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# Treating trauma in psychosis

**Submission date**
22/12/2011

**Recruitment status**
No longer recruiting

**Registration date**
27/02/2012

**Overall study status**
Completed

**Last Edited**
19/02/2019

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
People who suffer from psychosis very often also have other disorders at the same time, such as anxiety, depression or post-traumatic stress disorder (PTSD). Patients with psychosis and PTSD often ask for treatment of PTSD, but clinicians are reluctant to do so as they fear a worsening of symptoms, although there is no proof of this in the scientific literature. There are a number of small studies that show successful reduction of symptoms and no unwanted effects such suicidal ideation and gestures, worsening of symptoms, hospital admissions, crises contacts with the mental health services and so on. This study is treating PTSD in people with a lifetime psychotic disorder to find out if symptoms will reduce and no accidents will happen. It will compare two forms of therapy that have proven to be effective in the treatment of PTSD.

Who can participate?
Adults who have a lifetime psychotic disorder and PTSD and are registered in one of the 13 participating institutions.

What does the study involve?
Patients will be randomly allocated to one of three conditions: prolonged exposure (PE), eye movement desensitisation and reprocessing (EMDR), or waiting list. Prolonged exposure is a proven effective treatment for PTSD. The patient will have a maximum of eight 90-minute sessions. In the session people are asked to think, imagine and relive the most terrifying traumatic event. Recordings of the sessions have to be listened at home on a daily schedule. The experience is that anxiety will wane over time. When anxiety disappears another traumatic event is selected and the procedure is repeated. EMDR is also a proven effective treatment for PTSD. The patient is asked to relive the traumatic event and select the most horrible picture and describe what makes this event still so horrible. This is formulated in a negative cognition and a goal positive cognition is formulated as well. Then the patient is asked to imagine the most horrible picture and then look at the fingertips of the therapist, who waives the fingers back and forth. The patients eyes moves from left to right in a quite high pace. When anxiety disappears another traumatic event is selected and the procedure is repeated. The waiting list group has to wait for 6 months and then has the therapy of choice. All groups are assessed at the beginning, after two months at the end of treatment, and after 6 months. The PE and EMDR groups have a last assessment at 12 months. Patients who hallucinate are also assessed for two times during

six days at the beginning and end of treatment with the PSYMATE. This is a device that looks like a mobile phone and rings ten times a day. The participant then has to answer some questions on the place he/she is, the company, the thoughts, the feelings, and his/her behaviour.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The study is a multi-site study in 13 mental health services in the Netherlands. These are GGz Noord-Holland-Noord in Almaar and surroundings, Arkin in Amsterdam, GGz Duin en Bollenstreek (Leiden and surroundigs), Lentis (province of Groningen), Yulius (Dordrecht and surroundings), Altrecht (Utrecht and surrounidngs), Parnassia Psychiatric Institute (The Hague and Zoetermeer), Bavo-Europoort (Rotterdam), Pro Persona (Nijmegen and surroundings), GGz Eindhoven (Eindhoven and surroundings), GGz Oost Brabant (Boxmeer and Oss and surroundings), GGz Drenthe (province of Drenthe), GGNet (Apeldoorn, Doetinchem, Zutphen and surroundings).

When is study starting and how long is it expected to run for?
The study started in September 2011 and is expected to run for about three years. For the PE and EMDR patients the study will take 12 months: a 2-month treatment intervention with 6-month and 12-month follow-up assessments. The waiting list group will have a waiting period of 6 months and then a 2-month treatment phase.

Who is funding the study?
The study is funded by the Stichting tot Steun VCVGZ.

Who is the main contact?
Prof. dr. Mark van der Gaag
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Mark van der Gaag

### Contact details
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
NL36649.091.11

# Study information

### Scientific Title
The effect of treatment of posttraumatic stress disorder in people with a lifetime psychotic disorder: a multi-site randomized controlled trial

### Acronym
T-TIP

### Study objectives
Are Eye Movement Desensitization and Reprocessing (EMDR) and Prolonged Exposure (PE) effective in treating posttraumatic stress disorder compared to waiting list in people with lifetime psychotic disorders?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
METiGG Ethics Comittee [Medisch-ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg], 17/10/2011, ref: NL36649.097.11

### Study design
Randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Psychosis and post-traumatic stress disorder/ psychiatry and psychology

### Interventions

In all three arms treatment as usual will be provided for the psychotic disorder for which the person sought help. In the experimental arms there will be a maximum of 8 sessions (over two months) of either prolonged exposure or EMDR with a trained CBT therapist aimed at reducing PTSD symptoms. Treatment duration is two months, patients will be followed-up at 6 months and 12 months.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
1. Clinician Administered PTSD Scale (CAPS) diagnosis and severity
2. PTSD Symptom Scale Self-Report (PSS-SR) severity

### Secondary outcome measures
1. Influence on psychosis (PANSS 8-item Remission Tool, GPTS and DRS in case of delusions, AHRS and AVH-BAS in case of auditory hallucinations)
2. Depression (BDI-II)
3. Social functioning (PSP)
4. Adverse events (TTIP Adverse Events Questionnaire)
5. Quality of life and cost-effectiveness (EQ5D, TIC-P)

### Overall study start date
01/11/2011

### Completion date
01/11/2013

## Eligibility

### Key inclusion criteria
1. Lifetime psychotic disorder as assessed by MINI
2. PTSD as assessed by CAPS
3. Outpatient
4. Age 18 to 65 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
240

### Key exclusion criteria
1. IQ under 70
2. No competence of the Dutch language
3. Not willing or able to travel to treatment location

### Date of first enrolment
01/11/2011

### Date of final enrolment
01/11/2013

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Prinsegracht 63**
The Hague
Netherlands
2512 EX

## Sponsor information

### Organisation
Stichting tot Steun VCVGZ (Netherlands)

### Sponsor details
c/o Dr Fam Meuwese
PO Box 9219
Arnhem
Netherlands
6800 HZ

### Sponsor type
Research organisation

### Website
http://www.stichtingtotsteunvcvgz.nl

### ROR
https://ror.org/05yh1h167

# Funder(s)

### Funder type
Research organisation

### Funder Name
Foundation for Support VCVGZ [Stichting tot Steun VCVGZ] (Netherlands)

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 23/05/2013 | | Yes | No |
| Results article | results | 01/03/2015 | | Yes | No |
| Results article | results | 01/05/2016 | | Yes | No |
| Results article | results | 01/08/2016 | | Yes | No |
| Results article | results | 06/09/2016 | | Yes | No |
| Results article | results | 01/10/2016 | | Yes | No |
| Results article | results | 01/10/2016 | | Yes | No |
| Results article | results | 01/03/2018 | | Yes | No |
| Results article | results | 21/01/2019 | | Yes | No |