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Testing whether a co-produced mental imagery therapy for anxiety is feasible for adults with mild to moderate intellectual disabilities

Submission date
10/08/2026

Recruitment status
Recruiting

Registration date
18/08/2026

Overall study status
Ongoing

Last Edited
08/10/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with intellectual disabilities have difficulties with their thinking, communication, and completing everyday tasks. Many people with intellectual disabilities are also anxious. This can stop them from going out and seriously affect their relationships. There are talking therapies that help anxious people. However, because people with intellectual disabilities have difficulties with thinking and communication, these therapies cannot be used without being adapted.
We have worked with people with intellectual disabilities and their families to adapt the ideas behind talking therapy in a new way by using mental images for those with mild to moderate intellectual disabilities. This new therapy is called 'Co-MAID'. Mental images are the pictures we have in our heads. It is easier for people with intellectual disabilities to change their mental images than their verbal thoughts, to help them feel less anxious.
Co-MAID teaches people different ways to change upsetting mental images over 9-12 individual, weekly, hour-long sessions with a therapist. Participants are encouraged to involve a supporter to attend therapy sessions and help with homework. People with intellectual disabilities say that Co-MAID is easy to understand and use. The research aims to: (a) To develop a Co-MAID training package, (b) To check whether Co-MAID can be run in the NHS, (c) To see if a larger study to test whether Co-MAID works is possible.

Who can participate?
40 adults (aged 18+ years), with mild to moderate intellectual disabilities and clinical anxiety levels. Participants in the intervention arm may also have a carer involved (up to 20 carers). Five therapists, 10 patients, and 10 supporters will be recruited for the process evaluation.

What does the study involve?
Adults with mild to moderate intellectual disabilities will be allocated to receive the Co-MAID intervention and treatment-as-usual, or only treatment-as-usual. Co-MAID will be delivered by trained therapists over 9-12 sessions. Participants will complete outcome measures at baseline and follow-up. After the intervention study, people with intellectual disabilities, therapists and supporters will participate in interviews to evaluate Co-MAID feasibility.

What are the possible benefits and risks of participating?
Participants will receive £15 and reimbursed travel expenses for taking part in the intervention study. Participants may receive a novel anxiety intervention which may be provided to them more quickly than treatment-as-usual. Staff trained in the intervention will have new skills and receive additional training and supervision.

There is a risk that participants may find some component of the intervention aversive. However, people with intellectual disabilities and stakeholders have been involved throughout the development and initial testing of this intervention and no aversive experiences have yet been experienced. Risk of distress will be mitigated through the intervention being delivered by an experienced healthcare professional familiar with working with people with intellectual disabilities who has received training in the intervention and will receive ongoing supervision throughout delivery.

Where is the study run from?
Participants will receive the intervention and complete outcome measures in a clinical or residential setting. The study is being run across five NHS trusts in central and southern England.

When is the study starting and how long is it expected to run for?
November 2026 to December 2027.

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Dr Olivia Hewitt, olivia.hewitt@oxfordhealth.nhs.uk.

Contact information

Type(s)
Principal investigator, Scientific, Public

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Dr Olivia Hewitt

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Additional identifiers

Integrated Research Application System (IRAS)

349099

Central Portfolio Management System (CPMS)
64636

National Institute for Health and Care Research (NIHR)
208933

Study information

Scientific Title
A co-produced mental imagery intervention to reduce anxiety in people with mild to moderate intellectual disabilities (Co-MAID): a feasibility study

Acronym
Co-MAID feasibility

Study objectives
Primary Objective: To investigate the feasibility of implementing a novel anxiety intervention with 40 patients and up to 20 carers

Secondary Objectives:
1. Train 15 intellectual disabilities clinicians (e.g. clinical psychologists, learning disability nurses, psychiatrists, occupational therapists) working within specialist intellectual disabilities and mainstream mental health services to deliver Co-MAID and assess fidelity to the treatment.
2. Implement the manualised intervention in NHS services to determine the acceptability of delivering/receiving the intervention for patients, supporters, and clinicians, respectively.
3. Determine treatment adherence and fidelity.
4. Describe factors that facilitate or challenge the implementation of the intervention through NHS services.
5. Further refine the intervention logic model.
6. Determine feasibility of participant recruitment and retention rates.
7. Assess the feasibility of collecting proposed outcome measures for a definitive trial.
8. Assess the acceptability of randomization for participants, supporters and therapists.
9. Assess the acceptability of linking data between patients and their supporters in a future trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/07/2026, North West - Liverpool Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8340; liverpoolcentral.rec@hra.nhs.uk), ref: 26/NW/0187

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety in people with mild to moderate intellectual disabilities

Interventions
Current interventions as of 08/10/2026:
Design
This study aims to test the feasibility of delivering the Co-MAID intervention in NHS settings. We are testing this out with 40 adults who have mild to moderate intellectual disabilities and anxiety. We will recruit these people from 5 NHS Trusts. Half will be randomly allocated to receive treatment as usual for anxiety (TAU), and half will receive TAU plus the Co-MAID intervention. This feasibility study is being conducted in advance of a full clinical trial of the intervention. Therefore, we are modelling a number of processes such as collecting information about resources for health economic analysis, and randomisation to allow us to investigate the acceptability of this for participants and therapists.

Participants may have a supporter to attend sessions with them and help with any between-session tasks, although this is not mandatory. Participants may also have a proxy complete informant-report measures about their mood and use of health services.

We will train 15 therapists across the 5 NHS trusts to deliver the Co-MAID intervention. We will capture information about the therapist, such as demographic information, professional background, years of experience etc.

Randomisation
Patients will be randomised using block randomisation on a 1:1 basis to either the intervention or comparator arm. The randomisation list will be produced in advance and will use a block size of 4. Randomisation will be conducted using R version 4.4.1 (2024-06-14) and the 'blockrand' package.

The study team will communicate the outcome of randomisation for each participant to the site PI. They will then pass on this information to the participant and therapist.

How will participants be recruited?
All participants will be recruited through NHS services. Clinicians working in the service will identify people who meet the eligibility criteria (having a mild to moderate intellectual disability and anxiety disorder) by checking waiting lists for the service, discussion with other clinicians,

searching electronic patient records and checking referrals coming into the service. Any potentially eligible participants (and their supporter if applicable) will be contacted by clinicians in the service and provided with brief information about the study in an accessible format (this study advert will be co-designed by the CDG).

Participants and/or supporters can then contact the study team via two routes:
(a) Participants (and supporters) tell clinicians that they want their contact details passed to the study team when asked. The study team will receive the details from clinicians and then contact the participants (and supporters).
(b) Participants (and supporters) contact the study team directly using the contact information they were provided.

Once they have contacted the study team, a research assistant from the study team (or site R&D) will complete screening to determine eligibility and gather informed consent.

Timetable
Broadly, Phase 1 involves developing project resources alongside our Co-Design Group (CDG), which will take place during months 1-6. These include a therapist's manual, a training package for therapists, a person's workbook, and fidelity checklists. Recruitment of 40 participants will take place in months 7-12, with the intervention being delivered in months 7-15. Process evaluation (including interviews with participants, supporters and therapists) will be conducted in months 12-19. Dissemination, report writing and feedback to funders will occur in months 19-21. Therefore, for participants taking part in the study, their involvement will last for about 6 months in order to screen them for eligibility, collect baseline data, randomise them and deliver the intervention (if applicable) and collect follow-up data 20 weeks post-randomisation.

Data collection
Data will be gathered from participants at two time points: (1) screening and baseline assessment, and (2) follow-up assessment within 20 weeks of randomization.

The questionnaires that will be administered at these time points include a measure of anxiety (primary outcome measure) and may also include secondary measures such as (a) anxiety diagnosis, (b) symptoms of depression, (c) challenging behaviour, (d) quality of life, (e) wellbeing, and (f) mental imagery. Several potential outcome measures appropriate for this population will be presented to the Co-Design Group, who will make a recommendation to the study team about which measures should be included.

Data will be collected by members of the research team, except for the therapists' rated fidelity checklist, which will be completed by therapists themselves and returned to the study team.

We will carry out semi-structured interviews with 10 patients, 10 supporters, and 5 therapists to understand what people thought about the intervention and to understand the facilitators and barriers to delivering this intervention in NHS settings. These interviews will be held online or in the person's home or community setting, depending on personal preference. The interviews will be carried out by the research assistant.

Data analysis
We will recruit 40 patients (20 in each treatment arm), up to 40 proxies and up to 20 supporters. Five therapists will take part in process evaluation interviews. As this is a feasibility study, and the purpose is to provide estimates of key parameters to inform a future pilot trial rather than to power the current study to detect statistically significant differences, a formal a priori power calculation will not be conducted. Descriptive statistics will be reported for the study.

Interviews will be audio-recorded, transcribed and analysed using Template Analysis.

PPI Input
The proposed research focuses on a feasibility study into Co-MAID. Co-MAID has been co-designed with people with intellectual disability and their family members, along with wider stakeholders. A group of 6-8 people with mild or moderate intellectual disability and their family members have formed our PPI group throughout our research and will continue to guide this feasibility study. PPI has been central to the design and preliminary testing of Co-MAID in NHS settings and disseminating findings from prior research stages.

