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

Submission date
15/03/2013

Recruitment status
No longer recruiting

Registration date
27/03/2013

Overall study status
Completed

Last Edited
25/05/2022

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
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
Thomas.Craig@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Jamieson Craig

Contact details
PO 33 HSPRD
Institute of Psychiatry
De Crespigny Park
London
United Kingdom
SE5 8AF
-
thomas.craig@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures

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

Voices outcomes:
1. Beliefs about Voices Revised BAVQ-R (Chadwicket 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 (Chadwicket 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. Beliefs about problems (Watson et al., 2006)
4. Calgary Depression Scale (Addington et al., 1993)

Quality of life:
1. Manchester Short Assessment of Quality of Life - MANSA (Priebe et al., 1999)
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Service use:
Client service receipt inventory (Beecham and Knapp, 2001)

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

Overall study start date

01/06/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
142

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
England

United Kingdom

Study participating centre
PO 33 HSPRD
London

United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Keith Brennan
Director of Research Management
Room 1.8 Hodgkin Building
Guys Campus
King's College London
London
England
United Kingdom
SE1 4UL

Sponsor type
University/education

Website
http://www.kcl.ac.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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date

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?
Protocol article	protocol	13/08/2015		Yes	No
Results article	results	01/01/2018		Yes	No
Other publications	participant experiences	24/05/2022	25/05/2022	Yes	No
HRA research summary			28/06/2023	No	No