Mapping and Evaluating Services for Children with Learning Disabilities and Behaviours that Challenge (MELD): Stage 1

v1.3 22.09.2021

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Project Duration	01 Feb 2021 to 30 Apr 2024 (39 months) (to 31 Dec 2021 for Stage 1)

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 relevant study regulations, GCP guidelines, and CTU SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the intervention 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.

Chief Investigator:		
Richard Hastings		**22/09/21**
Name	**Signature**	**Date**

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

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This protocol has been developed by the MELD Study Management Group (SMG).

For **all queries** please contact the MELD team through the main study email address. Any clinical queries will be directed through the Study Manager to either the Chief Investigator or a Co-Investigator.

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Glossary of abbreviations

AE	Adverse Event
AIC	Akaike's Information Criterion
ASD	Autism Spectrum Disorder
BtC	Behaviours that Challenge
CAMHS	Child and Adolescent Mental Health Service
CCG	Clinical Commissioning Group
CF	Consent Form
CI	Chief Investigator
CQC	Care Quality Commission
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HS&DR	(NIHR) Health Services and Delivery Research
ICS	Integrated Care Systems
iDMEC	independent Data Monitoring and Ethics Committee
ISRCTN	International Standard Randomised Controlled Study Number
LD	Learning Disability
LCA	Latent Class Analysis
NHS	National Health Service
NIHR	National Institute for Health Research (NIHR)
PPI	Patient and Public Involvement
PIS	Participant Information Sheet
R&D	Research and Development
RA	Research Assistant
REC	Research Ethics Committee
SAG	Study Advisory Group
SAP	Statistical Analysis Plan
SIN	Service Identification Number
SMF	Study Master File
SMG	Study Management Group
SSC	Study Steering Committee
STP	Sustainable Transformation Partnerships
TCP	Transforming Care Partnership

1 Amendment History

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

Amendment No. *(specify substantial/non-substantial)*	**Protocol version no.**	**Date issued**	**Summary of changes made since previous version**
1 (Non-substantial)	v1.1	04.02.2021	Changed the name of the Sponsor Contact. Removed one reference to using Zoom as this is not congruent with the method of data collection (i.e., Microsoft Teams, Starleaf).
2 (Non-substantial)	V1.2	21.05.2021	Interview data collection changed to reflect use of an online survey + short interview rather than interview only. The same data will be gathered. Amendments made to protocol sections to reflect this change (section 2, section 3.1, section 3.2, section 3.3, section 7, section 9.4, section 11, study flow diagram, participant flow). Edited the 14.1 Progression for Stage of the research from 'interviews completed' to 'data collected' to reflect that not all data are now collected by interview. Inclusion criteria in section 8.1 amended due to previous omission to refer to services focused on behaviours that challenge
3 (Non-substantial)	V1.3	21.09.2021	Added "and Evaluating" into the study title, with "Stage 1" to clarify that this protocol only pertains to Stage 1 of the MELD Study.

			Added the ISRCTN number onto the front page. Added the project duration onto the front page. Added Dr Paul Thompson as the Study Statistician, Rebecca Lane as the Study Administrator, and added Gemma Grant and Kate Sutton as co-applicants in place of their predecessors.

