

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

<b>Submission date</b> 14/01/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/02/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

**Contact name**  
Mr David van den Berg

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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](http://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](http://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?
<a href="#">Protocol article</a>	protocol	06/03/2018		Yes	No
<a href="#">Other publications</a>		13/05/2021	27/10/2022	Yes	No
<a href="#">Results article</a>		26/01/2024	14/02/2024	Yes	No