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# Trauma-focused therapy in people at risk of psychosis

**Submission date**
30/04/2018

**Recruitment status**
No longer recruiting

**Registration date**
03/05/2018

**Overall study status**
Completed

**Last Edited**
25/06/2024

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Current plain English summary as of 01/08/2019:
Background and study aims
Psychotic illnesses are some of the most disabling illnesses, with more than 21 million people affected worldwide. These illnesses cause a huge burden on sufferers and their families. About 22% of people with an at-risk mental state (ARMS) will make a transition to psychosis within 1 year. Current treatments to prevent the onset of psychosis are not very effective. More than 80% of the people at-risk of psychosis report traumatic events, especially during childhood. Studies suggested that memories of these events can lead to some people developing hallucinations (e.g. hearing voices) and delusions (e.g. paranoid beliefs), which are the most common symptoms of psychotic illnesses. Eye Movement Desensitisation and Reprocessing ( EMDR) is a type of trauma-focused therapy which helps people deal with traumatic memories by changing how these are stored, and altering negative beliefs caused by the event (e.g. 'It is my fault'). EMDR is an effective therapy for post-traumatic stress disorder, another illness caused by memories of traumatic events, but no studies have yet investigated whether EMDR could prevent the onset of psychosis in people at-high risk. To investigate this, a large randomized controlled trial is needed. First, however, the aim of this study is to investigate whether such a trial would be feasible and acceptable to patients.

Who can participate?
Patients aged 16 or over who are at risk of psychosis, have a history of trauma and at least one symptom of post-traumatic stress disorder.

What does the study involve?
Participants will be offered up to 12 EMDR sessions. Participants are followed up for 1 year, and data is collected on transition to psychosis and severity of symptoms. Patients and therapists are interviewed about their views of EMDR, study materials and participation experiences to help design a large study to find out whether EMDR is effective at preventing the development of psychotic illnesses.

Additional qualitative work
Recruitment to the study has been much lower than expected. It appears that one key reason for low recruitment is because the number of ARMS patients in the Early Intervention Services in

AWP is much lower than expected based on data which had been given to us from the Trust prior to the study starting.
Therefore the qualitative element of the study has been expanded to:
1) better understand how ARMS patients are managed in primary and secondary care settings, in order to identify possible reasons for why recruitment to the study has been much lower than expected and
2) consider how best to recruit ARMS patients to future research studies.
In-depth interviews with GPs and clinicians from secondary care services will be conducted to explore how potential ARMS patients are identified in primary and secondary care, how they are managed, and the facilitators and barriers of referral to secondary care early intervention services. We would also like to interview UK researchers with experience of recruiting ARMS patients to their studies.
Thus, the qualitative components of the study will entail:
a. Interviews with GPs, clinicians from Primary Care Liaison Services and other secondary care services
b. Interviews with patients who did not participate in the interventional part of the study but who have been identified as ARMS by the EI teams we are recruiting from
c. Interviews with researchers who have been involved in recruiting ARMS patients to research studies in the UK

What are the possible benefits and risks of participating?
By taking part in this study, participants will help researchers better understand how to manage individuals who are at risk of developing psychosis. At the end of the study, participants will be sent a summary of the results. Patients will be asked to fill out questionnaires about traumatic experiences they had in the past. This may be upsetting for some of them. However, patients will be told prior to assessment that they do not have to answer a specific question if they do not feel comfortable doing so. Likewise, before the interview, patients will be told that they can stop the interview at any time and without having to give a reason. Their medical care will not be affected. The researchers administering the scales and conducting the interviews have previously worked in the area of mental health and dealt with sensitive issues.

Where is the study run from?
Avon and Wiltshire Mental Health Partnership NHS Trust (UK)

When is the study starting and how long is it expected to run for?
October 2017 to May 2021 (updated 29/05/2020, previously: April 2020)

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

Who is the main contact?
Prof. Stanley Zammit

Previous plain English summary:
Background and study aims
Psychotic illnesses are some of the most disabling illnesses, with more than 21 million people affected worldwide. These illnesses cause a huge burden on sufferers and their families. About 22% of people with an at-risk mental state (ARMS) will make a transition to psychosis within 1 year. Current treatments to prevent the onset of psychosis are not very effective. More than 80% of the people at-risk of psychosis report traumatic events, especially during childhood. Studies suggested that memories of these events can lead to some people developing hallucinations (e.g. hearing voices) and delusions (e.g. paranoid beliefs), which are the most

common symptoms of psychotic illnesses. Eye Movement Desensitisation and Reprocessing (EMDR) is a type of trauma-focused therapy which helps people deal with traumatic memories by changing how these are stored, and altering negative beliefs caused by the event (e.g. 'It is my fault'). EMDR is an effective therapy for post-traumatic stress disorder, another illness caused by memories of traumatic events, but no studies have yet investigated whether EMDR could prevent the onset of psychosis in people at-high risk. To investigate this, a large study is needed. First, however, the aim of this study is to investigate whether such a study would be feasible and acceptable to patients.

