STUDY PROTOCOL

STUDY TITLE

Optimising community C(E)TRs through understanding the experience of people with learning disability and autistic people and investigating their impact on care

SHORT TITLE

OptiCaT

FUNDED BY

National Institute for Health and Care Research (NIHR)

FUNDER REFERENCE

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 investigation 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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FUNDING AND SUPPORT IN KIND

FUNDER	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
National Institute for Health and Care Research (NIHR)	£1,631,664.61

ROLE OF STUDY SPONSOR AND FUNDER

The lead sponsor, King's College London, will take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. King's College London also provides cover under its No Fault Compensation Insurance, which provides for payment of damages or compensation in respect of any claim made by a research subject for bodily injury arising out of participation in a clinical trial or healthy volunteer study (with certain restrictions).

The co-sponsor, South London and Maudsley NHS Foundation Trust, take responsibility for arranging the initiation and management of this research, and will take responsibility for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff involved with the project.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Management Group (SMG)

The SMG consists of 15 members, including the joint Co-Chief Investigators. SMG members are Co-Investigators on the project.

SMG members are associated with the following institutions: King's College London, Queen Mary University of London, Cheshire and Wirral Partnership NHS Foundation Trust, University College London, and the University of Birmingham. Some Patient and Public Involvement (PPI) SMG members are not formally associated with a higher education institution.

SMG members collectively bring expertise in the following areas: learning (intellectual) disability, autism, neurodevelopmental conditions, psychiatric epidemiology, health informatics, health economics, medical statistics, qualitative research, applied clinical research, and patient and public involvement (PPI). The SMG will meet every six weeks to discuss the project including monitoring progress against milestones and troubleshooting any problems that arise. Particular members of the SMG will be more involved at certain points of the project, according to their expertise.

Patient & Public Involvement (PPI) Groups

Four members of the SMG will act as PPI leads. They will form PPI groups to provide lived experience perspectives on the project from people with a learning disability, autistic people, children and young people, and family carers. PPI groups will advise the research team on the design and conduct of the study, discuss and help to interpret findings, and contribute to dissemination activities. Each PPI groups will meet on average four times a year. PPI group leads will meet regularly.

Study Steering Committee (SSC)

The SSC will monitor the progress of the study, approve the study protocol and proposed amendments, and be involved in decisions about continuing or stopping the study (e.g. following a pilot study that is built into the prospective study).

The SSC will comprise independent members including a chair, statistician, professionals with expertise in working with people with learning disability and autistic people across settings and two experts by experience. The SSC will meet four times over the duration of the project. All members of the SSC will sign a Charter that details the remit and responsibilities of the SSC.

A separate Data Monitoring and Ethics Committee (DMEC) has not been convened for this study, given the low overall risk involved in this research. As agreed with the funder, the functions of the DMEC will be met by the SSC.

AMENDMENT HISTORY

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.0	25/07/2025	Rory Sheehan	p.27 Change planned study period start date from 01 May 2025 to 01 September 2025 p.35 Made clear carers can be recruited alongside people with a learning disability and autistic people, where applicable p.36 and p.37 Change to minimum age of carers eligible from 18 to 16 years, on advice of Research Ethics Committee p.37 Clarified target number of participants with a learning disability or autism is 300 p.38 Additional detail provided to participant identification and recruitment to align with information provided to REC p.40 Additional detail provided around procedure for participants who turn 16 years of age during the study follow-up period, advised by REC

				p. 43 Schedule of assessments clarified based on whose information will be collected p.52 Change to minimum age of carers eligible from 18 to 16 years, on advice of Research Ethics Committee p.53 Broadening of methods to identify potential participants for the qualitative study p.55 Removal of option of Zoom as video conferencing software, on advice on study Sponsor and in view of data security regulations

KEY WORDS:	Care (Education) and Treatment Review (C(E)TR) Dynamic Support Register (DSR) Learning Disability Autism Hospital Admission Health Outcomes Quality of Life Health Services Research

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SUMMARY

The OptiCaT study comprises two Work Streams.

Work Stream 1 (WS1) is a study using electronic health records. Work Stream 2 (WS2) includes a Prospective Cohort Study, Qualitative Study, and Delphi Consensus Exercise. The two Work Streams complement one another in providing evidence of the use and impact of community C(E)TRs for people with learning disability and autistic people.

The protocols for WS1 and WS2 are presented separately in this document due to differences in the ethical and regulatory approvals that the work involved in those workstreams must undergo. The protocol for WS1 begins on page 18 and the protocol for WS2 begins on page 26 of this document.

WS1 uses de-identified patient data from secondary sources; use of data from these sources already has over-arching ethical approval and the study does not include participant recruitment or contact with health service users. The protocol presents the research aims and our plans for data extraction and analysis.

WS2 includes recruitment of people with learning disability and autistic people who are accessing health services. The protocol for WS2 includes full details of study methods and procedures in a format required by the Sponsor (King's College London and the South London and Maudsley NHS Foundation Trust) and the Health Research Authority.

Study Protocol for Work Stream 1 (WS1): Investigating the use and impact of Care (Education) and Treatment Reviews (C(E)TRs) in people with intellectual disability and autistic people: a study using electronic health records

Summary

In this study, de-identified electronic health record (EHR) data, obtained from the South London and Maudsley (SLaM) National Health Service Foundation Trust, will be extracted for all patients with a learning disability and/or autism receiving mental healthcare between 1 Jan 2007 to 31 December 2023. For children/young people and adults with a learning disability or who are autistic, we will examine the demographic/clinical profile of those receiving a community Care (Education) and Treatment Reviews (C(E)TRs) and the association of community C(E)TRs with mental health service use. We will also identify people with a learning disability or who are autistic who were admitted to psychiatric hospital and compare demographic and clinical profiles between those who had a community C(E)TR prior to admission with those who did not.

1. Research Question/Aims

This study will address the following research questions:

How can C(E)TRs be identified in the EHR?

- What are the demographic and clinical profiles of children/young people and adults with learning disability or who are autistic who receive a community C(E)TR?
- What is the association of community C(E)TRs with mental health service use (e.g., admission to hospital, contacts with professionals)?
- In children/young people and adults with learning disability or who are autistic who have been admitted to psychiatric hospital, what differences are there in demographic/clinical profile, length of hospital stay, and clinical and functional improvement whilst in hospital between those who had a community C(E)TR prior to admission with those who did not?

- Use and test the above method in the EHR of one other NHS Trust to increase and broaden the sample and increase capacity in bioinformatics research in this population

2. Study design

This is a retrospective cohort study using real-world EHR data. We will generate a sample of people with a learning disability and autistic people who have received care since 2015 and develop a method to identify C(E)TRs in the data source. We will report the demographic and clinical profiles of those who receive a community C(E)TR and the association of community C(E)TRs with health service use, also derived from routinely-collected health data. We will identify people with a learning disability and autistic people who have been admitted to psychiatric hospital and compare the demographic and clinical profiles, length of hospital stay, and clinical and functional improvement whilst in hospital between those who had a community C(E)TR prior to admission with those who did not.

3. Study setting

Data used in this study will be obtained from the South London and Maudsley (SLaM) NHS Foundation Trust. SLaM is one of the largest providers of mental healthcare in Europe and serves a diverse population of approximately 1.3 million residents in the London boroughs of Lambeth, Southwark, Lewisham and Croydon. The Trust provides specialist community clinical services for people with a learning disability and autistic through a well-established network of Community Learning Disability Teams (CLDTs) and Community Mental Health Teams (CMHTs).

4. Data source

SLaM has implemented a full EHR system 2006 and the SLaM NIHR Biomedical Research Centre (BRC) Case Register (the data source for this project) contains the clinical records of approximately half-a-million patients. The Clinical Record Interactive Search (CRIS) is a research tool that enables analysis of de-identified EHRs. Specified data are extracted from both structured fields and through interrogation of unstructured free text (e.g. clinic letters) using

validated Natural Language Processing (NLP) applications. Available variables include socio-demographic information, signs/symptoms, treatment (medication, psychosocial interventions), hospital admissions, and contacts with professionals and teams (e.g. CLDTs).

SLaM EHR data can be linked to hospital data collated in the Hospital Episode Statistics (HES) dataset. Hospital Episode Statistics (HES) is a national dataset curated by NHS Digital that includes details of all hospital in-patient admissions, out-patient appointments and attendances at A&E in England. A second linked data source, the Mental Health Services Dataset (MHSDS), captures mental health service activity across England and may be used as a second source of data on psychiatric admissions. CRIS data are linked to HES and the MHSDS within a secure data safe haven, increasing the power of the dataset and the range of variables that are available.

5. Sample and Recruitment

5.1. Eligibility criteria

All individuals with the following characteristics will be extracted from the SLaM EHR using CRIS:

- age ≥14 years
- a recorded diagnosis of learning disability or autism (derived from structured records or free text using NLP applications)
- received an episode of community care from any SLaM mental health service (including CLDT, CMHT) lasting at least one year between 01 January 2015 and 31 December 2023

6. Variables

6.1. Patient characteristics

We will extract the following variables for each participant to use in the analysis: age at cohort entry, gender, ethnicity, deprivation (as measured by the Index of Multiple Deprivation, a small area measure of relative deprivation), marital status, sexual orientation, living status (e.g. living

alone), receipt of a social care package, co-occurring psychiatric disorder (recorded according to ICD-10 chapter), mental/behavioural symptoms (e.g., aggression, anxiety), prescribed psychotropic medication (by broad drug class).

6.2. C(E)TR status

Records of completed C(E)TRs will be sought from the free text data for each participant within the study window (2015-2023). We will explore the feasibility of using focused keyword searches of the free text data to identify C(E)TR meetings. We may also seek to develop a new NLP application as an automated way of identifying C(E)TR meetings in the patient record and use this in the study, if an application can be created with acceptable levels of precision and recall.

6.3. Mental health service use

Admission to psychiatric hospital is the primary service use variable of interest; we will record the dates of admission, discharge, and the type of admission ward (e.g. CAMHS, general ward, forensic ward, psychiatric intensive care unit). Other service use variables will include contacts with community mental health professionals (by group e.g. psychiatry, psychology), input from the Home Treatment Team (also known as the mental health crisis team, a team providing high-intensity input in the community), and attendances at emergency care / hospital Accident and Emergency departments. Clinical and functional improvement of those admitted to hospital will be measured using the Health of the Nations Outcome Scale (HoNOS) relevant to the patient population (i.e. child/adolescent, adult with learning disability, autistic adult) before and during hospital admission.

7. Statistical Analysis

A statistical analysis plan will be written by members of the project team in conjunction with the CRIS data extraction team. Analysis methods may include the following:

7.1. Descriptive Statistics

Descriptive statistics will be presented for demographic and clinical variables, including age, gender, ethnicity, co-occurring mental health conditions, C(E)TR status, psychiatric hospitalization, and service use in the six months following a C(E)TR meeting. Frequencies and

percentages will be obtained for categorical variables and mean, and SD will be obtained for continuous variables. We will describe these data separately by group (i.e. child/adolescent, adult with learning disability, autistic adult).

Demographic and clinical characteristics of those admitted to psychiatric hospital will be compared based on whether or not they had a recorded pre-admission community C(E)TR using standard statistical comparisons for categorical (Chi square) and continuous variables (t-test or Kruskall-Wallis).

7.2. Multivariable regression

Multivariable regression analyses will investigate associations between community C(E)TRs and personal (e.g. age, sex, ethnicity) and clinical and service variables (e.g. symptoms, diagnoses, community team engagement), length of hospital stay, and clinical and functional improvement (using Health of the Nations Outcome Scale ratings (HoNOS)) during any admission. This will help us establish which personal, socio-demographic and/or clinical characteristics may contribute to receiving or not receiving a community C(E)TR.

