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Mentalisation-based treatment for socially isolated older adults with personality disorder

Submission date
01/09/2025

Recruitment status
Recruiting

Registration date
16/12/2025

Overall study status
Ongoing

Last Edited
16/12/2025

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
1 in 15 people over the age of 65 has a problem called a personality disorder. Many people find the personality disorder label negative. Therefore, this study will use the term complex emotional needs (CEN) instead. Older people with CEN sometimes harm themselves. They feel low in mood and use health services often. This costs the NHS millions of pounds per year. Mentalisation-based treatment (MBT) is a talking treatment designed for younger adults with CEN. It lasts for 2 years and requires 2 appointments per week. Research has shown MBT reduces suicide, self-harm and service use in younger people. This makes MBT cost-effective. It is unknown whether MBT is suitable for older people. Nobody has researched whether MBT works for older adults. MBT helps people with how they think. Other treatments for older adults with CEN have had a different focus. They focus on what people do. Studies suggest that older adults may need help with how they think. This type of support is likely to help them feel less lonely.

This research aims to see: 1. How suitable is MBT for older people with CEN? 2. What changes to MBT do older people need? 3. Is it possible for older people to take part in MBT research? and 4. Are there any potential benefits to emotional health and loneliness?

Who can participate?
Senior individuals aged 65 or over with a confirmed Personality Disorder diagnosis via the Structured Clinical Interview for DSM-5 Personality Disorders (SCID-5-PD) or significant associated traits (Personality Disorder trait specified according to DSM-5).

What does the study involve?
The study uses a mixture of methods:
1. Up to 14 older people will take part in 18 months of MBT. They will fill out two questionnaires each week. This will help to find out if MBT has any potential benefits
2. These data will record how many people take part in the study. I will also record how many people drop out. This will help to find out if older people can do MBT
3. A lived experience researcher will ask participants questions about their experience of MBT. This will help to find out if MBT is suitable for older people.

Working with diverse people and communities with relevant lived experience and needs
A lived experience group helped shape this proposal. It includes older people from different backgrounds. The group will have continued input throughout the study.
Older people with CEN sometimes have disabilities, are low-income, and come from different backgrounds. This can make it difficult for them to access support. To support inclusion, the study will:
• Be flexible around missed appointments
• Offer home visits
• Follow up on missed appointments
• Offer free transport
• Tell the local carer groups about the study.
• Tell the British Muslim Heritage Centre about the study.
• Tell the Afro Caribbean Centre about the study.
• Tell the Manchester Equality and Diversity Group about the study
• Conduct a review of how inclusive the study has been.

What are the possible benefits and risks of participating?
No benefits and risks given at registration

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
July 2022 to December 2028

Who is funding the study?
Greater Manchester Mental Health NHS Foundation Trust, UK

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
341968

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
x750

Study information

Scientific Title
A mixed methods pilot study exploring the feasibility, acceptability and potential benefits of mentalisation-based treatment for older adults with complex emotional needs

Acronym
MBT-OA

Study objectives
Primary Outcomes:
To evaluate the feasibility of MBT in older adults. The feasibility of the study will be assessed by examining recruitment rate, consent rate, proportion of participants lost to follow-up, number of sessions attended, and dropout rate.

To evaluate the acceptability of MBT in older adults. The acceptability will be evaluated by using Semi-structured qualitative interviews. These interviews will be delivered by 2-3 lived-experience researchers. The study aims to determine what adaptations are indicated, integrating findings from qualitative and quantitative analysis to assess the feasibility of MBT. This will result in a fully adapted intervention.

The team will use the Theoretical Framework for Acceptability to ensure the interviews assess acceptability. The interviews will focus on the seven constructs of acceptability:
- To evaluate the change in personality functioning and social isolation in older adults undergoing MBT.
- Changes in Personality Functioning Using the Level of Personality Functioning Scale Brief Form (LPFS-BF 2.0). The LPFS 2.0 is a 12-item questionnaire that assesses personality functioning on a 4-point scale. This tool offers insights into the severity of personality pathology and sheds light on self and interpersonal functioning. The LPFS 2.0 has been empirically validated for older adults and has proven valuable in assessing personality functioning in this demographic. To ensure adequate statistical power, the LPFS-BF will be administered weekly, following each individual therapy session. This frequent data collection will enhance the reliability of observed changes.

Ethics approval required

Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Multiple single case-series design

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Treatment

Health condition(s) or problem(s) studied
Treatment of suicidality, self-harm, personality functioning and loneliness in older adults with personality disorder

Interventions
This study uses a multiple single case series design, a form of Single Case Design (SCD). It will employ quantitative methods to track changes in personality functioning over time using the LPFS 2.0 scale and changes in loneliness using the Social Isolation Short Form 4a. Data from a participant will be compared within the participant between treatment phases (baseline, treatment and follow-up), so participants serve as their own controls. Initial data collection will take place at an outpatient clinic in Manchester, United Kingdom. Data will be gathered weekly away from the Mentalisation-Based Treatment (MBT) clinic. The research team, primarily involved in clinical practice, will use an established older adult MBT service in Manchester for the sample. This approach mitigates some challenges of assessing multi-modal psychological treatments, as there's no need for the research team to establish a new therapy program.

