THE TEMSTEM TRIAL: Reducing distress and dysfunction caused by auditory verbal hallucinations via a smartphone application.

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

Summary

ID

NL-OMON45092

Source
ToetsingOnline

Brief title
TEMSTEM

Condition

- Schizophrenia and other psychotic disorders

Synonym
hallucinations, voice hearing

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Parnassia Groep innovatie fonds.

Intervention

Keyword: coping, hallucinations, mHealth, psychosis

Outcome measures

Primary outcome

The primary outcomes are changes in distress, disturbance to life and social dysfunction caused by AVHs.

Secondary outcome

Changes in frequency and severity of AVHs; control and power over AVHs; ability to cope with AVHs; self-esteem; depression; quality of life; paranoid ideations.

Study description

Background summary

Temstem is a smartphone application which was designed to help people that suffer from auditory verbal hallucinations (AVHs) to cope better with these experiences, which may reduce distress and improve social functioning.

Study objective

The primary objective is to test the effects of temstem on distress, disturbance to life and social functioning. Second, we aim to investigate the effect of temstem on frequency and severity of AVH, to determine working mechanisms, to identify predictors and mediators of effects and to study the usability (user friendliness) of temstem, to improve customer satisfaction in the future. Third, we want to determine the psychometric properties of two new questionnaires that which may be useful in the clinical usage of temstem, the Trauma and Life Event Checklist (TALE) and the Trauma Voice Associations questionnaire (TVAq).

Study design

A multicentre single blind randomized clinical trial with two arms and a 3-week follow-up using experience sampling method.

Intervention

Temstem + AVHs monitoring will be compared with *AVH monitoring only*. In the AVH monitoring only condition participants will daily monitor their AVHs in a 30 second assessment. In the temstem + AVHs monitoring condition participants will daily monitor AVHs and will be provided with the temstem app, a smartphone application that was developed to assist the user in coping better with AVHs via language games, enhance self-esteem, and possibly reduce vividness and emotionality of AVHs.

Study burden and risks

All participants will be assessed with a number of clinical scales/interviews. There are no risks for individuals to participate in this study.

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

* Presence of AVHs (with distress) for longer than a month
* Presence of AVHs during a minimum of four days a week, in at least three of the last four weeks

Exclusion criteria

* Changes in medication regiment in the last month
* Estimated IQ under 70; the researchers will examine the schoolcareer of the patient. If problems during the primaryschool period are found, the short version of the WAIS-IV will be conducted to determine intelligence.
* Insufficient competence in the Dutch language
* Previous use of temstem
* Not willing or able to learn to use a smartphone
* Currently undergoing cognitive behavioural therapy for AVHs
* Current involuntary admission in a closed ward

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:	Recruitment stopped
Start date (anticipated):	23-03-2016

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2018
Application type:	Amendment
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	NL53684.029.15