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A scientific study into the effects of Temstem, an app for voice hearers

Submission date
14/01/2016

Recruitment status
No longer recruiting

Registration date
14/01/2016

Overall study status
Completed

Last Edited
14/02/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Auditory verbal hallucinations (AVH), commonly referred to as “hearing voices”, can be a distressing experience which often has a negative impact on social functioning (how a person behaves in a social setting). Until recently, they were generally associated with mental disorders such as schizophrenia (a mental illness in which a person experiences disordered beliefs and experiences) and psychosis (a serious mental illness in which thoughts and emotions are impaired, causing a person to lose touch with reality), however a recent study suggests that that it may affect around 13.2% of the general population. AVH can be very difficult to cope with, making it hard for sufferers to manage their lives. Temstem is a mobile phone application which has been developed to help users to cope better with AVH. The app uses language games which can be played at any time and do not require significant effort from the user, working on the principal that when the language centre in the brain is occupied with a task, AVH can be suppressed. Coupled with active support for the user, it is hoped that the app will help to enhance self-esteem and reduce the vividness and the emotionality of AVH. The aim of this study is to find out whether using the Temstem app can have a positive effect on users and help to suppress AVH, as well as the overall user-friendliness of the app.

Who can participate?
Adult patients of participating mental health organizations who have been hearing voices for longer than a month or on at least four days a week in at least three out of the last four weeks.

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups are provided with a smartphone for 6 weeks, which can be monitored by the investigative team. Those in the first group have their AVH monitored using the PSYMATE smartphone application. This monitoring involves a 30 second assessment which is completed daily. Those in the section group also have their AVH monitored, however they also receive access to the Temstem app for 6 weeks. Participants in this group can play the language-based games in the app at any time over the 6 week study period. For both groups, six days of daily experience sampling are completed in the first and final week of the study, so participants can report on their thoughts and feelings of the

study experience. At the start of the study, and then again after 1, 5, 6 and 9 weeks, all participants complete a number of questionnaires in order to assess their social functioning and levels of distress, AVH symptoms, self-esteem, and general mental wellbeing.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Nine mental health organizations in the Netherlands

When is the study starting and how long is it expected to run for?
January 2015 to December 2017

Who is funding the study?
Innovation Fund Parnassia Group (Netherlands)

Who is the main contact?
Mr David van den Berg
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The TEMSTEM trial: reducing distress and dysfunction caused by auditory verbal hallucinations via a smartphone application

Acronym
TEMSTEM

Study objectives
The aim of this study is to:
1. Test the effects of temstem on distress and social functioning
2. Investigate the effects of temstem on frequency and severity of AVH, control and power over AVH, the ability to cope with AVH, self-esteem, depression, quality of life, and paranoid ideations
3. Determine working mechanisms, to identify predictors and mediators of effects and to study the usability (user friendliness) of TEMSTEM

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch ethische toetsingscommissie (medical ethics committee) VU Medical Center, 22/12 /2015, ref: NL53684.029.15

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information is available in Dutch via https://www.temstem.nl

Health condition(s) or problem(s) studied
Auditory verbal hallucinations (AVH) in patients diagnosed with a psychotic disorder

Interventions
Participants are randomly allocated to one of two study arms.

Group 1: Participants receive AVH monitoring only. AVH monitoring means that AVH will be monitored daily in a 30-second assessment via a smartphone application, the PSYMATE (www.psymate.eu).

Group 2: Participants receive AVH monitoring in addition to being provided with Temstem. Temstem is a smartphone application that was developed to reduce the burden of voices and to help people with AVH experience more control over their voices. The Temstem app uses language games that can be played at any moment and require little cognitive effort. Temstem is based on three principles. First, Temstem can be used as a tool to cope with AVH. By activating the language production areas in the brain while doing a motoric task, Temstem aims to temporarily suppress AVH. Second, the temstem app reinforces and supports the user in such a way that it enhances self-esteem. Third, Temstem contains a potential therapeutic mechanism as playing language games while recalling an episodic memory of hearing voices may reduce the vividness and emotionality of AVH.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Levels of distress and of social functioning are measured using the Experience Sampling Method (psymate.eu) at baseline, 5 weeks (with daily monitoring for 6 days), as from baseline to six weeks as well as the with the daily monitoring function of the ESM

