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The EASE trial: Trauma-focused therapy in early psychosis

Submission date
14/07/2026

Recruitment status
Not yet recruiting

Registration date
11/08/2026

Overall study status
Ongoing

Last Edited
11/08/2026

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
Psychosis can cause distressing experiences such as hearing voices, unusual beliefs and paranoia. Many people with psychosis have experienced traumatic life events, which may contribute to the development and persistence of their symptoms.

Eye Movement Desensitisation and Reprocessing for psychosis (EMDRp) is a talking therapy designed to help people process traumatic experiences. Previous research suggests that EMDR may improve trauma-related symptoms, but it is not yet known whether it can also reduce psychotic symptoms in people experiencing psychosis for the first time.
This study aims to investigate whether EMDRp, alongside usual care, is more effective than usual care alone in reducing psychotic symptoms in people receiving support from Early Intervention in Psychosis (EIP) services who have experienced trauma.

Who can participate?
People aged 16 years and over who are receiving support from an NHS Early Intervention in Psychosis service, have active psychotic symptoms, have experienced at least one traumatic life event that continues to affect their mental health, and can provide informed consent.

What does the study involve?
A total of 314 participants will be randomly allocated to one of two groups:

- EMDRp plus treatment as usual
- Treatment as usual only

Treatment as usual will consist of the standard care provided by participants' EIP teams, which may include medication, psychological support and other treatments.
Participants allocated to the EMDRp group will receive up to 16 therapy sessions over six months. Sessions may take place in person or remotely, depending on participant preference.
Participants in both groups will complete assessments over 12 months. These assessments will measure psychotic symptoms, recovery, trauma symptoms, mood, quality of life and day-to-day

functioning.
Some participants will also be invited to take part in an interview about their experiences of the therapy.

What are the possible benefits and risks of participating?
Participants may benefit from receiving additional psychological therapy that could help reduce the impact of trauma and psychotic symptoms. The findings may help improve treatment options for people experiencing psychosis in the future.
Some participants may find discussing traumatic experiences upsetting or emotionally challenging. Appropriate clinical support will be available throughout the study.

Where is the study run from?
NHS Early Intervention in Psychosis services across England, including sites in Manchester, London, Chorley, Southport and Northumberland.

When is the study starting and how long is it expected to run for?
September 2026 to May 2029.

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Professor Filippo Varese, filippo.varese@manchester.ac.uk.

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Principal investigator

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Additional identifiers

Central Portfolio Management System (CPMS)
60392

National Institute for Health and Care Research (NIHR)
168901

Study information

Scientific Title
Trauma-focused therapy in early psychosis: A randomised controlled trial assessing the efficacy and mechanisms of action of Eye Movement Desensitization and Reprocessing for psychosis (EMDRp) in comparison to treatment as usual in Early Intervention settings

Acronym
EASE

Study objectives
The trial aims to test the clinical efficacy of EMDRp (Eye Movement Desensitisation Reprogramming for psychosis) in reducing overall psychotic symptoms when compared to treatment as usual (TAU) for users of EIP services who have a history of trauma, and to examine the degree to which EMDRp +TAU impacts psychotic symptoms via changes in trauma memory characteristics and reductions in maladaptive beliefs. The specific aims and hypotheses are:

Efficacy Objectives
1. Aims:
1.1. Primary: To examine the clinical efficacy of EMDRp in reducing overall psychotic symptoms when compared to TAU for EIP service users with a history of trauma.
1.2. Secondary: To determine whether the treatment gains of EMDRp extend to other valued secondary outcomes (perceived personal recovery, severity of hallucinations, delusions, persecutory ideas and paranoid thinking, post-traumatic sequelae, affective symptoms, personal and social functioning, and health-related quality of life).

