

# AVATAR\_VRSocial therapy for auditory verbal hallucinations in early psychosis

<b>Submission date</b> 29/11/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/11/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/04/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 persisting 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](mailto:mar.rus-calafell@ruhr-uni-bochum.de)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

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

### **Study type(s)**

Treatment

### **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(s)**

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).

## **Key secondary outcome(s)**

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

### **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 F31.2 in 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

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Sex**

All

**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

Ruhr-Universität Bochum

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**Sponsor information****Organisation**

Ruhr University Bochum

ROR

<https://ror.org/04tsk2644>

## Funder(s)

### Funder type

Charity

### Funder Name

Alexander von Humboldt-Stiftung

### Alternative Name(s)

Humboldt Foundation, Alexander von Humboldt Foundation, Humboldt-Stiftung, 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 Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Germany

## Results and Publications

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?
<a href="#">Protocol article</a>	Participant information sheet	17/04/2025	23/04/2025	Yes	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes