

efficacy of evidence based exposure- or EMDR-treatment for PTSD with patients with a vulnerability for psychosis. A multiple baserate pilot study.

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The aim of the study is to explore the effects of two first choice PTSD treatments according to the guidelines, EMDR and prolonged exposure, in patients with a history of psychotic episodes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32890

Source

ToetsingOnline

Brief title

efficacy of PTSD-treatment in patients with psychoses. A pilot study.

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym

post traumatic stress disorder, psychosis, traumas

Health condition

posttraumatische stresstoornis

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)

Source(s) of monetary or material Support: vooralsnog wordt het pilotonderzoek nog niet gefinancierd door de GGZ of enige andere subsidieverlener/sponsor. Het pilotonderzoek wordt in eigen tijd gedaan; met toestemming van de Raad van bestuur en zorggroep-directeur.

Intervention

Keyword: EMDR, Exposure, psychosis, PTSD

Outcome measures

Primary outcome

- PTSD symptoms
- The frequency of PTSD-symptoms will be assessed with Posttraumatic Stress Symptom Scale, Self Report, PSS- SR; Foa et al., 1993; Dutch translation; Engelhard & Arntz, 2005; Questionnaire, 17 items).
- Psychotic symptoms
- Psychotic symptoms will be measured by the PSYRATS (Haddock et al., 1994, vert de Hert et al., 1996), which measures the frequency and influence of hallucinations and delusions.

Secondary outcome

1. Style of reasoning in psychotic patients, measured by the O-Life (Mason, 1995; 2006).
2. Level of functioning, measured by the Outcome Questionnaire (OQ; Lambert & Burlingame, 2001).

3. Social functioning, measured by the Social Functioning Scale (van Birchwood, 1990.
4. Medication; changes
5. Number of admissions or crises during treatment

Study description

Background summary

Recent studies showed that PTSD treatment can be effective in patients with severe psychopathology (such as borderline personality disorder, alcohol abuse, dissociative disorders). In addition, no adverse treatment reactions, such as symptom exacerbation or decompensation were found, despite the fears of some therapists in the clinical field. In contrast, patients improved, both on PTSD and on other symptoms.

Thusfar, little treatment studies have been conducted in patients with PTSD who have shown psychotic episodes in their psychiatric history. This study will exploratively study the effects of PTSD treatment in this population.

Study objective

The aim of the study is to explore the effects of two first choice PTSD treatments according to the guidelines, EMDR and prolonged exposure, in patients with a history of psychotic episodes.

Study design

A multiple baserate study consisting of 8 single cases will be performed. After inclusion, patients are randomly divided to one of the two treatment conditions, EMDR or prolonged exposure. The treatment will comprise 12 weeks. Before and after and during the treatment sessions, psychopathological symptoms, social behavior, endorsement, medication, medical consumption behavior (crisis, admissions) will be monitored.

Intervention

Participants will be allocated to one of two treatment conditions, which are active PTSD treatment programmes, aimed at processing of traumatic experiences, EMDR and prolonged exposure. Both treatments are first choice treatment for PTSD in several national and international guidelines for the treatment of

PTSD.

Study burden and risks

In clinical practice, some therapists may fear that PTSD treatment in patients with comorbidity, due to the high emotional burden of the treatment, will lead to an increase in PTSD symptoms, or/and an increase in the co-morbid disorder. In contrast, a recent study showed that PTSD treatment was successful in decreasing the PTSD symptoms and in decreasing the psychotic symptoms (Mueser et al., 2007).

In clinical practice, therapists may fear to treat PTSD in other co-morbid conditions as well. However, several studies have been conducted in psychiatrically vulnerable populations, such as PTSD-patients with co-morbid borderline personality disorders, alcohol abuse, and dissociative and depressive symptoms and PTSD -patient who experienced sexual abuse in childhood.

However, thusfar little studies in patients with psychotic disorders have been conducted, and it can't be predicted whether or not adverse reactions may appear. Therefore, several precautions and safety procedures are in order, and are included in the treatment study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Having had one or more psychotic episodes due to psychiatric illness (SCID-1; structured clinical interview for DSM-IV-diagnosis)
2. PTSD (CAPS: clinician-administered PTSD scale, originally by Blake, Weathers, Nagy, Kaloupek, Charney, & Keane, 1995)

Exclusion criteria

1. Severe dissociative disorders. High-scores on the SDQ-20 (scores above 35) are excluded because of the severe possibility of having a serious dissociative disorder. (somatoform-dissociation questionnaire, 20 items; Nijenhuis, Spinhoven, Van Dyck, Van der Hart, & Vanderlinden, 1996),
2. Severe psychosis at the time of investigation (SCID-1)

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-04-2009

Enrollment: 8

Type: Actual

Ethics review

Approved WMO

Date: 09-04-2009

Application type: First submission

Review commission: METIGG: Medisch Ethische Toetsingscommissie Instellingen
Geestelijke Gezondheidszorg (Utrecht)

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	NL24519.097.08