ISRCTN43816889 https://doi.org/10.1186/ISRCTN43816889

# Trauma Therapy for Psychosis: Eye Movement Desensitisation and Reprocessing (EMDR) for people with a psychotic illness

**Submission date**
10/07/2014

**Recruitment status**
No longer recruiting

**Registration date**
24/10/2014

**Overall study status**
Completed

**Last Edited**
07/12/2023

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Psychosis is a mental illness where those affected hear things that others may not be able to hear, and believe things that others find hard to believe. The suggested therapy is called Eye Movement Desensitisation and Reprocessing (EMDR) and is known to be safe and work well in treating disorders clearly linked to trauma such as Post-Traumatic Stress Disorder (PTSD). Psychosis is understood to be linked with trauma in a similar way to PTSD but this therapy has not been tested for how well it works in this illness. We hope to offer people with psychosis a new brief therapy treatment to reduce the impact of previous difficult or traumatic experiences.

Who can participate?
This study is open to patients who are known to suffer from psychosis and normally have support from the psychiatric services locally.

What does the study involve?
12 patients will be randomly allocated to not receive treatment but continue their normal care with the psychiatric services (treatment as usual). They will be offered the treatment at the end of the study. 24 patients will be randomly allocated to have the EMDR treatment. Everybody will have an interview with a researcher before and after the treatment period, as well 6 months after treatment. At these interviews patients will be assessed on measurement scales that test for the impact of previous traumatic events, the symptoms of psychosis and PTSD, and a measurement of their quality of life.

What are the possible benefits and risks of participating?
We hope to see that patients who receive this treatment have improvements in their symptoms of mental health problems as well as their quality of life. The potential risks of participating include the general risks of participating in a one-to-one therapy. These include increased distress and worsening of symptoms due to the process as well as not getting on with the therapist. These risks will be modified by providing patients with resources and skills to prepare for the treatment including use of relaxation exercises. There is a risk that the patient finds the process difficult and distressing but this risk will be modified by ensuring there is a thorough

consent process, recruitment involves the awareness that the therapy is about treating previous traumatic experiences / memories, and the ensuring that patients are briefed about the EMDR therapeutic process before commencing.

Where is the study run from?
The study will be run from Cornwall Foundation NHS Trust (UK) sites. The trust is based at Shaw House, Porthpean Road, St Austell, Cornwall. Bases will include local Community Mental Health Team bases including Trevillis House, Liskeard; Elfordleigh, Launceston; East Resource Centre, Bude; Alexandra House, St Austell; Banham House, Bodmin; Newquay Resource Centre (Roswyth), Newquay; Pydar Street, Truro; Trengweath, Redruth; and Bolitho House, Penzance.

When is the study starting and how long is it expected to run for?
January 2015 to December 2021

Who is funding the study?
Cornwall Partnership NHS Foundation Trust (UK)

Who is the main contact?
Dr Simon Marlow
simonmarlow@nhs.net

# Contact information

### Type(s)
Scientific

### Contact name
Dr Simon Marlow

### Contact details
Trengweath Mental Health Unit
Penryn Street
Redruth
United Kingdom
TR15 2SP
-
simonmarlow@nhs.net

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
v1.2

# Study information

## Scientific Title
The use of Eye Movement Desensitisation and Reprocessing (EMDR) for the treatment of psychosis

## Acronym
TTP

## Study objectives
We hypothesise that a providing EMDR therapy to patients with psychosis will lead to an improvement in the negative impact of a traumatic event, and subsequent improvements in the symptoms of psychosis, quality of life, and symptoms of post-traumatic stress disorder (PTSD).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South West - Cornwall & Plymouth Research Ethics Committee, 05/05/2015, ref: 15/SW/0034

## Study design
Exploratory randomized control study of the treatment effectiveness of EMDR therapy in people with psychosis.

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

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

## Health condition(s) or problem(s) studied
Mental health difficuties

## Interventions
Patients are randomised to two groups:
1. Eye Movement Desensitisation and Reprocessing Therapy: A course of 8 x 90 minute sessions.
2. The control group will have Treatment As Usual.

## Intervention Type
Other

## Phase

Not Applicable

### Primary outcome measure
Impact of Events Scale (IES) measured at baseline, then after 10 weeks (to allow for the up to 8 week therapy course to complete) and then after 6 months from baseline.

### Secondary outcome measures
1. Positive and Negative Symptoms of Schizophrenia Scale (PANSS)
2. Subjective Quality of Life (MANSA)
3. PTSD Checklist (PCL)

The measures will be done at baseline, then after 10 weeks (to allow for the up to 8 week therapy course to complete) and then after 6 months from baseline.

### Overall study start date
01/01/2015

### Completion date
01/12/2021

## Eligibility

### Key inclusion criteria
Patients with a psychotic illness without comorbid PTSD currently receiving care from secondary care psychiatric services between the ages of 18-65 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
65 Years

### Sex
Both

### Target number of participants
36

### Total final enrolment
36

### Key exclusion criteria
Having a severe learning difficulty, being unable to speak English or travel to the appointments. Having a serious concern about risk or being placed in a locked psychiatric unit.

**Date of first enrolment**
01/01/2015

**Date of final enrolment**
06/07/2021

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Trengweath Mental Health Unit**
Penryn Street
Redruth
United Kingdom
TR15 2SP

# Sponsor information

**Organisation**
Cornwall Foundation NHS Trust (UK)

**Sponsor details**
C/O Dr Ellen Wilkinson
Trust HQ
Shaw House
Porthpean Road
St Austell
Cornwall
England
United Kingdom
PL26 6AD

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/0517ad239

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Cornwall Partnership NHS Foundation Trust (UK) - Research and Development Team

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

### Intention to publish date
01/07/2022

### Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 18/11/2023 | 07/12/2023 | Yes | No |