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Mentalization-based therapy (MBT) for individuals with antisocial personality disorder

Submission date
18/02/2015

Recruitment status
No longer recruiting

Registration date
24/03/2015

Overall study status
Completed

Last Edited
23/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Personality disorder is the name given to describe the persistent problems that some people have in managing their feelings, and managing their feelings in relation to other people. Up to 3% of the general population and up to 63% of offenders suffer from Antisocial Personality Disorder (ASPD). Someone with ASPD may not care about the feeling or rights of other people. Typical features include aggressiveness, failure to follow rules and not respecting the law. Its more severe consequences commonly include violent criminal behaviour with direct emotional and physical injury to victims. ASPD poses a significant health and financial burden both for individuals who have it, and for wider society. People with ASPD are more likely to suffer from additional health problems and are significantly more likely to die at a younger age than people without the disorder. Despite its high prevalence and harmful consequences, there is almost no evidence about which treatments are more effective for ASPD. One possible reason that an effective treatment has not yet been found is that most treatments that have been tested are not specifically designed for ASPD. We aim to test a treatment that has been specifically adapted for ASPD, from a model of treatment known as Mentalization Based Treatment (MBT). MBT is a psychological treatment that focuses on understanding of our own and others' thoughts, feelings, wishes, dreams and desires. MBT has been shown to be effective in patients with another type of personality disorder called Borderline Personality Disorder (BPD). It has also been shown to be effective in patients who have both BPD and ASPD, and has now been specially adapted for people who suffer from just ASPD. Despite its promise, the question of whether MBT is effective for ASPD has not yet been investigated. The aim of the initial study is to investigate whether MBT can reduce aggressive acts and antisocial behaviour of offenders with ASPD, and whether it does so more effectively and cost-effectively than the usual services offered to offenders on probation. Following this, a full study will be conducted across thirteen sites, which aims to find out the benefits of MBT on a larger scale.

Who can participate?
We are looking for males aged over 21 who are currently on probation or community sentence, have a diagnosis of ASPD and do not want to offend anymore.

What does the study involve?
In both the initial study and the full-scale study, participants are randomly allocated to receive

MBT or standard probation as usual (PAU) for 12 months. The MBT involves receiving a monthly 1-hour individual mentalization-based therapy session and a weekly group mentalization-based therapy for 75 minutes. The results of the two groups are compared by asking participants how often they are violent, and look at police records to see if the participant has re-offended. Other possible differences between the two groups such as impact of the treatment on quality of life and social functioning are also examined. Participants are asked these questions every 3 months throughout the year that they receive their treatment (either MBT or PAU), and for 24 months after they have completed treatment. This data is collected by members of the research team through questionnaires and interviews. All the this data is then analysed in order to find out whether the expected benefit of MBT is achieved and whether the treatment would be a more cost-effective option to be used across the country.

What are the possible benefits and risks of participating?
This is the first ever large scale research study of MBT for offenders with ASPD in the community and will provide evidence to inform treatment decisions for this population. The main benefits of the treatment are an expected reduction in aggressive behaviour and therefore a reduction in arrests and offences. All participants will receive help and support during this process. There are no identifiable risks for anyone who wishes to take part in the research.

Where is the study run from?
The pilot study takes place in three probation services in the UK and the full study takes place in 13 services around the UK.

When is the study starting and how long is it expected to run for?
From June 2014 to December 2020

Who is funding the study?
1. The Michael J Samuel Charitable Trust (UK)
2. National Institute for Health Research (UK)

Who is the main contact?
1. Ms Elizabeth Simes
2. Dr Stephen Butler

Contact information

Type(s)
Public

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3

Study information

Scientific Title
Mentalization for Offending Adult Males: A National Randomised Controlled Trial (MOAM)

Acronym
MOAM

Study objectives
Pilot study:
The aim of this study is to conduct a feasibility randomised controlled trial (RCT) across four sites in preparation for a larger multi-site RCT to investigate whether MBT adapted for individuals with ASPD (MBT-ASPD) is an effective treatment for individuals with a diagnosis of antisocial personality disorder (ASPD) in the community when compared to probation as usual (PAU).

Randomised controlled trial:
The aim of this study is to conduct a randomised controlled trial (RCT) across thirteen sites in to investigate whether Mentalization Based Therapy (MBT) adapted for individuals with antisocial personality disorder (ASPD) is an effective treatment for individuals with a diagnosis of ASPD in the community when compared to Probation as Usual (PAU).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Pilot study:
1. NHS Ethics: NRES Committee London - South East, 09/01/2015, REC ref: 14/LO/1696
3. NOMS Ethics: National Research Committee, ref: 2014-315

Randomised controlled trial:
Approved 09/01/2015, NRES Committee London- South East (Bristol Research Ethics Committee Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44(0)1173421382; nrescommittee.london-southeast@nhs.net), ref: 14/LO/1696

Study design
Pilot study:
Multi-centre pilot two-arm randomized controlled trial

Randomised controlled trial:
Multi-centre three phase pragmatic randomised controlled superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Antisocial personality disorder

Interventions
Pilot study:
Participants will be randomly allocated in a 1:1 ratio to receive Mentalization Based Therapy (MBT) or Probation as Usual (PAU).

MBT arm
Mentalization-based therapy integrates cognitive and relational components of therapy and has a theoretical basis in attachment theory. MBT-ASPD targets mentalizing problems through a programme of group and individual psychotherapy. All participants randomised to MBT-ASPD will have an allocated psychiatrist, a therapist who will provide individual therapy and two group therapists (one of whom will be their individual therapist). The therapist will provide a monthly 1-hour individual mentalization-based therapy session. Participants will also attend weekly group mentalization-based therapy for 75 minutes. Therapy will last for 2 months after which patients will be reassessed by a member of the trial clinical team and referred for further management if required. Each MBT group will have a maximum of 8 participants. The main purpose of MBT-ASPD is to help participants develop an understanding of their difficulties with violence and to

achieve control over their aggressive behaviour by stabilizing emotional expression. The MBT-APSD programme aims to develop a therapeutic process in which the offender's mind becomes the focus of treatment, to enable them to understand more about how they think and feel about themselves and others, and how this influences their actions and behaviours. MBT sessions will focus on identifying the thoughts and feelings associated with aggressive impulses and which may trigger aggressive or violent behaviour, with particular emphasis on (1) understanding emotional cues; (2) recognising emotions in others (3); exploring sensitivity to hierarchy and authority (4); understanding others' experiences in relation to ones' own (5); clarifying threats to loss of mentalizing. Sessions will also give participants a place to discuss the difficulties they have experienced in their life which may have contributed to their violent behaviour.

PAU arm
Participants who are randomised to the PAU arm of the trial will remain under the supervision of their Probation Trust for the duration of their licence or community sentence. It is hoped that this will facilitate the participants being available for outcome measures and data collection. Participants will be free to be referred by their Probation Officer for any suitable and appropriate treatments available locally e.g. anger management programmes. However, as there are limited treatments available in the community for people with Antisocial Personality Disorder the participants may not be able to access alternative treatments. In these cases, contact with the Probation Officer may provide an important containing and therapeutic, as well as supervisory, function. Participants will be offered treatment review meetings where appropriate, including medication review, with the Consultant Psychiatrist. Medication use will be monitored carefully and only offered for comorbid conditions according to NICE guidance. In order to address potential bias, site-specific strategies will be put in place to ensure that MBT principles and practice do not directly influence the management of those randomised to PAU. One strategy that will be applied to all sites is that MBT therapists and MBT supervisors will not be allowed to be in contact with participants in the PAU arm of the trial. PAU will last for 12 months, after which participants who still have time remaining on their licence or community sentence will remain under the supervision of their Probation Trust for the duration of their licence or community sentence. It is hoped that this will facilitate the participants' availability for outcome measures and data collection.

Randomised controlled trial:
Participants will be randomly allocated in a 1:1 ratio to receive Mentalization Based Therapy (MBT) or Probation as Usual (PAU), and will follow the same protocol as the pilot study (see above).

Intervention Type
Behavioural

Primary outcome measure
Pilot study and randomised controlled trial:
Frequency of aggressive acts will be measured using a self-report 5-item version of the Overt Aggression Scale Modified at baseline and at every 3 months during treatment (i.e., months 3, 6, 9, and 12) and every 3 months post-treatment for one year (i.e., months 15, 18, 21, and 24).

Secondary outcome measures

Pilot study:
Unless otherwise stated, the secondary outcome measures are collected at baseline and every 6 months during treatment (i.e., months 6 and 12) and every 6 months post-treatment for one year (i.e., months 18 and 24).

1. Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM). A self-report questionnaire designed to be administered before and after therapy. The client is asked to respond to 34 questions about how they have been feeling over the last week, using a 5-point scale ranging from 'not at all' to 'most or all of the time'. The 34 items of the measure cover four dimensions: Subjective well-being, Problems/symptoms, Life functioning, and Risk/harm.
2. Psychopathic Personality Inventory- Revised (PPI-R 154; Lilienfeld, 2005). The PPI-R is a 154-item self-report measure of both global psychopathy and the component traits of psychopathy. Like the original PPI, the PPI-R is construct valid, time efficient, and can detect response styles potentially relevant to psychopathy (i.e. positive or negative impression management, random or careless responding). Rather than focusing exclusively on antisocial or criminal behaviors, the PPI-R measures the continuum of psychopathic personality traits present in a range of individuals and can be used in both clinical (e.g. forensic) and non-clinical (e.g. student, community) settings.
3. MacArthur Community Violence Screening Instrument (MCVSI; Steadman et al., 1998; 2000): 18-item semi-structured interview to measure the frequency with which individuals have been subject to and/or have engaged in particular violent behaviours.
4. Offending behaviour structured interview for offending behaviour designed to record offending activity. Consists of 17 “yes” or “no” self-report response-type questions. Each question is related to a different type of offence (e.g., theft of motor vehicles, shoplifting, possession of an offensive weapon/firearms, and drug offences). Adapted from adapted from the self-report offending questionnaire from the Cambridge study by David Farrington (2006).
5. State Trait Anger Expression Inventory 2 (STAXI-2; Spielberger, 1999): 57-item self-report measure to investigate the experience, expression of anger and control of anger. Comprises of six subscales, including state anger, trait anger, anger expression out, anger expression in, anger control out and anger control in, and anger expression index.
6. Euroqol5 (EQ5D): Standardised self-report instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple 5-item descriptive profile and a single index value for health status.
7. Brief Symptom Inventory (BSI; Derogatis, 1993; Derogatis & Melisaratos, 1983): A short form of the Symptom Checklist90Revised, is a 53-item self-report screening instrument used to assess the psychological symptom patters of the participants. Nine primary symptom scales: Somatization, Obsessive Compulsive, Interpersonal Sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation, and Psychoticism.
8. Social Functioning Questionnaire (SFQ; Tyrer et al., 2005): 8-item self-report scale, with items covering the domains of home, work, leisure, and relationships.
9. Barratt Impulsiveness Scale (BIS; Patton et al., 1995): The most widely used self-report measure of impulsive personality traits, consists of 30-items.
10. Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993): 10-item self-report test developed by the World Health Organization to determine if a person's alcohol consumption may be harmful.
11. Drug Use Disorders Identification Test (DUDIT; Berman et al., 2007): 11-item self-report test developed as a parallel instrument to the AUDIT for identification of use patterns and various drug-related problems.
12. Secure Facilities Service Use Schedule (SFSUS; Barrett & Byford, 2007): Researcher is able to collect meaningful individual level service use information for the economic evaluation of services provided within secure facilities. The schedule includes information on the service user’s accommodation, including time spent in a secure facility such as prison or secure NHS unit, use

of all health, social, voluntary sector services, psychotropic medication and contact with the police, lawyers and the courts.
12. Service Engagement Scale (SES; Tait et al, 2002): 14-item clinician-rated measure consisting of statements that assess client engagement with services. The scale has high internal consistency and retest reliability, including discrimination between criterion groups, in an assertive outreach team (Tait et al, 2002).
13. Client Satisfaction Questionnaire (CSQ; Larsen et al., 1979): 8-item self-report statement of satisfaction with health services. This will be collected at 12 months only.
14. Suicidal Behaviours Questionnaire–Revised (SBQ–R; Osman et al., 2001): brief 4-item self-report measure of suicidal behaviour and past attempts.
15. Self Harm Inventory (SHI; Sansone, 1998): 22-item, yes/no, self-report questionnaire used to assess self harm and suicidal behaviour.

A subsample of the participants (50%) will also have the oppertunity to complete the following measures:
1. Reflective Functioning Questionnaire-54 (RFQ54; Luyten, under development): 54-item self-report scale to measure mentalization capacities with regards to self and others.
2. Movie for the Assessment of Social Cognition (MASC) is a sensitive video-based test for the evaluation of subtle mind reading difficulties.
3. Social Hierarchy game is interpersonal exchange game in which two players make decisions that determine which player has control of a monetary endowment and one which has no control of monetary endowments across a series of interactions. The paradigm tests how participants evaluate the benefits and costs of aggressive actions, as they learn, develop, and update expectations of social partners.
4. InvestorTrustee game (King Casas et al., 2008) is an interpersonal exchange game in which a player makes a series of decisions to either trust or repay trust in a social partner.