The involvement of a PPI co-applicant, Chrissy Marsh, has been central to this application. CM brings a wealth of expertise as the mother of a person with intellectual disability, and through her previous expertise as a teacher within a special educational school. The decision to apply for a feasibility study was made in collaboration with PPI members, and they have provided extensive feedback and support for this proposal. The research team has met with a PPI group regularly (every 6 weeks) over the past 14 months to develop the current application. This group is very familiar with the Co-MAID intervention, and some members of the PPI group have provided input into the project over the past 6 years (since the original inception of the idea for this intervention). Input from this group has included the development and refinement of the plain English summary, refining the research design, structuring the process evaluation (including the topics to be covered in qualitative interviews), designing and planning the input from the Co-Design Group, and feeding into guidance around membership of this group. PPI input has shaped and developed ideas around dissemination, including the use of a dissemination matrix to ensure the needs of all stakeholders will be addressed, and advocating for various innovative and creative methods of dissemination.

Without the consistent support from our PPI partners, this research simply would not have been possible, and we continue to rely on their collaboration at each stage of our work.

Previous interventions:
Design
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Participants may have a supporter to attend sessions with them and help with any between-session tasks, although this is not mandatory.

We will train 15 therapists across the 5 NHS trusts to deliver the Co-MAID intervention. We will capture information about the therapist, such as demographic information, professional background, years of experience etc.

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or comparator arm. The randomisation list will be produced in advance and will use a block size of 4. Randomisation will be conducted using R version 4.4.1 (2024-06-14) and the 'blockrand' package.

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Data collection
Data will be gathered from participants at three time points: (1) screening, (2) baseline assessment within 4-weeks of randomisation, and (3) follow-up assessment within 20-weeks of randomisation.

The questionnaires that will be administered at these time points include a measure of anxiety (primary outcome measure) and may also include secondary measures such as (a) anxiety diagnosis, (b) symptoms of depression, (c) challenging behaviour, (d) quality of life, (e) wellbeing, and (f) mental imagery. Several potential outcome measures appropriate for this population will be presented to the Co-Design Group, who will make a recommendation to the study team about which measures should be included.

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Data analysis
We will recruit up to 40 patients (20 in each treatment arm), and up to 20 supporters. Five therapists will take part in process evaluation interviews. As this is a feasibility study, and the purpose is to provide estimates of key parameters to inform a future pilot trial rather than to power the current study to detect statistically significant differences, a formal a priori power calculation will not be conducted. Descriptive statistics will be reported for the study.

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Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety measured using the Adapted General Anxiety Disorder-7 (GAD-7) at baseline and follow-up (20 weeks after randomization)

Key secondary outcome(s)

1. Anxiety measured using the Glasgow Anxiety Scale for people with intellectual disabilities (GAS-ID) at baseline and follow-up (20 weeks after randomization)

2. Depression measured using the Adapted Patient Health Questionnaire-9 (PHQ-9) at baseline and follow-up (20 weeks after randomization)

3. Quality of life measured using the European Quality of Life 5 Dimensions 3 Level version (EQ-5D-3L) at baseline and follow-up (20 weeks after randomization)

4. Mental imagery measured using the Mental Imagery Questionnaire for people with intellectual disabilities (MIQ-ID) at baseline and follow-up (20 weeks after randomization)

5. Resource use measured using the Client Service Receipt Inventory (CSRI) at baseline and follow-up (20 weeks after randomization)

6. Mood measured using the Anxiety Depression and Mood Scale (ADAMS) completed by proxies at baseline and follow-up (20 weeks after randomization)

08/10/2026: A key secondary outcome (6.) was added for proxies to complete measures on behalf of participants.

Completion date
01/12/2027

Eligibility

Key inclusion criteria
1. Mild to moderate ID diagnosis confirmed by case note review
2. Existing diagnosis of an anxiety disorder confirmed or initially made at screening
3. Capacity to give informed consent to participate in accordance with the Mental Capacity Act (2005)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Currently receiving another psychological therapy
2. Actively suicidal, experiencing hallucinations or delusions
3. Severe or profound intellectual disability diagnosis

Date of first enrolment
01/11/2026

Date of final enrolment
03/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Berkshire Healthcare NHS Foundation Trust
London House
London Road
Bracknell
England
RG12 2UT

Study participating centre
Tatchbury Mount Hospital
Calmore
Southampton
England
SO40 2RZ

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield
England
AL10 8YE

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital

77 London Road
Kettering
England
NN15 7PW

Study participating centre
Littlemore Mental Health Centre
Sandford Road
Littlemore
Oxford
England
OX4 4XN

Sponsor information

Organisation
Oxford Health NHS Foundation Trust

ROR
https://ror.org/04c8bjx39

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			12/08/2026	No	No