2. Hypotheses:
2.1. (Primary efficacy hypothesis) EMDRp+TAU will lead to improved overall psychotic symptoms (PANSS scores) at the end-of-treatment (6-month follow-up) compared to TAU.
2.2. The treatment effect of EMDRp+TAU on overall psychotic symptoms will be maintained at

the 12-month follow-up.
2.3. EMDRp+TAU will lead to improved personal recovery, post-traumatic sequelae, affective symptoms (e.g. anxiety and depression) and the severity of participants' hallucinations, delusions, persecutory ideas / paranoid thinking, functioning and quality of life at the end-of treatment (6-month follow-up) and 12-month follow-up compared to TAU.
2.4. Treatment effects will remain evident after accounting for the effect of concomitant psychological therapies delivered as part of TAU.

Mechanistic objectives
1. Aims:
1.1. To examine the degree to which EMDRp+TAU impacts on psychotic symptoms via changes in trauma memory characteristics and reductions in maladaptive beliefs.

2. Hypotheses:
2.1. EMDRp+TAU will improve key mechanistic measures targeted by the intervention: trauma memory characteristics and negative self-beliefs targeted as part of EMDR interventions.
2.3. Treatment effects on PANSS at 6-months and 12-month follow-up assessments will be mediated via changes in key mechanistic measures at the 4-month post-randomisation (mechanistic) assessment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/04/2026, North West Liverpool Central Research Ethics Commitee (2 Redman Place, Stratford, London, E201JQ, United Kingdom; +44 02071048340; liverpoolcentral.rec@hra.nhs.uk), ref: 26/NW/0046

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied

The target population for this multi-centre RCT is individuals engaging with Early Intervention for Psychosis NHS services, who present with co-occurring psychotic symptoms and a history of trauma affecting their current mental health.

Interventions

Randomisation processes
Participants will be randomised to each trial arm (either EMDRp + TAU or TAU only) on a 1:1 ratio. Randomisation (at the individual level) will be stratified by site and generated using randomly-permuted blocks of varying size, and will be implemented using a centralised, independent and concealed randomisation service at King's Clinical Trials Unit (KCTU). The randomisation service is web-based, and randomisation will only be known to unblinded staff such as Trial Managers and therapists.

Treatment summary
Control group: Treatment as Usual (TAU)
TAU will be the standard care provided by participants' Early Intervention for Psychosis (EIP) teams - including social, psychological, medical, or other treatments as decided by the care team. As such, treatment offer and uptake will vary on an individual basis, e.g. due to the person's most pressing clinical needs, service offer and capacity, and patient choice. Access to TAU in either arm of the trial will be delivered and directed by EIP teams, without any interference or influence from the study team.

Treatment: EMDRp (Eye Movement Desensitisation Reprogramming for psychosis) intervention
Participants allocated to the EMDRp + TAU arm will receive up to 16 sessions of EMDR (up to 90 minutes per session), over a 6-month treatment window, in addition to TAU. Access to TAU will not be restricted in any way. Therapy delivery will be in person (e.g. participant's home, NHS premises) or remote, depending on participant preference.

EMDR is a protocolised therapy designed to reprocess adverse or traumatic life experiences, and related distress. EMDRp (EMDR for psychosis) is consistent with the standard EMDR protocol, but tailored to the needs of clients with early psychosis. An EMDRp manual has already been evaluated and implemented successfully in our feasibility trial.

EMDRp will be delivered by dedicated EMDR therapists, additionally trained in EMDRp, and attend fortnightly supervision sessions with experienced EMDR supervisors. Treatment fidelity will be monitored using procedures already successfully implemented in the EASE feasibility RCT.

