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Eye movement desensitization and reprocessing therapy in early psychosis

Submission date
11/02/2019

Recruitment status
No longer recruiting

Registration date
28/03/2019

Overall study status
Completed

Last Edited
05/12/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a study of Eye Movement Desensitization and Reprocessing (EMDR) therapy for patients suffering early psychosis (patients with a schizophrenia or related diagnosis who experience hallucinations and/or delusions) who have experienced significant trauma in their life. EMDR is a proven and NICE-recommended treatment for Post-Traumatic Stress Disorder PTSD); it involves recalling traumatic events while performing eye-tracking under the direction of a therapist, usually by following the therapist's finger movements. It is thought that this processes leads to recoding of the traumatic experiences in the brain so that the memories no longer evoke strong negative emotion. This treatment is worth considering for patients with psychosis because previous work has shown that many have a history of severe trauma and because a trial carried out in the Netherlands with patients suffering from both psychosis and PTSD had positive effects.The main aim of this study is to collect data that will inform the design of a large, multi-site definitive trial.

Who can participate?
Service users aged at least 16 years with early psychosis

What does the study involve?
Participants are randomly allocated to either EMDR plus Treatment As Usual (TAU). Those receiving EMDR are offered up to 16 sessions over 6 months with an experienced EMDR therapist. Follow-up interviews are conducted by research assistants 6 and 12 months later, who assess psychotic symptoms. Interviews with patients and service staff are also conducted to assess the acceptability of the treatment.

What are the possible benefits and risks of participating?
This study does not involve any known physical risks or harm to participants or the researchers. However, talking about personal experiences and feelings may be difficult and can cause emotional upset. The protocol for assessing and reporting risks and the distress protocol for the current study will be followed in such cases.

Where is the study run from?
Lancashire Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to May 2022

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
41092

Study information

Scientific Title
Eye movement desensitization and reprocessing therapy in early psychosis (EYES): a feasibility randomised controlled trial

Acronym

EYES

Study objectives
1. Is it possible to recruit and retain sufficient numbers of participants for a definitive trial?
2. Is it possible for therapists to maintain high levels of adherence to the treatment protocol?
3. Which are the most appropriate and acceptable outcome measures for a definitive trial?
4. What is the optimal sample size for a definitive trial of EMDR for psychosis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/04/2019, North West – Liverpool Central REC (nrescommittee.northwest-liverpoolcentral@nhs.net), ref:19/NW/0065

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia, schizotypal and delusional disorders

Interventions
60 patients who have been ill for a maximum of three years will be randomly assigned to either Eye Movement Desensitisation and Reprocessing adapted for psychosis (EMDRp) plus Treatment As Usual (TAU) or TAU only at a ratio of 1:1. Randomisation will be achieved by means of concealed random allocation conducted by the study statistician using an online pseudo-random list hosted by sealedenvelope.com with random permuted blocks of varying sizes. Allocation will be concealed from the RAs who will conduct post-randomization assessments. Those receiving EMDR will be offered up to 16 sessions over 6 months with an experienced EMDR therapist.

Intervention: EMDRp
Participants allocated to the intervention arm will receive up to 16 sessions of EMDRp delivered over a 6-month treatment window, in addition to TAU. Each session will last up to 90 minutes and will be audio-recorded for fidelity monitoring purposes.

Comparator: Treatment As Usual (TAU)
TAU will be in line with all standard and individually prescribed clinical interventions as directed by national clinical guidelines for psychosis and the participants' clinical team, and may include antipsychotic medications and/or psychological interventions (CBT, family therapy). Although EMDR is not routinely employed in the treatment of psychosis, TAU participants with comorbid PTSD may be referred by their clinical teams to other services to receive a trauma-focused intervention (TF-CBT or EMDR), as per NICE guidelines for PTSD. For ethical reasons (and in the light of recommendations voiced during PPI consultations the trialists conducted to develop this

project), clinical teams will not be asked to withhold such referrals/interventions. Instead, the trialists will carefully monitor the care received by TAU participants (through case notes reviews after the 12-month assessment) to examine the proportion of TAU participants who received EMDR.

Follow-up interviews will be conducted by research assistants who are blind to the group assignment at 6 and 12 months after randomization, who will assess psychotic symptoms. Qualitative interviews with patients and service staff will also be conducted to assess the acceptability of the treatment.

Intervention Type
Other

Primary outcome(s)
Feasibility assessed after completion of 6 and 12 months battery assessment follow-ups by calculating:
1. Recruitment rate: the number of participants consented into the trial and randomised
2. Therapy/assessment retention: % who drop-out of therapy
3. Therapy fidelity: % who did not receive treatment allocated
4. Adherence: ratings from therapy tapes
5. Therapy safety: number of Serious Adverse Events (SAEs)