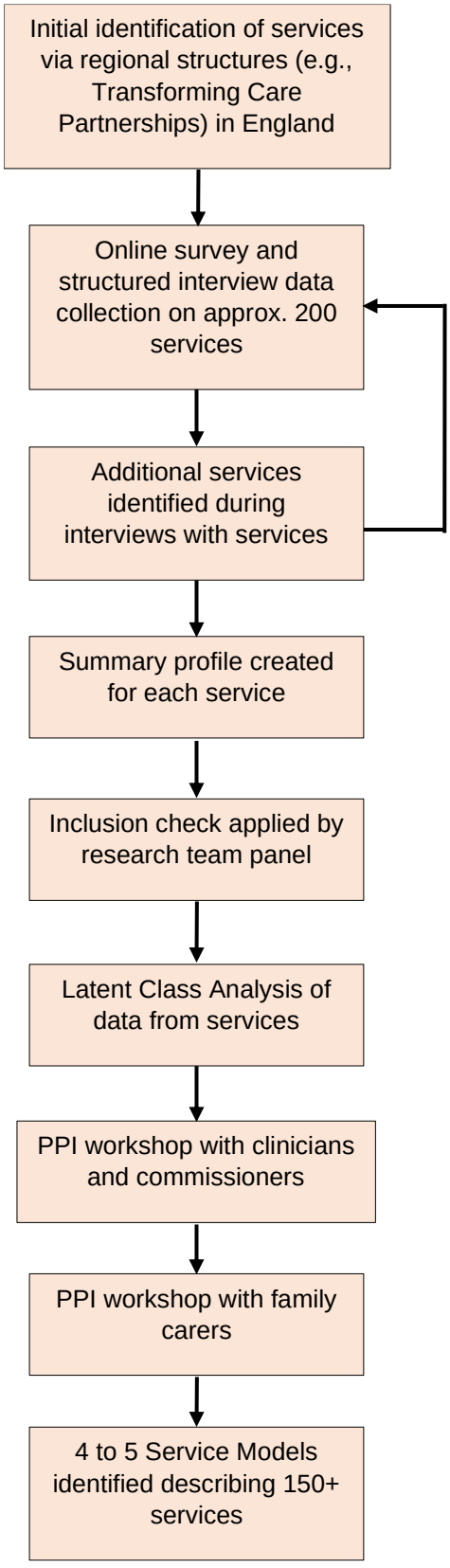
2 Synopsis

Title	Mapping Services for Children with Learning Disabilities and Behaviours that Challenge
Acronym	MELD
Funder and ref.	NIHR 129577
Study design	Survey to identify distinct service models in England for children with learning disability and behaviours that challenge
Study participants	Staff in community services for children with a learning disability and behaviours that challenge
Planned sample size	48 leads for Transforming Care Partnerships in England (or successor organisations) Two staff from each of approximately 200 community services for children with learning disability and behaviours that challenge (400 Staff)
Inclusion criteria	The inclusion criteria for services are: 1. Geographically located in, and at least partially drawing referrals from, England 2. Community-based service 3. NHS, local authority or other (e.g., private, charity) service commissioned by a CCG/local authority/STP/ICS, or a service where individual places are purchased by CCG/local authority or other commissioners 4. Providing supports for children with LD 0-17 years of age with learning disabilities and behaviours that challenge or providing supports to this group of children as a clearly distinct care pathway (whilst also providing other services). Services will not be excluded if they also provide services to individuals 18+ years of age as well as within the 0-17 age range.
Exclusion criteria	Exclusion criteria are: • Inpatient service • Service commissioned by non-CCG or local authority commissioner (e.g., solely a special school service)

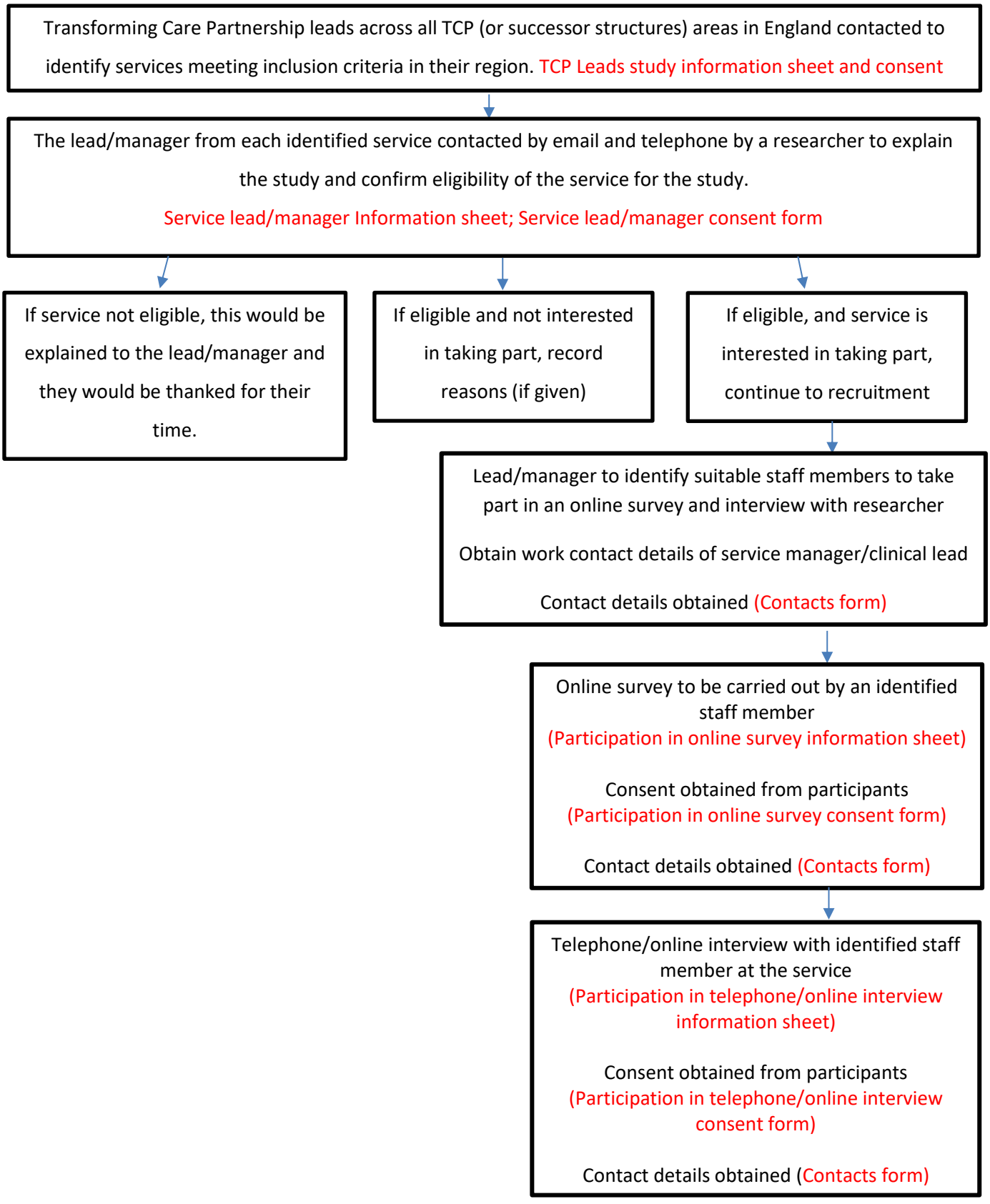
	• Service that is not yet operational (i.e., has received no referrals at the time of data collection)
Planned study period	12 months
Primary objective	To map community services for children with learning disability (LD) and behaviours that challenge (BtC) in England, to describe distinct service models
Methodology summary	Leads of all 48 Transforming Care Partnerships (TCPs) (or successor structures) in England will be contacted for initial information about community services for children with LD and BtC in their region. Researchers will then contact service managers/lead clinicians from identified community services. Service managers/lead clinicians will identify suitable staff members to complete an online survey and an interview to gather information about each service's structure, organisation and functions. We estimate that there may be 200 such services in England. Latent Class Analysis combined with stakeholder consultation will be used to define distinct service models.