7.3. Propensity score matching

Since the retrospective analysis of EHRs is not a randomized controlled study, we will consider a propensity matching technique to adjust for certain confounds in the data. In this study, a propensity score is the probability of receiving a C(E)TR, conditional on a number of observed characteristics (e.g. diagnosis, age, gender, ethnicity). Certain characteristics, and combinations thereof, may increase or decrease the probability of someone receiving a C(E)TR, and we wish to account for these in further models. The propensity score is calculated by fitting a multivariable logistic regression model with C(E)TR status as the dependent variable, and characteristics (e.g. diagnosis, age, gender, ethnicity) as predictors. The estimated propensity score provides one score for each research subject and summarizes the information about all the variables of interest. The propensity scores can then be used in further analyses assessing the risk of hospitalization on those who received a C(E)TR compared to those who did not, helping to balance the treatment groups on confounding factors to make them comparable. This will be carried out in two ways. Firstly, a fully adjusted regression analysis will be carried out with the propensity score included as a covariate, replacing the CETR covariate, with e.g., hospitalization status as the dependent variable. Secondly, another fully adjusted regression model will include only those patients who had a near-equal probability of receiving a C(E)TR or

not receiving a C(E)TR based on their propensity scores, to restrict the analysis to patients at a similar stage in their risk of being admitted to hospital. This technique follows on from Section 7.2 - if we find that certain attributes e.g. personal or socio-demographic, do contribute to receiving a C(E)TR, then this analysis adjusts for those confounds, thereby allowing us to assess the fair association between having had a C(E)TR or not and subsequent hospitalization, having accounted for any underlying bias in who received a C(E)TR in the first place.

7.4. Cohort matching

For cohort matching, we will take data of one patient when they have had a C(E)TR and assemble up to 5 controls with similar characteristics to the patient, but who do not receive a C(E)TR. This method is generally feasible given the volume of data in CRIS, although the controls must be matched on only a limited number of variables (e.g., age, sex, diagnosis). This is an additional method/analysis to help reduce the variability between C(E)TR status groups, so that any differences in outcome measures are not being driven by inherent variability in the characteristics of this real-world sample.

7.5. Repeated measure ANOVA

Repeated measures ANOVA will be used to investigate change in HoNOS score in each group over their admission. This analysis will expose differences in who receives a pre-admission C(E)TR and who does not and the impact that C(E)TRs have on patient progress and the hospital stay. Although this is carried out in people who have been admitted to hospital, this analysis will assess whether those who have had a C(E)TR show functional improvement during their hospital admission compared to those who didn't.

7.6. Clustering analysis

We will explore the use of clustering analysis, an unsupervised machine-learning method, applied to the data of patients who receive a C(E)TR. We will test different clustering strategies (e.g. a Latent Class Model) to determine the best performing method (23). Derived clusters (e.g. sub-groups of patients) for the best performing model will be assessed using measures of survival probability, predictive ability, and differences across clusters. Survival probability will be defined as the likelihood that a patient will not be admitted to hospital from the day of their C(E)TR to six months following the C(E)TR. This method should reveal particular patient profiles

(sub-groups) that are more likely to receive a C(E)TR, and are more likely to be admitted to hospital despite having had a C(E)TR.

8. Missing data

We expect there may be different degrees of missing data across variables within the EHR data. We will review the type and amount of missing data in each variable and consult with the project statistician. We anticipate two analyses will be conducted: a full sample analysis including missing data as a category in regression analyses, and a complete case analysis which excludes individuals who have one or more missing covariates

9. Health economic analysis

An economic analysis will focus on the costing perspective of secondary care services. This will include:

- Identifying all relevant resource use variables from CRIS and HES and contributing to the preparation of the application of CRIS and HES data
- Data cleaning and checking, involving a manual check of discordant records for the same patient across CRIS and HES
- Data analysis, including the use of HRG grouper and Spell Converter software for assigning tariff and regression analysis to estimate the impacts of community C(E)TR on patients' cost of secondary healthcare services

10. Replication

We will replicate our method in the EHR of Camden & Islington NHS Foundation Trust. It is not possible to combine data obtained across different Trusts, but we will follow the same data extraction and refined analysis strategy (assuming numbers are sufficient) to present data from a different population group and healthcare provider / Integrated Care Board.

11. Ethical approvals

The SLaM BRC Case Register and Clinical Record Interactive Search (CRIS) tool has received over-arching ethical approval for secondary mental health research from Oxfordshire REC C (Ref: 18/SC/0372). This study has received approval from the SLaM CRIS Oversight Committee which includes input from service users. Section 251 approval is in place for linkage of CRIS data with HES data for adults; a project-specific amendment will be submitted to the HRA Confidentiality Advisory Group to enable linkage with HES data for those aged <18 years.

12. Data protection and confidentiality

To comply with all necessary data protection regulations, EHR data will be stored and analysed using encrypted workstations and virtual machines hosted in a UK- based Microsoft Azure data centre. Members of the research team have no access to identifiable data and will have required permissions in place before starting work on this project. Only de-identified aggregate results from the dataset will be included in any outputs of this work.

13. Dissemination

Study findings of the EHR study will be disseminated through conference presentations and open access peer-reviewed publications in relevant medical journals. We will work together with the study PPI groups to co-produce outputs in a format that will reach and engage people with a learning disability, autistic people, and their carers.

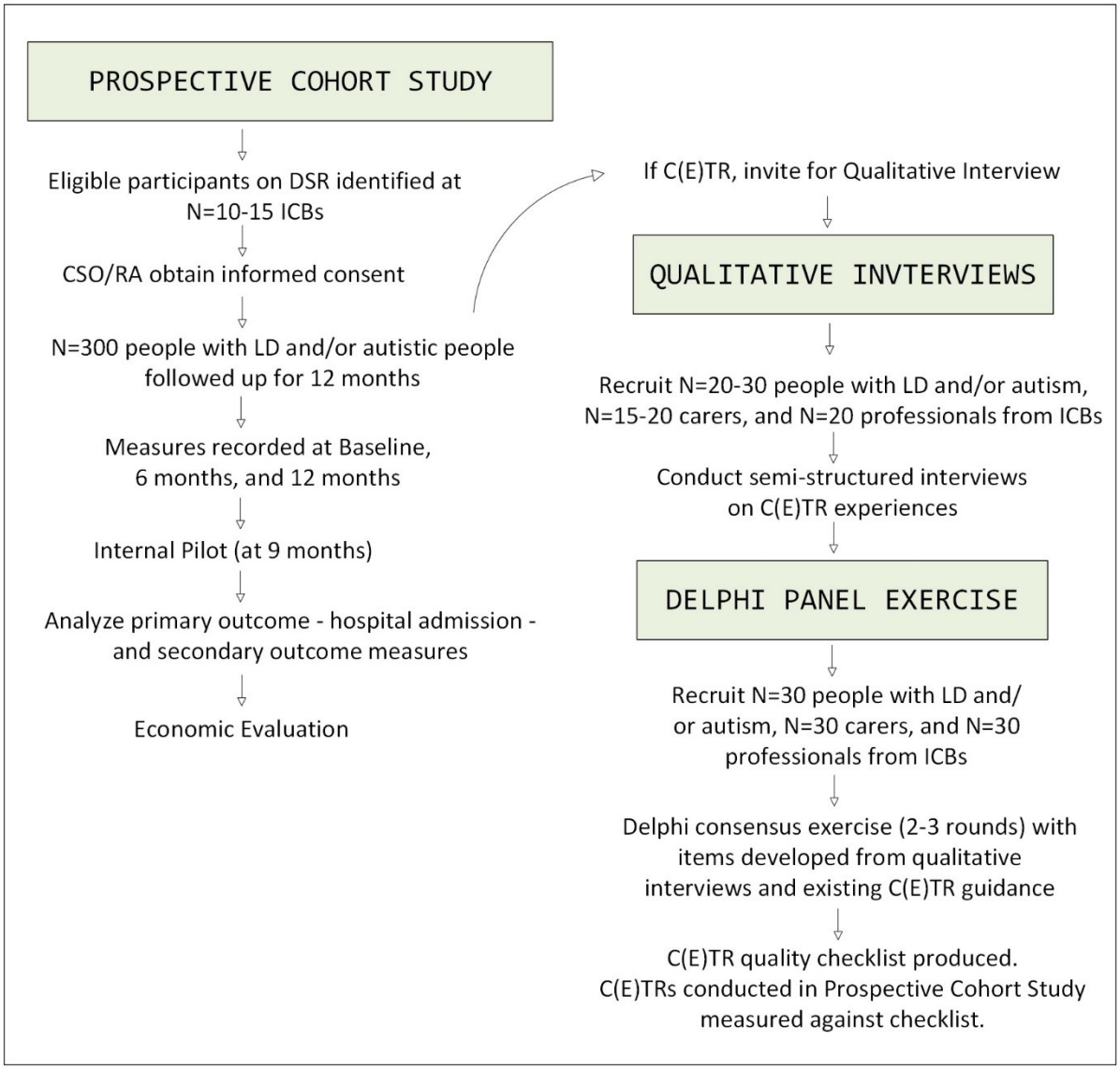
Study Protocol for Work Stream 2 (WS2): Optimising community C(E)TRs through understanding the experience of people with learning disability and autistic people and investigating their impact on care

STUDY SUMMARY

Study Title	Optimising community C(E)TRs through understanding the experience of people with learning disability and autistic people and investigating their impact on care
Short Title	OptiCaT
Study Design	i) In a **Prospective Cohort Study**, we will follow-up participants with a learning disability and/or autistic people who are rated as red or amber on Dynamic Support Register (DSR) to compare clinical (primary outcome: psychiatric hospital admissions), social and cost outcomes in those who have had a community Care (Education) and Treatment Review (C(E)TR) with those who have not. ii) In a **Qualitative Interview Study**, we will conduct semi-structured interviews with patients, carers, social and healthcare professionals and C(E)TR panel members to collect experiences of C(E)TRs and to identify aspects of the C(E)TR process that are working well and what needs improvement. iii) We will conduct a **Delphi Panel Exercise** with people with intellectual disability and autistic people, carers, social care and health care professionals and C(E)TR panel members to establish what constitutes a high-quality C(E)TR action plan. Results will be used to

	develop a rating checklist that will be used to rate C(E)TR plans from the Prospective Cohort Study to assess the association between the quality of C(E)TR plans and patient outcomes.
Study Participants	People with learning disability and autistic people, paid and family carers, clinicians/professionals, and C(E)TR panel members
Planned Size of Sample (if applicable)	300 (Prospective Cohort Study) 55-70 (Qualitative Interview Study) 90 (Delphi Panel Exercise)
Follow up duration (if applicable)	12 months per participant (Prospective Cohort Study)
Planned Study Period	01 September 2025 – 29 Feb 2028
Research Question/Aim(s)	To compare psychiatric hospital admission rates and other outcomes (e.g. duration of admission, psychiatric symptoms, behaviour, health and social functioning, costs) in children and adults with learning disability or who are autistic who have and have not received a C(E)TR. To explore stakeholder perspectives of the C(E)TR process and examine the association between the quality of C(E)TR recommendations and outcomes.

STUDY FLOW CHART



Glossary of Terms and Abbreviations

CAMHS	Child and Adolescent Mental Health Services
C(E)TR	Care (Education) and Treatment Review
CI	Chief Investigator
CLDT	Community Learning Disability Team
CMHT	Community Mental Health Team
CPA	Care Programme Approach
CSO	Clinical Studies Officer
DSR	Dynamic Support Register
EHCP	Education, Health and Care Plan
HoNOS	Health of the Nation Outcome Scale
ICB	Integrated Care Board
ICF	Informed Consent Form
ID	Identification
IST	Intensive Support Team
HRA	Health Research Authority
KCL	King's College London
LA	Local Authority
LAEP	Local Area Emergency Protocol
NHS	National Health Service
NIHR	National Institute of Health and Care Research
NPT	Normalisation Process Theory
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
QoL	Quality of Life
RAG	Red, Amber, Green rating scale
REC	Research Ethics Committee
SLaM	South London and Maudsley NHS Foundation Trust
SMG	Study Management Group
SSC	Study Steering Committee
RA	Research Assistant / Research Associate

1. Background

Over 2,000 people with a learning disability or who are autistic are currently in psychiatric hospital and over 50% of these have been admitted for more than two years (1). Care (Education) and Treatment Reviews (C(E)TRs) were introduced as standard care within NHS services in 2015 as part of the Transforming Care policy following an investigation into the abuse of people with a learning disability at Winterbourne View hospital (2,3). Transforming Care aims to reduce the number of people with a learning disability admitted to a psychiatric hospital by ensuring that community C(E)TRs are conducted for patients who are at high risk of psychiatric hospital admission. Their purpose is to generate actions and recommendations to enable patients, families and carers access to timely and appropriate support in the community that can prevent unnecessary hospital admission. When a person is admitted to hospital, further C(E)TRs should be held to ensure the right community services are in place that will facilitate prompt discharge. However, wide variations in the use of Dynamic Support Registers (DSRs) to monitor patients at risk of admission (4) and the subjectivity of stratifying this risk has led to differences in implementation of community C(E)TRs and variability in the quality of C(E)TR recommendations. Consequently, 75% of people admitted to psychiatric hospitals currently do not have a C(E)TR prior to admission (1) and only a modest reduction in the number of admissions of people with a learning disability and autistic people has been achieved (19% vs a target 30-50%) (5). There is scant research on (i) whether C(E)TRs cause a reduction in the number of hospital admissions; (ii) whether C(E)TRs cause an increase in positive outcomes, including clinical and mental health outcomes, for children and adults with a learning disability and/or autistic people and (iii) the lived experience of patients, carers and clinicians with the C(E)TR process.

There are sound reasons to minimise hospital admissions for people with a learning disability and/or autistic people. Patients and their families and carers can find psychiatric admissions difficult and disempowering (6-8). When they are admitted, people with a learning disability and/or autism stay longer in hospital than those without a learning disability and/or autism and are at risk of prolonged hospital stays (9). People with a learning disability and autistic people have been subjected to significant restrictive interventions during hospital admissions, including physical restraint and seclusion (10). Further, admissions to 'out-of-area' and specialist hospitals can disrupt relationships with families and carers and cause social dislocation (11-12). Almost half of adults with a learning disability who are admitted to

psychiatric hospitals are discharged to a different residence from which they were admitted (13). Psychiatric hospital admissions are financially costly, reducing the resources available to develop and sustain community services.

C(E)TRs are person-centred meetings in which an independent panel hears from the person and their family/carers, along with health and social care professionals, and reviews the care received by the person with a learning disability or autistic individual. The panel includes an expert-by-experience, a clinical expert, and a commissioner. A community C(E)TR is convened when a person living in the community is considered at risk of psychiatric hospital admission; the remit of the meeting is to identify and recommend alternatives to admission or additional community supports that might be implemented to avoid the admission or, when the admission is not avoidable, to ensure the admission has a clear focus and planning for discharge occurs from the start of the admission (4). Hospital C(E)TRs occur six weeks after intervals a person is admitted to psychiatric hospital and then after every three months, with the aim to expedite discharge.

To support the C(E)TR process, a Dynamic Support Register (DSR) is maintained by each Integrated Care Board (ICB) that identifies people at higher risk of admission (4). People on the DSR are stratified by risk, with those categorised as 'red' being at high risk, 'amber' having moderate risk, and 'green' having low risk of admission; people who are rated red should have a community C(E)TR, although a C(E)TR may also be arranged for those rated as amber. The DSR is the central, living document that informs attempts and directs resource to avoid unnecessary admission; for example, in addition to C(E)TRs, from 2023/24, children and young people on the DSR will be provided with a keyworker to co-ordinate their care and follow-up on recommendations.

This protocol describes three studies which will be undertaken to provide an evidence base for the use of community C(E)TRs and to explore the experiences of different stakeholders involved in the process by assessing their uptake and impact on care. The findings can be used to optimise community C(E)TRs, with the potential for tangible benefits for people with a learning disability and autistic people, their families and carers, professionals who work in mental health and specialist services, and the health service as a whole.

Three studies are described in this protocol:

i) Prospective Cohort Study (*Section 4*)

We will conduct a longitudinal prospective cohort study including people with a learning disability and autistic people who are at risk of hospital admission, that is, who have been rated as red or amber on the DSR. Participants will be followed-up over a 12-month period with validated questionnaires that capture health status, quality of life, and service use. As this is an observational study, we expect some of the participants will have a C(E)TR over the course of the study and some will not. Some participants may be admitted to hospital. We will compare hospital admission rates and other clinical and social care outcomes (e.g. duration of admission, psychiatric symptoms, behaviour that challenges, health and social care functioning, quality of life, service use and costs) in those who have had a C(E)TR compared to those who have not had a C(E)TR.

ii) Qualitative Interview Study (*Section 5*)

We will conduct individual semi-structured qualitative interviews to gather the perspectives of people with a learning disability, autistic people, paid and family carers, and professionals, about the C(E)TR process. We will seek people's experience and views of C(E)TRs and important aspects of what works well and what does not will be addressed.

iii) Delphi Panel Exercise (*Section 6*)

In our final study, we will develop a checklist to assess the quality of C(E)TRs through the use of the Delphi consensus method. We will use existing C(E)TR policy and themes emerging from the qualitative interview study to create initial items for the exercise. Items that gain the greatest consensus over 2-3 rounds will be used to create the quality checklist. The checklist will be used to determine the quality of C(E)TRs that took place during the Prospective Cohort Study and we will assess if the quality of the C(E)TR is predictive of better outcomes, e.g. reduced likelihood of hospitalization and improved clinical outcomes. We will make the checklist available to practitioners across England so that it can be used as a means of standardising processes and improving the quality of C(E)TRs.

2. Rationale

Following the exposure of systematic and criminal abuse at Winterbourne View Hospital in 2011, there has been a strong focus on the care of people with a learning disability and autistic people, particularly those with additional needs including co-occurring mental health conditions and behaviours that challenge. A major element of this has been a drive to reduce inappropriate psychiatric hospital admissions and length of hospital stay for people with a learning disability and/or autism. Improving access to the right community health and social care support for people with a learning disability and/or autistic people is at the centre of the Transforming Care national policy (3). A core part of achieving this has been the introduction of Care (Education) and Treatment Reviews (C(E)TRs) in 2015 (4).

The initial target set by Transforming Care of reducing psychiatric hospital admissions by 30-50% by March 2019 was not met and a reduction of only 19% has been achieved (5). One study suggests that hospital admission rates for people with a learning disability and/or autistic people have not changed since 2015 and 40% are re-admitted following discharge (13). One explanation for these findings is that only 25% of patients who are admitted to psychiatric hospitals have a community C(E)TR prior to admission (1) indicating the need for improved implementation of C(E)TRs. The reasons for the low numbers of community C(E)TRs are unclear and we do not know whether patients with specific demographic or clinical characteristics are more or less likely to have a community C(E)TR. Furthermore, the costs and impact of community C(E)TRs on patient outcomes and service use, including the duration of subsequent admissions, has not been demonstrated. Robust evaluation data are needed to ensure the C(E)TR process maintains credibility with all stakeholders (14).

We also know little about how C(E)TRs are experienced by people with a learning disability, autistic people and their carers (15). A survey conducted for NHS England found there were areas for improvement (16) and the CQC have highlighted problems with variable quality of C(E)TR action plans and failure to implement them (17). Research involving children is particularly lacking. The proposed research questions across the three studies have been established to address the substantial lack of research and evidence-based guidance in this area.

3. Theoretical framework

A **mixed-methods approach** will be used which includes statistical analysis of a longitudinal clinical cohort study, the gathering of qualitative data from research participants, and a consensus exercise to integrate views across different stakeholders. Justification for our methods is given in this section.

A trial of C(E)TRs as an intervention is not possible, given they are now embedded in routine clinical practice. In this instance, a prospective cohort study is valuable in the characterization of risk factors that lead to better or worse outcomes for a particular cohort (18).

Qualitative Interviews are an appropriate method to gain very rich data and to explore the perspectives of a diverse range of stakeholders who are involved in the C(E)TR process. An analysis using Framework Analysis and Normalisation Process Theory (NPT) can support an understanding of how complex interventions become embedded in routine practice and can offer maximal benefits.

The Delphi panel method has been widely used in healthcare research to gain consensus from a group of individuals who have knowledge in a particular area. The method is useful where there is limited evidence and potentially conflicting views. Practically, an online version is helpful to gather broad input where participants are geographically dispersed, and where anonymity is preferable in order that power dynamics do not influence respondents (19). The Delphi technique is a suitable format to gather multistakeholder consensus and can help in the development of credible professional guidelines on the implementation of C(E)TRs in the community.

4. Prospective Cohort Study

4.1. Research question/aims

The aim of this study is to investigate the impact of C(E)TRs for people with a learning disability and/or autistic people on clinical, health and social outcomes, and their health economic impacts. We will address the following research questions:

- Do C(E)TRs reduce hospital admissions (primary outcome) and duration of hospital stay in people with learning disability and/or autistic people who are at risk of psychiatric hospital admission?
- Do C(E)TRs improve other clinical, health and social outcomes?
- Are C(E)TRs cost-effective?

4.2. Study setting

Integrated Care Boards (ICBs) are NHS organisations responsible for planning health services for their local population. There are 42 ICBs across England and each covers a population of approximately 1-2 million people. In this study, ten to fifteen diverse and representative ICBs (e.g. South East London; Cheshire & Merseyside, Cornwall & the Isles of Scilly) will be identified and invited to take part. The use of multiple ICBs as the research setting for this study is appropriate, given the number of participants to be recruited and to ensure fair representation of different population groups.

Each ICB has a named person with responsibility for the DSR (usually a health service Commissioner) who will be identified and approached with details of the study. ICBs may delegate responsibility for holding the DSR to other statutory organisations, such as NHS Trusts or Local Authorities (LAs). In this case, with the agreement of the ICB (which retains overall responsibility for the DSR), the NHS Trust or LA will be invited to take part via the DSR lead.

We will recruit approximately 20-30 participants with a learning disability and/or autistic participants who are on the DSR at each ICB, and their carers where applicable. We expect that eligible participants may receive care from different NHS clinical teams including Child and Adolescent Mental Health Services (CAMHS), Community Learning Disability Teams (CLDTs), or mainstream Community Mental Health Teams (CMHTs).

4.3. Sample and Recruitment

4.3.1. Eligibility Criteria

4.3.1.1 Inclusion criteria

ICBs:

- Have a DSR for people with a learning disability and/or autistic people
- Use Red, Amber and Green (RAG) ratings to stratify risk of admission
- Agreement from Commissioner/named person with responsibility for DSR to support the study

Participants:

- Children/adolescents (aged between 14 and 17 years, inclusive) or adults (≥18 years) with a clinical diagnosis of learning disability (of any degree) or autism (diagnosis based on service records, expected to conform to ICD-10 chapter F7- criteria for learning disability or ICD-10 F84 criteria for autism)
- Under the care of a community mental health service (e.g. CAMHS, CLDT, CMHT)
- Rated as red or amber on the DSR
- Provide informed consent to taking part or, where an adult lacks capacity to consent to participate, a personal or nominated consultee has signed a declaration form or, in the case of children/adolescents (<18 years), a parent/guardian has signed a consent form

Carers:

- Family or paid carer of a participant enrolled into the study
- Age ≥16 years
- Provide informed consent to take part in study

4.3.1.2 Exclusion criteria

ICBs:

- Do not keep an active DSR as a list of people with learning disability or autism who are considered at high risk of admission to psychiatric hospital
- Do not stratify risk of admission using a RAG rating system
- Do not agree to support recruitment to the study

Participants:

- Children <14 years of age
- No clinically-confirmed diagnosis of learning disability or autism

- Not on the DSR
- Currently admitted to a psychiatric hospital or discharged from a psychiatric hospital within the previous 6 months
- Does not provide informed consent or, where an adult lacks capacity, there is no consultee declaration or, in the case of children/adolescents (<18 years) a parent/guardian has not signed a consent form

Carers:

- Age <16 years
- Does not provide informed consent to take part in study

4.3.2. Sampling

4.3.2.1. Size of the sample

Due to reliable data on C(E)TR outcomes not being available, we have made some assumptions in calculating our sample size. We estimate the proportion of admissions will be higher in the group who have not had a C(E)TR of 17.5% and this will be reduced to 5% in those that have a C(E)TR, thus an absolute reduction of 12.5% at 12 months. In order to achieve this clinically meaning reduction, using a two independent sample test of proportions, with 90% power and type-1 error of 5%, 266 participants will need to be analysed. After accounting for a dropout rate of 10% we will enrol 300 participants with LD/autism. To improve the robustness of our assumptions, we will consult with clinicians, commissioners, carers and people with learning disability and autistic people about what they perceive would be an important and meaningful difference in admission rates, and we will undertake a focused meta-analysis of the literature to identify effect sizes of community interventions aimed at reducing psychiatric admissions (e.g. crisis teams). We will complete this exercise before recruitment commences and will use our findings to update the sample size calculation, if appropriate.

