ISRCTN76699092 https://doi.org/10.1186/ISRCTN76699092

A feasibility trial of psychological therapies for trauma survivors at risk of severe mental health difficulties

Submission date
20/06/2023

Recruitment status
No longer recruiting

Registration date
29/06/2023

Overall study status
Ongoing

Last Edited
05/01/2026

Condition category
Mental and Behavioural Disorders

[X] 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
Many young people and adults who have had unusual experiences (such as hearing unusual sounds or murmurs, feeling like something is different or not quite right, periods of confusion, or feeling unsafe) have also experienced distressing life events in their past, which can affect their wellbeing. The psychological and emotional impact of these distressing life events is, however, often not considered in routine psychological therapies that are offered to this clinical group. Previous research has shown that people who have experienced distressing life events can have more severe long-term mental health difficulties, and specific psychological therapies focused on traumatic experiences are safe for and acceptable to people who have already 'transitioned' to a first full-blown episode of psychosis.
Eye Movement Desensitization and Reprocessing (EMDR) and Trauma-Focussed Cognitive Behaviour Therapy (TF-CBT) are both used as therapies for people who have experienced stressful life events and mental health difficulties that result from traumatic life experiences. However, we still do not know which of the therapies could be most helpful for people who have had distressing life experiences and unusual experiences, but who have not yet 'transitioned' to a first full-blown episode of psychosis.
This study is a feasibility randomised controlled trial (RCT) which aims to find out whether EMDR and TF-CBT can be delivered to and are safe and helpful for and acceptable to people who have experienced distressing life experiences and might be at risk of a future episode of psychosis. The trial will involve comparing patients who receive sessions of EMDR, patients who receive TF-CBT, and patients who only receive their usual care, over a 9-month therapy period. The trial, if successful, will pave the way for a larger-scale research study across multiple NHS Trusts to clarify whether EMDR and/or TF-CBT could be offered routinely to clients who have experienced trauma, and psychological difficulties as a result of difficult life experiences.

Who can participate?
Patients 16 years of age or older who have been assessed as having an at-risk mental state (ARMS) and have had traumatic experiences in the past

What does the study involve?
Following consent, participants will be asked to meet with a researcher to complete some questionnaires and an interview about unusual experiences and difficulties they may have had in the past and about the care they have been receiving from NHS mental health services. These questions will help the research team to understand if the trial is right for individuals.
If the trial is suitable, participants will be asked to complete some more questionnaires with a member of our research team, before then being allocated at random to one of the three groups:
1. Trauma-focused cognitive behaviour therapy (TF-CBT) for 9 months plus usual NHS treatment (TAU).
2. Eye Movement Desensitization and Reprocessing (EMDR) for 9 months plus usual NHS treatment over 9 months.
3. Usual NHS treatment only.
Participants who are assigned to receiving EMDR plus TAU or TF-CBT plus TAU as part of the study will meet with a trained trial therapist in person, over the phone or via video call for up to 24 90-minute therapy sessions over a 9-month period with the number and frequency of sessions decided by participants.
In a typical session of EMDR, the therapist will work with participants to teach them strategies to deal with distressing thoughts and feelings. They will be then asked to call to mind a disturbing issue or event while the therapist will encourage them to do some other tasks that can help people to reduce the distress caused by the event (for example, perform side-to-side eye movements). In a typical session of TF-CBT, the therapist will work with participants to improve difficulties brought about by trauma. They will be asked to work on memories or images linked to difficult events from their past. For example, they could be asked to recall a memory and talk through it and explore it. The idea behind this is that the more we revisit a memory the less distressing it may become.
During the study, all participants will continue to receive their usual NHS care. This may or may not involve taking medication or receiving other help arranged by other NHS professionals involved in their care.
After completing the therapy sessions, roughly 9 months into the study, a member of the research team will meet with all participants for the follow-up assessment, which involves completing most of the questionnaires they helped the team with at the beginning of the trial. They may also be asked to take part, if they wish to, in a more in-depth interview with a member of the research team about their experiences of the therapy. With their permission, the research team will check their NHS medical notes 12 months after they started the trial to better understand how the therapies might impact people's wellbeing.