Key secondary outcome(s))
Measured at baseline, 6 and 12 months:
1. Psychotic symptoms measured using:
1.1. The PANSS, the most widely-used research measure to assess the severity of positive and negative symptoms of psychosis as well as symptoms of general psychopathology
1.2. The Psychotic Symptoms Rating Scales, a semi-structured interview completed alongside the PANSS to provide a more fine-grained assessment of auditory hallucinations and delusions, including measures of subjective distress caused by these symptoms
1.3. The Green et al. Paranoid Thoughts Scale, a brief self-report questionnaire assessing paranoid thinking and persecutory delusions.
2. Trauma exposure and trauma-related difficulties, measured using:
2.1. The TSQ, a brief measure used to screen for trauma exposure and post-traumatic stress. In the present study, the modified version of the TSQ developed by de Bont and colleagues for use in people with psychosis will be used to check the participants' potential eligibility in this trial
2.2. The Trauma and Life Events checklist (TALE), a measure specifically designed to assess exposure to adverse and traumatic life experiences that are commonly reported by people with psychosis
2.3. The PTSD Checklist for DSM-5, a self-report questionnaire assessing the presence and severity of post-traumatic symptoms.
2.4. The 12-item version of the International Trauma Questionnaire (ITQ), a brief measure assessing the severity of symptoms of PTSD and complex PTSD as defined in the recently published ICD-11.
2.5. The Dissociative Experiences Scale-II, a self-report measure of dissociation.
3. Health economic measures:
3.1. The EQ-5D-5L (Devlin et al., 2018; Jansen et al., 2013), a health status questionnaires used in health economics analyses.
3.2. An adapted version of the Economic Patient Questionnaire, and health economics measures developed by co-applicant Davies and used in previous NIHR-funded mental health trials.
4. The Generalized Anxiety Disorder Questionnaire and the Patient Health Questionnaire, two

brief and widely-used questionnaires assessing symptoms of anxiety and depression.
5. The Personal and Social Performance Scale, a scale assessing patients' functioning in four areas (socially useful activities, personal and social relationships, self-care and disturbing /aggressive behaviours).
6. The Questionnaire about the Process of Recovery, a service user-defined measure of subjective recovery.
7. Case notes review: after the 12-month assessment, the trial manager will contact the participants' care co-ordinators and ask them to review their clinical notes and document the interventions each participant received during the study duration period

Completion date
31/05/2022

Eligibility

Key inclusion criteria
1. Aged at least 16 years
2. Capacity and willingness to provide informed consent
3. ICD diagnosis of schizophrenia-spectrum disorders (ICD codes F20, F22, F23, F25, F28, F29; ICD-11 codes 6A20, 6A21, 6A23, 6A24, 6A2Y,6A2Z) or LCFT EIS psychosis criteria, 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)
4. In contact with mental health services, and have an assigned care-coordinator
5. Within 3 years from psychosis onset
6. Judged by the assigned care-coordinator/responsible clinician as clinically stable (no treatment change in the previous month)
7. Reporting at least 1 traumatic event on the Trauma Screening Questionnaire (TSQ), and at least subsyndromal post-traumatic symptoms in the previous week (scores > 0 on items 3_1 to 3_5 of the TSQ)
8. Meet a criterion level of positive symptoms severity, indicated by a score > 3 (symptom present) on the delusions (P1), hallucinations (P3), grandiosity (P5) or suspiciousness (P6) items of the PANSS in the previous week

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
60

Key exclusion criteria

1. Primary diagnosis of substance/alcohol dependence, intellectual disability or cognitive dysfunction, as provided by the participant care-coordinator/clinical team
2. Non-English speaking or requiring an interpreter for the intervention (the therapy and assessment battery at present can only be delivered in English)
3. Receipt of EMDR from a qualified psychological therapist in accordance with NICE guidelines for PTSD in the past 12 months

Date of first enrolment
01/03/2019

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lancashire Early Intervention Service East Spoke Team
The Mount
Whalley Road
Accrington
United Kingdom
BB5 5DE

Study participating centre
Lancashire Early Intervention Service Central Spoke Team
Euxton Lodge
16 Euxton Lane
Chorley
United Kingdom
PR7 1PS

Study participating centre
Lancashire Early Intervention Service North Spoke Team
Second Floor
Blackpool Football Stadium
Seasiders Way
Blackpool
United Kingdom
FY1 6JX

Sponsor information

Organisation
Lancashire Care NHS Foundation Trust

ROR
https://ror.org/03zefc030

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0317-20037

Results and Publications

Individual participant data (IPD) sharing plan
The PI, key investigators and collaborators will be responsible for access to the participant data, audio recordings and consent forms. The consent forms may also be accessed by LCFT staff from which the participant is recruited for audit purposes.
All relevant data security and confidentiality standards will be applied as per the University of Manchester Research Data Management Policy and relevant LCFT policies. Consent forms and paper copies of assessment tools will be stored in locked filing cabinets in secured offices within LCFT. All anonymised, computerised data will be encrypted and password protected and replicated on the LCFT server. Additional electronic copies of the data will be stored using the University of Manchester Research Data Management Service, which provides robust, managed, secure replicated storage. The RDMS allows researchers to store, manage and curate their data, as well as preserve data after project completion. Sufficient meta-data capturing content, quality, condition, and other relevant characteristics of datasets will be recorded to enable future efficient use of the data generated as part of this study. Hardcopy will be stored securely in accordance to the LCFT Good Research Guidelines Policy, which states that primary research data (and where possible/relevant specimens, samples, questionnaires, audiotapes, etc.) must be retained in their original form within the research establishment that generated them for a minimum of ten years from completion of the project (NHS Code of Practice Records Management).
The trial will be coordinated at LCFT under the direct supervision of the PI and with support from Bentall, Sellwood and trial manager Aseem. The study will be managed by the Trial Management Group and will follow MRC Good Clinical Practice in RCT guidelines, and appropriate Ethics and Research Governance arrangements to ensure minimisation of security risk.

The trialists will make fully anonymised data available to other researchers. However, they will hold the right to not share data for a period until they have gained sufficient publication of their work.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/11/2020	16/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes