

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of Audio Visual Assisted Therapy Aid for Refractory hallucinations (AVATAR) in reducing auditory hallucinations in patients with schizophrenia.

Protocol summary

Study aim

Overall Objective: To determine the effectiveness of Audio Visual Assisted Therapy Aid for Refractory auditory hallucinations (AVATAR therapy) software in reducing auditory hallucinations in patients with schizophrenia.

Design

A clinical trial with a control group, parallel groups, without blinding, will be randomized and performed on 40 patients with schizophrenia. A simple randomization table will be used.

Settings and conduct

This study will be performed at the Razi Educational and Medical Center of Tehran. Patients will be treated with AVATAR or treatment as usual. Pre-test. post-test and follow-up evaluation will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Experiencing annoying auditory hallucinations 2. Age: 18-50 3. Minimum intermediate education 4. Adequate command of the Persian language 5. The patient is able to identify a major sound and hallucination (to reduce). Exclusion Criteria: 1. Refuse to take any medication 2. Initial dependence on drugs 3. serious thoughts of harming oneself or another

Intervention groups

Patients with schizophrenia will be randomly assigned to an experimental or control group. In the experimental group, AVATAR treatment will be performed and in the control group, treatment, as usual, will be performed.

Main outcome variables

Duration and severity of auditory hallucinations, Depression, Quality of life.

General information

Reason for update

Acronym

AVATAR

IRCT registration information

IRCT registration number: **IRCT20220226054121N1**

Registration date: **2022-05-28, 1401/03/07**

Registration timing: **prospective**

Last update: **2022-05-28, 1401/03/07**

Update count: **0**

Registration date

2022-05-28, 1401/03/07

Registrant information

Name

Vida Yousefi Asl

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Audio Visual Assisted Therapy Aid for Refractory hallucinations (AVATAR) in reducing auditory

hallucinations in patients with schizophrenia.

IR.USWR.REC.1400.292

Public title

AVATAR therapy in refractory auditory hallucinations.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Experience annoying auditory hallucinations Age range 18 - 50 years Minimum Intermediate Education Sufficient command of Persian language The patient is able to identify a sound and the main hallucination (to reduce).

Exclusion criteria:

Refuse to take any medication Primary drug dependence There are serious thoughts of harming oneself or another

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple and individual randomization using a table of random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of social welfare and Rehabilitation Sciences.

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Duration and severity of resistant auditory hallucinations

Timepoint

Before intervention, after intervention and 1 month after intervention

Method of measurement

The Psychotic Symptom Rating Scale (PSYRAT)

Secondary outcomes

1

Description

beliefs about voices

Timepoint

Before intervention, after intervention and 1 month after intervention

Method of measurement

The revised beliefs about voices questionnaire (BAVQ-R).

Intervention groups

1

Description

Intervention group: In the experimental group, patients undergo Audio Visual Assisted Therapy Aid for Refractory auditory hallucinations (AVATAR therapy) . This treatment consists of 6, 45-minute treatment sessions in which the patient and the therapist communicate through the designed AVATAR software and a conversation is formed between them that helps the patient gradually feel in control and the duration and intensity Reduce illusions.

Category

Treatment - Other

2

Description

Control group: In the control group, patients undergoing treatment as usual under the supervision of a psychiatrist. The dose and duration of use will be determined by a psychiatrist.

Category
Treatment - Drugs

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi psychiatric hospital
Full name of responsible person
Dr. Ali Nazeri Astaneh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Person responsible for general inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr. Farhad Tareman
Position
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Person responsible for updating data

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Name of organization / entity
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Vida Yousefi Asl

Position

PhD candidate

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available