ISRCTN16062949 https://doi.org/10.1186/ISRCTN16062949

Multi-component anxiety management programme for people with intellectual disability

Submission date
25/07/2023

Recruitment status
No longer recruiting

Registration date
31/07/2023

Overall study status
Completed

Last Edited
04/04/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This research project is about trying a novel treatment to help people to manage their anxiety. We have developed an anxiety management treatment with people who have an intellectual disability and we want to investigate if this treatment helps people manage their anxiety. There are an estimated 1.5 million people in England with an intellectual disability, with nearly half of people experiencing some difficulty with anxiety. The effect anxiety can have on a person' s life can be significant which can result in increased medication being prescribed to help the person cope with their mental health. There are not many effective therapies available that can help and support people with self-management of their
anxiety. People with intellectual disabilities can develop these skills, but need adapted therapies to develop and retain self -management skills. For people who have a more severe intellectual disability and have difficulty with their communication, anxiety can be demonstrated through difficult behaviour, resulting in higher levels of medication being prescribed. There is some evidence which suggests that adapting therapies to help people with their anxiety can be effective, but this is limited to a single psychological therapy approach with no evidence of any long-term effects. We have developed an anxiety management programme using a range of different psychological therapies.

Who can participate?
Adults over 18 years, with intellectual disabilities.

What does the study involve?
This research project will include 60 people with intellectual disabilities. We will test our treatment with 30 people. A separate 30 people will receive a different therapy treatment called cognitive behaviour therapy (treatment as usual). Both of the treatments will be for people with intellectual disability who suffer with anxiety. We will use outcome measures to understand the treatment effects and any differences between groups. We will obtain feedback from participants using interviews to make improvements to the anxiety management programme.

What are the possible benefits and risks of participating?
The study poses minimal risk to participants. In our development group, the participants identified the current CBT based practices as being often difficult to follow but recognised effective components within this therapy. The multi-component anxiety management programme in question has been designed to be more accessible than the treatment currently available.

Where is the study run from?
Cheshire and Wirral Partnership NHS Foundation Trust (UK)

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

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

Who is the main contact?
Daniel Acton (Clinical Nurse Specialist), danny.acton@nhs.net

Contact information

Type(s)
Principal investigator

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Mr Daniel Acton

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315557

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55443, IRAS 315557, NIHR 204370

Study information

Scientific Title
Evaluation of a novel multi-component anxiety management programme: a mixed methods quasi-experimental feasibility study

Acronym
M CAMP-ID

Study objectives
Is it feasible to evaluate the effectiveness of a novel multi component anxiety management treatment programme in reducing levels of anxiety in people with intellectual disability within a randomised control trial study design?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/03/2023, East Midlands - Derby Research Ethic Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8154; derby.rec@hra.nhs.uk), ref: 23 /EM/0044

Study design
Single centre feasibility study for a single blind randomized controlled quasi-experimental trial of a novel multi-component anxiety management intervention in comparison to treatment as usual

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety

Interventions
Sixty people with intellectual disability will be invited to participate in the study across four intellectual disability services within one mental health trust in England. The specialist services will be randomly selected to deliver either treatment as usual (TAU) or the novel intervention (M CAMP-ID). M CAMP-ID comprises of ten individual sessions delivered by a member of the clinical team once a week for between 10 – 12 weeks.
Patients will be followed up for 20 weeks.

Intervention Type
Other

Primary outcome(s)
Levels of anxiety measured using the Glasgow Anxiety scale (GAS-ID) at baseline, 12 and 20 weeks

Key secondary outcome(s))
1. Anxiety and mood measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 12 and 20 weeks
2. Quality of life measured using the World Health Organisation Quality of Life Measure (WHOQOL-8) at baseline, 12 and 20 weeks
3. NHS service costs measured using the Client Service Receipt Inventory (CSRI) at baseline, 12 and 20 weeks
4. Satisfaction with Interventions measured using the Client Satisfaction Questionnaire (CSQ-8) at 12 weeks

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Participants aged over 18 years of age.
2. Registered diagnosis of mild or moderate intellectual disability with or without autism.
3. Scores above seven (range 7-18) on the anxiety component on the MOSS Pas-ID (Moss et al., 1998).
4. Required to provide informed consent and sign a declaration form indicating agreement to participate.

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
60

Key exclusion criteria

1. If they choose not to be involved in the study.
2. Have a severe or profound intellectual disability.
3. Lack capacity to consent.
4. Under the age of 18 years old.
5. Participants who score below 7 on the anxiety component of the Moss PAS-ID.

Date of first enrolment
30/03/2023

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Trust Headquarters Redesmere
The Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1BQ

Sponsor information

Organisation
Cheshire and Wirral Partnership NHS Foundation Trust

ROR
https://ror.org/03ky85k46

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 are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/09/2023	21/09/2023	Yes	No
Participant information sheet	version 1.5	06/03/2023	28/07/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes