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Body-oriented psychological therapy for patients with complex post-traumatic stress disorder

Submission date
25/03/2024

Recruitment status
No longer recruiting

Registration date
08/05/2024

Overall study status
Ongoing

Last Edited
02/09/2025

Condition category
Mental and Behavioural Disorders

[X] 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
Patients suffering from the consequences of significant life trauma who have been diagnosed with complex post-traumatic stress disorder (PTSD) experience significant problems with their emotion regulation and often display a range of somatic symptoms such as increased arousal, generalised pain and numbness, dissociation (fragmentation between mind and body) and self-harming or suicidal behaviours. Up to 50% of these patients do not significantly improve following standard psychotherapeutic treatments such as trauma-focused talking therapies (cognitive behaviour therapy or CBT). According to trauma therapy experts, the variety of physical symptoms following experiences of trauma (in particular abuse or neglect) are regarded as significantly important for the prognosis of the disorder. Body-centered approaches have therefore been recommended to become a key component of trauma therapy as a key part of the healing process. There is however a lack of systematic research to explore the efficacy and effectiveness of these treatments. As many of the core symptoms are psychosomatic, this proof-of-concept study aims to ascertain if manualised body-oriented psychological therapy (BOPT), an innovative therapeutic intervention, will be acceptable for complex-PTSD sufferers and is likely to impact trauma symptoms including PTSD, subjective quality of life, physical health and emotional regulation.

Who can participate?
Adult patients aged from 18 to 65 years old and a confirmed diagnosis of complex PTSD identified as suitable for trauma therapy and registered on a waiting list for therapy at one of the research sites

What does the study involve?
The study will take place in two NHS Trusts, both with specialist trauma services. The study will assess the acceptance, safety and therapeutic impact of the intervention. 30 patients (15 from each Trust), diagnosed with complex PTSD, will be invited from the trauma therapy waiting lists. 24 patients (12 per site) will be recruited and offered 40 sessions of group BOPT. Patients will be

assessed pre-post therapy and 3-months after the treatment on a range of quantitative and qualitative measures. The experience of taking part in this therapy will be evaluated systematically, and adherence to and utility of the manual will also be evaluated.

What are the possible benefits and risks of participating?
What are the potential benefits of participating?
According to the main hypothesis, the study team assumes that research participants will have direct therapeutic benefits from taking part in this group therapy study. The rationale for the benefits of BOPT for people with complex PTSD disorder is strong, given the importance of somatisation/dissociation and emotional dysregulation problems for the course and prognosis of the illness and given the fact that the body is often the place where the trauma took place. In addition, there is preliminary positive evidence of this type of intervention gathered for people who had been traumatised as well as for people with other diagnoses. Participants receive this novel intervention in the absence of other available treatments on the NHS, i.e. whilst waiting for significant periods of 12 months on average, and the therapy is provided by experienced trauma therapists. The treatment offers an intensive support package with in-between-session check-in and the format being investigated (group therapy) is well established and promises to add additional elements of peer support for the benefit of participants.

Emphasis is placed on the 'patient-therapist' alliance aspect and co-production elements (peer-support, homework tasks) within group BOPT, which means that a positive working alliance is built with therapist and co-therapist to foster engagement with the therapy, maximise learning within training sessions, and aid in the process of setting goals. It is believed that the results from this BOPT in complex-PTSD study will lead to a better understanding of the processes involved in developing complex-PTSD symptoms and to significant improvements in mental health care (i.e. diversification of portfolio of evidence-based interventions for this patient group).

Potential risks of participating and mitigating actions.
Research participants will be offered a trauma-focused body psychotherapeutic intervention. Therapy aims to support patients in making sense of and addressing their difficulties whilst exploring and acknowledging the complex psychosomatic nature of their symptoms and their physical resilience. The therapy process can understandably be unsettling, as it aims to help participants connect with and process difficult experiences and feelings. Importantly, the examination of the potential occurrence of and dealing with adversity comprises part of the study aims to ascertain whether manualised group BOPT is acceptable to cPTSD patients.

There is a small risk that patients will not engage positively with, or more importantly have an adverse emotional reaction to the intervention. As in any form of psychological trauma therapy, patients may be experiencing distress temporarily whilst processing memories of the trauma they experienced. Patients may understandably feel stirred up during this process. However, the research clinicians are aware of this and experienced in working with individuals who have experienced trauma and following a therapeutic pace that acknowledges and monitors patients' window of tolerance. It is envisaged that the therapy will be challenging enough, so that emotional connection and processing can take place, but not too disturbing, so that individuals will remain safe and contained. There is existing preliminary evidence indicating that people find a body-oriented psychological therapy approach helpful and acceptable due to its focus on resilience and resource orientation. The study team will ensure that the therapists are comprehensively trained and prepared to handle such situations. Participants will be aware of the opportunity to take breaks or ask questions whenever required.
Both locations in which the study will take place (Tavistock Trauma Centre, East London NHS Trust mental psychological therapy service) provide standard safeguarding measures for adverse

situations. Therapeutic progress is closely monitored during monthly weekly supervision sessions and at both locations, therapists can always access crisis services.

Additional measures have been put in place to monitor participant distress:
1. Participants are asked to rate their overall well-being and optimism (0–10) before and after each session, which is used to assess the immediate session impact
2. After each session, participants complete a 5-item questionnaire rating attributes of the session on a continuum from 1 to 7 with their response to the session. The construct measures are personal safety, self-confidence, quality of relationship with others, stress reduction, and somatic symptom severity.

If individuals become distressed and the risk to themselves or others increases significantly, additional crisis support available in the participating services or boroughs can be offered with access to the full range of mental health services, this includes (but is not limited to) access to a crisis line, crisis services, such as the Home
Treatment Team, and acute inpatient care. In the unlikely event that a researcher may need to break confidentiality due to concern for any individual's welfare, the researcher will make contact with the study clinicians to inform them of any potential risks. This process will have been discussed in advance with study participants and also documented in the Participant Information Sheet. Participants will be encouraged to express their preferences as to whom they would like to be contacted and how they would prefer this to be done. This specific information for each participant will also be separately documented in a contact form, which is held in a secure NHS electronic facility.

Where is the study run from?
East London NHS Foundation Trust

When is the study starting and how long is it expected to run for?
March 2023 to April 2026

Who is funding the study?
1. City, University of London
2. Tavistock and Portman NHS Trust Charity

Who is the main contact?
Prof Frank Rohricht, frank.rohricht@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
337610

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 337610

Study information

Scientific Title
Exploring group body-oriented psychological therapy for the treatment of patients with complex PTSD: a proof of concept cohort study utilising a manualised treatment protocol

Acronym
COBOLT

Study objectives
This proof-of-concept study aims to ascertain how manualised group body-oriented psychological therapy (group-BOPT) can be offered to patients with complex PTSD and to explore the potential benefits of the therapy (i.e. determining its fitness for purpose, relevance, and potential effects in reducing core symptoms of complex PTSD and corresponding subjective quality of life).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/06/2024, London – City & East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048171; cityandeast.rec@hra.nhs.uk), ref: 24/LO/0372

Study design
Two-site proof-of-concept uncontrolled interventional study

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life, Treatment

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

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

Interventions
The present intervention was developed whilst building upon the existing theory of psychological trauma and a model of embodied cognition informed by psychoanalytic theory; it integrates elements of various forms of body-oriented psychological therapy into a theory-driven manualised approach that is mapped into a total of 40 therapy sessions over 12 months.

• 10 sessions in a stabilization phase, thematically defined according to the core symptomatology targeted by the intervention
• 20 sessions in a trauma processing phase (here the therapists use modified interventions from the repertoire of the stabilization phase to be able to respond flexibly to the processes in the group)
• 10 sessions of narrative formation and closure

The intervention broadens its scope from core symptoms to incorporate the interpersonal targets of social benefits in a group intervention, and the intrapersonal targets of somatic adjustments.
Two groups of 12 patients with a diagnosis of complex PTSD will be recruited from the waiting list of the Specialist Tavistock Trauma Centre and East London NHS Foundation Trust to participate in a 40-session manualised group therapy programme, developed for this study by a group of international body psychotherapists with experience in psychotrauma therapy. All patients will be included in the study analysis and offered follow-up assessments irrespective of the number of sessions attended (according to proof-of-concept study questions and aims).
The therapy will be delivered by a UKCP-registered psychotherapist with accredited training in one of the body-oriented psychological therapy modalities and co-facilitated by a trauma therapist from the trauma service. The co-therapist will be identified from each of the two clinical sites (trauma therapist with training in psychodynamic or psychoanalytic psychotherapy). Both therapists will receive monthly supervision from one of two experienced trauma therapists (one Consultant Psychiatrist, and one Dance Movement Psychotherapist).

Intervention Type
Behavioural

Primary outcome measure
PTSD symptoms measured using the PTSD Checklist for DSM-5 (PCL-5) at baseline, after therapy at 42 weeks, and at follow-up 3-months after the end of therapy

Secondary outcome measures
The pre-test/post-test design will assess the following secondary outcome measures at baseline, at the end of the 40-week therapy, and 3-months follow-up:
1. Health-related subjective quality of life measured using the Subjective Quality of Life (Short Form-36 Health Survey)
2. Somatic symptom severity measured using the Patient Health Questionnaire-15 (PHQ-15)
3. Body image aberration measured using the Dresdner Body Image Scale (DKB-35)
4. Degree of somatic dissociation symptoms measured using the Somatoform Dissociation Questionnaire (SDQ-20)
5. Difficulties in Emotion Regulation measured using the Emotion Dysregulation Scale, short version (EDS-short)
6. Self-selected personal therapy goals measured using the Measure Yourself Medical Outcome Profile (MYMOP) scale

1. The intervention feasibility outcomes will be measured as:
1.1. The intervention sessions attended by each participant using data recorded during the study
1.2. Participants will be asked to rate the following questions after completing each session "How easy was it to participate in and complete this session?" and "How useful was this session for you?", on a scale of 0 (very difficult/not helpful) to 10 (very easy/very helpful).

2. The feasibility of outcome measures will be assessed as:
The percentage of pre- and post-intervention questionnaires completed measured using data recorded during the study

3. Session impact will be assessed as:
Participants are asked to rate their overall wellbeing and optimism (0–10) before and after each session, which are used to assess the immediate session impact.

4. Process evaluation will be assessed as:
Personal safety, self-confidence, quality of relationship with others, stress reduction, and somatic symptom severity measured using a 5-item questionnaire rating attributes of the session on a continuum from 1 to 7 with their response after each session

5. Adherence to treatment fidelity measured according to a specific adherence scale (core components of the manual).

6. Experiences of the therapy will be measured through semi-structured interviews with participants and the therapists to determine their views of the intervention and potential future implications, analysed using a framework approach informed by the therapeutic model at the end of therapy

Overall study start date
01/03/2023

Completion date
30/04/2026

Eligibility

Key inclusion criteria

1. A confirmed diagnosis of complex PTSD according to the International Trauma Questionnaire (ITQ)
2. Identified as suitable for trauma therapy and registered on a waiting list for therapy at one of the research sites
3. Age range 18-65 years old
4. Capacity to give informed consent and a basic command of the English language
5. Stable psychotropic medication (no medication or no change in medication in the last 3 months and no anticipated change)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20-24

Key exclusion criteria
1. Organic mental disorder
2. Confirmed Diagnosis of Dissociative Identity Disorder
3. Psychotic mental states
4. No capacity to give informed consent (monitoring of capacity will occur throughout)
5. Risk of suicide or self-harming behaviour necessitating hospitalisation
6. Any medical condition that restricts movements severely (immobility)

Date of first enrolment
01/07/2024

Date of final enrolment
30/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
London
United Kingdom
E1 8DE

Study participating centre
Tavistock and Portman NHS Foundation Trust
The Tavistock Centre
120 Belsize Lane
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United Kingdom
NW3 5BA

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.elft.nhs.uk

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
University/education

Funder Name
City, University of London

Alternative Name(s)
City, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Tavistock and Portman NHS Trust Charity

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication

Intention to publish date
01/06/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from the principal investigator, Prof Frank Rohricht, frank.rohricht@nhs.net. The type of data that will be shared are anonymized data sets at reasonable request once study results have been published. Written informed consent will be obtained from participants. All information obtained will be pseudonymised using identifier codes and separating assessment records from a list of identifier codes. The study will await ethical approval through REC/UK before commencing.

IPD sharing plan summary
Available on request