3 Study summary & schema

3.1 Study flow diagram



3.2 Participant flow



3.3 Study lay summary

Aims

This research is about community based services across England that support children with a learning disability and behaviours that challenge, and their families. We want to find out how these services are structured and organised (known as "service models").

Background

1 in every 5 children with a learning disability in the UK display behaviours that challenge. These are not a medical diagnosis, but are behaviours (like aggression or self-injury) that may cause harm to the child or other people or prevent the child being included in the community. Children with learning disability and behaviours that challenge are at risk of negative outcomes (like abusive care), their families are more likely to experience stress, and these children's care is costly for services. When the National Institute of Health and Care Excellence (NICE) reviewed the evidence, they found little research about how best to design and deliver health and care services to these children.

Design/methods

We will find all the community NHS/local authority services in England supporting children with learning disabilities and behaviours that challenge. We will contact service managers/lead clinicians at each service who will identify suitable staff members to complete an online survey and interview to collect information about the service. We will then use a combination of statistical methods and the expert views of family carers and professionals to describe groups of similar services. These similar groups will be our "service models".

Patient/public involvement

Family carers have been working with us for 5+ years to tell us how services can be better for children with learning disability and behaviours that challenge. Their ideas have sparked this research. We will work with an advisory group of families throughout the research to make key decisions, drawing on their expertise, and working together to think about what the findings mean.

4 Background and rationale for the current study

Learning disability (LD), used as the official term in the UK health system, is known as Intellectual Disability internationally. Intellectual Disability/LD is a condition described in ICD-11 as a Disorder of Intellectual Development (Salvador-Carulla et al., 2011). Consistent with contemporary definitions of this condition, LD emerges during the "developmental period" (usually taken to mean before age 18 years), and is characterised by low cognitive ability (using standardised tools an IQ <70) and low levels of adaptive behaviour (such as communication, social skills, independence skills - also assessed using standardised tools). Prevalence studies internationally suggest that approximately 2% of children and adolescents have a LD (Maulik et al., 2011). UK Learning Disability Observatory data also show just over 2% of children in England have been identified by local authorities/schools as having LD (Hatton et al., 2014). Prevalence varies slightly with socio-economic factors but is broadly similar across the UK. In practice, and this is also reflected in the ICD-11 "sub-types" of intellectual disability, it is helpful to distinguish between levels of LD severity: mild (2-3 SDs below the mean on standardised IQ/adaptive behaviour assessments), moderate (3-4 SDs below the mean), and severe/profound (4 or more SDs below the mean). In addition, LD is associated with significantly higher prevalence of other neurodevelopmental conditions; in particular Autism Spectrum Disorder (ASD). The prevalence of LD among children and adolescents with ASD in UK population-based data has been shown to be as high as 52% (95% CI: 42%, 62%) (Totsika et al., 2011).

Children with LD are also likely to display challenging behaviour (or Behaviours that Challenge; BtC). Approximately 1 in 5 children with LD in the UK in contact with services display BtC (Emerson et al., 2001). Recent analysis of UK population data suggest 10-17% of children with LD show aggression towards others (Emerson et al., 2014). In some settings, prevalence rates are higher (e.g., 53% of children in a special school context; Nicholls et al., 2020). BtC are associated with poor care outcomes for children (e.g., increased exposure to restrictive care), for family carers (e.g., increased stress and mental health problems; Hastings, 2016), and increased costs of care to families (Einfeld et al., 2010) and to health and social care services (Iemmi et al., 2016). Children with more severe LD, and those with LD who also have autism, are more likely to display BtC (Nicholls et al., 2020).

BtC are understood theoretically from a contextual perspective in terms of definition, vulnerability factors, and maintaining processes (Bowring et al., 2019; Hastings et al., 2013). First, BtC are a socially defined health and social care issue, rather than a medical disorder or diagnosis; defined as behaviours that are not typical for the culture the person lives in and that occur at a frequency,

severity, or duration that places an individual at risk of harm, places carers or others at risk of harm, or that hinder inclusion in typical community settings (Emerson & Einfeld, 2011). BtC are defined in terms of their effects rather than topography. Nevertheless, individuals with LD often engage in a number of behaviours that are typically considered challenging, regardless of context: injuring themselves (e.g., banging their heads against hard surfaces, eye-poking, skin scratching leading to bleeding), physical aggression towards others (e.g., kicking, biting, pulling hair), physically destructive behaviours (e.g., throwing furniture, pulling down curtains), and other actions (e.g., absconding, high rate unusual repetitive behaviours such as body rocking, inappropriate touching, screaming). The second contextual dimension is that the vulnerability factors for BtC are primarily (though not exclusively) psycho-social, relating to the inequalities and life experiences of people with LD (e.g., impoverished social networks, lack of communication skills, exposure to negative life events including abusive care, barriers to accessing health and care services). The third contextual dimension is that BtC are functional for the person engaging in them – they allow a certain amount of control over the (social) environment: the behaviour/response of others is then the main mechanism through which BtC are maintained and may worsen over time.

Given the prevalence of BtC, and continued high profile care scandals (e.g., BBC Panorama exposés of Winterbourne View in 2011, and Whorlton Hall in 2019), effective community-based services and supports are a national priority (NHS England, 2015). However, NICE guidelines for BtC (2015, 2018) found no high quality evidence relating to the design and organisation of services for children. This study focuses on that evidence gap.

There are currently no data on an England-wide basis about how health services are delivered for children with LD and BtC (service models), and the key features of these models. Given the lack of evidence overall, the findings from the proposed research will be directly relevant to the ongoing planning and delivery of health and social care services across the UK.

5 Study objective

In the proposed research, we will conduct a mapping study in England to describe all community services for children with LD and BtC; and use the data gathered to develop a typology of “service models” for this population.

If we can successfully identify distinct services models, we will proceed to a second stage of research in which examples of these service models are evaluated; testing effectiveness and cost-effectiveness of different models. This second stage will be described in a separate protocol and research ethics application.

The *research objective* is to develop a typology of the different models for providing services to children with LD and BtC currently operating in England.

6 Study design and data collection methods

The research design is a total population mapping exercise of services in England for children with LD and BtC. The current provision of services for children with LD and BtC will be described, and a number of distinctive service models will be identified using a combination of statistical analysis and expert (including PPI) interpretation.

The mapping exercise to identify and gather data about services for children with LD and BtC will proceed through three main phases:

Phase 1 - Identification of services

We will make contact with all 48 Transforming Care Partnerships (TCPs) across England, or (where these have recently evolved) with relevant Sustainable Transformation Partnerships (STPs) or Integrated Care Systems (ICS). TCPs have been an organisational structure associated with the Transforming Care Policy Programme and link together commissioners and services in a region of England. Each TCP has a named lead who will be contacted by a researcher to carry out an initial telephone interview to identify in each TCP area the health/care services to which children with LD and BtC would be referred for community based support (not inpatient only services). The NHS England and Improvement Long Term Plan Implementation Framework requires that where TCPs have been embedded within STPs or ICS, that there remains a named senior responsible officer for LD and Autism. Thus, we can still identify and contact these key individuals. “Children” are defined as 0-17 years of age for the purposes of the current research, but services will not be excluded if they provide support to young people beyond this age range. Our NHS England and Improvement child LD policy team partner (North) already has excellent and regular links with TCP/STP/ICS contacts across England. Thus, we anticipate a high response rate. At the end of Phase 1, we will have more detailed information about the likely total population of services for children with LD and BtC in England and

some initial information about basic characteristics of those services (e.g., whether services are NHS, Local Authority, other).

Phase 2 - Selection of services/Sample size

In the absence of current service mapping data, and drawing on the project team's detailed knowledge of several current TCPs, we anticipate an approximate average of 4-5 services per TCP/STP/ICS area (a total population of no more than 200 services). Therefore, we plan to collect detailed data about all of the identified services across England. If we identify during Phase 1 significantly more services than expected (more than 250), we will seek approval from the Study Steering Committee for an amendment to the protocol to use stratified random sampling with proportionate allocation (by English NHS region) to select a sample of 200 services to take forward into Phase 3.

Phase 3 - Data collection about selected services

If not already known from Phase 1, contact names for the service manager and/or clinical lead or equivalent person in each individual service will be identified. Email contact will be made with this person to invite them to take part in the research. Data collection will then proceed through the six-step procedure (see Section 11 below) based on previous experience of mapping of services, and professionals' input about practical issues in gathering data about services.

6.1 Risk assessment

This is a low risk study. NHS and other community services staff are providing information about their services (not data about themselves), data are being gathered remotely, and no patient data are being gathered.

7 Site and Investigator selection

This study is a single site study. Services are not viewed as sites, they are not delivering an intervention but identifying staff participants who are willing to take part. These staff participants can also self-identify to complete the online survey and be interviewed about their service. The study is based on online surveys and interviews with staff and will be carried out at University of Warwick, under the supervision of the Chief Investigator (Hastings). Fully trained Research Fellows and Research Assistants at the University of Warwick will be responsible for recruitment and all data collection. A Site Delegation Log and Roles and Responsibilities document will be completed and full

contact details will be recorded. A site file, containing all relevant study documents will be prepared at the University of Warwick.

Once all study documentation is in place, and study-specific training (including obtaining informed consent, completion of the Qualtrics structured survey), and staff induction has been completed, recruitment of services into the study will begin.

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

8 Selection of Services and Participants

Services and staff participants will be selected as described in Section 6 above.

8.1 Inclusion criteria

Inclusion criteria for services are:

- Geographically located in, and at least partially drawing referrals from, England
- Community-based service
- NHS, local authority or other (e.g., private, charity) service commissioned by a CCG/local authority, or a service where individual places are purchased by CCG/local authority commissioners
- Providing supports for children with LD 0-17 years of age with learning disabilities and behaviours that challenge or providing supports to this group of children as a clearly distinct care pathway (whilst also providing other services). Services will not be excluded if they also provide services to individuals 18+ years of age as well as within the 0-17 age range.

Inclusion criteria for staff in each service are:

1. The staff member has been identified by the service manager/lead clinician of the service as being in a position to be able to provide information about the service
2. The staff member gives their consent to take part in the research

8.2 Exclusion criteria

Exclusion criteria for services are:

- Inpatient service

- Service commissioned by non-CCG or local authority commissioner (e.g., solely a special school service)
- Service that is not yet operational (i.e., has received no referrals at the time of data collection)

The only exclusion criteria for staff are not meeting the inclusion criteria.

9 Recruitment, Screening and registration

9.1 Identification of Services

Our main strategy for identification and recruitment of services is described in Section 6 above, and uses the national organisational structure of TCPs.

9.2 Screening logs

The research staff will keep a log of all services considered/ approached and whether they are ineligible or eligible so that any biases will be detected. They will note if the service was identified from TCP contacts or through an interview with staff from another service.

9.3 Recruitment rates

A total of approximately 200 services will be recruited at an expected rate of approximately 30 per month.

9.4 Informed consent

Professionals (lead clinician, service manager, and suitable staff members) involved in each service will be consented into the study. A Study Information Sheet will also be provided to the TCP leads. Online consent forms (hosted on Qualtrics) will be provided to service managers/lead clinicians to store their work contact details and to all identified staff participants who will be completing the online survey and/or the interview prior to them taking part. Staff participants taking part in the interview with a researcher will also have their consent confirmed verbally at the beginning of the interview. At the end of the interview, contact information for participants will be confirmed (telephone, email address) in case of data queries. Following the interview, the researcher will electronically sign the consent form for each participant and a copy of this consent form will then be emailed to each participant individually for their records.

The right of the participant to refuse to participate in the study without giving reasons will be respected. Similarly, a participant is free to withdraw their consent for contact information to be held in case of data queries.

9.5 Registration

The MELD study will be registered with the ISRCTN database.