A multiple single-case series design will enhance experimental control since participants serve as their own control. To get a stable and representative estimate of the baseline state, all participants will have a waiting period of 8 weeks before starting treatment. Participants who drop out of the research completely during this phase won't have any further data collected. The study team will ask anyone who drops out of the therapy to consent to providing data relating to their reason for dropping out.

The strength of an SCD study is that it produces statistical power by taking a large number of data points with a small number of participants. Due to the high number of data points per participant, changes to outcome measurements can be accurately described. Additionally, due to the low number of participants, there is a lower cost to the intervention, which means that it is more feasible to carry out long-term studies of psychological treatments for personality disorders, which often span multiple years.

Therapists providing MBT will not know the outcome scores provided by participants. Participants will complete these measures independently away from the clinic each session. These measures will be placed in an envelope and sent to a research assistant who will input the data into an anonymised database inaccessible to therapists. If participants need assistance with the measures, the research assistant will help in person before the session starts. Each participant will receive an anonymous participant number, unknown to the clinical team. There is increasing interest in adaptive designs for clinical trials, defined as the use of accumulating data

to decide how to modify aspects of a trial as it continues, without undermining the validity and integrity of the trial. Examples of potential adaptations include stopping the trial early, modifying the allocation ratio, re-estimating the sample size, and changing the eligibility criteria. The most valid adaptive designs are those in which the opportunity to make adaptations is based on pre-specified decision rules that are fully documented in the protocol.

Qualitative interviews will be conducted at the beginning and end of the study using the theoretical framework of acceptability. Thematic analysis of these interviews will provide insight into the acceptability of MBT for older adults, as well as required adaptations. Data relating to the recruitment rate, participation, drop-out, and completion of the intervention will be analysed to determine feasibility.

All participants will undergo a comprehensive MBT program.
This includes a weekly individual session lasting 50 minutes and a weekly group session of 75 minutes. The treatment will last for 18 months, as per the time specified in the treatment manual. The four clinicians delivering the treatment will participate in a weekly 90-minute peer supervision and receive bi-weekly group supervision of 60 minutes from an MBT expert, who is an accredited MBT supervisor. All these clinicians either have 'practitioner level status in MBT' or are in a program working towards this status.

Intervention Type
Behavioural

Primary outcome(s)
1. Changes in personality functioning will be measured using the Level of Personality Functioning Scale Brief Form (LPFS-BF 2.0) administered weekly, following each individual therapy session
2. Loneliness will be measured using the Social Isolation Short Form 4a, administered weekly, following each individual therapy session
3. Service use will be investigated to determine if there is any potential cost saving for the NHS. Participants will be asked to consent to the research team to take a record of:
3.1. Unplanned contact with the service
3.2. A and E attendances
3.3. Crisis line contacts
3.4. Days in psychiatric hospital
3.5. Days spent in the general hospital
4. Self-harm and suicidal behaviour will be measured by collecting data on incidents of self-harm recorded in the clinical record, and incidents where the participant has engaged in self-injury or self-neglect, where they intended to cause life-threatening injury

Key secondary outcome(s))
The following secondary outcome measures will be assessed at the start of baseline, start of treatment, 6, 12, 18 months into the treatment and at the end of follow-up:
1. Quality of Life will be measured using the Recovering Quality of Life (ReQol-10) scale
2. Patient Satisfaction will be measured using the Dialog Satisfaction Scale
3. Suicidality will be measured using the Columbia Suicidality Response Severity Scale (CSRSS)

Completion date
01/12/2028

Eligibility

Key inclusion criteria
1. Resident of Manchester, England
2. Aged 65 or over
3. Confirmed Personality Disorder diagnosis via the Structured Clinical Interview for DSM-5 Personality Disorders (SCID-5-PD) or significant associated traits (Personality Disorder trait specified according to DSM-5). If individuals don't fully meet the criteria, their sub-threshold presentation will be explicitly noted (one criterion less than the cut-off point for the personality disorder)
4. Ability to provide informed consent
5. Under the care of a local community mental health team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
110 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Primary issues related to psychosis, dementia, or mild cognitive impairment
2. Primary concerns associated with antisocial personality disorder or significant violent /aggressive traits
3. Ability to attend the outpatient clinic (free transport provided)
4. A diagnosis of autism won't be an exclusion criterion if all other inclusion criteria are met. The study's service site has seen referrals for individuals with autism over the past 18 months, and they've shown improvement in their outcome measures.

Date of first enrolment
01/12/2025

Date of final enrolment
06/06/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Greater Manchester Mental Health NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.4		16/09/2025	No	Yes

Protocol file	version 1.4	07/08/2025	16/09/2025	No	No