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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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

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(s)
1. Clinician Administered PTSD Scale (CAPS) diagnosis and severity
2. PTSD Symptom Scale Self-Report (PSS-SR) severity

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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

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?
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
Protocol article	protocol	23/05/2013	Yes	No