10 Withdrawal

The service manager for a service may withdraw their service from the mapping exercise at any time up to the data analysis phase of the project. Any individual staff member participant may withdraw their consent for their contact details being held in case of data queries.

The researcher will complete a withdrawal form for the service if the manager's consent for the service's participation in the study is withdrawn. Any contact details held for a staff member who withdraws their consent for these details to be retained will be deleted on receipt of such a request made either in writing or verbally.

11 Study procedures

The following six steps will be followed to gather information about services:

Data gathering step	**Methods, and additional information/rationale**
Step 1. Background check on service	Research staff will complete an initial background data check on each identified service. This will involve checking NHS Trust, CCG and other commissioner's websites, gathering data on socio-economic profile of the area (through Index of Multiple Deprivation data for the local area), and identifying and summarising Care Quality Commission (CQC) reports on the service.
Step 2. Data collection from service	Service managers/clinical leads will identify key staff members to complete an online survey and a tele- or videoconference to gather data about the service. The structured protocol for the online survey and

	tele/videoconference interview has drawn on existing documents and tools to inform key questions about the nature of provided services (e.g., PBS Academy quality checklist, NICE guideline recommendations, INVOLVE guidelines, Challenging Behaviour Foundation (CBF) guide on features of the Building the Right Support service model for children with LD). The online survey (hosted on Qualtrics) will be used to gather the majority of closed/numerical data about services, as reported by a key staff member (who can consult with others). The interview will be arranged with one key person from the identified service, as identified by the service manager and/or lead clinician. The researcher conducting the interview will enter responses into a computerised data collection tool (a closed Qualtrics survey), and interviews will also be audio/video-recorded for back-up and to check accuracy of researcher recorded responses. From the online survey and interview, data will be gathered on all key dimensions of the service, including: funding/commissioning model, inter-agency working, stand-alone/within another service, connections with mainstream and any other services [including local special school provision available], management structure, staffing, access criteria, referral rates, referral routes, rate of exclusions/referrals not accepted, waiting lists, characteristics of children and families, what interventions and training are offered, assessment procedures and tools used, any outcome tools used, total caseload, transition arrangements, co-production work (families and children), stakeholder involvement, diversity/language issues in service delivery, how long service has been in place, plans to continue/expand/ develop the service, what services were present before the service started up. These data elements have again been informed by consultation with clinicians and with the Challenging Behaviour Foundation as potentially important variables to help describe services.

	Following Step 2, some services may be excluded because they very clearly do not meet inclusion criteria for the study (see Step 6 below). In such cases, the interviewing researcher will briefly summarise the reasons why the service does not meet the inclusion criteria, providing evidence in support of each criterion not met. This case will be reviewed by Professor Langdon and at least one other research team member. The service may either be excluded from the study, the decision deferred pending additional information, or the service retained for the remaining phases of data gathering for a final inclusion decision at Step 6.
Step 3. Identification of other local services	As a part of the structured interview, the researcher will also explicitly check with interviewees to identify other similar services in their local area. This check has been included because it is possible that TCP named leads will not be familiar with all local services (e.g., if they are relatively new in post). Clinicians and managers are likely to have experienced flow of children between local services, questions about local catchment areas, or have formed local peer supervision/support networks. Interviewees will be asked about all other local similar services of which they are aware or with which they have clinical links. If any new services are identified (i.e., not already identified via TCP named leads), these services will proceed through the same data collection steps (beginning at Step 1).
Step 4. Follow-up telephone data gathering	Step 4 is optional, and will be used if key information about a service was not available during the scheduled telephone interview at Step 2, or was unclear. A follow-up telephone call or email with a manager and/or clinician will be arranged to gather the missing information.
Step 5. Summary service profile	To inform Step 6, the research staff will produce a summary profile of each service following a standard proforma based on the online survey and telephone interview data. This profile will first be confirmed for accuracy with the service. The summary profile will be emailed to both the manager and clinical lead for confirmation/checking of accuracy and completion of any information that is still missing or unclear.
Step 6. Research team expert panel	The research staff will produce a short summary profile of each service with a focus on the eligibility criteria for the research. Key evidence supporting eligibility will be presented for each criterion and a recommendation

decision for inclusion	provided about inclusion/exclusion. This summary profile will be reviewed by a panel of research co-applicant team members. The panel for each service will include co-applicant Langdon (lead for the mapping exercise stage) and two other research team co-applicants. This panel will reach a consensus decision (potentially, after requesting additional information about the service). If no consensus can be reached, the service will be deemed excluded from the study. The inclusion and exclusion criteria for services are described in Sections 8.1 and 8.2 of the protocol.

