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Mapping and evaluating services for children with learning disabilities and behaviours that challenge

Submission date 10/05/2022	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 05/07/2022	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 02/07/2025	**Condition category** Mental and Behavioural Disorders	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

1 in every 5 children with a learning disability in the UK displays 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 from being included in the community. Children with learning disabilities 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. This research is about community-based services across England that support children with learning disabilities and behaviours that challenge, and their families. The researchers want to find out if the way that services are structured and organised (known as "service models") has any effect on the outcomes of children with learning disabilities and behaviours that challenge and their families. They also want to understand the experiences of children and families, and the ways that services for children with learning disabilities and behaviours that challenge work with families, carers, children and young people to develop services with them.

Who can participate?

Services from Stage 1 that are eligible and would be interested to take part. To be eligible, services must have been included in Stage 1 analysis and nothing significant has changed in their service model since the analysis. Services must have also been established for more than 1 year and have more than 10 children typically referred/re-referred over 6 months.

Family carers and children with learning disabilities and behaviours that challenge who have been referred/re-referred into the service, and are eligible to take part, will also be invited to take part in the current study. To be eligible, children must be aged 0-15 years of age and have a learning disability as defined administratively or otherwise by the service. The child must have been referred at least in part for support in relation to behaviours that challenge. Family carers must consent to take part in the research and they are able to complete the research in English.

Other professionals will also be invited to take part in the study. These professionals will include: health or social care/education staff who receive training or advice, or are involved in individual cases of children with learning disabilities and behaviours that challenge; commissioners of community services for these children; and staff (internal or external) who are involved in co-production in services.

What does the study involve?
The researchers will select 15 services (from five different service models identified in Stage 1 of the MELD project) to study in detail. They will ask families of 244 children newly referred to these services to complete questionnaires when they first come to the service and again after 12 months. They will gather detailed information about each service (like how many children they see in the year, and estimate costs), and they will ask people who are involved in the children's care (but not employed by the service) how satisfied they are with the service. The researchers will also interview children (using special communication techniques), families, and staff in each service model about their experiences receiving and delivering care, as well as reviewing any relevant documents. Family carers and professionals in our advisory groups, as well as members of the study team, will help the researchers to select from all Stage 1 services or their own networks four examples of co-production; where services work with children with a learning disability and/or families to design or improve services together. The researchers will carry out additional interviews with children, family carers, and staff to find out how co-production is working, how much it costs, and will review any relevant documents (e.g., policies, if any).

What are the possible benefits and risks of participating?
There are no direct and immediate benefits to taking part in this study, but participation will enable the researchers to evaluate the different identified service models for children with learning disabilities and behaviours that challenge in England. This will contribute to the evidence base about community-based service provision for these children, which may inform developments in service provision across England. The researchers are not aware of any risks related to taking part in this study.

Where is the study run from?
University of Warwick (UK)

When is the study starting and how long is it expected to run for?
February 2021 to July 2026

Who is funding the study?
National Institute for Health Research Health and Social Care Delivery Research (UK)

Who is the main contact?
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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
310149

Central Portfolio Management System (CPMS)
52467

Study information

Scientific Title
Mapping and evaluating services for children with learning disabilities and behaviours that challenge (MELD): stage 2

Acronym
MELD

Study objectives

For children with learning disabilities with behaviour that challenges, the specialist behavioural service model leads to better outcomes than other service models.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 25/04/2022, London – City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8171; cityandeast.rec@hra.nhs.uk), ref: 22/PR/0389
2. Approved 25/04/2022, HRA and Health and Care Research Wales (HCRW, Castlebridge 4, 15 - 19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)29 2023 0457; approvals@hra.nhs.uk), ref: 310149

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Children with learning disabilities and behaviours that challenge

Interventions

In Work Package 2.1, the researchers will recruit 15 services representing five service models (as identified in Stage 1 of the MELD Study) and 244 children and carers to take part in an observational study. Outcome measures assessing child behaviours that challenge, child mental health, child health, child quality of life, and adaptive skills, family carer wellbeing, family carer quality of life, services received, and (follow-up only) family carer experience and satisfaction will be completed by family carers at baseline (referral or re-referral to the service) and 12-month follow-up. Each service will also complete a service-level data collection proforma about key elements of their service (including reach, mean time to treatment, mean time to discharge, take-up of services, costs). The researchers will ask external stakeholders (e.g., social worker, education professional, referrer) to complete a satisfaction with the service measure about one child who is being supported by the service who they are involved with in a professional capacity. Statistical analyses will examine 12-month outcomes across service models, accounting for baseline scores and potential confounders or other key factors (informed by stakeholder consultation). Health economic analyses will examine the costs and cost-effectiveness of each service model.

