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Narrative exposure therapy in early intervention in psychosis: a study providing an initial assessment of safety and acceptability of this psychological therapy for individuals with a first episode of psychosis who have experienced repeated trauma

Submission date
10/07/2025

Recruitment status
Recruiting

Registration date
14/07/2025

Overall study status
Ongoing

Last Edited
03/12/2025

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

Many people with first episode psychosis, which can involve hearing voices others cannot and feelings of paranoia, have experienced past trauma. A large proportion of them (as high as 80% in some studies) report repeated childhood trauma such as abuse and discrimination. The effects of repeated trauma on recovery from psychosis are large: symptoms do not get better, people are less likely to do everyday activities, they are more likely to feel suicidal and have more hospital admissions. Not assessing and treating trauma extends their and their carers' suffering. It also costs an estimated £2.44 billion to the NHS per year.

Early intervention in psychosis (EIP) services offer support to approximately 10,000 new people experiencing psychosis per year in England. Their aim is to help recovery and avoid relapse. In many EIP services, it's not usual to ask about trauma and people do not receive effective therapies for trauma provided by trained therapists.

Narrative exposure therapy (NET) is unique as an NHS-approved treatment that was designed for repeated and complex trauma. It was developed for survivors of conflict, but is also relevant for people from marginalised backgrounds, different cultures and ethnicities. It starts with the physical building of a person's lifeline, including traumas and positive events (represented by stones and flowers). This is a starting point for development in the following sessions of a story that makes sense of experiences and allows trauma memories to feel less emotionally intense. Training to provide NET is brief and straightforward, so there is potential for many therapists to be trained. Despite this promise, NET has not yet been evaluated in EIP.

The study will aim to:

1. Provide an initial assessment of safety and acceptability of NET for individuals with a first episode of psychosis who have experienced repeated trauma.
2. Tell us whether it is possible to train EIP clinicians to deliver NET.

Answers to these questions will tell us how best to conduct a large study to look at how effective NET is in EIP.
People with personal experience of psychosis and trauma have advised on our study design and will continue to do so.

Who can participate?
Participants aged 18 years or above who are under the care of an Early Intervention in Psychosis service, who report a history of multiple trauma and current intrusive trauma experiences (e.g. flashbacks, nightmares and/or unusual distressing experiences such as voices).

What does the study involve?
People who are under the care of EIP services will be invited to take part in a study in which chance will decide whether they receive NET as well as usual treatment or usual treatment alone. NET therapy will involve 15 weekly 90-minute sessions (approximately 4 months). Everyone taking part will fill in questionnaires at the start and after 4 and 8 months. These will include questions about trauma impact and psychosis symptoms. We will also ask about their experiences of NET and the study.

What are the possible benefits and risks of participating?
Completing the research assessments will take up some of the participants' time and may feel burdensome. These questionnaires cover a range of topics which might be sensitive. This will include discussing intrusive impacts of trauma on mental health, and psychosis experiences, for example. It is possible that talking about personal experiences could sometimes lead to feeling distressed. The research team will offer support during the research meetings or at any point during the study. There are experienced clinicians in the study team, including Clinical Psychologists and Psychiatrists, and the participant will continue to receive the usual support from your Early Intervention Service.
If participants are randomly allocated to the NET group, it is possible that talking about personal experiences of trauma could lead to feeling temporarily distressed. The mental health practitioner providing the therapy will be sensitive to the person's needs. They have specialist training and experience working with people who have experienced trauma.
Participants will be free to withdraw from the research study at any point, and this will not affect the ongoing care they receive.
If participants are randomly allocated to the group of people who are not offered NET (routine care group), they may feel disappointed, but they will continue to receive their usual support from the Early Intervention in Psychosis team as they did before. Once they complete the study (i.e. after the 8-month follow-up) they will also be offered NET then as a goodwill gesture.

