Feasibility of Schematherapy for Punitive Auditory Verbal Hallucinations: A Pilot Study

Published: 16-07-2019
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The primary goal is to study the feasibility of schematherapy for AVH's.

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

Summary

ID

NL-OMON48884

Source
ToetsingOnline

Brief title
Schematherapy for punitive voices

Condition

- Schizophrenia and other psychotic disorders

Synonym
Auditory Verbal Hallucinations, Hearing Voices

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Noord-Holland-Noord
Source(s) of monetary or material Support: door de uitvoerende instelling;GGZ-NHN

Intervention

Keyword: Auditory Verbal Hallucinations (AVH), Psychosis, Schematherapy, Voices

Outcome measures

Primary outcome

The main study parameter will be the feasibility of the program as defined by

the evaluations of the participants on closed and open ended questions and the

drop-out rate and reasons for dropout.

Secondary outcome

The secondary outcomes are patients* self-reported self-worth, mood, psychotic

(positive) symptoms and the perceived power of and beliefs about voices.

Study description

Background summary

Schema therapy is an integrative therapy that finds its origins in cognitive behavioral therapy and appears applicable in treating adverse effects of punitive Auditory Verbal Hallucinations (AVH).

Study objective

The primary goal is to study the feasibility of schematherapy for AVH's.

Study design

The feasibility will be messured with questionaires deisgned for this purpose. Participants will be asked closed and open-ended questions. Therapists will evaluate the protocol after each session. For the secundary measures a multiple baseline across subjects study is used.

Intervention

Participants will receive 20 weeks of schematherapy. The baseline period is six to ten weeks.

Study burden and risks

Participants will be assessed before treatment, after treatment, and at three months follow-up. In total, these assessments will take approximately 270 minutes. For each participant self-esteem, mood, and cognitions about voices will be measured between sessions; that is, 24 to 28 times in 24 to 28 weeks (due to the variable baseline). This will take approximately 260 minutes in total (less than 10 minutes per session). Patients will receive a maximum dose of twenty sessions therapy with a maximum of 60 minutes each.

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

Participants have a current psychotic disorder, assessed by Mini International Neuropsychiatric Interview (MINI) with punitive Auditory Verbal Hallucinations. Age ranges between 18 and 65 year.

Exclusion criteria

No competence of the Dutch language, a (known) intellectual disability (estimated IQ < 70). For safety reasons, participants with a BEck Depression Inventory-II (BDI-II) score higher then 35, whom are actively suicidal and/or have made a suicide attempt in the past three months are excluded. Participants who are mentally incompetent.

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):	09-08-2019
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL66846.029.18