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Testing a new intervention for anxiety in people with mild to moderate intellectual disabilities

Submission date
01/05/2024

Recruitment status
No longer recruiting

Registration date
10/05/2024

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study is about adults with mild to moderate intellectual disabilities who have problems with anxiety. People with anxiety often have unhelpful mental images (pictures in their heads) which keep them feeling anxious. Mental imagery interventions can help to change these unhelpful pictures or mental images, and so reduce anxiety. The study team have worked with people with intellectual disabilities and other stakeholders to develop a mental imagery intervention specifically for people with intellectual disabilities. This study aims to try out this new mental imagery intervention and get feedback from participants and their families.

Who can participate?
Adults aged 18 years old and over with mild to moderate intellectual disabilities who have clinical levels of anxiety

What does the study involve?
Participants will be randomly allocated to a 2-, 3- or 4-week baseline phase. Participants will provide daily mood recordings during the baseline, intervention, and follow-up phases. In addition, they will complete 5 standardised questionnaires at baseline, mid-intervention, end of intervention and at 2-week follow-up. At the end of the intervention, all participants will be invited to an interview about what it was like to do the study and the intervention. Participant's supporters (paid carers or family members) will also be asked what they thought of the intervention. This will help the study team know whether people liked the intervention, and what changes might need to be made.

What are the possible risks and benefits of participating?
Participants who consent to take part in the intervention may be offered psychological support more quickly than if they were to wait for treatment as usual through their local psychological service for people with learning disabilities. Participants will be able to access a novel intervention that is not available through routine NHS services at present.

Participants will be taking part in a novel mental imagery intervention. Whilst all components of the intervention have been carefully adapted specifically for people with intellectual disabilities and are based (both theoretically and practically) on existing well-established interventions in

the general population, there is a risk that the participants may find some component of the intervention aversive. However, people with intellectual disabilities and stakeholders have been involved throughout the development of this intervention and no aversive experiences of trying out any component of the intervention have yet been experienced.

Any risk of distress will be mitigated through the intervention being delivered by a highly experienced clinical psychologist with over 15 years of clinical experience in delivering psychological interventions to people with intellectual disabilities. Therefore, the clinician is well able to identify and manage any signs of distress or concerns regarding the delivery of the intervention

Participants taking part in the intervention will experience additional burdens in terms of reading information sheets and consent forms, completing consent forms, and completing measures of psychological well-being at baseline, throughout the intervention and at follow-up. Participants will also complete an interview following the completion of the intervention to provide feedback on their experience of participating in the intervention.

Participants who consent to take part in the intervention may be offered psychological support more quickly than if they were to wait for treatment as usual through their local psychological service for people with learning disabilities.

Where is the study run from?
Berkshire Healthcare NHS Trust

When is the study starting and how long is it expected to run for?
June 2023 to October 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) through a Clinical Doctoral Research Fellowship (CDRF)

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
334578

Central Portfolio Management System (CPMS)
60053

National Institute for Health and Care Research (NIHR)
300501

Protocol serial number
23CYPFLDN334578

Study information

Scientific Title
Testing a Co-designed Mental imagery Anxiety intervention for people with mild to moderate Intellectual Disabilities (Co-MAID)

Acronym
Co-MAID

Study objectives
Can people with intellectual disabilities and anxiety engage with the novel co-designed mental imagery intervention (Co-MAID)?
• Is the novel mental imagery intervention (Co-MAID) acceptable to people with mild to moderate intellectual disability and anxiety?
• Is the novel mental imagery intervention (Co-MAID) acceptable to supporters of people with intellectual disabilities?
• Can people with intellectual disabilities engage with the mental imagery components of the intervention?
• Can people with intellectual disabilities complete candidate outcome measures, including target variable measures?
• Are research processes undertaken during a larger feasibility trial of the intervention likely acceptable to people with intellectual disabilities and their supporters?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/03/2024, West of Scotland REC 3 (Ground Floor, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA27DE, United Kingdom; +44 (0)141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 24/WS/0022

Primary study design

Observational

Study design
Single-centre interventional study using mixed methods (single case experimental design and qualitative evaluation)

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of clinical levels of anxiety in people with mild to moderate intellectual disabilities

Interventions
A single case experimental design with a process evaluation will be conducted with 6 individuals to assess the acceptability of the Co-MAID intervention and associated research procedures. Participants will be people with mild to moderate intellectual disabilities with a diagnosis of anxiety. Each participant may choose to have a supporter to help them engage with the therapy and complete between-session tasks.