Intervention Type

Behavioural

Primary outcome(s)

1. overall psychotic symptoms measured using the total score of the Positive and Negative Syndrome Scale (PANSS) at baseline and 6 months

Key secondary outcome(s)

1. recovery measured using the Questionnaire about the Process of Recovery (QPR) at baseline, 6 and 12 months

2. severity of delusions and hallucinations measured using the Psychotic Symptoms Rating Scale (PSYRATS) and the Multi-Modal Hallucinations Inventory at baseline, 6 and 12 months

3. persecutory ideas and referential thinking (aspects of paranoia) measured using the Revised Green et al. Paranoid Thoughts Scale (R-GPTS) at baseline, 6 and 12 months

4. symptoms of post-traumatic stress disorder (PTSD) and and complex PTSD (CPTSD), as per ICD-11, measured using the International Trauma Questionnaire (ITQ) at baseline, 6 and 12 months

5. symptoms of PTSD as per DSM-5 measured using the PTSD Checklist for DSM-5 (PCL-5) at baseline, 6 and 12 months

6. Symptoms of oppression-based traumatisation measured using the Oppression-Based Traumatic Stress Inventory (OBTSI) at baseline, 6 and 12 months

7. Trauma-related dissociation measured using the Dissociative Subtype of PTSD Scale (DSPS) at baseline, 6 and 12 months

8. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 6 and 12 months

9. Anxiety measured using the General Anxiety Disorder scale (GAD-7) at baseline, 6 and 12 months

10. Functioning measured using the Personal and Social Performance Scale (PSP) at baseline, 6 and 12 months

11. Health-related quality of life measured using the EQ-5D-5L at baseline, 6 and 12 months

12. Mental health-related quality of life measured using the Recovering Quality of Life (ReQoL) at baseline, 6 and 12 months

13. Trauma memory characteristics measured using the Adapted Trauma Memory Quality Questionnaire (ATMQQ) at baseline, 4, 6, and 12 months

14. Negative beliefs about self and others measured using the Brief Core Schema Scale (BCSS) at baseline, 4, 6, and 12 months

15. Experiences of the EMDR intervention measured using semi-structured qualitative interviews at post-treatment

Completion date
31/05/2029

Eligibility

Key inclusion criteria
1. Meeting Early Intervention for Psychosis (EIP) service entry criteria for First Episode Psychosis (FEP) support, operationally defined using the Positive and Negative Syndrome Scale (PANSS) and/or the psychosis transition criteria of the Comprehensive Assessment of At Risk Mental States (CAARMS) or other locally approved clinical definition of FEP
2. Have an assigned key worker / care coordinator, to enable appropriate risk management at time of trial enrolment
3. Aged ≥ 16 years

4. Willing and able to provide informed consent
5. Judged by their responsible clinician and/or clinically qualified members of the research team as clinically stable (e.g. no medication changes in past month; no current suicidal intent and no suicide attempt in past two months; sufficient substance misuse management and/or stable accommodation to enable reliable engagement in EIP psychological therapies)
6. Active psychotic symptoms indicated by a score of at least 3 (i.e. symptom present) on the P1 (delusions), P3 (hallucinations), P5 (grandiosity) or P6 (suspiciousness/paranoia) items of the PANSS
7. Reporting at least 1 traumatic event on the Trauma and Life Events (TALE) checklist (Carr et al., 2018a), with reported impact on current mental health problems, operationalised as a score ≥5 on item 21c of the TALE

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Moderate/severe/profound intellectual disability
2. Non-English speaking
3. Previous receipt of EMDR from a qualified psychological therapist in accordance with NICE guidelines

Date of first enrolment
01/09/2026

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Complex Trauma and Resilience Unit (C-TRU)
GMMH Research & Innovation Office
1st Floor, Building B
One Central Park
Manchester
England
M40 5BP

Study participating centre
South London and Maudsley NHS Foundation Trust
Early Intervention Services
190 Kennington Lane
London
England
SE11 5DL

Study participating centre
Lancashire and South Cumbria NHS Foundation Trust
Tudor House
18 Euxton Lane
Chorley
England
PR7 1PS

Study participating centre
Mersey Care NHS Foundation Trust
Early Intervention Services
Hatley Hospital
1B Curzon Road
Southport
England
PR8 6PL

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
Early Intervention in Psychosis Service
Greenacres Centre
Green Lane
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NE63 8BL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type

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

IPD sharing plan summary
Data sharing statement to be made available at a later date