To identify and tackle any issues related to inadequate recruitment, the research team will work closely with the participating sites during an internal pilot (i.e. in the first nine months of recruitment) by examining participant flow into the study. The research team will discuss recruitment screening logs with CIs/CSOs at each site in monthly meetings. Where appropriate, further training and feedback will be provided to enhance the identification of potential

participants and their recruitment into the study. Any amendments to the study protocol will be made promptly.

4.3.2.2. Sampling Technique

C(E)TRs are established practice and a trial with randomisation would not be possible. Participants will be people with a learning disability and autistic people who are at risk of being admitted to hospital and, as such, have been added to the local DSR. We will attempt to approach all eligible participants on the DSR at each ICB.

We will approach 10-15 ICBs with diverse populations across the country and ensure that both urban, rural, and coastal areas in the north and south of the country are represented. The named person for responsibility for the DSR at each participating ICB will be asked to provide basic information about the population they serve, the mental health teams that they work with, and how they manage the DSR.

4.3.3. Recruitment

4.3.3.1. Participant identification

We will contact 10-15 Integrated Care Boards (ICBs; NHS organisations responsible for planning NHS services across a defined geographic area) covering diverse areas of England (e.g. South East London; Cheshire & Merseyside, Cornwall & the Isles of Scilly). We will gain agreement from the named person responsible for the Dynamic Support Register (DSR; a community register of people with learning disability or autism who are considered at higher risk of admission to hospital) that they will support the study. The ICB will not be involved in any participant-facing activities and will not provide the identities of any eligible participants, only the clinical teams overseeing eligible participants' care. We will then gain agreement from NHS Mental Health Trusts (or other providers of secondary mental health services) within the identified ICB footprint that they can support this work. Principal investigators will be established at these Trusts and the Organisation Information Document (OID) will be the agreement between the sponsor and these sites. There may be more than one mental health provider/Trust in each ICB. South London and Maudsley NHS Foundation Trust is expected to be a participating Trust.

We will ask the ICB to give us the names of the mental health teams that provide care to people who are rated as red or amber on the DSR (i.e. at the highest risk of admission). The teams are likely to be Community Mental Health Teams, Community Learning Disability Teams, or Child and Adolescent Mental Health Services. We will approach service managers and clinicians in these mental health teams to explain the study and eligibility criteria. If they are happy to help with this study, we will ask that they identify potential participants who are rated red or amber on the DSR and make an initial approach to them to inform them. This will include providing potential participants with a short leaflet and details of the study team. If the person with learning disability or autism (or their carer, acting for someone who may lack capacity) agrees, a member of their direct care team will provide their contact details to the research team. The research team (or a Clinical Studies Officer as part of the Research Delivery Network) will then make contact with the potential participant to further explain the study and receive consent. This process will also include seeking information about any paid or unpaid (usually family) carers that the potential participant may have. If they do have a carer, we will include them in the discussion around recruitment, unless the potential participant with learning disability or autism objects to this. If the person with learning disability or autism is recruited, we will aim to recruit their carer to the study (following providing full information about the study and answering questions) in order that they can complete carer outcome measures.

4.3.3.2. Consent

Potential participants (or their parents/guardians, or carers) who express an initial interest in taking part in the study will be contacted by a CSO or RA to arrange a suitable time and venue (including online) to further discuss the study. Participant Information Sheets (PIS) will be shared with the potential participant.

At the initial meeting with the CSO or RA, the details of the study and the expectations of study participants and carers will be described. It will be made clear to potentially-eligible participants that their involvement is voluntary and that their care will in no way be affected if they decide not to participate. The potential participant (and/or their parents/guardians, or carers) will have the opportunity to ask questions about the research and will be given time to decide if they would like to participate. They will be informed that they are free to withdraw their

consent at any point in the study, without having to provide a reason. CSOs and RAs will receive training in consent procedures employing role-play and pre-prepared scripts that most effectively explain the study to potential participants.

Eligibility will be confirmed by the CSO or RA and the capacity of the potential participant to give consent to being involved will be assessed. If the potential participant lacks capacity to make a decision to be involved in the study, we will seek advice from a personal or nominated consultee. In children (aged ≥14), we will assess Gillick competence (20); if it is deemed that they have enough intelligence, competence and understanding to fully appreciate what is involved in the study, they may be able to consent for themselves, otherwise we will approach their parent or guardian to provide consent. CSOs and RAs will receive training and supervision on assessment of eligibility and decision-making capacity. RAs will also follow the Clinical Research Network's training on Good Clinical Practice and Valid Informed Consent, and how it applies to adults who may lack capacity.

Consent may be obtained in writing or verbally. Methods for obtaining written consent include e-consent, and may be collected as simple electronic signatures in accordance with guidance from the HRA and MHRA.

The participant's clinician (nominated by the site Principal Investigator (PI), expected to be the participant's psychiatrist or other clinician working closely with the patient) will be informed of the person's enrolment into the study. They will be asked to provide information at baseline and will thereafter act as a contact point for clinician follow-up at 6 and 12 months. We will keep contact with clinical teams who manage people who are participating in the study to aid ongoing recruitment, answer questions that arise, and improve completion of follow-up questionnaires.

Children who turn from 15 to 16 whilst taking part in the study will need to re-consent. They will be provided with the adult participant information sheet and will need to complete the associated adult consent form. Any participants who are 15 when recruited will be notified of this process at their initial consent meeting. The RA or CSO will take note of their birthday and ensure the necessary materials are sent to the participant at least 2 weeks before their 16th birthday. Upon turning 16, participants can re-consent via email, telephone, or an online video call can be arranged to answer any further questions. If the participant lacks capacity upon

turning 16, the RA or CSO will contact their carer and/or clinician at least one month before their 16th birthday to obtain the name and contact details of a willing consultee. Consultee information and declaration of opinion materials will be provided. The collection of any further study data will be paused until a consultee has provided us with a declaration that the participant can continue to take part in the study.

4.3.3.3. Study information and consent forms

Participant Information Sheets, consent forms, and consultee forms have been developed in accordance with guidance from the Health Research Authority (21) and with input from study PPI Co-Investigators and group members.

4.3.3.4. Recruitment timeline

Internal pilot

Given potential issues in the recruitment to this study, and as advised by reviewers, we will run an internal pilot. The internal pilot will run over the first nine months of the recruitment period (the total recruitment period is 18 months). We expect to have recruited half the total number of participants during this nine month period (n=15) from at least three ICBs. If the number of recruited participants is below expectations, if the number of C(E)TRs being conducted is very low, or if almost all of participants who are admitted to hospital have had a C(E)TR prior to admission, it will not be feasible to continue the study. Data will be reported to the funder and to the Study Steering Committee (SSC), where a decision to continue, adapt, or discontinue the study will be made.

We will be guided in our decision as to whether the prospective cohort study should progress by the use of traffic light criteria for recruitment (Table 1). The study will progress if the green target is met. If recruitment falls within the amber range, we will discuss possible reasons for lower-than-expected recruitment within the Study Management Team and with the Study Steering Committee, and whether this can be addressed with changes to the recruitment strategy (e.g. recruit additional ICBs). If fewer than 50% of our target number of participants have been recruited at 9 months (i.e. <75 participants), we will take advice from the SSC and funder and we will follow their recommendation.

Table 1: Traffic light criteria to determine study progression at 9 months. Target is n=150 participants with LD/autistic participants, and their carers where appropriate.

Criteria	**Green**	**Amber**	**Red**
Recruitment of participants	150 participants (100% target)	75-149 participants (50-99% target)	<75 participants (<50% target)
Participant retention*	90%	80-89%	<80%

*of those eligible for the first follow-up assessment 6 months after entry into the study

4.3.3.5. Schedule of Procedures

	Baseline	6 months	12 months
Person with LD and/or Autistic Person	• Informed consent • Socio-demographic & health • Primary outcome measure • MOS-PAS – Check • CANDID-R • WHOQOL-DIS • EQ-5D-3L / EQ-5D-5L • AD-SUS • BPI-S (when no carer)	• Socio-demographic & health updates • Primary outcome measure • MOS-PAS – Check • CANDID-R • WHOQOL-DIS • EQ-5D-3L / EQ-5D-5L • AD-SUS • BPI-S (when no carer)	• Socio-demographic & health updates • Primary outcome measure • MOS-PAS – Check • CANDID-R • WHOQOL-DIS • EQ-5D-3L / EQ-5D-5L • AD-SUS • BPI-S (when no carer)
Informant (Carer, Parent)	• Informed consent • Socio-demographic & health • BPI-S • K6 • EQ-5D-5L	• Socio-demographic & health updates • BPI-S • K6 • EQ-5D-5L	• Socio-demographic & health updates • BPI-S • K6 • EQ-5D-5L
Clinician / CSO	• HoNOS-ID / HoNOS • CGI-S • Restrictive Practices • Hospitalization and C(E)TR status • Other approaches to care received by participant • Psychiatric medication • Service-level information	• HoNOS-ID / HoNOS • CGI-S • Restrictive Practices • Hospitalization and C(E)TR status • Other approaches to care received by participant • Psychiatric medication	• HoNOS-ID / HoNOS • CGI-S • Restrictive Practices • Hospitalization and C(E)TR status • Other approaches to care received by participant • Psychiatric medication

Figure 1. *Prospective Cohort Study - data to be collected at each time-point. See Section 4.4 for descriptions of measures.*

4.3.3.6. Baseline assessments

After consent has been received, a baseline assessment will be completed with the participant and/or their carer (if applicable) by the CSO or the RA. This may occur in a face-to-face meeting, telephone call, or online meeting using video conferencing software using MS Teams. This will include a questionnaire developed for the study to gather socio-demographic (e.g. age, gender, ethnicity, living situation, support received), health data (mental and physical health conditions, behaviour that challenges, current treatment, history of admission to mental health hospital), and whether they have ever received a C(E)TR. It will also include a baseline assessment of

health service use for the health economic evaluation. A £20 gift voucher will be provided to participants (people with learning disability or autism, carers) as a token of thanks for completing the baseline assessment.

The participant's nominated clinician will be asked to provide information and to complete clinician-rated outcome measures at baseline and at 6- and 12-month follow-up (Section 4.4.2.2.).

4.3.3.7. Retention of participants and follow-up assessments

Participants and carers (if applicable) will complete outcomes measures at 6 and 12 months after enrolment. Again, these may be completed in a face-to-face meeting, telephone call, or online meeting using video conferencing software. Further details of follow-up measures are provided in section 4.4 of this protocol.

Prior to the follow-up date, participants (and carers, where appropriate) will be contacted by telephone, text message, or e-mail (with consent for contact and preference collected at enrolment) so that suitable arrangements can be made to conduct the follow-up assessments, and to answer any questions. A £20 gift voucher will be provided to participants (people with learning disability or autism, carers) as a token of thanks at each follow-up assessment.

We will produce a newsletter twice a year to be sent to participants and clinicians/clinical services with updates about the study to increase engagement. The research team will make themselves available to participants, parents/guardians/carers, and clinicians throughout the research period and will be able to offer advice or answer questions that arise.

4.4. Measures

4.4.1. Primary outcome measure

Data on admission to psychiatric hospital over a one-year follow-up period (date of admission (and discharge, if applicable), type of ward (i.e. CAMHS, general ward, forensic ward, psychiatric intensive care unit)) will be obtained from the clinician responsible for the participants' community care at follow-up assessments. The participant (or carer, where applicable) will also

provide this information at their follow-up assessment as part of the service use questionnaire (see section 4.4.2.1); any discrepancy between data provided by the clinician and that provided by the participant (or carer) will be resolved through further discussion with the clinician.

4.4.2. Secondary outcome measures

4.4.2.1. Participant and family carer measures

Outcome measures with participants and carers (if applicable) will be administered by the CSO or RA in face-to-face meetings, telephone calls, or online meetings using video conferencing software.

Psychiatric symptoms

Broad psychiatric symptomology be assessed using the Moss Psychiatric Assessment Schedule - Check (Moss-PAS (Check)) (22), an easy-to-complete 25-item questionnaire that screens for symptoms of anxiety, depression, elevated mood and hyperactivity, obsessive compulsive disorder, psychosis and organic disorder, suitable for use with children and adults with and without learning disability.

Behaviour that challenges

Will be assessed using the 20 item Behavior Problems Inventory - short form (BPI-S), which has been developed for use in people with learning disability (23). It is used to measure problem behaviour on three subscales (self-injurious behaviour; stereotyped behaviour and aggressive/destructive behaviour), which are rated on a frequency (0=never to 4=hourly) and severity scale (0=no problem to 3=severe problem). This will be administered to the participant's carer, where possible. If administered directly to the participant, wording around the final section 'Stereotyped behaviour' will be handled appropriately to convey understanding that these behaviours are not considered problematic and may be used to regulate emotions and self-soothe.

Unmet need

Unmet need will be assessed using the Camberwell Assessment of Needs for Adults with Developmental and Intellectual Disabilities - Research version (CANDID-R) (24). This is a semi-

structured interview covering 25 domains including needs related to food, accommodation, risk of exploitation and welfare benefits. For each domain, items address whether there is a need, whether it is met or unmet, what help has been received from professionals and carers and if the individual is satisfied with the help. This will be conducted by a RA/CSO with participants or their carer.

Quality of Life (QoL)

Will be measured using the 13-item WHOQOL Disabilities module (WHOQOL-DIS) (25), which will be completed with participants or carers. Items include one general item about wellbeing and 12 items covering impact of disability, discrimination, choice, control, social inclusion and contribution, which are rated on a three-point scale.

Health-related QoL

Will be assessed using the EuroQoL. A modified version - the EuroQoL Five Dimensions - Three Levels (EQ-5D-3L) has been recently developed for people with mild to moderate learning disability (26,27). The descriptive system comprises five dimensions: walking about (mobility), looking after myself (self-care), doing things I want to do (usual activities), pain (pain/discomfort) and feeling worried, sad or unhappy (anxiety/depression). Each dimension has 3 levels: no problems, a bit or some difficulty (some problems) and lots of difficulty (extreme problems). Autistic participants will complete the standard Five Levels version (EQ-5D-5L). Children/adolescents will complete a version for young people (EQ-5D-Y-3L). A proxy version of the EQ-5D-5L will also be completed by carers for all people with learning disability.

Service use

Information about health and social care contacts in the preceding six months will be collected using a modified version of the Adult Service Use Schedule (AD-SUS) which will be adapted to include services for children/adolescents (28). The number and duration of contacts with various services and professionals, including contacts with primary care, professionals within community learning disability services or mental health teams (e.g. psychiatrists, nurses, social workers), secondary care (outpatient, A&E visits, hospital admissions) and day services will be recorded. Participants and carers will be given a diary to record information in order to aid recall.

Family carer distress

For participants who have a family carer enrolled in the study, family carer distress will be measured with the self-rated version of the 6 item Kessler Psychological Distress Scale (K6) which rates 5 symptoms on a 5-point Likert scale (29).

Family carer health-related QoL

For participants with a family carer enrolled in the study, health-related QoL will be assessed using a self-rated version of the EQ-5D-5L (30).

4.4.2.2. Clinician-provided data

Information from clinicians and clinician-rated assessments will be requested by e-mail or post. These will be competed at baseline, 6, and 12 months by the participant's clinician (or their deputy). Information may also be gathered in face-to-face meetings or via telephone or video conference, if preferred. Information on how to complete the outcome measures will be provided to clinicians.

Service level information

Service-level information will be obtained for each participating service (i.e. CAMHS team, CLDT, CMHT) at baseline via a questionnaire sent to a clinician in the service or the team service manager. This will include the team staffing complement, working hours and days, whether the service has a 'duty' system for managing immediate (but non-emergency) concerns, if there is access to an Intensive Support Team (IST) for people with a learning disability or an autism team, access to specialist CAMHS, learning disability, and mainstream psychiatric in-patient beds, whether the team operates as an 'integrated' team with social care.

Participant symptom severity

Will be assessed using the Clinical Global Impression-Severity (CGI-S) Scale, a brief, well-established clinician-rated scale of the patient's global functioning (31). The item is rated on a 7-point scale. The scale will be modified to include a measure of behavioural disturbance.

Participant health and social functioning

Will be measured using the Health of the Nation Outcome Scales (HoNOS). Autistic adults will complete the main version (HoNOS). The child/adolescent version (HoNOSCA) will be used for participants <18 years at study entry, and the intellectual disability version (HoNOS-ID) will be used for those ≥18 at study entry (32,33). Items include mental and physical health, behavioural problems, risk, activities of daily living, relationships and occupational functioning, rated on a 5-point scale.

Use of restrictive practices

Restrictive practices will be assessed by recording the level of one-to-one support/observations, use of physical, mechanical, or chemical restraint, and isolation (seclusion or segregation) as well as the legal frameworks for restriction (e.g. Mental Health Act, Deprivation of Liberty Safeguards). This will be gathered by use of a standardised questionnaire created by the research team.

Psychotropic medication

A brief questionnaire developed for this study will be used to collect information on current prescribed psychotropic medication (name and dose) and its indication.

C(E)TR document and action plan

The C(E)TR document and action plan for those who have a C(E)TR during the study period will be obtained from the clinical service.

4.5. Statistical analysis

A statistical analysis plan will be drafted before data collection. The primary outcome (1-year hospital admission) will be analysed using a multi-level logistic regression. A random intercept will be fitted for service/site. Fixed effects will include: time point, age, sex, ethnicity, degree of learning disability, autism diagnosis, living arrangement. Secondary outcomes will be analysed in a manner consistent with the primary outcome, but with an appropriate model. Length of

stay in hospital will be analysed using a multi-level Cox regression with shared frailty for service and consistent fixed effects. Continuous outcomes will be analysed using a multi-level regression model. Adjusted mean differences (or odds ratios) with 95% confidence intervals will be presented. Missing data will be explored using pattern missingness. The statistical plan will also detail a formal framework for causal inference.

4.6. Health economic evaluation

A within-trial economic evaluation will be conducted to compare the cost-effectiveness of having a community C(E)TR compared to no C(E)TR over 12 months. The primary analysis will be conducted from an NHS and personal social services (PSS) perspective, as recommended by NICE. A secondary analysis will be undertaken from a societal perspective, encompassing the out-of-pocket costs and productivity losses experienced by patients and their carers. Information about patients' use of healthcare and social care services will be collected using ADSUS or an adapted version for children/adolescents (28). Health Related QoL will be measured using the self-rated adapted version of the EQ-5D-3L that has been developed for people with learning disability, the EQ-5D-5L for autistic people, the ED-5D-Y (for those aged <18 years at study entry), and a proxy measure of the EQ-5D-5L (completed by parents/guardians or carers). Quality adjusted life-years (QALYs) will be estimated by linear interpolation between QoL measures.

The primary outcome of the economic evaluation will be total cost per patient, total QALY per patient, and incremental cost-effectiveness ratio, which is the ratio of the additional cost divided by the additional effectiveness (i.e. QALYs) of having a C(E)TR compared to not having a C(E)TR. In line with NICE recommendations, interventions with an ICER less than £20,000-30,000 per QALY are considered cost-effective. Uncertainty in the data will be summarised in cost effectiveness acceptability curves showing probability of the treatment strategies being cost effective at different threshold levels of willingness-to-pay per QALY. Sensitivity analysis will be performed to explore impact on cost effectiveness of variations in key parameters.

If the within-trial analysis suggests community C(E)TRs may have long-term impacts on patients' costs and/or outcomes, an economic model will be developed to assess the lifetime cost-effectiveness of community C(E)TRs compared to no C(E)TR. The modelling method will follow

the revised Brennan's taxonomy (34), with parameters informed by trial data, supplemented by published literature and expert opinion.

Further details and full descriptions of analyses will be given in the Health Economics Analysis Plan which will be established prior to data collection.

4.7. Data processing and storage

Data will be de-identified, transferred, stored, accessed, and archived only by members of the research team. Any hard copies of questionnaires or assessments will be stored in a locked, fire and water-resistant filing cabinet at the Department of Forensic & Neurodevelopmental Sciences, Institute of Psychiatry, Psychology and Neuroscience, King's College London. Digital data will be stored in a folder on King's College London's One Drive cloud services with access only by with named members of the research team.

Each participant will be pseudonymised with an identification (ID) code which will be used across study forms. A central spreadsheet linking participant identifying information (e.g. name, contact details) with participant IDs, will be stored in a separate location to the study data, and will be accessed only by core members of the research team.

Information from baseline and follow-up assessments will be transferred to a centralized digital spreadsheet which will be used for analysis. This will not contain identifiable patient information. Analyses will be conducted using Excel, R (RStudio), Python, and JASP software.

The data retention schedule will be compliant with legislative record keeping requirements including UK GDPR (General Data Protection Regulation and the Data Protection Act 2018) and the Code of Practice on the management of records issued under Section 46 of the Freedom of Information Act 2000. Participants will be notified of the period over which their personal data will be stored and their rights under GDPR at the time the study is explained to them as part of the consent procedure.

Participant contact details will only be stored for as long as is necessary to administer the research.

With KCL as joint Sponsor for this work, we will adhere to the KCL policy regarding retention schedules for research data. In this policy, non-clinical trial research that involves children (<18

years old) should be kept for 5 years after the completion of the study or 3 years after the youngest subject reaches 18 years of age (whichever is longest). If participants who lack capacity to consent are enrolled, KCL policy requires us to keep the data for a minimum of 25 years. However, overarching NIHR policy caps the retention period of all research data at 20 years.

4.8. End of Study

The end of the study will be the date of the 12-month follow-up assessment of the last participant.

5. Qualitative Interview Study

5.1 Research Question/Aims

The aims of the qualitative study are to explore the views of stakeholders (patients, family carers, paid carers, clinicians, independent C(E)TR panel members) about their views and experiences of C(E)TRs. The objective is to elucidate which aspects of the C(E)TR process are helpful, which are perceived as not helpful, and to understand how the process may be improved.

5.2. Study setting

Participants with a learning disability and autistic people and family carers will be recruited from the ICBs participating in the prospective study i.e. participants will be drawn from those who attend a community C(E)TR during the course of this study. Paid carers and professionals will be recruited from participating ICBs and through other means, e.g. advertising via local networks.

5.3. Sample and recruitment

5.3.1. Eligibility criteria

5.3.1.1 Inclusion criteria

Participants with learning disability or who are autistic:

- Enrolled as a study participant in the prospective study or having a C(E)TR organised by a participating ICB
    - Mild or moderate learning disability or diagnosis of autism
- Aged 14 years or over
- Participated in a community C(E)TR in the last three months
- Consent to take part in the study

Carers:

- Family or paid carer for a participant with learning disability (any severity) or autistic individual enrolled into the study
- Age ≥16 years
- Participated in a community C(E)TR within the last three months
- Consent to take part in the study

Clinicians/professionals:

- Any clinician or social care professional (e.g. psychiatrist, community nurse, occupational therapist, social worker, commissioner)
- Working in a community learning disability or mental health service or Local Authority

C(E)TR panel members:

- Independent expert-by-experience member (e.g. a carer)
- Independent panel clinician (e.g. nurse, psychiatrist, psychologist) with experience of working with people learning disability and/or autism
- Independent chair (e.g. commissioner)
- Participated in a community C(E)TR in the last three months.