What are the possible benefits and risks of participating?
The initial assessment may help to highlight any problems participants are experiencing. If appropriate, the team will signpost participants to other services that they may find helpful. They will also be offered the chance to discuss the initial assessment with a clinically qualified member of the research team.
About two-thirds of the people in the study will be allocated at random to receive EMDR or TF-CBT. It is possible that receiving these therapies will improve their mental health. However, this cannot be ensured, but the information we get from this study will help us to better support people who have experienced psychological difficulties because of traumatic life events in the future.
It is possible that talking about some of these issues during the assessments may be upsetting. Participants will have the opportunity to discuss any concerns they have with the researchers, and they are free to withdraw from the study at any point without giving a reason. If they decide they would like to withdraw from the research, this decision will not affect any care they may receive now or in the future.

The results of the study will be made available to participants, if they wish to, to give them a deeper insight into the therapy and how other people responded to it. The results and findings will not contain any information regarding the identity of any of the participants in the study.

Where is the trial run from?
The trial is sponsored by The University of Manchester and is being run from Greater Manchester Mental Health NHS Foundation Trust. Participants will be recruited from four additional NHS Trusts including:
1. Pennine Care NHS Foundation Trust
2. Manchester University NHS Foundation Trust
3. Mersey Care NHS Foundation Trust
4. Lancashire and South Cumbria NHS Foundation Trust

When is the trial starting and how long is it expected to run for?
December 2022 to April 2026

Who is funding the trial?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Kim Cartwright (Project Manager) Kim.Cartwright@gmmh.nhs.uk
2. Filippo Varese (Chief Investigator) Filippo.Varese@manchester.ac.uk

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323676

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 323676, CPMS 56377, NIHR300850

Study information

Scientific Title
The RESTART Trial: a feasibility clinical trial of psychological therapies for trauma in people with an at-risk mental state

Acronym
RESTART

Study objectives
The principal research question is to determine whether it is feasible to conduct a future definitive trial of trauma therapies (eye movement reprocessing and desensitization [EMDR] and trauma-focused cognitive behaviour therapy [TF-CBT]) for people with an at-risk mental state (ARMS) (for psychosis) via examination of four key feasibility outcomes:
1. Trial recruitment
2. Trial retention
3. EMDR/TF-CBT treatment engagement
4. EMDR/TF-CBT treatment fidelity

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/05/2023, West Midlands - South Birmingham Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8345; southbirmingham.rec@hra.nhs.uk), ref: 23/WM/0113

Study design
Single-blind feasibility randomized controlled trial with two nested qualitative studies

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
NHS service users who meet at-risk mental state (ARMS) criteria, operationally defined using the Comprehensive Assessment of At-Risk Mental States (CAARMS) interview

Interventions
Participants will be randomised using a ratio of 1:1:1 to one of three different groups including:

1. Eye Movement and Desensitization Reprocessing (EMDR) plus treatment as usual (TAU) - EMDR involves memory representations of traumatic life experiences being reprocessed in order to decrease the distress caused by them and change the dysfunctional beliefs and perceptual associations related to the traumatic event. This is achieved through an eight-phase treatment protocol that aims to address past memories, present triggers and future templates. The intervention offered as part of this trial has been modified and expanded relative to the usual approach taken in the treatment for post-traumatic stress disorder (PTSD) in order to account for specific issues related to the experience of psychotic symptoms and their impact on the client's well-being.

2. Trauma-Focused Cognitive Behaviour Therapy (TF-CBT) plus TAU - TF-CBT is a formulation-based intervention tailored to the specific needs of the clients, depending on their individual presenting problems (e.g., different trauma-related symptoms, prodromal symptoms or other

difficulties that may exacerbate their risk of transition to psychosis). The TF-CBT intervention delivered as part of this trial will be adapted for delivery in individuals with an ARMS from a similar, manualised intervention already developed for a definitive trial of trauma-focused therapy for individuals with schizophrenia-spectrum disorders by integrating intervention strategies and models for the treatment of PTSD and psychotic symptoms (Peters et al., 2022).

3. TAU only - TAU will be in line with all standard and individually prescribed clinical interventions as directed by national clinical guidelines for psychosis/ARMS (National Institute for Health and Care Excellence, 2014) and the participants' clinical teams.

Participants randomised to either EMDR plus TAU or TF-CBT plus TAU will receive 24 sessions of EMDR or TF-CBT over a 9-month treatment window, in addition to TAU. Each session will last up to 90 minutes and will be audio/video-recorded for fidelity monitoring purposes when participants consent to this. Therapy sessions will take place at a mutually convenient location for therapists and participants (e.g., the participant's home, on NHS premises) or remotely.

Randomisation will be independent and concealed, via an online pseudo-random list hosted by sealedenvelope.com with random permuted blocks of varying sizes.