An ABA multiple baseline design will be used. Participants will be randomly allocated to a two-, three- or four-week baseline condition (A1) and follow-up phase (A2) of two, three or four weeks. Simple randomisation will be used to allow participants to one of the three baseline /follow-up conditions using an online random number generator (https://www.random.org/). The intervention phase (B) consists of 9-12 weekly sessions. Each session will last approximately 60 minutes.

During the 60-minute intervention sessions, the participant and therapist will work through a series of stages of the therapy. Initial sessions will focus on rapport building and understanding the intervention. Subsequent sessions will concentrate on providing psychoeducation about anxiety and mental imagery. The therapy sessions will then cover four different mental imagery components. These will help the participant engage with different types of mental imagery components, including generating positive images, switching attention away from distressing images, and learning to change the properties of mental imagery. The final therapy sessions focus on remembering and retaining skills and helping to incorporate these new skills into everyday life. Sessions will be delivered in a 1:1 format, although the option of having a supporter accompany the participant and attend some or all sessions is encouraged.

As well as daily monitoring of a target variable, participants will complete standardised candidate outcome measures at 4-time points; at the pre-intervention assessment (which will be at least 2 weeks before the first intervention session), midway through the intervention (after the intervention session 5), post-intervention (at the end of the final intervention session) and at follow up (2, 3 or 4 weeks after the final intervention session). Brief session-by-session feedback consisting of a visual analogue scale and several open-ended questions will be collected at the end of each intervention session. Individual semi-structured interviews will be conducted with all participants, and separately with their supporters at follow-up (2, 3 or 4 weeks after the end of the intervention). These will be analysed using Template Analysis.

Intervention Type
Behavioural

Primary outcome(s)

Anxiety measures using the Glasgow Anxiety Scale (GAS) at baseline, weeks 5 and 9 of the intervention and 2 weeks follow-up

Key secondary outcome(s)
1. Psychological well-being measured using the adapted Patient Health Questionnaire (PHQ-9), Generalised Anxiety Disorder (GAD-7) questionnaire and Psychological Therapies Outcome Scale for people who have Intellectual Disabilities (PTOS-ID) at baseline, weeks 5 and 9 of the intervention and 2 weeks follow-up
2. Mood measured using daily recording that is undertaken throughout the baseline, intervention and follow-up phases in line with the SCED methodology

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Diagnosis of mild or moderate intellectual/ learning disabilities
2. Aged 18 years or older
3. Score of 15 or more on the Glasgow Anxiety Scale
4. Capacity to decide whether they wish to partake in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Currently receiving another psychological therapy for a mental health problem
2. Presenting with mental health symptoms of a disorder other than anxiety which are judged likely to interfere with their ability to successfully participate in the intervention by the study team (e.g., hallucinations and delusions or suicidality).

Date of first enrolment
01/05/2024

Date of final enrolment
01/04/2025

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Berkshire Healthcare NHS Foundation Trust

ROR
https://ror.org/03t542436

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
The datasets generated during and/or analysed during the current study will be available upon request from Dr Olivia Hewitt, olivia.hewitt@berkshire.nhs.uk). Anonymised data will be shared on request, once the data has been analysed and submitted for publication, and will remain available for 2 years. For qualitative data that has been collected, summary-level data will be available. Individual participant interview transcripts will not be made available, as even with anonymisation, this is a small group of participants who could potentially be identifiable through characteristics such as rare genetic syndromes etc. Data will be made available to other researchers. Participants gave informed consent for anonymised data to be shared with other researchers.

IPD sharing plan summary
Available on request