Where is the study run from?
1. Cambridge and Peterborough NHS Foundation Trust (UK)
2. North London Mental Health Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2024 to December 2026

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

Who is the main contact?
Dr Miriam Fornells-Ambrojo, miriam.fornells-ambrojo@ucl.ac.uk

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)
337365

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR 206724; CPMS 59773

Study information

Scientific Title
Narrative exposure therapy in early intervention in psychosis: a feasibility randomised controlled trial

Acronym
NETp

Study objectives
The overall research question is whether it is feasible and acceptable to deliver and test through a pilot randomised control trial, narrative exposure therapy (NET) in early intervention in psychosis (EIP) services to reduce symptoms of post-traumatic stress disorder, as they are known to impact recovery from psychosis.

The current feasibility study aims to address the following specific questions:
1. Is NET acceptable for people in EIP services?
2. Are people in EIP services willing to be recruited to a trial and randomised to NET or Treatment as Usual (TAU)?
3. Are there any adaptations required when delivering NET in EIP services for a larger randomised controlled trial (RCT)?
4. Are the proposed outcome measures acceptable and important for those with lived experience?
5. Is it feasible to train EIP clinicians in the delivery of NET?

This feasibility study will not have sufficient power to assess the effectiveness of NET, so no formal hypothesis testing will be carried out. However, to trial the analysis envisaged for a future, fully powered effectiveness RCT, clinical outcomes at the 4-month follow-up and 8-month follow-up will be compared between study arms, using a multilevel model and adjusting for the baseline assessment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/05/2025, London - City & East Research Ethics Committee (Research Ethics Committee Centre, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048171; cityandeast.rec@hra.nhs.uk), ref: 25/LO/0350

Study design
Multi-site feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
History of multiple trauma, early intervention for psychosis, post-traumatic stress disorder

Interventions
A multi-site feasibility randomised control trial will be conducted to investigate recruitment and intervention delivery parameters and obtain initial evidence as to whether the trial process and outcomes are consistent with the intervention being potentially effective.

Participants will be randomized to either NET or TAU, stratified by site and ethnicity using randomly permuted block sizes, with block sizes 2 and 4, within each stratum. All primary and secondary measures will be collected at baseline, 4 months post randomisation, and 8 months post-randomisation. Experience Sampling Method data will be completed by participants allocated to the NET intervention who agree. This will involve daily entering of data on their progress on a mobile app (m-path) from 1-week pre (post randomisation) to 1 week post NET therapy completion.

Qualitative interviews will be undertaken with up to n = 15 service users who received the NET intervention as part of the RCT and up to n=10 clinicians who delivered the NET intervention.

Treatment arm (NETp):
Narrative Exposure Therapy (NET) is an evidence-based psychological treatment for PTSD for multiple or prolonged traumatic events. Through detailed narration, traumatic memories are processed and contextualised, helping the person to develop a coherent autobiographical narrative. At the start of therapy, there is a co-construction of the person's lifeline using physical materials, including traumatic events (represented by stones) and positive events (represented by flowers). Events are narrated in subsequent sessions in chronological order to 'process' the trauma memory and make meaning. At the end of therapy, the patient receives the written narrative as a documented testimony.

The NETp manual for this feasibility trial will follow the standard NET manualised intervention, but it will also include specific guidance for addressing psychosis co-morbidity and delivery within an Early Intervention for Psychosis (EIP) service, in line with learning from pilot work and consultation with people with lived experience who have received NET, their carers, NET therapist and multi-disciplinary staff from EIS services.

Each participant will receive 15 weekly 90-minute sessions of NETp. The intervention will be delivered by a range of professionals who have received NET training, including band psychologists (band 7/8a), CBT therapists (band 7), mental health nurses and occupational therapists (band 5/6) (or professionals with equivalent experience, including those in the final year of training) within EIP. Although face-to-face delivery will be prioritised, we will offer online delivery following consultation with experts with lived experience. When online delivery is offered, e-NET guidance will be followed.

The trial intervention (NETp) will be provided as an addition to mental health care (Early Intervention in Psychosis) of usual type and quality, received by members of these groups.