The allocation sequence will be held at an external centralised randomised service and will be revealed via a secure web-based service (sealedenvelope.com). The allocation will use random permutated blocks of varying size, which will not be known to the study team, so allocation concealment is assured.

Following the completion of the baseline assessment, RAs will notify the trial manager and study CI that a given participant can be randomised by providing them with the relevant participant ID. The trial manager or the project CI will be responsible for entering the participant ID on the secure web-based randomisation service provided by sealedenvelope.com. The system will generate an immediate allocation to the trial arm and confirmation emails will be sent to specific members of the team (the trial manager and/or the project CI). In addition to being recorded centrally on the sealedenvelope.com system, allocations will be recorded by the trial manager on a randomisation log accessible only to unblinded members of the research team. The RAs who will conduct the 9-month post-randomisation assessments will be blind to treatment allocation.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of a future definitive trial:
1. The feasibility of trial recruitment and retention and EMDR and TF-CBT engagement to inform a future definitive trial, by establishing the number of participants identified, approached, consented and randomised, and the percentage of participants retained at the 9-month follow-up, and the number of sessions attended by participants allocated to the EMDR+TAU and TF-CBT+TAU arms of the trial, respectively. Data pertaining to recruitment, retention and engagement with the interventions considered in the trial will be gathered via the collection of detailed information on the participants' flow in the RCT, aligned with all relevant fields of the CONSORT framework for feasibility studies as well as information on the number of sessions attended by each individual participant allocated to the EMDR+TAU and TF-CBT+TAU arms of the trial.
2. Sample size calculations for a future larger scale trial informed by examining the 'promise of efficacy' of EMDR and TF-CBT on important quantitative clinical outcomes in this client group at

baseline and the 9-month follow-up and the variance of these outcomes.
3. The feasibility of extracting, via case note reviews, information on psychological interventions and mental health support received as part of usual NHS care (i.e. treatment as usual [TAU]), and information suggestive of a possible transition to first episode psychosis up to 12 months after participant allocation to treatment.
4. The acceptability of the trauma-focussed therapies (i.e. EMDR and TF-CBT) and trial procedures (including randomisation and intended outcome measures to be considered in a future larger scale trial and measures that will enable the possible mechanisms of actions of trauma therapies in people with an At Risk Mental State (ARMS) in a definitive trial) to trial participants via the analysis of transcripts of qualitative interviews with trial participants collected following the 9-month follow-up assessment. The views of and recommendations made by trial participants will be used to refine/make any adaptations to the therapies and trial procedures in preparation for a future definitive trial.
The acceptability of quantitative measures collected will also be examined by considering the completeness (% of missing responses and reasons for missingness) of a range of outcome measures used in previous clinical trials with clients with early psychosis and ARMS (described under secondary outcomes), alongside the completeness of additional mechanistic measures collected at baseline and 9-months follow-up, and during the delivery of EMDR and TF-CBT.
The acceptability of EMDR and TF-CBT will also be examined using the Distress/Endorsement Validation Scale, a brief questionnaire that has previously been used to assess tolerance /acceptability of psychological therapies for trauma, completed at the end of contact with their therapist by trial participants randomly allocated to EMDR+TAU or TF-CBT+TAU.
5. EMDR and TF-CBT fidelity (i.e. the extent to which therapists are able to deliver EMDR and TF-CBT with high levels of treatment, defined as the percentage of therapists and therapy sessions with adequate ratings on measures of EMDR and TF-EMDR treatment adherence/fidelity) assessed using a sample of therapy session video recordings (for a maximum of 10% of the total number of sessions delivered as part of the RCT) which will be rated using relevant treatment fidelity/adherence scales (EFRS and an adapted version of the CTS-R used in other trials of trauma-focussed therapy in people with psychosis).
6. The safety of EMDR and TF-CBT in people with ARMS, assessed via the systematic collection and scrutiny of detailed adverse event (AE) forms (e.g., number of AEs and SAEs related and unrelated to trial procedures and interventions) and signals of symptom exacerbation measured using therapy session measures assessing prodromal and post-traumatic symptoms adapted from previous trials of trauma-focused therapy in psychosis, which will be collected at each therapy session by trial therapists.
7. The views of professional stakeholders on the adaptation and implementation (including the barriers and enablers of successful implementation) of EMDR and TF-CBT in future NHS care for the ARMS group via the analysis of qualitative interviews with trial therapists, supervisors and other professional stakeholders from referring clinical teams and services collected as part of the nested qualitative component of this research.
8. The measurement of health economic outcomes in a future definitive trial using two quality of life and health economic measures (described in the secondary outcome measures).

