

Reducing the frequency and severity of auditory hallucinations: the AVATAR clinical trial

Submission date 15/03/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/05/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The experience of distressing voices that persist despite medical treatment is a serious problem for many patients suffering from severe mental health problems. Avatar therapy is a new computer-assisted therapy that has shown some benefit in a small pilot study. The aim of this study is to test whether avatar therapy is more effective than supportive counselling.

Who can participate?

Anyone aged over 18 who has experienced voices speaking in English that have persisted for at least 12 months despite medical treatment.

What does the study involve?

After consenting to take part, participants are asked questions about the voices they hear, their mental and physical health and how the voices affect their quality of life. Participants are then randomly allocated to either avatar therapy or supportive counselling. Participants allocated to the avatar therapy are helped to use a computer program to develop an 'avatar' (image and voice) similar to the person or entity whose voice bothers them. The therapist uses this avatar in the therapy sessions to talk with them and help them to practice ways of coping with the voices. Participants allocated to supportive counselling do not create or use the avatar but talk with the therapist about the voice, their everyday life and how they are feeling more generally. Both types of treatment are given over six sessions of a half-hour each. All treatment sessions are recorded and participants are given these recordings on a small MP3 player to take away to use on their own at any time. After the six therapy sessions a researcher asks them the same questions they were asked before they started therapy. Participants are contacted again at 12 weeks and 6 months from when they joined the study to see whether any improvement has continued. Participants also provide their views about the therapy and how it may be improved in future.

What are the possible benefits and risks of participating?

The possible benefits are reductions in the frequency, severity and distress caused by the voices. The risks are that the treatment may be distressing and may not be effective.

Where is the study run from?

Clinics in the South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

June 2013 to June 2016

Who is funding the study?

Wellcome Trust (UK)

Who is the main contact?

Prof. Thomas J Craig

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

1

Study information

Scientific Title

Reducing the frequency and severity of auditory hallucinations: a randomised clinical trial of a novel Audio-Visual Assisted Therapy Aid for Refractory auditory hallucinations (AVATAR) compared to supportive counselling

Acronym

AVATAR

Study objectives

AVATAR therapy will result in a greater decrease in the frequency and subjective severity of auditory hallucinations than is achieved by supportive counselling.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Hampstead, 26/04/2013, REC ref: 13/LO/0482

Study design

Single-centre pragmatic two-arm observer-blind randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Severe mental illness

Interventions

1. AVATAR therapy: an average of 6 x ½ hour weekly sessions
 2. CONTROL therapy: supportive counselling also for 6 x ½ hour weekly sessions
- Six sessions of a half an hour each, once per week

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current primary outcome measures as of 21/09/2017:

Total score on the auditory hallucinations component of the Psychotic Symptoms Rating Scale PSYRATS-AH (Haddock et al., 1999), measured at baseline, 12 weeks and 6 months

Previous primary outcome measures:

Total score on the auditory hallucinations component of the Psychotic Symptoms Rating Scale PSYRATS-AH (Haddock et al., 1999), measured at baseline, 8 weeks, 12 weeks and 6 months

Key secondary outcome(s)

Current secondary outcome measures as of 21/09/2017:

Voices outcomes:

1. Beliefs about Voices Revised BAVQ-R (Chadwick et al., 2000)
2. Voices Acceptance and Actions Scale (Shawyer et al., 2007)
3. Voice power differential scale (Birchwood et al., 2000)

Global:

1. Scales for the Assessment of Positive and Negative Symptoms (SAPS/SANS - Andreasen, 1984)
2. Psychotic Symptoms Rating Scale- Delusions (Haddock et al., 1999)
3. Modified Illness Perceptions Questionnaire (Watson et al 2006, Marcus et al 2014)
4. Calgary Depression Scale (Addington et al., 1993)

Quality of life:

1. Manchester Short Assessment of Quality of Life - MANSA (Priebe et al., 1999)
2. EQ5-D (EuroQol, 1999)

Service use:

Client service receipt inventory (Beecham and Knapp, 2001)

Measured at baseline, 12 weeks and 6 months

Previous secondary outcome measures:

Voices outcomes:

1. Beliefs about Voices Revised BAVQ-R (Chadwick et al., 2000)
2. Voices Acceptance and Actions Scale (Shawyer et al., 2007)
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1. Scales for the Assessment of Positive and Negative Symptoms (SAPS/SANS - Andreasen, 1984)
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Quality of life:

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Client service receipt inventory (Beecham and Knapp, 2001)

Measured at baseline, 8 weeks, 12 weeks and 6 months

Completion date

01/06/2016

Eligibility

Key inclusion criteria

Male or female, aged 18+ who have experienced persistent auditory hallucinations despite medical treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

150

Key exclusion criteria

1. Age under 18
2. Primary diagnosis of organic brain disease or substance dependency
3. Auditory hallucinations in a language not spoken by therapists

Date of first enrolment

01/06/2013

Date of final enrolment

01/06/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

PO 33 HSPRD

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust (UK), FWBC-AVATAR 098272/z/12/z

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Results and Publications

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No
Protocol article	protocol	13/08/2015		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	participant experiences	24/05/2022	25/05/2022	Yes	No