ISRCTN92005743 https://doi.org/10.1186/ISRCTN92005743

Mentalization-based therapy for individuals with probable complex post-traumatic stress disorder

Submission date
27/05/2025

Recruitment status
Recruiting

Registration date
19/09/2025

Overall study status
Ongoing

Last Edited
19/09/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
To date, treatments that effectively address both the symptoms of complex trauma and personality difficulties that characterise complex post-traumatic stress disorder (CPTSD) are rare. The burden of CPTSD in the UK includes significant psychiatric comorbidity, chronic illness, and an elevated risk of suicide. Mentalization-Based Treatment - Trauma Focused (MT-TF) aims to directly address the impact of trauma in a complex presentation and alleviate patients' distress in tailored, inclusive, non-stigmatising and non-discriminating treatment pathways that mitigate the risk of drop out by integrating trauma processing. This study aims to compare MBT-TF with TAU for adults meeting the diagnostic criteria for CPTSD in personality disorder services.

Who can participate?
Males, females, individuals who do not identify as male or female, aged 18 - 65 years old, who meet PTSD criteria with sufficient knowledge of the English language.

What does the study involve?
Participants are randomised to MT-TF or Treatment as Usual (TAU). Participants randomised to MBT-TF will receive weekly group therapy sessions lasting 90 minutes. Treatment will involve approximately 36 group sessions and up to 5 individual supportive therapy sessions as needed over a 9-month period. Baseline data will be collected pre-randomisation. Participants will be followed up at 3, 9 and 15 months post-randomisation.

What are the possible benefits and risks of participating?
There is minimal risk from randomisation and treatment to the participants themselves. Both MBT-TF and TAU will be delivered by experienced professionals used to working with this client group. Those who agree to participate in the trial will be involved in a number of time-consuming interviews and assessments, which may be somewhat burdensome but do not carry specific risk. The researchers are experienced in conducting assessments and encourage regular breaks to be taken by the participant if necessary. By agreeing to take part, the participant will receive a treatment intervention that would not normally be offered. The outcomes of the evaluation could also improve the provision of interventions for other patients.

Where is the study run from?
North London NHS Foundation Trust is sponsoring the study and University College London is the lead.

When is the study starting and how long is it expected to run for?
March 2025 to June 2028

Who is funding the study?
University College London (UK)

Who is the main contact?
1. Dr Tobias Nolte, Tobias.NolteMD@annafreud.org
2. Prof. Patrick Luyten, p.luyten@ucl.ac.uk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
340141

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Randomized controlled trial to compare clinical effectiveness and cost-effectiveness of mentalization-based treatment - trauma focused versus treatment as usual for people with probable complex post-traumatic stress disorder in mental health services in England

Acronym
MBT-TF

Study objectives
The aim of this study is to conduct a randomised controlled trial (RCT) to investigate whether Mentalization-Based Treatment - Trauma Focused (MT-TF) is an effective treatment for individuals who meet threshold for diagnostic criteria for complex post-traumatic stress disorder (CPTSD) in personality disorder (PD) services compared to Treatment as Usual (TAU).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/03/2025, London - Hampstead Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8284; hampstead.rec@hra.nhs.uk), ref: 25/LO/0137

Study design
Multi-site superiority single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Complex post-traumatic stress disorder (CPTSD)

Interventions
Participants are randomised (minimization, 1:1) to Mentalization-Based Treatment - Trauma Focused (MT-TF) or Treatment as Usual (TAU).

Participants randomised to MBT-TF will receive weekly group therapy sessions lasting 90 minutes. Treatment will involve approximately 36 group sessions and up to 5 individual supportive therapy sessions as needed over a 9-month period.

Participants will be followed up at 3, 9 and 15 months post-randomisation.

Intervention Type
Behavioural

Primary outcome(s)
Symptoms of complex post-traumatic stress disorder (CPTSD) assessed by the International Trauma Questionnaire (ITQ) at baseline (T1), 3-month follow-up (T2), 9-month follow-up (T3) and 15-month follow-up (T4).