Who can participate?
Patients aged 16 or over who are at risk of psychosis and have a history of trauma

What does the study involve?
Participants are randomly allocated to either 12 EMDR sessions or treatment as usual (TAU). Participants are followed up for 1 year, and data is collected on transition to psychosis and severity of symptoms. Patients and therapists are interviewed about their views of EMDR, study materials and participation experiences to help design a large study to find out whether EMDR is effective at preventing the development of psychotic illnesses.

What are the possible benefits and risks of participating?
By taking part in this study, participants will help researchers better understand how to manage individuals who are at risk of developing psychosis. At the end of the study, participants will be sent a summary of the results. Patients will be asked to fill out questionnaires about traumatic experiences they had in the past. This may be upsetting for some of them. However, patients will be told prior to assessment that they do not have to answer a specific question if they do not feel comfortable doing so. Likewise, before the interview, patients will be told that they can stop the interview at any time and without having to give a reason. Their medical care will not be affected. The researchers administering the scales and conducting the interviews have previously worked in the area of mental health and dealt with sensitive issues.

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Who is the main contact?
Prof. Stanley Zammit

# Contact information

### Type(s)
Scientific

### Contact name
Prof Stanley Zammit

### ORCID ID

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Oakfield House
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# Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
37404

# Study information

**Scientific Title**
A feasibility study of eye-movement desensitization and reprocessing (EMDR) in people with an at-risk mental state (ARMS) for psychosis

**Study objectives**
Psychotic illnesses are some of the most disabling illnesses, with more than 21 million people affected worldwide. These illnesses cause a huge burden on sufferers and their families. Approximately 22% of people with an at-risk mental state (ARMS) will make a transition to psychosis within 1 year. Current treatments to prevent the onset of psychosis are not very effective.

More than 80% of the people at-risk of psychosis report traumatic events, especially during childhood. Studies suggested that memories of these events can lead to some people developing hallucinations (e.g. hearing voices) and delusions (e.g. paranoid beliefs), which are the most common symptoms of psychotic illnesses. Eye Movement Desensitisation and Reprocessing (EMDR) is a type of trauma-focused therapy which helps people deal with traumatic memories by changing how these are stored, and altering negative beliefs caused by the event (e.g. 'It is my fault').

EMDR is an effective therapy for post-traumatic stress disorder, another illness caused by memories of traumatic events, but no studies have yet investigated whether EMDR could prevent the onset of psychosis in people at-high risk. To investigate this, a large randomised-controlled trial is needed. First, however, we need to investigate whether such a trial would be feasible and acceptable to patients.

This study seeks to establish whether it would be feasible to conduct a large multi-centre RCT to evaluate the clinical and cost-effectiveness of EMDR to prevent the onset of psychosis in people with an at-risk mental state.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South West - Exeter Research Ethics Committee, 19/03/2018, ref: 18/SW/0037

## Study design
Current study design as of 11/07/2019:
Single arm interventional study.

Previous study design:
Randomised; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Prevention

## Participant information sheet
See additional files

## Health condition(s) or problem(s) studied
Psychosis

## Interventions
Current interventions as of 01/08/2019:
We originally planned to randomise all consented participants to one of the two groups: 1) EMDR or 2) TAU. Randomization took place by means of a computerized service administered by the Bristol Randomised Trials Collaboration (BRTC). This ensured that allocations were concealed from the recruiting researcher. Randomization was minimized by psychotic symptom severity and patients were categorized based on the positive symptoms of CAARMS (i.e, sum of Unusual Thoughts, Non-Bizarre Ideas, Perceptual Abnormalities and Disorganised Speech Global Ratings scales), with cut-off at 11 on this scale. Participants were notified of their group allocation within 48 hours of the baseline assessment.

Given the change in study design from a randomised controlled trial to a single arm trial, all eligible consenting participants will now be offered EMDR. Patients will receive up to 12 sessions of manualized, weekly, face-to-face EMDR therapy. Each session will last approximately 90 minutes. EMDR therapy sessions will be held by trained EMDR therapists at the EI services, GP Surgeries, or other NHS/private clinical premises. Participants will be followed up for 1 year, and data on transition to psychosis and severity of symptoms will be collected. Patients and therapists will be interviewed about their views of EMDR, study materials and participation

experiences by telephone or face-to-face at the EI services. Follow-up assessments will take place at 4, 8 and 12 months after the baseline assessment. This will take place either at the EI Services, University of Bristol premises or at participants' home.

Previous interventions:
Randomization will take place by means of a remote automated telephone service administered by the Bristol Randomised Trials Collaboration (BRTC). Randomization will be minimized by psychotic symptom severity and patients will be categorized based on the positive symptoms of CAARMS (i.e, sum of Unusual Thoughts, Non-Bizarre Ideas, and Perceptual Abnormalities Global Ratings scales), with cut-off at 11 on this scale.

