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AVATAR_VRSocial therapy for auditory verbal hallucinations in early psychosis

Submission date	Recruitment status	[X] Prospectively registered
29/11/2023	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/11/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
AVATAR_VRSocial therapy aims to help people who hear distressing voices. It is based on AVATAR Therapy, which involves building an image or 'avatar' of the distressing voice that the person hears on a computer and then, with help from a therapist, the person is given the opportunity to talk to the avatar. Over time, the person is supported to stand up more to the avatar with the hope that they will feel less anxious or upset when hearing the voice in their everyday life. Additionally, AVATAR_VRSocial uses virtual reality environments to empower people to manage their voices better when they are in social situations. In between therapy sessions people are given recordings of their conversations with the avatar that they can listen to as an extra source of support. This trial is a feasibility study, which will test the study procedures and develop the treatment further before the researchers conduct a larger study to test if AVATAR_VRSocial works.

Who can participate?
Patients aged 16 years or older, who have been hearing a distressing voice persisiting for at least 6 months, and have had their first episode of psychosis or first presentation to mental health services in the last 5 years.

What does the study involve?
Everybody who takes part will meet with a project worker for an initial meeting and then after 3 and 6 months. At each meeting, they will be asked about their experiences of voices, their mood, things that worry them and their overall wellbeing. The researchers expect each of the meetings will take about an hour and a half. These can be shorter if the person would like, and they will also be offered breaks during the meetings. The researchers will try to do them at times and locations that are most convenient for them.
After the first meeting, the participant will be randomly allocated by a computer to either continue with their usual care, or to receive AVATAR_VRSocial therapy (10 sessions) and their usual care. A member of the project team will tell them the outcome.

What are the possible benefits and risks of participating?
It is hoped that AVATAR_VRSocial therapy will help people feel less distressed by their voices and feel more confident to deal with everyday social situations. However, this cannot be

guaranteed. Everyone taking part in the trial including those who do not receive AVATAR_VRSocial will be reimbursed for their time. The information from all participants may help us to support others with similar problems. If AVATAR_VRSocial therapy is shown to work, then the researchers plan to make it more widely available in Germany in the future. The researchers do not anticipate that there are any risks in taking part. However, the questionnaires and therapy procedures do ask about mental health, which may be considered a sensitive topic.

Where is the study run from?
Mental Health Research and Treatment Centre, Ruhr-Universität Bochum (Germany)

When is the study starting and how long is it expected to run for?
December 2019 to March 2026

Who is funding the study?
1. The Alexander von Humboldt Foundation (Germany)
2. Ministry of Education and Research (BMBF) (Germany)

Who is the main contact?
Prof. Dr Mar Rus-Calafell, mar.rus-calafell@ruhr-uni-bochum.de

Study website
https://www.ruhr-uni-bochum.de/avatar-psy

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.9

Study information

Scientific Title
AVATAR_VRSocial therapy for early psychosis: a single-blind parallel-group randomised controlled feasibility trial

Acronym
AVATAR_VRSocial Study

Study objectives
The primary objective is to assess the feasibility and acceptability of a targeted intervention for distressing auditory verbal hallucinations and their impact on daily life in people with early psychosis. The secondary research objective is to gather data on clinical outcomes to provide preliminary estimates of the efficacy of the intervention (AVATAR_VRSocial) for people with early psychosis experiencing distressing auditory hallucinations and seeking help.

The hypotheses related to clinical outcomes are:
1. Compared to TAU, AVATAR_VRSocial therapy added to usual care will reduce the distress associated with voices.
2. Compared to TAU, AVATAR_VRSocial therapy added to usual care will reduce social avoidance and social distress.
3. Compared to TAU, AVATAR_VRSocial therapy added to usual care will reduce total voice severity and improve wellbeing and mood-related psychopathology.
4. Treatment effects will be maintained at follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/04/2020, Ethics Committee of the Faculty of Psychology at the Ruhr University Bochum (Universitätsstraße 150, Bochum, 44801, Germany; +49 (0)234 32 24606; ethikkommission-psychologie@ruhr-uni-bochum.de), ref: 632/2020

Study design
Prospective parallel-group feasibility randomized controlled trial with single-blind assessment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Schizophrenia spectrum disorder or affective disorder with psychotic symptoms

Interventions
Participants are randomized (1:1) to the AVATAR_VRSocial Therapy added to treatment as usual or treatment as usual.

Participants will be randomized once they have completed the baseline assessment. Participants will be allocated to one of the trial arms using a 1:1 allocation ratio. Randomization will be carried out by a validated online system.

AVATAR_VRSocial therapy is built up upon AVATAR therapy as delivered in Craig et al., (2018), with three additional sessions focusing on interference of voices during social interactions (by incorporating Virtual Reality technology). The therapy involves (for 7 sessions) a three-way conversation between therapist, patient and a digital simulation ('avatar') of one of his/her hallucinated voices. The therapist, sitting in a room remotely from the patient, speaks either as him/herself or in his/her digitally transformed voice as the avatar. The patient sits in front of a monitor on which the avatar appears. The avatar changes over time to be less intimidating and persecutory in response to changes in the participant’s responses, guided by the therapist. The voice-hearer is supported throughout by the therapist who, while physically located in another room, uses visual (webcam) and audio feedback to adjust the dialogue to ensure optimal engagement. The therapy involves also three sessions of virtual reality assisted activities. The aim is to help the person manage their voices when being in daily social situation, based on what they have learned during the conversations with their avatar.
The intervention is delivered on an individual basis in up to 10 1-hour sessions over 12 weeks.

Participants who are allocated to treatment-as-usual, will be offered AVATAR_VRSocial at the end of the study.

Everyone who takes part will be asked to meet with a research assessor at the beginning of the study, after 3 months and after 6 months. During these meetings they will be asked about their experiences of voices, their mood, things that worry them and their overall wellbeing. The researchers expect each of the meetings will take about an hour and a half. At the end of the study some participants will be invited to take part in an interview with a research worker to talk about their experiences of the study.

Intervention Type
Behavioural

Primary outcome measure

The primary outcome measures relate to the feasibility and acceptability of the trial procedures and intervention.
The primary clinical outcome is distress associated with voices as measured by the Psychotic Symptoms Rating Scale - Auditory Hallucinations measured at baseline, 12 weeks and 24 weeks.

Feasibility markers measured at baseline, 12 weeks and 24 weeks:
1. Recruitment and retention: number of patients identified, recruited, declined and retained
2. Referral procedure: number of referrals per month
3. Data collection methodology: completion rate of each assessment measure
4. Acceptability of the intervention: attendance at treatment sessions; feedback from qualitative interviews; Acceptability of Intervention Measure (AIM) and the Intervention Appropriateness Measure (IAM).

Secondary outcome measures
1. Frequency of voices and overall severity as measured by the Psychotic Symptoms Rating Scale - Auditory Hallucinations frequency dimension and total score measured at baseline, 12 weeks and 24 weeks
2. Remission of voices (standalone item) measured using Hallucinations Remission Score at baseline, 12 weeks and 24 weeks
3. Beliefs about the voices measured using the Beliefs about Voices Revised (BAVQ-R) at baseline, 12 weeks and 24 weeks
4. Voices acceptance measured using the Voices acceptance and action scale (VAAS) at baseline, 12 weeks and 24 weeks
5. Voice power measured using the first item from the Voice Power Differential Scale at baseline, 12 weeks and 24 weeks
6. Agoraphobic avoidance measured using the Oxford – Agoraphobic Avoidance Scale (O-AS) at baseline, 12 weeks and 24 weeks
7. Worries before or when outside measured using the Oxford Cognitions and Defences Questionnaire (O-CDQ) at baseline, 12 weeks and 24 weeks
8. Negative voices when outside measured using the Brief assessment of negative hallucinations when outside, at baseline, 12 weeks and 24 weeks
7. Wellbeing measured using the Wellbeing EQ-5D-5L at baseline, 12 weeks and 24 weeks
8. Other psychopathology measured using DASS-21 at baseline, 12 weeks and 24 weeks
9. Delusions measured using the PSYRATS-Delusions at baseline, 12 weeks and 24 weeks
10. Trauma measured using the International Trauma Questionnaire at baseline, 12 weeks and 24 weeks
11. Negative symptoms measured using the Clinical Assessment Interview for Negative Symptoms at baseline, 12 weeks and 24 weeks

Overall study start date
01/12/2019

Completion date
03/03/2027

Eligibility

Key inclusion criteria
1. Have current frequent and distressing voices (as measured by a score of at least 1 on each intensity of distress and frequency items of the PSYRATS-AH), persisting for at least 6 months and speaking German

2. Confirmed diagnosis of affective and non-affective psychosis (F20-29, F32/33.3 and F31.2in ICD-10; World Health Organization, 1993) on the medical records or through consultation with the clinical team
3. With onset of the first psychotic episode or first presentation to mental health services in the last 5 years
4. ≥16 years old
5. Adequate German language skills to provide informed consent and engage with assessment and therapy sessions
6. To be able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Primary diagnosis of substance disorder, personality disorder or learning disability
2. Auditory verbal hallucinations (AVH) secondary to an organic disorder
3. Currently attending or to be confirmed to attend another individual psychological therapy for auditory verbal hallucinations
4. Profound visual/hearing impairment or insufficient comprehension of German to be able to engage in assessment or therapy
5. Currently experiencing an acute mental health crisis

Date of first enrolment
01/12/2023

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
Germany

Study participating centre
Mental Health Research and Treatment Centre, Ruhr-Universität Bochum
Clinical Psychology and Digital Psychotherapy
Mental Health Research and Treatment Center

Faculty of Psychology
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Sponsor type
University/education

Website
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ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Charity

Funder Name
Alexander von Humboldt-Stiftung

Alternative Name(s)
Humboldt-Stiftung, Humboldt Foundation, Alexander von Humboldt Foundation, Humboldt Stiftung, AvH

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
It is intended that the results of the study will be reported and disseminated at international conferences and in peer-reviewed scientific journals and will be made available to participants in an accessible format and on the study website. It will also be accessible in print and digital media and presented at stakeholder's events.

Intention to publish date
01/09/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Mar Rus-Calafell (mar.rus-calafell@ruhr-uni-bochum.de) after the publication of the main trial outcomes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/04/2025	23/04/2025	Yes	No