subsequent findings, along with the development of our good practice guidance and dissemination. Each LEAP will meet 11 times (approximately every 4-months) throughout the duration of the project with 1 meeting per year being a joint meeting with all three LEAPs.

20.2 PT (Project Team)

The Project Team (PT) will meet at least monthly and include Langdon, Bunning, and Barnoux, research staff, and our project administrator. The PT will be responsible for the day-to-day running of the project and will be organised and chaired by the Study Manager.

20.3 SMG (Study Management Group)

The Study Management Group (SMG) will also meet monthly to discuss study progression and key management issues. The SMG will be chaired by one of the two co-leads (Langdon or Bunning). All investigators, research staff, project administrators, and a representative from each of our three LEAPs will attend. The co-leads are responsible for the running and coordination of the study as well as the workload of the primary research staff. The research staff will be managed by Langdon, Bunning and Barnoux. SMG members have signed up to the remit and conditions as set out in an SMG Charter.

20.4 Independent SSC (Study Steering Committee)

The Study Steering Committee (SSC) will meet four times throughout the project. An independent chair will be appointed who will have experience of working within NHS inpatient settings for people with learning disabilities and autistic people who will have also taken part within C(E)TRs. Other independent members will be a researcher who has completed work about psychiatric bed utilisation by people with learning disabilities or autistic people, a statistician, a health economist, and a person with learning disabilities, an autistic person, and at least two family members or carers. Non-independent members will be the co-leads (Langdon and Bunning) study statistician (Dr Paul Thompson), the Study Manager, and two other study researchers who will be observers. The SSC will have primary oversight of this study and will provide advice and recommendations as required. SSC members have signed up to the remit and conditions as set out in an SSC Charter.

As this is a low-risk study with no blinding or delivery of intervention, a Data Monitoring and Ethics Committee is not required. This has been agreed with the funder.

21 Quality Control and Assurance

21.1 Monitoring

Investigators will facilitate study related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents as required. Participant consent for this will be obtained. Findings generated from any monitoring will be shared with the Sponsor.

21.2 Audits and inspections

This study may be subject to inspection and audit by Coventry and Warwickshire Partnership NHS Trust under their remit as Sponsor.

22 Dissemination, outputs and impact

In addition to traditional dissemination methods (peer-reviewed publication, funder reports, and conference presentations), our wider dissemination strategy will be co-produced and led by our PPI partners: Learning Disability England, the National Autistic Society, and the Challenging Behaviour Foundation. They have initially planned to:

1. Place information about our study on their websites and within their newsletters throughout the duration of the project and beyond
2. Develop accessible videos about our study and our findings and also place them in the public domain
3. Develop accessible summaries of our study findings which can be shared with our participants directly and also placed in the public domain.

It is anticipated that the LEAPs will generate other ideas and suggestions that can be taken forward (e.g., publishing podcasts). We also plan on developing an accessible study website where all our study resources, findings, and outcomes can be accessed by the public. Finally, we will hold at least three accessible dissemination events organised collaboratively with our PPI partners to help ensure maximum reach where we will be able to showcase our good practice guidance, tools, and resources. We are experienced in running these events and engaging in these activities collaboratively with our PPI partners.

The major output from this study will be the publication of good practice guidance for C(E)TRs developed in collaboration with our LEAPs and based upon our research findings inclusive of a logic model about the C(E)TR process. The exact nature of our good practice guidance will depend upon the preferences of our LEAPs and our findings, but it is likely to include guidance about:

1. The promotion of good communication and engagement during a C(E)TR, including how to conduct meetings to support needs
2. The development of clear outcomes that can be understood and how to implement them across a patient's care pathway
3. Working effectively with multiple teams across different systems
4. Meeting the needs of autistic people and people with learning disabilities
5. Methods for engaging with carers and families as valued and equal partners
6. Methods for overcoming barriers and promoting discharge
7. Information about the costs incurred in delivering C(E)TRs that need to be understood

Our guidance, tools and resources are likely to be tailored to specific audiences to maximise impact and aimed at all stakeholders. The research team will work in partnership with the LEAPs to develop a communications strategy – with key findings and messages targeted at specific stakeholders to maximise impact. Presentation of findings will range from traditional written reports to "top tips" and "questions to ask" type resources. To ensure our guidance is accessible, we will develop easier-to-read versions together with our PPI partners including alternative formats (e.g., videos, animations) to help disseminate key recommendations.

We anticipate that the findings from this project and our good practice guidance will help autistic people and people with learning disabilities leave hospital and prevent future admission, leading to marked improvements in quality of life which may lead to improvements in efficiency. It is likely that the findings from this study may have implications for working with people with learning disabilities and autistic people more broadly within the NHS. For example, our findings around and about communication may have implications for other types of meetings (e.g., CPA meetings). Together with our PPI partners and LEAPS, we will consider how our findings may have applications more broadly and include such within our dissemination of our results as outlined above.

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