12 Safety reporting

There are no expected adverse events (AE) related to the research procedures. The ethics committee will be asked to approve that adverse events should not be reported for this study.

13 Statistical considerations

13.1 Sample size

In the absence of current service mapping data, and drawing on the project team's detailed knowledge of several current TCPs, we anticipate an approximate average of 4-5 services per TCP/STP/ICS area (a total population of no more than 200 services). Therefore, we plan to collect detailed data about all of the identified services across England. If we identify significantly more services than expected (more than 250), we will seek approval from the Study Steering Committee for an amendment to the protocol to use stratified random sampling with proportionate allocation (by English NHS region) to select a sample of 200 services to take forward into Phase 3 (Section 11 above). We anticipate (allowing for 20% refusal to participate in Phase 3 (Section 11), or exclusion – see Step 6 in Section 11) approximately 150 services will be available for analysis.

A typology for service models will be informed by Latent Class Analysis (LCA). Statistical power in LCA depends on a number of inter-connected parameters, and as such a closed-form sample size formula does not exist. However, a sample size of 150 services will provide approximately 90% power (based on the bootstrap likelihood ratio test with an alpha of 0.05), or at least 93% power (based on using information criterion), for selecting a three-class model over a two-class model (Dziak et al., 2014). The final power in this study will depend on the number of classes to select, as well as class sizes,

prevalence of items, and number of items. As detailed below, the LCA findings will not be confirmatory in their own right, but will be supplemented by consultations with key stakeholders.

13.2 Missing data

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

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

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

13.4 Inclusion in analysis

All eligible services' data will be included in analysis.

14 Analysis

Data will first be summarised using descriptive statistics (including confidence intervals) to provide an overall picture of services for children with LD and BtC in England. Latent class analysis (LCA) will be then be used to inform the development of descriptions of service models. By using this statistical approach, we assume that "service type" is a latent variable that can be characterised by a number of observed variables. Variables to include in LCA would be features of services (see Section 11, Step 2) and not other descriptors (such as deprivation in the catchment area, rural/urban mix). Variables will first be evaluated for lack of availability across services (floor and ceiling effects). Analysis will then be conducted using the *gsem* (Generalized Structural Equation Model) command in Stata, whereby we will estimate the probability of "service type" membership, given observed variables. We will use Akaike's Information Criterion (AIC) to indicate the number of service types to take forward for further examination.

The identification of service models will not rely solely on statistical criteria. For any LCA, expert interpretation of the validity of identified classes is an important part of the decision about the most parsimonious solution. Statistically-derived classes will be identified and the contributing variables summarised for each class to provide an holistic description of the potential service model. Data describing the context for the services (e.g., regional deprivation, rural/urban mix), not used in the LCA, will also be used to enrich the descriptions of each potential service model. These descriptions and statistical information together will be brought to two sequential consultation workshops also

involving the co-applicant team – first with professionals/commissioners and TCP leads, and second with family carers. These workshops will examine the available data and identify distinct service models (models with multiple examples, and also unique models if they can be clearly articulated). The findings from the latent class models will be presented to stakeholders (specifically, the number of meaningful classes, their defining characteristics, and a selection of services which exhibit high probabilities of belonging to each of the classes). The face validity of these classes and the classification of services will be discussed, and decisions around further groupings (either collapsing or expanding classes) will be documented leading to a final description of current service models for children with LD and BtC.

A detailed statistical analysis plan will be written and agreed by the study management team prior to any analysis taking place.

14.1 Progression criteria for Stage 2 of the research

The following progression criteria using a Traffic Light model will be used to inform a decision to move on from the current project to research evaluating outcomes and costs of service models (Stage 2 of the research):

1. TCP contacts – interviews completed

   Green – Initial interviews with a lead from 75% or more of TCPs in England are completed

   Amber - Initial interviews with a lead from 60% or more of TCPs in England are completed, but larger TCPs have mainly been included

   Red - Initial interviews with a lead from fewer than 60% of TCPs in England are completed

2. Leads from identified services – Data collected

   Green – Data collected from 70% or more of services identified at the TCP interview step

   Amber - Data collected from 60% or more of services identified at the TCP interview step, but there has been a higher level of engagement from services other than LD CAMHS (that we anticipate will be a common service model)

   Red - Data collected from fewer than 60% of services identified at the TCP interview step

3. Service models identified from the Latent Class Analysis and Stakeholder consultation

Green – At least 4 service models are identified to take forward to Stage 2

Amber – 2 or 3 services models are identified to take forward to Stage 2, and there are sufficient numbers of these services to be included in Stage 2

Red – No distinct service models are identified

A recommendation to progress will be made if green criteria are met. Progression will also be recommended if green criteria are missed but amber criteria are met; and the recommendations made will then include consideration of the implications for the proposed second stage of the research (observational study).