Key secondary outcome(s))

The outcome measures that will be evaluated within this feasibility study have been adapted from previous studies by the research team, including clinical trials of trauma-focused therapy in people with first-episode psychosis and cohort studies examining the impact of trauma in people with an At Risk Mental State (ARMS), and are as follows:

Trauma symptom measures, completed at baseline and 9 months post-baseline:
1. Trauma, measured using the International Trauma Questionnaire

2. Post-Traumatic Stress Checklist for DSM-5
3. Dissociative Subtype of PTSD Scale

Process of recovery measures, completed at baseline and 9 months post-baseline:
1. Questionnaire about the Process of Recovery

Other symptom measures, completed at baseline and 9 months post-baseline:
1. General Anxiety Disorder Scale (7-item version)

Health-related quality of life/health economic measures, completed at baseline and 9 months post-baseline:
1. EuroQoL 5-Dimension Level (EQ-5D-5L)
2. Adapted version of the Economic Patient Questionnaire

Mechanisms of action of trauma-focussed therapy measures, completed at baseline and 9 months post-baseline:
1. Trauma Memory Questionnaire
2. Brief Post-Traumatic Cognitions Inventory
3. Metacognitions Questionnaire for Post-Traumatic Stress
4. Cognitive Attentional Syndrome Questionnaire
5. Post-Traumatic Growth Inventory Short-Form
6. Expectations of Therapy Questionnaire (developed by lived experience consultants in the research team) to measure/capture common concerns that trauma survivors may have about engaging in trauma focussed interventions and that may have relevance to their individual likelihood of engaging versus discontinuing the interventions offered as part of the trial. With participants' consent, participants will be audio-recorded while completing this measure and asked to elaborate on their answers using techniques/prompts drawn from 'Cognitive Interviewing' methods, to enable an embedded validation of this scale within this trial and to inform strategies to promote client engagement as part of the current feasibility trial and future definitive trial.

Quality of the therapeutic relationship (an important predictor of treatment outcome in psychological therapies for psychosis and trauma), completed at three timepoints over the course of therapy (by session 3, at session 12 and at the last therapy session):
1. Working Alliance Inventory - Short Form Revised

Completion date
30/04/2026

Eligibility

Key inclusion criteria
Inclusion criteria for the feasibility randomised controlled trial (RCT):
1. 16 years of age or older
2. Meeting at-risk mental state (ARMS) for psychosis criteria as defined by the Comprehensive Assessment of At-Risk Mental States (CAARMS)
3. Capacity and willingness to provide informed consent
4. Reported exposure to at least one potentially traumatic life event, as assessed by the Trauma and Life Events checklist (TALE)

Inclusion criteria for the nested qualitative study with RCT participants:
1. Participated in the feasibility RCT
2. Capacity and willingness to provide informed consent

Inclusion criteria for nested qualitative study with NHS professional stakeholders:
1. Being a RESTART trial therapist and/or an NHS professional who worked in services involved in the RESTART feasibility RCT
2. Capacity and willingness to provide informed consent

Participant type(s)
Health professional, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
65 years

Sex
All

Total final enrolment
76

Key exclusion criteria
Exclusion criteria for a feasibility randomised controlled trial (RCT):
1. Under 16 years of age
2. Non-English speaking or requiring an interpreter for the intervention (the assessment battery at present can only be delivered in English)
3. Evidence of recent or past transition from at-risk mental state (ARMS) for psychosis status to first episode psychosis (FEP), operationally defined as meeting Comprehensive Assessment of At-Risk Mental States (CAARMS) transition criteria (i.e., history of a treated or untreated psychotic episode of one week's duration or longer) and/or previous or current treatment with antipsychotics at a dose of over 5 mg of haloperidol or equivalent for over 3 weeks
4. Judged by the assigned care coordinator/responsible clinician and the research team as not being sufficiently clinically stable to engage safely in a clinical trial of trauma-focused therapy (e.g., acutely suicidal and suicide attempt in the previous two months; in a current mental health crisis; not in stable housing)

Exclusion criteria for nested qualitative study RCT participants:
1. Unwilling or unable to provide consent

Date of first enrolment
17/07/2023

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
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Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

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 and/or analysed during the current study will be available on request from Prof. Filippo Varese (Filippo.Varese@manchester.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		08/12/2024	16/01/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes