

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/10/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/12/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
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Redruth
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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mental health difficulties

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

United Kingdom

England

Study participating centre

Trengweath Mental Health Unit
Penryn Street

Redruth
United Kingdom
TR15 2SP

Sponsor information

Organisation

Cornwall Foundation NHS Trust (UK)

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

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?
Results article		18/11/2023	07/12/2023	Yes	No
HRA research summary			28/06/2023	No	No