In Work Package 2.2a, the researchers will use a multiple case study design approach, and will select one service of each service model type within which to gather data through a review of any relevant documentation and interviews (per case study) with 6-7 children with learning disabilities, 4-5 family carers, 2-3 service staff, 2-3 external staff who are involved in the cases, and a key commissioner.

In Work Package 2.2b, with input from the family carer advisory group, professionals advisory group, and SMG members, the researchers will also select up to four case studies to examine coproduction of services with children and/or family carers; again reviewing any relevant documentation and interviewing 4-5 children, 4-5 family carers, 4-5 staff (internal or external) working with co-production, and 2-3 external staff who are involved in the cases. Cross-case comparison and synthesis with documentary evidence about each service/coproduction model (and synthesis with quantitative data about each service from Stage 1) will be used to examine experiences, perceptions, and processes.

Intervention Type
Other

Primary outcome(s)
Child-related outcomes (all completed by family carers):
Child behaviours that challenge measured using the Behaviour Problems Inventory Short Form (BPI-S) at baseline and 12 months post-referral

Key secondary outcome(s))
Child-related outcomes (all completed by family carers):
1. Child physical health is measured using the Children's sleep habit questionnaire (CSHQ) and non-communicating children's pain checklist – revised (NCCPC-R) at baseline and 12 months post-referral
2. Child mental health is measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline and 12 months post-referral
3. Child quality of life is measured using the EQ-5D-Y Health Questionnaire at baseline and 12 months post-referral and either Paediatric Quality of Life Inventory (PedsQL) infant scales (only for children aged 0-24months) or Paediatric Quality of Life Inventory (PedsQL) Generic Core Scales (only for children aged 2+ years) at baseline and 12 months post-referral.
4. Child skills are measured using GO4KIDDS at baseline and 12 months post-referral.
5. Child services received are measured using the Client Service Receipt Inventory (CSRI) at baseline and 12 months post-referral

Family carer related outcomes (all completed by family carers):
1. Family carer quality of life is measured using the EQ-5D-5L Health Questionnaire at baseline and 12 months post-referral
2. Family carer wellbeing is measured using Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and 12 months post-referral
3. Family carer services received are measured using Client service receipt inventory (CSRI) at baseline and 12 months post-referral
4. Family carer experience/satisfaction with service is measured using the Experience of service questionnaire (ESQ) satisfaction with care items at 12 months post-referral

Service-level outcomes (completed by services using standard proforma):
1. 'Reach' to population at 12 months post-referral
2. Timings of service delivery (e.g., mean time to start support from referral, and length of time to discharge) at 12 months post-referral
3. Service take-up at 12 months post-referral
4. Costs at service level at 12 months post-referral

Other-stakeholder-related outcomes (completed by external stakeholders):
1. Satisfaction of external stakeholders (e.g., referrer, health, social-care, or education professionals) brief measure (developed for the purposes of this study) at 12 months post-referral

Completion date
31/07/2026

Eligibility

Key inclusion criteria
The inclusion criteria for services are:
1. They were a service included in the analysis for Stage 1 of the MELD study
2. Nothing significant has changed in their service model since the Stage 1 analysis

The inclusion criteria for children referred/referred to services included in Stage 2 of the MELD Study are:
1. Child (0-15 years of age) has learning disabilities as defined administratively or otherwise by the service
2. Child has been referred at least in part for support in relation to behaviours that challenge (including those referred to the relevant learning disability/behaviours that challenge pathway in any broader service)
3. Child’s parental caregiver consents to take part in the research
4. Child’s parental caregiver is able to complete, by questionnaire or interview with a researcher, study outcome measures in English

For the case studies, children and young people who will be interviewed will be between 6 and 15 years of age. Consent from their parental caregiver will be obtained before they take part.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 years

Upper age limit
15 years

Sex
All

Key exclusion criteria

The exclusion criteria for services are:
1. Services that have been established for less than one year, and so have had little chance to become reasonably stable within the current study timeframe
2. Services that have a typical referral/re-referral rate over 6 months of fewer than 10 children
3. Services that indicate at Stage 1 of the MELD Study they would not wish to be contacted about involvement in Stage 2
4. Co-applicants Lovell and Liew’s services – to address potential conflicts of interest

Date of first enrolment
01/07/2022

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Not provided at time of registration
United Kingdom
-

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR 129577

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to research ethics restrictions.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications		04/12/2023	05/12/2023	Yes	No
Protocol file	version 1.2	25/05/2022	06/07/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes