Intensive prolonged exposure therapy for posttraumatic stress disorder in patients with a psychotic disorder: a single trial design

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The primary objective is to determine the effects of iPE on the PTSD diagnosis, on the self-rated and clinician-rated severity of PTSD symptoms. The secondary objectives are to determine the effects on psychotic symptoms, depression symptoms,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON51923

Source
ToetsingOnline

Brief title
IPE for PTSD in patients with a psychotic disorder

Condition

- Anxiety disorders and symptoms

Synonym
(1) PTSD (2) trauma

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Intensive trauma-focused treatment, Posttraumatic Stress Disorder (PTSD), Prolonged exposure (PE), Psychotic disorder

Outcome measures

Primary outcome

The main outcome is self-rated changes in severity of PTSD symptoms on the PTSD checklist for DSM 5 (PCL-5) and clinician-rated PTSD symptoms and diagnosis measured with the Clinician-Administered PTSD Scale (CAPS-5).

Secondary outcome

- Self-reported psychotic symptom severity, measured with the Community Assessment of Psychic Experiences (CAPE)-42.

- Self-reported paranoia severity, measured with the Revised Green et al. Paranoid Thought Scales (R-GPTS).

- Self-reported hallucination severity, measured with the modified Launay Slade Hallucination Scale (LSHS).

- Self-reported depression symptom severity, measured with the Inventory of Depressive Symptomatology - SR (IDS-SR).

- Self-reported general functioning, measured with the Outcome Questionnaire (OQ-45).

- Self-reported treatment safety, monitored with self-report of adverse events (e.g. suicide attempt, self-harm, aggressive behavior, problematic alcohol/drug abuse, crisis contact with mental health care, psychiatric hospitalization).

- Subjective experienced burden, measured in an ecologically valid manner,

using a questionnaire with an 11-point Likert-scale and additional open-ended

questions.

Study description

Background summary

Studies show positive effects of prolonged exposure (PE) treatment on posttraumatic stress disorder (PTSD) and beneficial side effects on psychosis in patients with both PTSD and psychosis. Intensive prolonged exposure therapy (iPE) is a relatively new strategy to deliver trauma focused treatment sessions in a highly intense format and therefore shorter duration compared to regular PE, resulting in a low drop-out and fast symptom reduction. However, little is known about the effects of this iPE on PTSD and psychotic symptoms in the patient group.

Study objective

The primary objective is to determine the effects of iPE on the PTSD diagnosis, on the self-rated and clinician-rated severity of PTSD symptoms. The secondary objectives are to determine the effects on psychotic symptoms, depression symptoms, general functioning, experienced burden and treatment safety

Study design

The study design is a within-subject, time-series design in which all subjects will receive the same intervention (iPE). Before iPE starts, subjects are randomized to varying baseline length (3 to 9 weeks). The post-treatment phase varies in length as well in such a way that baseline, intervention phase and post-treatment together equal 18 weeks. Self-reported PTSD and psychotic symptoms will be weekly measured during these 18 weeks (as well as during a follow-up phase (four-weekly measurements) after 3 months. Furthermore, the clinician administered PTSD symptom severity and diagnosis, self-rated psychotic symptoms (hallucinations and paranoid thoughts), self-rated depression symptom severity and self-rated general functioning secondary were measured at 3 single time points: at baseline (right before the start of the treatment), posttreatment (at the end of the iPE therapy;) and at 3-month follow-up. Adverse events will be measured at multiple time points during the intervention phase and posttreatment (at the end of the iPE therapy). Expected burden will be evaluated at the start of the iPE therapy, and experienced burden posttreatment (at the end of the iPE therapy).

Intervention

The iPE therapy program is based on Foa*s PE protocol, but given in a highly intensive format instead of weekly sessions. The total duration of the intervention is 6 weeks. The intensive phase of the treatment will have a duration of four weekdays, delivered in two weeks. After the intensive phase, the subject will participate in the booster phase in which the subject will receive a 90-minute PE booster session weekly over the next four weeks.

Study burden and risks

Prior research shows that iPE programs are safe. Worsening of symptoms or other adverse events are not expected. Furthermore, patient follow up-care as usual is embedded. During and after the study subjects will continue their regular psychosis treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1) a minimum age of 18 years;
2) a diagnosis of PTSD that meets the criteria of the DSM-5 (American Psychiatric Association, 2013) measured with the Clinician-Administered PTSD Scale (CAPS-5; Weathers, Keane, & Davidson, 2001; Weathers, et al., 2018) and;
3) a co-morbid current diagnosis of a psychotic disorder according to the Mini-International Neuropsychiatric Interview-S (MINI-S) (Sheehan, et al., 1998)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) high acute suicide risk, characterized as a suicide attempt within the past 2 months;
2) changes in antipsychotic or antidepressant medication within two months before the start of this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2022
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL75271.091.21