Self-esteem and paranoia, COMET for paranoid patients

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The main goal is to investigate whether COMET can be used as an intervention to reduce paranoia in patients with psychotic disorder and paranoid thoughts. An aim is also to see if the treatmenteffect is stable after eight weeks.

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

Summary

ID

NL-OMON46663

Source
ToetsingOnline

Brief title
Self-esteem and paranoia

Condition

- Schizophrenia and other psychotic disorders

Synonym
self-esteem and paranoia

Research involving
Human

Sponsors and support

Primary sponsor: De Forensische Zorgspecialisten
Source(s) of monetary or material Support: De kosten van het onderzoek worden betaald door de Forensische Zorgspecialisten

Intervention

Keyword: COMET, paranoia, Self-esteem

Outcome measures

Primary outcome

The main outcome measure is the degree of paranoia. This will be measured using a self-screening list, the Green Paranoid Thoughts Scale. This is a symptom-specific tool for measuring paranoid thoughts. Self-esteem is measured using the Rosenberg Self-esteem scale. Eight weeks after the last training, both questionnaires will be taken again. In addition, the Positive And Negative Syndrome Scale (PANSS) will be used. This is a semi-strucured interview to measure the positive and negative symptoms and other psychopathology in psychotic patients.

Secondary outcome

Eight weeks after completion the training participants, both of the experimental and the control group, will be asked to fill in the questionnaires again and the PANSS will be taken to investigate whether the effects of the long-term training remain.

In addition, the degree of drop-out will be viewed.

Study description

Background summary

In this study, patients with psychotic disorder and paranoia are asked to participate in a self-esteem training, the COMET. The expectation is that enhancing the self-esteem by COMET reduces paranoid thoughts. The results are measured using an RCT, where an experimental group is offered the COMET and a

control group 'treatment as usual'. The groups will be compared to each other with self-report questionnaires and an semi-structured interview before and after the training.

Study objective

The main goal is to investigate whether COMET can be used as an intervention to reduce paranoia in patients with psychotic disorder and paranoid thoughts. An aim is also to see if the treatmenteffect is stable after eight weeks.

Study design

After informed consent, participants will be randomly assigned to an experimental condition in which they receive the COMET training or a control condition in which they are offered a training called "Grip op je leven", the treatment of usual.

Intervention

One group (experimental group) is offered the COMET, this is a self-esteem training, developed by Kees Korrelboom (2011), and for which scientific evidence has been found in other patient groups. Another group is offered 'treatment as usual'. This condition consists of a training group, called "Grip op je leven ". Patients in this group receive a number of modules aimed at improving regulation of emotions and coping skills. This training group will be offered at the same time as COMET. The duration of the training is ten week, for both groups.

Study burden and risks

The risks are expected to be very minimal or absent. The COMET has been investigated before and proved to be effective and safe, even in patients with a psychotic disorder. There are no studies known in which patients have been psychologically harmed as a result of this training. The treatment as usual group is offered a treatment which had been developed for patients with psychotic vulnerability and previously offered to this group of patients. If during the investigation psychological (and possibly psychotic) symptoms from patients increase or worsen, appropriate (medical) intervention will be applied. Participants are free at all times to withdraw from the study without having any negative consequences for their treatment.

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

Men and women, age of 18 and older, diagnosed with any psychotic disorder with paranoia and who are hospitalized. Patients are capable of reporting low self-esteem and their paranoid thoughts. All patients are mentally competent.

Exclusion criteria

Younger than 18 and older than 70
insufficient capacity of speaking and understanding Dutch language
Not capable of training in a group

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:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	31
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-08-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL63893.078.17