Control arm:
Treatment as usual: This includes the routine care provided by the Early Intervention for Psychosis (EIP) service, multi-disciplinary care from mental health nurses, psychiatrists, occupational therapists and psychologists in a community setting with associated crisis and inpatient settings if required. EIP services offer up to 3 years of multidisciplinary support, including an allocated care coordinator, and offer of antipsychotic medication and psychological interventions, such as CBT and Family Intervention for psychosis.

Randomisation method:
Participants will be randomized to either NET or TAU, stratified by site and ethnicity (ethnic minority vs. White British) using randomly permuted block sizes, with block sizes 2 and 4, within each stratum. The randomization sequence will be generated from random numbers generated in the R software for statistical computing and pre-loaded into the REDCap data management platform, which will be used for data collection. The randomization sequence will be stored but concealed within the REDCap data capture system. When all information relevant for stratification (site and ethnicity) has been completed, a researcher has the option to initialize randomization. Only then will the allocation be revealed within the REDCap database, and the local PI, NET therapist and client will be informed of the result of the randomization, so that treatment can be initiated 1 week following allocation.

Intervention Type
Behavioural

Primary outcome(s)

1. Feasibility outcomes:
1.1. Recruitment: Number of eligible referrals received and willingness to consent and be randomised, recorded from the start of recruitment to the end of recruitment
1.2. Attrition:
1.2.1. Assessment retention: Number of participants who are lost to end-of-treatment assessment (4 months) and follow-up assessment (8 months) points
1.2.2. Therapy engagement: Intervention-specific data will include therapy engagement and the number of sessions attended, measured by the end of therapy, around 4 months
1.2. Acceptability of measures, assessed by non-response rates to questionnaires and items, and by the Feedback about Measures Tool completed by both groups at the three timepoints (baseline, 4 months [end of treatment] and 8-month follow-up)
1.3. Safety will be assessed through monitoring and assessing adverse events from randomisation to 8 months

2. Primary outcomes (whose feasibility is being assessed are for a future trial): the following primary outcome candidates are completed by both groups at the three timepoints (baseline, 4 months [end of treatment] and 8 months follow-up):
2.1. PTSD: Severity of PTSD, disturbances in self-organisation, PTSD and cPTSD diagnosis:
2.1.1. Traumatic intrusions measured using the PTSD Checklist for DSM-5 (PCL-5)
2.1.2. Complex PTSD symptoms measured using the International Trauma Questionnaire (ITQ)
2.2. Psychotic symptom severity measured using the psychotic symptom rating scales for voices and distressing beliefs (PSYRATS) and the Hallucinations in Other Modalities adapted PSYRATS

Key secondary outcome(s))

Secondary outcomes (whose feasibility is being assessed are for a future trial):
Completed by both groups at the three timepoints (baseline, 4 months [end of treatment] and 8-month follow-up) include:
1. Recovery from psychosis measured a service user-defined measure of recovery, Questionnaire about the Process of Recovery (QPR)
2. Dissociation measured using the Shutdown Dissociation Scale (Shut-D)
3. Paranoia measured using the revised Green et al. paranoid thought scales (R-GPTS)
4. Guilt and shame measured using the 12-item Event Related Brief Shame and Guilt Scale (ERB-SGS)
5. Emotional distress measured using the Depression Anxiety Stress Scales (DASS-21)
6. Narrative identity measured using the Awareness of Narrative Identity Questionnaire (ANIQ)

Economic evaluation outcomes:
1. The EQ-5D-5L tool to measure quality of life adjusted years QALYs will be included to pilot its use for health economic analysis in a full trial, alongside the Client Service Receipt Inventory (CSRI).

