Treatments for auditory verbal hallucinations in patients with borderline personality disorder: Cognitive Behavioural Therapy for hearing voices (CBT) and treatment with Flupentixol

Published: 08-10-2019
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The aim of the study is to observe the changes in severity of AVH symptoms during standard treatment of CBT or antipsychotics in patients with BPD.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48446

Source
ToetsingOnline

Brief title
CBT and Flupentixol for AVH in BPD

Condition

- Other condition
- Personality disorders and disturbances in behaviour

Synonym
Borderline personality disorder, Borderline. Auditory verbal hallucinations, hearing voices

Health condition

Auditieve verbale hallucinaties

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Antipsychotics, Auditory verbal hallucinations, Borderline personality disorder, Cognitive behavioural therapy

Outcome measures

Primary outcome

Primary outcome measure: AVH-related items of the Psychotic Symptom Rating

Scales.

Secondary outcome

Secondary outcome measures: Voice Power Differential scale (VPDS), Visual

Analogue Scale (2 items severity

malevolence and omnipotence of the voices), Korte Klachten Lijst, Brief State

Paranoia checklist and the Sheehan

Disability Scale. These data will be collected once a week during the baseline,

intervention and follow-up period.

Furthermore for CBT, the Beliefs About Voices Questionnaire (BAVQ) and the

Social Comparison Rating Scale to voices

(SCRS) will be looked at.

In case of flupentixol treatment: Subjects Reaction to Antipsychotics will be

assessed three times.

Study description

Background summary

Auditory verbal hallucinations (AVH) are prevalent in patients with borderline personality disorder (BPD) and are
associated with distress and severe consequences such as suicide attempts and hospitalization.

Study objective

The aim of the study is to observe the changes in severity of AVH symptoms during standard treatment of CBT or antipsychotics in patients with BPD.

Study design

Multiple Baseline case series design. Patients complete questionnaires weekly before, during and (only in case of CBT) after treatment for hearing voices. Treatment is either CBT for hearing voices or treatment with flupentixol. Patients choose which treatment they get. The baseline period, i.e. the amount of weeks patients will fill out questionnaires before the treatment is determined by lottery.

Study burden and risks

No risks are expected due to the data collection. The observed treatments are standard treatments, therefore risks are estimated as low. Flupentixol will be prescribed according to the Parnassia Groep guidelines. Flupentixol administration can be accompanied with side-effects such as weight gain, mood symptoms, movement disorders and sleeping problems. CBT for voices will be according to the protocols provided for this treatment (www.gedachtenuitpluizen.nl)

Benefits of participation are possible relieve of symptoms, contribution to knowledge about treatment and improving quality of treatments.

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

Age 18 years or older, BPD confirmed with the Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID II), AVH occurring at least daily, and written informed consent for participation into this study from the patient.

Exclusion criteria

Pregnancy and schizophrenia spectrum disorders, except for 1. Brief psychotic disorder with hallucinations, and 2. Other specific or nonspecific schizophrenia spectrum and other psychotic disorder in case of persistent auditory hallucinations.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	26
Type:	Anticipated

Ethics review

Not approved

Date:	08-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL69811.058.19