5.3.2. Sampling

5.3.2.1. Size of sample

The determination of sample size in qualitative studies is contentious and an area of practical uncertainty. A recent systematic review found that qualitative studies can be conducted with relatively small sample sizes, indicating as few as 9–17 interviews may be needed to provide

sufficient data for analysis (35). We will purposively sample 25-30 participants with a learning disability and autistic people (with half being children and young people aged 14-25 years), 15-20 family or paid carers, and 15-20 clinicians/professionals (including independent C(E)TR panel members), with final numbers determined by the diversity of views encountered and the information power of the sample (36).

5.3.2.2. Sampling technique

We will use a purposive sampling technique to obtain a diverse range of stakeholders and capture a wide range of perspectives. We will include participants with a learning disability and autistic participants from a range of socio-demographic backgrounds (e.g. age, sex, ethnicity, severity of learning disability, mental and physical health co-morbidities and living arrangements, admitted to hospital or not after C(E)TR). Family carers will be selected to include parents, siblings or other relatives, and different ages, gender and ethnicity. We will aim to recruit paid carers from different residential settings (e.g. supported living, residential care (and varying age, gender, ethnicity and number of years of experience) and professionals and C(E)TR panel members with a range of different health and social care backgrounds and with varied experience of working with people with learning disability and/or who are autistic.

5.3.3. Recruitment

5.3.3.1. Sample identification

People with learning disability, autistic people, and family carers

Participants with learning disability or autism and paid or family carers who are enrolled in the Prospective Cohort Study who have been involved in a C(E)TR during the study follow-up period will be approached and informed of the opportunity to take part in an interview about their experience of the C(E)TR. We will know whether people have had a C(E)TR during the follow-up period by asking them for this information at the 6 and 12 month follow-up assessments, and we will also ask their clinician to inform the research team if/when a community C(E)TR is undertaken for anyone enrolled on the study. For those who are interested in hearing more, a mutually-convenient time will be arranged to further explain the study and receive informed consent. We will also share our advert on social media and via other networks, such as the Take

Part in Research (TPiR) initiative at SLaM, or charities, to bolster the participation of people with learning disability and/or autism who have had a C(E)TR.

Paid carers, clinicians and C(E)TR panel members

Paid carers, professionals, and C(E)TR panel members will also be recruited to the Qualitative Interview Study. The pool of potential participants from these groups will be broad in order that we gain sufficient diversity in the sample and fair representation of different groups. We will recruit clinicians and C(E)TR panel members from the ICBs and clinical services that are supporting the research; this may involve e-mails to potential participants in these organisations, short presentations at team meetings, and word-of-mouth approaches. We will also use publicity and recruit paid carers, professionals, and C(E)TR panel members through adverts and e-mails spread via professional networks, e-mail distribution lists, and at regional or national meetings and conferences

5.3.3.2. Consent

Consent will be obtained following the same procedures as the Prospective Study (section 4.3.3.2). Participants with a learning disability and/or autism who take part in the Qualitative Study will have undergone a C(E)TR and will be asked about their personal experiences.

Participant Information Sheets (PIS) and consent forms will be developed in accordance with guidance from the Health Research Authority (21), and in the same way as for the Prospective Study, described in section 4.3.

5.4. Study Design and Methods of Data Collection and Data Analysis

5.4.1. Interview procedures

Semi-structured, qualitative interviews will be conducted with approximately 55-70 participants who are C(E)TR stakeholders; adolescents and adults with a learning disability and/or autism, family carers, and clinicians/professionals (including independent C(E)TR panel members). We will recruit people from diverse backgrounds, locations and those who were and were not admitted to hospital following the C(E)TR.

Interviews will be arranged at a time and place convenient for the participant. This may be face-to-face or online, via video conferencing software (MS Teams). It is anticipated that interviews will last for between 30 and 60 minutes, though this may vary. Participants will be able to end the interview at any point. They will be able to have a carer, family member, friend, or other supporter with then during the interview, if they wish.

Each interview will begin with collecting demographic and basic clinical information about the participant according to a standard data collection sheet which will differ based on whether the participant is a person with a learning disability or autism who has had a C(E)TR, a family or paid carer, or a clinician or C(E)TR panel member.

The interview will be conducted according to a broad topic guide which will be developed based on the published literature, discussions within the research team, and with PPI group members.

A member of the research team with appropriate training will conduct the interview. PPI group members who have a learning disability or who are autistic may co-facilitate some interviews. Questions will include, how included people with a learning disability or autism felt and their carers felt in the C(E)TR process, how able they were to express their views, if the C(E)TR addressed issues important to them, and their satisfaction with the C(E)TR action plan and how this was implemented. Issues around the information (e.g. what did they knew about C(E)TRs before the meeting), organisation, and delivery of the C(E)TR will also be covered. We will explore the interaction and overlap of C(E)TRs with Education, Health and Care Plans (EHCPs) for children and young people and other clinical meetings such as Care Programme Approach (CPA) meetings.

Clinicians and C(E)TR panel members will give their views on the utility of C(E)TRs and their place in avoiding hospital admissions, perceived benefits and drawbacks of the process, the place of C(E)TRs amongst other statutory and non-statutory meetings (e.g. Mental Health Review Tribunals, CPA meetings) and the extent to which action plans are considered appropriate, deliverable and likely to impact care and outcomes.

In addition, we will use Normalisation Process Theory (NPT) as our theoretical model for understanding how C(E)TRs are being embedded into practice. Questions will be framed around the following areas: 1. coherence (what do participants understand about the purpose of the

C(E)TR process?; what benefits, if any, do they bring and to whom?); 2. cognitive participation (do they think C(E)TRs are a good idea; are they prepared to invest time and energy?); 3. collective action (how do participants feel about how C(E)TRs are arranged – do they feel they are included in the process and the development of action points?; how do C(E)TRs affect the work of clinicians and the division of labour, resources and responsibility between different professionals?); 4. Reflexive monitoring (what are stakeholder's perception of C(E)TRs, can they be adapted or improved?). Interviews will be audio-recorded and transcribed verbatim.

5.4.1.1. Adaptation of interview procedures

We will be flexible in our procedure for gathering qualitative interview data so as to respect the communication preferences and support needs of participants with a learning disability and those who are autistic.

Where possible, we will hold interviews as soon as possible after a C(E)TR (if considered appropriate to do so based on the individual's clinical presentation) due to potential difficulties distinguishing the C(E)TR from other meetings such as CPA meetings. To aid recall, and if possible, participants and their carers will be asked to complete reflective notes and/or a video diary about their experience of the C(E)TR process around the time that the meetings are taking place to use to augment the qualitative interview, and we will provide support and advice about how they might do this.

People with a learning disability can successfully take part in qualitative interviews (37). We will adapt our interviewing techniques to accommodate the differing communication preferences. This will include, where necessary, the use of Talking Mats, a method which uses symbols alongside verbal communication to improve understanding and expression in those with limited communication skills (38). We will also employ dyadic interviewing as a methodological approach to obtaining rich, in-depth qualitative data (39). This involves conducting interviews in three stages; there is a preliminary interview with the person with learning disability to gain trust and rapport and to obtain a general impression of the individual's experiences, followed by interviewing their carer/supporter to obtain information that supports, complements and adds validity to the information gained from the first interview. This additional perspective permits the researcher to gain a greater understanding of the issues and to prepare additional

topics and questions for the final interview with the participant, which is the last stage of the process.

We will also adapt our methods to ensure successful interviews of young participants (40), which will include collaborating with parents and using a tool kit of interview methods to personalise each interview (e.g. warm-up activities, vignettes, sentence starters).

People with severe and profound learning disability have limited verbal and symbolic language and will not be able to participate in interviews. In order to understand their experiences, we will obtain the perspectives of carers on how C(E)TRs have impacted the individuals that they care for. Carers will also be asked to keep a diary of how the individual is dealing with the experience and communicating this through behavioural and bodily expressions. Carers can supplement written accounts with photographs, which will be shared and reflected on during the interview.

5.4.2. Data analysis

Interviews will be recorded and transcribed verbatim, either by a professional UK-based transcription company or using the transcribe function of video conferencing software. Transcripts will be checked for accuracy against the original recording.

Data will be imported into software that aids qualitative analysis (e.g. nVivo) and analysed using Framework Analysis (41). This approach is appropriate as it allows responses from different stakeholder groups to be compared across different themes and permits contributions from multiple researchers which will be of benefit due to the volume of data collected. The process includes 1) data familiarisation; 2) identifying themes; 3) indexing of themes; 4) charting and summarising of the data; 5) interpreting and mapping of the data; 6) compiling a report. PPI group members will be involved in the coding process and identification of themes. Data from each stakeholder group (e.g. people with a learning disability, autistic people, paid and family carers, professionals) will be analysed separately initially, and then combined and compared with the other stakeholder groups in a second stage.

5.4.3. Data processing and storage

Data will be transcribed, coded, de-identified, stored/transferred, accessed and archived by core members of the research team.

De-identified demographic and processed data will be stored in the same way as described in Section 4.7.

In this study, the audio files of the interviews where participants give their personal views involve an additional level of personal identifiable data. We will store and process these audio files on the KCL Trusted Research Environment (TRE), a secured environment for processing sensitive confidential data. Redacted transcripts (where identifiable information such as names, dates, locations have been removed) containing only the study participant identification code will be stored on the KCL One Drive and accessed only by core research team members.

Retention of data will adhere to policy described in Section 4.7.

Analysis will be conducted using NVivo (software developed for qualitative data analysis), R (RStudio), and JASP.

5.5. End of Study

The end of the study will be the date of the interview of the final participant.

6. Delphi Panel Exercise

6.1. Research Question/Aims

The objectives of the Delphi exercise are:

- To establish multistakeholder consensus on what constitutes a good quality C(E)TR / C(E)TR action plan and to develop a checklist of C(E)TR quality indicators.
- To rate C(E)TRs from the Prospective Cohort Study against the items on the checklist, and test the association between the quality of C(E)TRs and good outcomes for patients (e.g. duration of hospital stays)
- To develop guidance for policy and practice on how C(E)TRs should be implemented and for whom

The associated research questions are:

- What are the most important components of a good quality C(E)TR from multiple stakeholders' perspectives?
- Do good quality C(E)TRs (i.e. consensus items) in the Prospective Cohort Study lead to better outcomes for those patients?

6.2. Study Setting

Stakeholders will be recruited from ICBs participating in the Prospective Cohort Study (and will include the South London and Maudsley NHS Foundation Trust and the East London NHS Foundation Trust) and existing collaborator networks. Unlike the Qualitative Interview Study, participants with a learning disability, autistic participants and carers in the Delphi Panel Exercise will not have been enrolled into the Prospective Cohort Study.

6.3. Sample and Recruitment

6.3.1. Eligibility Criteria

Participants with learning disability or who are autistic:

- Mild or moderate learning disability or diagnosis of autism
- Aged 18 or over
- Participated in a C(E)TR in the last 12 months
- Consent to take part in the study

Carers:

- Family or paid carer for a participant with learning disability (any severity) or autistic individual enrolled into the study
- Age ≥18 years
- Participated in a C(E)TR in the last 12 months
- Consent to take part in the study

Clinicians/professionals:

- Any clinician or social care professional (e.g. psychiatrist, community nurse, occupational therapist, social worker, commissioner)
- Working in a community learning disability team or community mental health service or Local Authority
- Participated in a community C(E)TR in the last 12 months

C(E)TR panel members:

- Independent expert-by-experience member (e.g. a carer of a person with learning disability or autistic individual)
- Independent panel clinician (e.g. nurse, psychiatrist, psychologist)
- Independent chair
- Participated in a C(E)TR in the last 12 months

6.3.2. Sampling

6.3.2.1. Size of sample

For the Delphi surveys with individual stakeholder groups (e.g. clinicians, carers, service users), a sample size of 20 to 30 per group (rating all items) has been shown to produce moderate replicability levels (64% - 77%) (42). We will therefore include a minimum of 20 participants for each stakeholder group (service users with learning disability and/or autism, parents or carers, and clinicians).

6.3.2.2. Sampling Technique

All respondents will have experience of attending a community C(E)TR and will be selected purposively to ensure wide representation of views and backgrounds (e.g. age, ethnicity, sex, professional and carer background, geographical areas).