Key secondary outcome(s))
1. Diagnosis of Borderline personality disorder will be measured by the Borderline Symptom List at baseline (T1), 9-month follow-up (T3) and 15-month follow-up (T4).
2. Childhood trauma will be measured by the Childhood Trauma Questionnaire at baseline (T1) only.
3. Disturbance, impulsivity, severity of personality disorder, global functioning, social functioning, interpersonal functioning, suicide ideation and behaviour, sense of belonging, self-care, emotional distress and health related quality of life will be measured by the International Consortium for Health Outcomes Measurement Personality Disorder List at Collected at baseline (T1), 9 month follow up (T3) and 15 month follow up (T4).
4. Diagnosis of PTSD will be measured by the Clinician Administered PTSD Scale for DSM-5 at baseline (T1), 9 month follow up (T3) and 15 month follow up (T4) and Clinician Administered PTSD Scale for DSM-5 at baseline (T1), 9 month follow up (T3) and 15 month follow up (T4).
5. Levels of personality functioning will be measured by the Level of Personality Functioning Screener-Brief Form at baseline (T1), 9-month follow-up (T3) and 15-month follow-up (T4).
6. Interpersonal difficulties will be measured by the Inventory of Personal Problems at baseline

(T1), 9-month follow-up (T3) and 15-month follow-up (T4).
7. Quality of life will be measured by the EQ-5D-5L at baseline (T1), 9-month follow-up (T3) and 15 month follow up (T4).
8. Dissociative experiences will be measured by the Dissociative Experiences Scale-II at baseline (T1), 3-month follow-up (T2), 9-month follow-up (T3) and 15-month follow-up (T4).
9. Psychological distress and psychiatric disorder will be measured by the Brief Symptom Inventory 18 at baseline (T1), 3-month follow-up (T2), 9-month follow-up (T3) and 15-month follow-up (T4).
10. Individual's feeling of loneliness will be measured by the UCLA Loneliness Scale Short Form at baseline (T1), 9-month follow-up (T3) and 15 month follow up (T4).
11. Trust in communicated knowledge will be measured by the Epistemic Trust, Mistrust and Credulity Questionnaire at baseline (T1), 9-month follow-up (T3) and 15-month follow-up (T4).
12. Reflective functioning will be measured by the Reflective Functioning Questionnaire at baseline (T1), 9-month follow-up (T3) and 15-month follow-up (T4)
13. Indicators of failures in mentalizing trauma and adverse relationships will be measured by the Failure to Mentalize Trauma Questionnaire at baseline (T1), 3-month follow-up (T2), 9-month follow-up (T3) and 15-month follow-up (T4).
14. Patient experiences will be measured by the Helping Alliance Questionnaire at baseline (T1) and 9-month follow-up (T3) and Client Satisfaction Questionnaire at 9-month follow-up (T3) only.
15. Feelings of shame related to experiencing traumatic events will be measured by the Trauma-Related Shame Inventory at Baseline (T1), 3-month follow-up (T2), 9-month follow-up (T3) and 15-month follow-up (T4).
16. Service use will be measured by the Adult Service Use Schedule at baseline (T1), 9-month follow-up (T3) and 15-month follow-up (T4).
17. Post-traumatic growth will be measured by the Posttraumatic Growth Inventory - Expanded at baseline (T1), 3-month follow-up (T2), 9-month follow-up (T3) and 15-month follow-up (T4).

Completion date
01/06/2028

Eligibility

Key inclusion criteria
1. Aged 18-65 years
2. Meeting PTSD criteria on the ITQ in combination with at least one symptom from each Disturbances in Self-Organization (DSO) cluster, with functional impairment associated with these symptoms as assessed by the ITQ at screening equivalent to CPTSD diagnosis.
3. Scoring ≥31 on the LPFS-BF (36) at screening, which corresponds to 1.5 standard deviations above the latent mean (T score of 65), indicating at least moderate severity in terms of personality disorder features.
4. Sufficient knowledge of the English language.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Current psychotic episode
2. Diagnosis of severe neurological disorder

Date of first enrolment
01/06/2025

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Oxleas NHS Foundation Trust
Pinewood House
Pinewood PLACE
Dartford
United Kingdom
DA2 7WG

Study participating centre
Merseycare NHS Trust
V7 Building
Kings Business Park
Prescot
United Kingdom
L34 1PJ

Study participating centre
Kent and Medway NHS and Social Care Partnership Trust
Farm Villa
Hermitage Lane
Maidstone
United Kingdom
ME16 9PH

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

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
United Kingdom
BA1 3QE

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
South West London and St. George's Mental Health NHS trust
Springfield Hospital
61 Glenburnie Road
London
United Kingdom
SW17 7DJ

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Trust Headquarters
Block B2
St Ann's Hospital
St Ann's Road
London
United Kingdom
N15 3TH

Sponsor information

Organisation
Noclor

Funder(s)

Funder type
University/education

Funder Name
University College London

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated for this study will be stored on secure systems at University College London in line with ethical approvals and data protection guidelines. Patient-level data will not be made available due to the sensitive nature of the data collected.

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	Participant information sheet	11/11/2025	11/11/2025	No	Yes