NET therapy group only:
Feasibility of collecting outcomes to monitor the evolution of therapy (participants allocated to receive NET only):
1. Experience Sampling Method (ESM): Daily entering of data on a mobile app (https://m-path.io /landing/) from 1 week pre (post randomisation) to 1 week post NET therapy completion. Areas covered include PTSD and CPTSD symptoms, unusual distressing experiences of psychosis, paranoia, mood, social connection, hope and context.
2. NET therapy weekly session monitoring: PTSD intrusions, unusual experiences, paranoia, hope, risk, therapeutic alliance, cultural humility, current distress and session feedback. Acceptability of collecting daily ESM data during therapy and weekly outcome monitoring will be assessed by non-response rates to items, and by the Feedback about Measures Tool completed at the end of

therapy by service user and clinician participants and at the last ESM data entry on m-path, 1 week after therapy completion.

Qualitative interviews:
Upon completion of the post-treatment assessment, a subset (n = 15) of participants who were offered NET will be invited to complete a semi-structured interview after they complete the 8-month (36 weeks) follow-up. Purposive sampling will be used to recruit a wide range of participants (e.g., including people who dropped out). NET therapists will also be interviewed (n = 10) by study Research Assistants or Doctorate Clinical Psychology trainees. Topic guides explore experiences of the NET intervention and its acceptability, barriers and facilitators, possible mechanisms of effect, potential benefits or harms, and recommendations.

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Service user participants:
Eligible participants will:
1. Report a history of multiple trauma (i.e. more than one event in the Trauma and Life Events (TALE) checklist that ended at least a month ago and that still affects them (operationalised as TALE 21c item >= 5)
2. Report intrusive trauma experiences as described below in 2.1 and/or 2.2:
2.1. At least subthreshold post-traumatic symptoms in the previous week (i.e., score of at least 2 on items 1-5) in the PTSD Checklist for DSM-5 (PCL-5)
and/or
2.2. Current distressing symptoms of psychosis (i.e. a score of 2 or above on the intensity of distress in the PSYRATS Delusions/Hallucinations or in the Adapted PSYRATS for Hallucinations in Other Modalities that are thematically linked to trauma (identified using an adapted version of section C of the TVAQ and reporting a score >0.
3. In the caseload of an EIP
4. Judged by the EIP care coordinator as clinically stable
5. Aged at least 18 years
6. Have the capacity to give consent at the time of recruitment. Please note individuals will not be excluded based on whether they are a voluntary or under section of the Mental Health Act (2007), but rather on their capacity to consent to participating in research. A key principle of the Mental Capacity Act (2005) is decision-specific, and many patients who are admitted to hospital under section retain the capacity to decide whether or not to take part in research and should therefore not be unfairly denied this opportunity.

Clinician participants (for the interviews NET intervention evaluation):
Eligible participants will be:
1. Completed Narrative Exposure Therapy Training
2. Currently working or have worked in an NHS Early Intervention for Psychosis during the trial
3. Have delivered at least one session of NET with a client in EIP
4. Be from a range of professional backgrounds, including band psychologists (band 7/8a), CBT therapists (band 7), mental health nurses and occupational therapists (band 5/6) (or professionals with equivalent experience, including those in the final year of training) within EIP.

Participant type(s)

Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Service user participants:
Participants will be excluded if they:
1. Had a primary diagnosis of substance/alcohol dependence, intellectual disability or cognitive dysfunction
2. Received a trauma-focused intervention from a qualified therapist for PTSD within the past 3 months
3. Insufficient English to provide informed consent or complete assessments without help from an interpreter
4. Lack the capacity to consent

Clinician participants:
None specified.

Date of first enrolment
21/07/2025

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Cambridge and Peterborough NHS Foundation Trust
Elizabeth House
Fulbourn Hospital Cambridge Road
Cambridge
England
CB21 5EF

Study participating centre
North London Mental Health Foundation Trust
4th Floor, East Wing
St Pancras Hospital
London
England
NW1 0PE

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

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

Anonymised datasets generated during and/or analysed during the current study will be available upon request post-publication of the trial results from the Principal Investigator Dr Miriam Fornells-Ambrojo (miriam.fornells-ambrojo@ucl.ac.uk), following a review of the appropriateness of the request by the trial team.

IPD sharing plan summary

Available on request

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