6.3.3. Recruitment

6.3.3.1. Sample identification

We will approach clinical leads and commissioners from participating ICBs from the Prospective Cohort Study and Qualitative Study to facilitate the recruitment of expert panel members who

are professionals (clinicians, social workers, commissioners), paid and family carers, and service users with a learning disability or who are autistic. The details of eligible potential participants will be provided to CSOs, who will confirm eligibility. The initial approach to potential participants will be made by a member of the clinical team or the CSO.

Paid carers, clinicians and C(E)TR panel members (including panel chairs, experts-by-experience, and clinical experts) will be sought through existing networks and the participating ICBs. This might include advertising the opportunity to be involved in the research through professional networks and groups, at academic meetings, via care providers, and through word-of-mouth. Standard e-mails and a recruitment advert will be used to reach a wide range of potential participants and may be posted to relevant forums or e-mail distribution lists.

6.3.3.2. Consent

Eligible participants with a learning disability who have agreed to be contacted will be contacted via telephone, letter/email, or their carer to discuss the study. If they are interested in participating, they will be provided with an accessible information sheet and an online meeting will be arranged to discuss the study, answer questions and to obtain consent. Reasonable adjustments will also be made for autistic individuals who require additional support.

For other stakeholder participants, they will be contacted via telephone or email. If they are interested in taking part, a link will be emailed to them which will contain the information sheet and consent form. They will complete the consent form electronically. They will have the opportunity to contact the research team via email or telephone if they have any questions.

Study information and consent forms:

Participant Information Sheets (PISs) and Informed Consent Forms have been developed in accordance with guidance from the Health Research Authority, in the same way as for the Prospective Cohort Study, described in section 4.2. See the Appendix for a list of associated documents.

Since this is an online study, information will be presented digitally. Participants will click boxes against specific statement to provide their consent.

6.4. Study Design and Methods of Data Collection and Data Analysis

6.4.1 Study design and procedures

We will develop an online survey for the Delphi exercise, hosted on a suitable platform, e.g. REDCap. The aim will be to identify what elements make a good C(E)TR and action plan. The survey items will be based on the literature, C(E)TR policy (4) and themes arising from the Qualitative Study. We will develop accessible versions of the survey with pictorial diagrams, and simple wording and response formats for people with learning disability and autistic people with input from the PPI groups. The survey will be piloted with at least five clinicians, five service users with learning disability or who are autistic, and five carers, prior to being used in Delphi consensus exercise.

Participants will be sent a secure online link which will take them to an online information sheet and consent form. After completing the consent form, they will be directed to complete a basic demographic questionnaire before completing the survey. For participants with learning disability or autistic individuals, we will collect data on their age, gender and ethnicity; for family carers, we will also collect information about their caring relationship (e.g. parent, sibling) and when they participated in a C(E)TR; for clinicians and C(E)TR panel members, we will collect information about their profession, years of experience working with people with learning disability and how many C(E)TRs they have attended. After completion of the demographics form, participants will be directed to complete the survey. Participants will be asked to rate their agreement with each item on a Likert scale from 1 (low importance) to 7 (crucial). They can provide free text responses explaining their reasons for giving a particular response. They will also be given the opportunity to make additional comments at the end of the survey where they can comment on whether there are other items that they feel should be included and whether certain items require amending.

Participants who are unable to complete the online survey independently will have the option of being supported online by a research assistant, with screen sharing enabled or via telephone.

There will be at least two survey rounds (4-6 weeks apart) and after each round, anonymised feedback will be provided on the results allowing participants to reflect on the views of others and reposition their own responses accordingly (see section 6.4.2). The survey will stop once a

consensus has been reached or if the response rate falls below 70%. If there are persistent areas of disagreement, this will be acknowledged rather than attempting to reach a consensus. To minimise the risk of panel members dropping out, we will ensure regular communication, including providing updates and reminders.

6.4.2. Analysis

Delphi Exercise

An analysis will be carried out according to (43). First-round results will be analysed by calculating the median response for each item per stakeholder group. In the second round, participants will view a personalised questionnaire showing their original response and the group median response for each item and will be invited to re-evaluate their responses and either maintain their original response or change their response to an alternative. Second-round responses will then be analysed and median values will again be calculated.

In cases where there is no median (i.e. due to an even number of responses), the mode will be calculated. Consensus on an item will be considered to have been achieved if at least 80% of participants are in agreement with the response. Items that achieve a consensus will be included in the C(E)TR quality indicators checklist. We will discuss our findings with the PPI groups and they will review and feedback on the final checklist before it is used.

Applying checklist to C(E)TRs from Prospective Cohort Study

C(E)TR reports and action plans of community C(E)TRs that were undertaken in participants during the Prospective Cohort Study will be obtained. They will be independently rated by two researchers using the checklist and a score will be given. Inter-rater reliability will be assessed using Cohen's kappa/percentage agreement. Reports will be categorised into "poor", "adequate" and "good". Disagreements in ratings will be resolved with another member of the team.

Secondly, we will use appropriate regression models to examine the association between the quality of C(E)TRs (rated poor, adequate or good), which will be added to the model as an independent variable, and outcomes (e.g. whether the person was admitted, length of hospital

stay, behaviour, quality of life), which will be the dependent variable. We will adjust for potential confounders (e.g. age, gender, presence of autism, mental health diagnosis).

6.4.3. Data processing and storage

Data will be de-identified, stored/transferred, accessed and archived by core members of the research team. De-identified demographic and processed data will be stored in the same way as described in Section 4.7. Retention of data will also adhere to policy described in Section 4.7. Analyses will be conducted using R (RStudio), Excel, JASP, and/or Python software.

6.5. End of Study

The end of the study will be the date on which the final participant has completed the last round of the survey.

7. Ethical and Regulatory Considerations

7.1. Assessment and management of risk

This research includes work with vulnerable participants, including young people, with a learning disability or who are autistic, who are either at risk of being admitted to hospital and/or have recently had a community C(E)TR. Some participants may lack capacity to consent to being involved in the research, have difficulties with communication and expression, may be mentally unwell, or may display behaviour that challenges.

If, during the course of this work, a member of the research team (e.g. RA or CSO) identifies instances in which there are grounds for concern about the welfare of a child or adult at risk, whether arising from home, or in the community, they will discuss this immediately with one of the Chief Investigators. They will follow local procedures to take appropriate actions to keep the participant safe. This might involve following safeguarding procedures of the local NHS Trust or service through which the participant has been recruited.

It is possible that some participants may display behaviour that challenges (e.g. aggression) that puts members of the research team at risk. Researchers will receive training on de-escalation and will conduct a risk assessment prior to visiting participants in person. They will follow the KCL lone working policy, including informing their line manager/research supervisor of when

lone working is to be undertaken, and supplying a contact number and location in case of an emergency. If they are concerned for their personal safety, they will leave the situation immediately and seek help and support from other staff members within a clinic setting, or the police, if they are in the community. They will always discuss these situations with their line manager and will have the opportunity for debrief afterwards.

7.1.1. Prospective study

In the prospective study, we will include participants with severe-profound learning disability who may lack capacity to consent to participate. We will follow the Mental Capacity Act Code of Practice for conducting research with this group, which will involve consulting a family member or close friend (personal consultee) for their views on the individual's participation in the study, or a professional (nominated consultee) if a personal consultee is not available. If participants with a learning disability initially have capacity, but at a follow-up assessment it is apparent that they now lack capacity (e.g. due to intervening illness), we will contact a consultee for their view on whether the participant should continue in the study. If their consultee does not wish for them to participate in the study, we will withdraw the person from the study, but data collected previously will be retained.

To permit the inclusion of participants with any degree of learning disability in the prospective study, we have included both self-report and informant measures to capture outcome data. We have been mindful to keep the number of measures to a reasonable number in order to reduce burden on participants and carers. We will provide a £20 gift voucher to participants with a learning disability, and carer participants at baseline and each follow-up point in the prospective study to thank them for their time and effort.

With regards to behaviour that challenges (e.g. aggression towards RA/CSOs), researchers will assess the risk prior to and in-person participant assessments. They will follow the lone working policy. If they assess participants in a clinic setting, they will inform reception/another member of staff and carry an alarm (if possible). If they are concerned for their personal safety, they will leave the situation immediately and seek help and support from other staff members within a clinic setting, or the police, if they are in the community. They will always discuss these situations with their line manager and will have the opportunity to de-brief afterwards.

7.1.2. Qualitative interviews

During the qualitative interviews, it is possible that sensitive issues or topics may be discussed that might remind service user and carer participants of previous trauma associated with a breakdown in community placements or need for hospital admission; this may cause distress. If this occurs, we will offer a break or terminate the interview, if necessary, and ensure the participant has access to support that is deemed appropriate. We will work with our PPI groups who will provide advice and insights into what materials could be used to support participants to express the need for a break or to stop the interview and what may help people to debrief after taking part.

7.1.3. Delphi Panel Exercise

The Delphi exercise will be low risk, as participants will be required only to respond to an online survey expressing their level of agreement with a list of items. Participants in the study will also be recruited from NHS Trusts/ICBs and will follow local NHS site procedures as described above.

7.2. Research Ethics Committee (REC) and Regulatory review and reports

We will obtain Sponsorship, NHS REC, Health Research Authority and local site approvals before commencing research activities.

Before the start of the study, a favourable opinion will be sought from the NHS REC for the study protocol, PISs, and ICFs.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

All correspondence with the REC will be retained. It is the Co-CIs' responsibility to produce annual reports as required. The Co-CIs will notify the REC of the end of the study.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

If the study is ended prematurely, the Co-CIs will notify the REC, including the reasons for the premature termination.

Within one year after the end of the study, the Co-CIs will submit a final report with the results, including any publications/abstracts, to the REC.

7.2.1. Regulatory Review & Compliance

Before any site can enrol patients into the study, the Co-CIs or a designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Co-CIs or a designee, in agreement with the Sponsor will submit information to the appropriate body in order for them to issue approval for the amendment.

The Co-CIs or a designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

7.2.2. Amendments

In accordance with Health Research Authority guidance on how to submit amendments for studies which do not require REC review, any amendments will be submitted by email to hra.amendments@nhs.net using the HRA amendment form (44). The HRA will then categorise the amendment and provide this information within 5 days. The amendment and the categorisations information will then be sent by the Co-CIs to participating NHS organisations (i.e., their Research & Development office).

The protocol amendment history will be tracked in at the head of the protocol. All previous versions will be listed here, along with details of changes made. The most recent protocol version can be identified on page ii of the protocol, under the heading 'Protocol Version Number and Date'.

7.3. Peer Review

This research proposal has been reviewed by independent experts as part of the peer review process conducted by the funder.

7.4. Patient & Public Involvement

We have consulted with people with a learning disability, carers and professionals in developing the proposal, in addition to feedback provided by our PPI expert by experience co-applicants.

Professionals indicated that the focus on community C(E)TRs is warranted due to confusion and inconsistency about when they are requested and undertaken. A method to rate and improve C(E)TR action plans was considered helpful as unrealistic or poor-quality action plans were highlighted as a major barrier to C(E)TR effectiveness. Given the time and resource implications of holding a C(E)TR, they thought that the research needed to be undertaken and felt that, although the sample size was large, the study would generate interest amongst ICBs, clinical services and willing participants. We have included an internal pilot for the prospective cohort study, in case recruitment issues threaten the viability of a full study.

Commissioners told us that C(E)TRs are rarely performed for children under the age of 13 years which informed our plan to focus the interviews on those aged 14 and above. C(E)TR Panel members highlighted the wide range of professionals involved in the C(E)TR process; we will ensure a range of professionals are recruited to the clinician interviews in the qualitative study and will include broad representation on the study steering committee. Our dissemination and engagement work will extend to social care, education, and allied health professional networks. We will link with C(E)TR Quality Oversight Panels in ICBs to ensure that our findings impact practice.

People with a learning disability and carers felt it would be helpful to promote the study via advocacy and carer networks to enhance recruitment and ensure people hear about the work. We have made links with networks (e.g. NewboldHope, Learning Disability England) who will support our project and broaden dissemination. They fed back how their lived experience could enhance the qualitative interviews and enable participants to speak more openly; we will invite members of our PPI groups to co-facilitate the qualitative interviews and our PPI Co-Investigators have contributed to the planning of this to ensure people are fully supported and adequately costed. Research outcome measures for the prospective cohort study were considered appropriate and the inclusion of carer measures was welcomed, as care burden can be high and increased if a person with a high level of need or in crisis is not admitted to hospital.

