Trauma-focused Therapies for Posttraumatic stress In Psychosis: the RE.PROCESS randomised controlled trial

Published: 27-03-2019
Last updated: 09-04-2024

Our primary objective is to test the effects on researcher-rated severity of PTSD symptoms of a full dose of prolonged exposure therapy (PE), eye movement desensitization and reprocessing therapy (EMDR), cognitive restructuring therapy without...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON54514

Source
ToetsingOnline

Brief title
RE.PROCESS

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis / Post-traumatic stress disorder, Schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Stichting tot steun VCVGZ

Intervention

Keyword: Eye-movement desensitization and reprocessing, Post-traumatic stress disorder, Prolonged exposure, Psychosis

Outcome measures

Primary outcome

The main outcome is researcher-rated changes in severity of PTSD symptoms on

the CAPS between baseline and 6-month follow-up.

Secondary outcome

Researcher-rated presence of PTSD diagnosis, self-rated severity of PTSD and

severity of complex PTSD symptoms, posttraumatic cognitions, dissociation,

depression, paranoia, auditory verbal hallucinations, social functioning,

disruption of social functioning by PTSD symptoms, resilience, personal

recovery, sexual functioning, adversities, and revictimization.

Study description

Background summary

Positive effects on PTSD, psychosis, adversities and revictimization were found in patients with psychosis for a small dose (8 sessions) of prolonged exposure (PE) or Eye Movement Desensitization and Reprocessing (EMDR). Replication is needed and there are many important issues that warrant further investigation, such as a test of a full treatment dose, improvement of the effects on psychosis symptoms, and an improvement of our understanding of mechanisms of change. Importantly, there is need for a head-to-head comparison of trauma-focused treatments with and without direct trauma memory processing in patients with psychosis.

Study objective

Our primary objective is to test the effects on researcher-rated severity of

PTSD symptoms of a full dose of prolonged exposure therapy (PE), eye movement desensitization and reprocessing therapy (EMDR), cognitive restructuring therapy without direct trauma memory processing (CR), and waiting list (WL). We will compare all arms, and are primarily interested in comparing the active treatments (PE, EMDR and CR) to WL, and in comparing the interventions with (PE and EMDR) to the intervention without (CR) direct memory processing.
The secondary objective is to investigate the effects of these treatments on researcher-rated presence of PTSD diagnosis, self-rated severity of PTSD and severity of complex PTSD symptoms, posttraumatic cognitions, dissociation, depression, paranoia, auditory verbal hallucinations, social functioning, disruption of social functioning by PTSD symptoms, resilience, personal recovery, sexual functioning, adversities, and revictimization. Third, with the 24-month follow-up we aim to test the long-term effects on all the outcomes for the first time.
Fourth, we aim to explore how post-traumatic stress and psychosis interact dynamically, how the experimental treatments influence these interactions, and what factors significantly predict treatment response.
Our fifth objective is to determine the cost-effectiveness of the interventions.
Sixth, we will conduct a process evaluation of the therapy process by conducting interviews to examine how participants experienced receiving trauma-focused treatment.

Study design

A single-blind multicentre randomised controlled trial with four arms: PE, EMDR, CR, and WL. All groups receive treatment as usual for psychosis. All the groups will be assessed at baseline (T0), mid-treatment (T1), posttreatment (T2), and at 6-month follow-up (T3). These assessments will take about 90 minutes to administer. Participants in the WL condition can choose to undergo treatment of choice after the 6-month follow-up assessment. The PE, EMDR and CR conditions will also be assessed at 12-month and 24-month follow-up. Up to the 6-month follow-up assessment, all groups weekly monitor the outcomes social functioning, adversities, and revictimization. Participants in the active treatment arms will receive two treatment sessions per week.

Intervention

The PE, EMDR and CR groups will receive a maximum of 16 sessions of treatment. The third group will be a waiting list group up to the 6-month follow-up, after which they may choose to receive treatment. All groups receive treatment as usual for psychosis

Study burden and risks

Participants in the active treatment arms will be tested five times. The

participants will receive a maximum of 16 trauma-focused treatment sessions of maximally ninety minutes. Some patients may experience a short increase in symptoms during or following the sessions. Based on prior research, no major adverse events are expected. CR was found to be safe in patients with psychosis, and both PE and EMDR were actually found to reduce adversities in this group. Participants in the WL condition will have to wait for treatment for 6 months.

Contacts

Public
Vrije Universiteit

van der Boechorstraat 1
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit

van der Boechorstraat 1
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• age 16+ years
• a lifetime diagnosis of a psychotic disorder in the schizophrenia spectrum, confirmed by the Structured Clinical Interview for DSM-5 (SCID-5)

• meeting DSM-5 symptom criteria for PTSD (cluster B to H) on the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) with a minimum score >=23
• willingness to undergo randomisation and a trauma-focused intervention

Exclusion criteria

• changes in antipsychotic or antidepressant medication regimen within 4 weeks before the inclusion interview assessment (to control for medication effects)
• insufficient competence in the Dutch language
• severe intellectual impairment, defined as an estimated IQ of 70 or less
• not being able to travel (or be accompanied) to the outpatient service
• not willing or able to learn to use a smartphone

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2019
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	27-03-2019

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL66431.029.19