Secondary outcome measures
1. Frequency and severity of AVH, distress and negative influence on social functioning caused by AVH are measured using experience sampling daily from baseline to 1 week and week 5 to 6, the daily monitoring function of the ESM daily from week 1 to 6 and the Auditory Hallucinations Rating Scale (AHRS) at baseline, 1, 5, 6, and 9 weeks
2. Power and ability to cope are measured using the Beliefs about voices questionnaire revised (BAVQ-R) and ESM at baseline, 1, 5, 6, and 9 weeks
3. Power in social rank to AVH is measured using the Voice Power Differential Scale (VPDS) at baseline, 1, 5, 6, and 9 weeks
4. Social rank to AVH is measured using the Social Comparison Rating Scale To Voices (SCRS) at baseline, 1, 5, 6, and 9 weeks
5. Self-Esteem is measured using the Self-Esteem Rating Scale - Short form (SERS-F) at baseline, 1, 5, 6, and 9 weeks
6. Depression symptoms are measured using the Beck Depression Inventory second edition (BDI-II) at baseline, 1, 5, 6, and 9 weeks
7. Quality of life is measured using the Manchester short assessment of quality of life (MANSA) at baseline, 1, 5, 6, and 9 weeks
8. Quality of life, including disturbance to it by AVH is measured using the PsyQ Kwaliteit van leven (KWAL) at baseline, 1, 5, 6, and 9 weeks
9. Paranoid ideations are measured using the Paranoid thought scales (GPTS) and ESM at baseline, 1, 5, 6, and 9 weeks

Overall study start date
01/01/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Aged 18 to 75 years
2. Presence of AVH (with distress) for longer than a month
3. Presence of AVH during a minimum of four days a week, in at least three of the last four weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100

Total final enrolment
89

Key exclusion criteria
1. Changes in medication regiment in the last month
2. Estimated IQ under 70
3. Insufficient competence in the Dutch language
4. Previous use of temstem
5. Not willing or able to learn to use a smartphone
6. Currently undergoing cognitive behavioural therapy for AVH
7. Current involuntary admission in a closed ward

Date of first enrolment
01/02/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
Parnassia
Monsterseweg 89
Den Haag
Netherlands
2553 RJ

Study participating centre
Dijk en Duin
Duinenboschweg 124
Castricum
Netherlands
1901 ZZ

Study participating centre
GGZ Noord-Holland Noord
Oude Hoeverweg 10
Alkmaar
Netherlands
1850 BA

Study participating centre
UMC Groningen
UCP
Noordzijde UMCG-terrein, ingang 32
Groningen
Netherlands
9700 RB

Study participating centre
GGZ Oost Brabant
Gezondheidslaan 65
Oss
Netherlands
5342 JW

Study participating centre
Altrecht
Lange Nieuwstraat 119
Utrecht
Netherlands
3512 PG

Study participating centre
UMC Utrecht
Heidelberglaan 100
Utrecht
Netherlands
3584 CX

Study participating centre
GGZ InGeest
Postbus 74077
Amsterdam
Netherlands
1070 BB

Study participating centre
Bavo-Europoort
Prins Constantijnweg 48 - 54
Rotterdam
Netherlands
3014 HH

Sponsor information

Organisation
VU University Amsterdam, Faculty of Behavioural and Movement Sciences (Vrije Universiteit Amsterdam, Faculteit der Gedrags - en Bewegingswetenschappen)

Sponsor details
Van der Boechorstraat 1
Amsterdam
Netherlands
1081 BT

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/008xxew50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Innovation Fund Parnassia Group (Innovatiefonds Parnassia Groep)

Results and Publications

Publication and dissemination plan
Planned submission to peer-reviewed journals following result analysis.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/03/2018		Yes	No
Other publications		13/05/2021	27/10/2022	Yes	No
Results article		26/01/2024	14/02/2024	Yes	No