All stakeholder groups expressed that C(E)TRs may occur when individuals and carers are experiencing difficulties in their life. Revisiting the C(E)TR in the qualitative interviews might be upsetting; this will inform our process for seeking consent for this work, training interviewers, and ensuring that adequate support is provided.

Our four PPI leads have relevant expertise; a highly experienced learning disability engagement officer at Cheshire and Wirral Partnership (CWP) NHS Trust and parent carer, a parent carer who has experience as a C(E)TR panel member, a children and young person's engagement officer at CWP with extensive links with relevant organisations across the Northwest, and an autistic expert-by-experience of C(E)TRs who also works as a research assistant at the Centre for Research in Autism and Education.

Four PPI advisory groups (people with a learning disability, autistic people, young people (14-25 years), family carers) will be formed, each with 4-6 participants. The learning disability and young people PPI groups will be recruited from across the Northwest including CWP and third sector services to allow for more frequent in-person contact. The carer and autism PPI groups will be recruited nationally via social media and our existing links with national organisations (e.g. Autistica) and networks (e.g. online carer forum) as well as the NIHR People in Research site. We will ensure and monitor inclusion of diverse and underserved groups. PPI group members will be actively involved four times a year and more frequently at critical times in the project (e.g. shorter, more frequent meetings at project initiation). Groups will be facilitated by the relevant PPI Co-Is. The learning disability and young people groups will be held in person and the autism and carer groups will be held online. When forming the groups, there will be discussion with each member on how to best support them to express their views and ideas. This includes individual meetings rather than group meetings (to involve those who may not be able to listen, process, and take turns in group settings), sharing information in advance of meetings in accessible formats, and options for contribution using speech or typing. We will follow best practice in holding virtual PPI meetings published by the NIHR. There will be ongoing dialogue between study joint-PIs and the PPI Co-Is/PPI groups throughout the project and the PPI Co-Is will attend study management group (SMG) meetings.

A payment and recognition policy will be available prior to recruiting PPI group members. Payment will include preparation and debrief time around each meeting and costs will cover additional support members may need (e.g. an accompanying adult) and other expenses. PPI

members will be acknowledged in all project outputs. We will discuss and jointly agree PPI group responsibilities. We will maximise PPI impact (4). Activities will be recorded in an impact log and regularly reviewed with the SMG to ensure the work is meaningful and the UK Standards for Public Involvement are met.

In outline, the PPI members will:

- discuss study procedures using their insights to suggest how these can best anticipate participants' needs
- co-produce participant material, including accessible recruitment videos
- refine interview topic guides
- help create lay summaries of findings and films
- write blogs about their contributions and reflections for publication on the project website
- help plan and attend the engagement event and have a platform to speak about the work
- PPI group members will be offered the opportunity to act as paid peer interviewers with a member of the research team in the qualitative interviews. Members will be provided with supervision and appropriate training

7.5. Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

7.6. Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The data controller of the study is King's College London. The study will comply with the UK Data Protection laws including the UK GDPR and the Data Protection Act 2018.

Data will be handled in accordance with information governance processes and existing Standard Operating Procedures within each NHS Trust. Participants will be allocated a unique ID number.

Hard copies of questionnaires or assessments will be stored in a locked filing cabinet at the FANS department, IoPPN, King's College London. Participant IDs will be written on these forms with no identifying names. The content of these questionnaires will include personal data but will not be linked to names on the same form. Information from these documents will be transferred to a centralized study database.

The online study database REDCap will be used for the Prospective Cohort Study and Delphi Panel Exercise. REDCap is a secure web application for building and managing online databases and surveys.□□

Digital data will be stored in a folder on King's College London's One Drive cloud services and shared only among core research team members, including co-chief investigators (Dr Rory Sheehan, Dr Afia Ali), research associates (Dr Bronagh McCoy, new RA TBC), and study statisticians (Ben Carter, Lauren Bell).

A central spreadsheet linking participant identifying information, e.g., names, contact details, with participant IDs, will be stored in a separate location to the study data, and will be accessed only by core members of the research team (see above).

Anonymised data from the Prospective Cohort Study may later be uploaded to a research data repository, e.g. King's Open Research Data System (KORDs), to be accessed by other researchers.

7.7. Indemnity

The lead Sponsor, King's College London, will take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. King's College London also provides cover under its No Fault Compensation Insurance, which provides for payment of damages or compensation in respect of any claim made by a research subject for bodily injury arising out of participation in a clinical trial or healthy volunteer study (with certain restrictions).

The co-Sponsor, South London and Maudsley NHS Foundation Trust, will take responsibility for arranging the initiation and management of this research, and will take responsibility for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff involved with the project.

7.8. Access to the final study dataset

Members of the research team will have access to the final dataset. They will be under the direct supervision of senior study investigators.

In the Qualitative Study, individual site investigators (e.g. CSOs and Principal Investigators) will have access to the data collected at their site only.

We do not envisage individual site investigators to require access to other data, as analysis of collected data will be carried out at King's College London. All patient documentation will include a lay overview of our research questions and the outcome measures to be assessed.

8. Dissemination Policy

8.1. Dissemination strategy

The data arising from the study will be owned by King's College London.

All publications arising from the study will be made available on a dedicated website and peer-reviewed publications on King's College London Research Portal, the University's online publications store.

We will work closely with our PPI groups to develop a dissemination strategy and materials that target commissioners, carers, clinicians, researchers and policy makers. It will include the following:

- A full NIHR report to the funder to be published in the NIHR journals library. We anticipate that there will be publications linked to each workstream, which will be published in open access scientific journals.
- Development of guidelines and recommendations to improve implementation of C(E)TRs. We will make the C(E)TR quality checklist available for use by NHS services.
- Contribute to policy/commissioning changes via policy briefings (e.g. C(E)TR guidance documents and tools); iv. poster and oral presentations at national and international conferences (e.g. RCPsych International Congress, International Association for the Scientific Study of Intellectual and Developmental Disability World Congress, Special Educational Needs and Disabilities conferences, Association of Directors of Adult Social Services conference).
- Summary documents in formats that are accessible for people with a learning disability and autistic people and their carers (e.g. co-produced newsletters, blogs, video clips) which will be hosted on a dedicated study website and sent to participating services and individuals.

We will utilise the professional contacts and networks of our co-applicants to cascade the findings to community learning disability services, educational settings (schools and colleges for people with a learning disability or autistic people), NHS England, Association of Directors of Adult Social Services, The Learning Disability Professional Senate, the Royal College of Psychiatrists, the British Psychological Society, and the Royal College of Nursing. Our PPI partners will support dissemination by sharing the findings with their members and wider network and charities (e.g. Mencap, BILD, Autistica).

Press releases, briefings, plain language summaries and videos will be shared via NIHR ARC and other communication channels and professional networks. We will submit articles to lay publications (e.g. Community Living magazine). We will use social media such as Facebook and Twitter (X) to promote and generate interest in the study and disseminate findings. PPI group

blogs will be published on the study website. At the end of the work, we will run a webinar hosted by Learning Disability England (LDE), to discuss the findings. We will also convene a one day in-person engagement event at KCL, co-produced with the PPI groups, to share our findings and their implications with stakeholders including clinicians, carers, advocacy groups, commissioners and policy makers. We will arrange online educational/training workshops for NHS staff on how to improve the implementation of C(E)TRs based on our findings. We will track the value and impact of our knowledge mobilisation activities with reference to published frameworks (e.g. the Research Contributions Framework (45,46)); this will include metrics of internet metadata (downloads of papers, engagement with social media), recording attendance at dissemination events, and asking knowledge users about their views of the work and intentions to use the research findings.

We will keep NHS England and the Care Quality Commission apprised of this work; members of the project team have existing relationships with the Learning Disability and Autism Programme (e.g. via the learning disability mortality review (LeDeR) and through ongoing work of our PPI lead). We will work with NHS England to provide training resources (e.g. videos and online short courses) to clinicians and social care professionals working in learning disability, mental health and autism services on using the C(E)TR checklist and implementing the recommendations from the findings. In addition, we will work with the NIHR Mental Health Policy Research Unit (PRU) at UCL and KCL to increase the impact of this work and directly influence policy makers in due course (e.g. via newsletters and existing 'meet the PRU' sessions) with a view to our recommendations (including C(E)TR checklist) being incorporated into the C(E)TR guidelines. We will include our PPI groups in publicising the findings to policy makers.

The outputs will be available free of charge and disseminated widely through professional networks, pre-prints of academic outputs, Open Access publications and social media. We anticipate that our findings and recommendations will benefit clinical and social care practice and inform guidelines on how high quality C(E)TRs can be delivered to provide maximum benefit for service users and carers, and strategies to increase the number of community C(E)TRs in groups that are less likely to have C(E)TRs prior to admission, as well as improving the overall experience of C(E)TRs.

8.2. Authorship eligibility guidelines

Any reports or publications to which a person provides substantial contributions and intellectual input are considered appropriate for authorship. We will follow the International Committee of Medical Journal Editors (ICMJE) guidelines which recommend that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work
- Drafting the work or reviewing it critically for important intellectual content
- Final approval of the version to be published
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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Appendices

Appendix 1 – Required documentation

Chief Investigator CVs	CV – Dr Rory Sheehan – Feb 2025 CV – Dr Afia Ali – Feb 2025
Participant Information Sheets	<u>Prospective Cohort Study</u> - Adults with a Learning Disability - Children/Young People with a Learning Disability - Autistic Adults - Autistic Children/Young People - Carers - Consultee <u>Qualitative Interview Study</u> - Adults with a learning disability - Children/Young People with a learning disability - Autistic Adults - Autistic Children/Young People - Carers - Clinicians, Professionals & Panel Members <u>Delphi Panel Exercise</u> - Adults with a learning disability - Autistic Adults - Carers - Clinicians, Professionals & C(E)TR Panel Members
Consent Forms	<u>Prospective Cohort Study</u>

	- Adults with a Learning Disability - Children/Young People with a Learning Disability - Autistic Adults - Autistic Children/Young People - Carers - Consultee declaration <u>Qualitative Interview Study</u> - Adults with a Learning Disability - Children/Young People with a Learning Disability - Autistic Adults - Autistic Children/Young People - Carers - Clinicians, Professionals & Panel Members <u>Delphi Panel Exercise</u> - Adults with a Learning Disability - Autistic Adults - Carers - Clinicians, Professionals & Panel Members
Questionnaires (validated)	<u>Prospective Cohort Study</u> - Moss-PAS (Check) - Behavioural Problems Inventory – Short Form (BPI-S) - Camberwell Assessment of Need for Adults with Developmental and Intellectual Disabilities – Research Version (CANDID-R) - WHO Quality of Life – Disabilities Module (WHOQOL-DIS) - EuroQoL Five Dimensions - Three Levels (EQ-5D-3L) - EuroQoL Five Dimensions – Five Levels (EQ-5D-5L)

	- Kessler Psychological Distress Scale – 6 items (K6) - Health of Nation Outcome Scales (HoNOS) - Health of Nation Outcome Scales - Intellectual Disability (HoNOS – ID)
Questionnaires (custom)	<u>Prospective Cohort Study</u> - Clinician Questionnaire - ICB Questionnaire - Resource Use Questionnaire (modified AD-SUS) - Resource Use Booklet - Resource Use Booklet (Accessible version) <u>Qualitative Interview Study</u> - Qualitative Interview Guide <u>All Studies</u> - Sociodemographic & Health Questionnaire – service user - Sociodemographic & Health Questionnaire – carer - Sociodemographic & Health Questionnaire – clinician
Adverts	Prospective Cohort Study Advert Qualitative Interview Study Advert Delphi Panel Exercise Advert
Letters	Prospective Cohort Study - Letter to Clinician
Presentations	Qualitative Interview Study – Presentation to Professionals Delphi Panel Exercise – Presentation to Professionals

Social Media Texts	Qualitative Interview Study – Social Media Texts for each group Delphi Panel Exercise – Social Media Texts for each group