Participants will be randomly allocated to eye-movement desensitization and reprocessing (EMDR) sessions or treatment as usual (TAU). Patients allocated to EMDR will receive up to 12 sessions of manualized, weekly, face-to-face EMDR therapy. Each session will last approximately 90 minutes. EMDR therapy sessions will be held by trained EMDR therapists at the EI services. Participants will be followed up for 1 year, and data on transition to psychosis and severity of symptoms will be collected. Patients and therapists will be interviewed about their views of EMDR, study materials and participation experiences by telephone or face-to-face at the EI services. Follow-up assessment at 4, 8 and 12 months post-randomization. This will take place either at the EI Services or at participants' home.

## Intervention Type
Other

## Primary outcome measure
Transition to psychosis assessed at 12 months post-randomization from clinical records (measured as an ICD-10 diagnosis of psychosis) or, if patients have dropped out of the Early Intervention Services, researchers will invite participants for an appointment where, via the CAARMS, it will be established whether they transitioned to psychosis.

## Secondary outcome measures
Current secondary outcome measures as of 01/08/2019:
1. Severity of psychotic symptoms, measured using CAARMS, PSYRAT, the negative scale of the PANSS, and CAPE-42
2. Severity of PTSD symptoms, measured using PCL-5
3. Severity of depression and anxiety, measured using PHQ-9 and GAD-7
4. Impaired functioning, measured using Work and Social Adjustment Scale (WSAS)
5. Health status, measured using EQ-5D-L
6. Drug use, measured using DAST 10
7. Medication use, measured with self-report questionnaires
8. Resource data use, measured with self-report questionnaires
All secondary outcomes apart from resource data use will be assessed at baseline, 4, 8 and 12 months after the baseline assessment. Resource use will be assessed only at 4, 8 and 12 months after the baseline assessment.

Previous secondary outcome measures:
1. Severity of psychotic symptoms, measured using PANSS, PSYRAT and CAPE-42
2. Severity of PTSD symptoms, measured using PCL-5
3. Severity of depression and anxiety, measured using PHQ-9 and GAD-7
4. Impaired functioning, measured using Work and Social Adjustment Scale (WSAS)
5. Health status, measured using EQ-5D-L

6. Drug use, measured using DAST 10
7. Medication use, measured with self-report questionnaires
8. Resource data use, measured with self-report questionnaires
All secondary outcomes apart from resource data use will be assessed at baseline, 4, 8 and 12 months post-randomization. Resource use will be assessed only at 4, 8 and 12 months post randomization.

### Overall study start date
03/10/2017

### Completion date
31/05/2021

## Eligibility

### Key inclusion criteria
1. Those aged 16 years or over who are at risk of psychosis (as defined in the Comprehensive Assessment of At-Risk Mental States (CAARMS) (A. R. Yung et al., 2005)
2. Presence of at least one positive symptom (perceptual abnormality, unusual thought, or non-bizarre ideas) scored ≥3 on CAARMS
3. History of traumatic experience as defined in ICD-10 F43.1, occurring prior to onset of first positive symptom
4. Presence of 1 or more symptoms of re-living, avoidance, hyper-arousal, or cognitive distortions in relation to the traumatic experience (assessed using the PTSD Checklist for DSM-V (PCL5) during the last month (Bovin et al., 2016))

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

### Total final enrolment
14

### Key exclusion criteria
1. People with past history of treated or untreated psychotic illness or learning disability
2. Current use of antipsychotics
3. Currently receiving psychological therapy
4. Completed a trauma-focused psychological therapy in the last 2 years
5. Insufficient fluency in English
6. Lacking mental capacity to provide valid informed consent

### Date of first enrolment

01/05/2018

**Date of final enrolment**
31/05/2020

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Avon and Wiltshire Mental Health Partnership NHS Trust**
United Kingdom
BS15 9TR

# Sponsor information

**Organisation**
University of Bristol

**Sponsor details**
Senate House
Tyndall Avenue
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United Kingdom
BS8 1TH

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/0524sp257

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Bristol Biomedical Research Centre; Grant Codes: BRC-1215-20011

# Results and Publications

## Publication and dissemination plan
The trialists intend to publish the results of the study in high impact peer reviewed journals. This will be done in two stages: qualitative data will be published within 12 months of finishing qualitative data collection (approximately September 2020), and quantitative results within 12 months after the trial end date (approximately August 2021).

## Intention to publish date
31/05/2023

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Stanley Zammit. Data will be available 1 year after the end of the study.

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version V2 | 06/03/2018 | 03/05/2018 | No | Yes |
| Protocol file | version V1 | 11/01/2018 | 03/05/2018 | No | No |
| Protocol file | version V3 | 19/04/2019 | 11/07/2019 | No | No |
| Protocol file | version v4 | 02/08/2019 | 14/01/2020 | No | No |
| Protocol article | protocol | 01/10/2020 | 07/10/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 09/05/2024 | 25/06/2024 | Yes | No |