15 Data Management

Source data will be an electronic record in Qualtrics, downloaded at least weekly into Microsoft Excel. Qualtrics and Excel will only contain a unique Service Identification Number (SIN) per service. No other identifiable information will be recorded. Records of consent will contain participant and service names, and contact forms will contain service manager/clinical lead contact details (email and telephone number). Consent and contact details, and data from services will be stored on a University of Warwick secure drive that can be accessed by the research team only.

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

Audio recordings of interviews with staff in services will be retained in case of data queries, and stored securely with other study data until the analysis is complete.

16 Protocol/GCP non-compliance

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

17 End of Study definition

The end of the study is defined as the date of final data capture from a service included in the research.

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

18 Archiving

The Study Master File (SMF) containing essential documents will be archived following departmental protocols for 10 years.

19 Regulatory Considerations

19.1 Ethical and governance approval

This protocol received approval from the Humanities and Social Sciences Research Ethics Committee at the University of Warwick, and from the Health Research Authority (due to the involvement of NHS staff as participants).

19.2 Data Protection

The research team will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained, or if abusive practice is disclosed that researchers would have a duty to report. Data will be stored in a secure manner and will be registered in accordance with the Data Protection legislation (in accordance with GDPR). Services will always be identified using a unique SIN. All other identifiable information will not be stored with collected data.

19.3 Indemnity

The University of Warwick has in force a Public and Products liability policy, and a professional Indemnity policy which provides cover for "negligent harm" and the activities here are included with in that coverage subject to the terms, conditions and exceptions of the policy. The University of Warwick does not provide compensation for non-negligent harm.

19.4 Study sponsorship

The University of Warwick will act as Sponsor for study.

19.5 Funding

The study is funded by National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) programme (Ref NIHR 129577).

20 Study management

20.1 SMG (Study Management Group)

The SMG, chaired by the Chief Investigator, will meet monthly and will include all Investigators, and all employed project staff to discuss study progression and key management issues. SMG members will be required to sign up to the remit and conditions as set out in a SMG Charter.

20.2 SSC (Study Steering Committee)

A SSC will be established and will meet twice during the project. It will comprise an independent chair with expertise in child learning disability applied research. Other independent members will include two senior child learning disability NHS clinicians (from Wales, Scotland or Northern Ireland – independent of this England-focused study), a statistician, a health economist, and two family carer representatives (parent/carers of a child with LD and BtC, at least one of whom will be the carer of a child with more severe LD and BtC); along with non-independent members: CI, Study Statistician (Melissa Wright), and research fellow as an observer. The SSC will provide overall supervision for the study and provide advice through its independent chair. The ultimate decision for the continuation of the study lies with the SSC. SSC members will be required to sign up to the remit and conditions as set out in a SSC Charter which will be filed in the TMF. The SSC will determine whether an independent Data Monitoring and Ethics Committee (iDMEC) is required for the study at their first meeting or whether the SSC will take on data monitoring function. As this is a low risk study with no blinding or delivery of intervention, it is expected that an iDMEC will not be required.

20.3 iDMEC (independent Data Monitoring and Ethics Committee)

See 20.2.

20.4 Project Advisory Groups (PAGs)

To support PPI input and ongoing input from professionals, two Project Advisory Groups (PAGs) will be established: (i) family carers of children with LD and BtC, supported by co-applicants Shurlock and Cooper and our PPI partner organisation the Challenging Behaviour Foundation, and (ii)

professionals working in child LD BtC services (clinicians, commissioners, service managers). These groups will not have a formal governance role, but will contribute to key decisions throughout the research, advise on engaging professionals and services, and will contribute to the definition of service models (see 14 Analysis) and interpretation of the study findings. The PAGs will also advise on information sheets and other ethics matters, and on co-production of dissemination outputs, act as ambassadors for the research project, and creating communication pathways with family carers and professionals. Each PAG will meet three times during the project, to ensure that PPI involvement and consultation with professionals is regular and closely informs the whole project.

20.5 Planning for the effects of COVID-19

Consent and data collection will all be completed via telephone/online and it is anticipated that this can continue during COVID-19 restrictions.

21 Quality Control and Assurance

21.1 Monitoring

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

21.2 Audits and inspections

This study may be subject to inspection and audit by the University of Warwick under their remit as Sponsor.

22 Publication policy

Outputs from the MELD study will include open access peer reviewed journal articles in international academic journals, presentations at national and international academic conferences and at public engagement/dissemination events. All publications and presentations relating to the study will be authorised by the SMG. A project publications policy and plan will be produced and approved by the SMG.

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