Competitive Memory training in patients with auditory verbal hallucinations: a randomized con-trolled trial.

Published: 14-12-2007
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The aim of this study is to determine whether the treatment is effective in reducing symptoms in patients suffering from AVH*s.

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

Summary

ID

NL-OMON31865

Source
ToetsingOnline

Brief title
COMET

Condition

- Schizophrenia and other psychotic disorders

Synonym
auditory verbal hallucinations, hearing voices

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: deelnemende instellingen

Intervention

Keyword: Cognitive therapy, Hallucinations, Schizophrenia

Outcome measures

Primary outcome

Primary study parameters/outcome of the study:

PSYRATS / AHRS (voices)

Secondary outcome

SCRS (social comparison rating scale)

BDI (depression)

BAI (anxiety)

PUL (self-efficacy)

BCIS (insight)

PSc (power differential scale)

SERS (self esteem)

MCQ30 (metacognitions)

A motivational inventory

A neuropsychological test measuring memory bias

Emotional stroop (attentional bias)

Study description

Background summary

Auditory Verbal Hallucinations (voices) are one of the most persistent and distressing symptoms in patients suffering from schizophrenia. AVH*s are also commonly found in other psychiatric disorders. Mostly they are resistant to medication en therefore they are often responsible for co-morbid symptoms such

as depression and anxiety. Training the memory bias shows hopeful re-sults in treating patients with AVH*s.

Study objective

The aim of this study is to determine whether the treatment is effective in reducing symptoms in patients suffering from AVH*s.

Study design

Following a recent pilot a randomised clinical trial is being started. The effectiveness of this new treatment is being evaluated in patients diagnosed with schizophrenia, schizo-affective disorder or psychotic disorder NOS experiencing severe distress from their auditory verbal hallucinations. Results are being measured by means of inventories and neuropsychological tests. There will be two conditions:
1) Patients who are in the experimental group receive a 9-session program following the COMET-protocol. Their treatment as usual (TAU) will be continued during the program
2) Patients who are in the control group receive treatment as usual (TAU). Usually this con-sists of sessions with an outpatient therapist and/or a psychiatrist.
Patients will be subjected to tests and inventories at the start, after 10 weeks and after 18 weeks.

Intervention

The experimental group will have 9 sessions of competitive memory trai ning; the control group is a waiting list

Study burden and risks

No burden, no documented risks and adverse events.

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

Patients suffering from persistent auditory verbal hallucinations in the age 18 to 65. Three particular items of the PSYRATS (Haddock et al. 1999) will be used to screen patients. These items measure frequency of voices (item 1) intensity of distress (item 9) and disturbance of daily functioning (item 10). Patients with results higher than 3 will be included. We defined the hallucinations *persistent* if they still cause distress despite the administration of two different types of antipsychotic medication.

Exclusion criteria

severe abuse of substances, insufficient knowledge and practice of Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	128
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	14-12-2007
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	NL19896.097.07