Randomised controlled trial:
Unless otherwise stated, the secondary outcome measures are collected at baseline and every 6 months post randomisation.
1. Violent behaviour is measured using the MacArthur Community Violence Screening Instrument (MCVSI) at baseline and every 3 months post randomisation until 24 months.
2. Health outcomes are measured using the Euroqol5 (EQ5D)
3. Psychological symptom patters are measured using the Symptom Checklist-90 Revised (SCL-90-R)
4. Alcohol use is measured using the Alcohol Use Disorders Identification Test (AUDIT)
5. Illegal drug use is measured using the Drug Use Disorders Identification Test (DUDIT)
6. Self-harm behaviours are measured using the Self-Harm Inventory (SHI)
7. Suicidal Behaviours are measured using the Suicidal Behaviours Questionnaire–Revised (SBQ-R)
8. Levels of service engagement is measured using the Service Engagement Scale (SES)
9. Individual level service use is measured using the Secure Facilities Service Use Schedule (SF-SUS)
10. Psychological Personality traits are measured using the Personality Inventory for DSM-5 Brief Form (PID-5-BF)
11. Mentalization capacities with regards to self and others is measured using the Brief reflective function Questionnaire (B-RFQ)

Overall study start date
01/01/2016

Completion date

31/12/2020

Eligibility

Key inclusion criteria
1. Subject to statutory provision by the National Probation Service
2. Male aged 21 or over
3. At least 6 months remaining of their license or community sentence
4. Adequate level of English
5. Evidence of a history of violent behavior, that may include:
5.1. Verbal assault
5.2. Assaults against objects
5.3. Assault against others
6. DSM-IV-R diagnosis of ASPD (using SCID-II)
7. Evidence of recent aggressive acts (using OAS-M)

Participant type(s)
Other

Age group
Adult

Sex
Male

Target number of participants
302

Key exclusion criteria
1. Conviction for child sexual offences (including child pornography)
2. Current diagnosis for schizophrenia or bipolar disorder
3. Neurodevelopmental disorder or significant cognitive impairment
4. Severe substance or alcohol dependency

Date of first enrolment
01/03/2016

Date of final enrolment
30/05/2018

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Westminster Probation Office (pilot and RCT)
1 Dorset Close
London
United Kingdom
NW1 5AN

Study participating centre
Mersey Forensic Psychology Services (pilot and RCT)
36 Rodney Street
Liverpool
United Kingdom
L1 9AA

Study participating centre
The Lincolnshire & North Yorkshire Probation Service (pilot and RCT)
8 Corporation Street
Lincoln
United Kingdom
LN2 1HN

Study participating centre
Southwark probation (pilot and RCT)
2 Great Dover Street
London
United Kingdom
SE1 4XW

Study participating centre
Llanelli Probation Service (RCT only)
Lloyd Street
Llanelli
United Kingdom
SA15 2PU

Study participating centre
Exeter National Probation Service (RCT only)
Queens House Little Queen Street
Exeter
United Kingdom
EX4 3LJ

Study participating centre
Tamworth Probation Office (RCT only)
Moor Street
Tamworth
United Kingdom
B79 7QZ

Study participating centre
Lancashire Probation Trust (RCT only)
50 Avenham Street
Preston
United Kingdom
PR1 3TD

Study participating centre
Bristol Central National Probation Service Office (RCT only)
Marlborough Street
Avon
Bristol
United Kingdom
BS1 3NU

Study participating centre
West Yorkshire Probation (RCT only)
Waterloo House
58 Wellington Street
Leeds
United Kingdom
LS1 2EE

Study participating centre
Castle Quay probation (RCT only)
9 Castle Quay
Castle Boulevard
Nottingham
United Kingdom
NG7 1FW

Study participating centre
Stoke Newington Probation Service (RCT only)
Reed House
2-4 Rectory Road
Stoke Newington
London
United Kingdom
N16 7QS

Study participating centre
Lewisham Probation Office (RCT only)
208 Lewisham High Street
London
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SE13 6JP

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
University College London
Gower Street
London
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WC1E 6BT

Sponsor type
Research organisation

Website
http://www.ucl.ac.uk/jro

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
The Michael J Samuel Charitable Trust (charity number: 327013)

Funder Name
National Institute for Health 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

Publication and dissemination plan
The results of the study will be disseminated through publications in peer reviewed journals as well as presentations, newsletters and articles through the probation and prison system and third sector organisations working within the criminal justice system.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/12/2020	04/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/03/2025	23/04/2025	Yes	No