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# Virtual reality-assisted cognitive behavioral therapy improves the theory of mind and decreases paranoia in patients with schizophrenia

**Submission date**
05/12/2023

**Recruitment status**
No longer recruiting

**Registration date**
28/12/2023

**Overall study status**
Completed

**Last Edited**
28/12/2023

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Paranoia is a recognized symptom of schizophrenia spectrum disorders, which includes misconceptions about the behavior of others. Different psychological processes are believed to be involved in the development of paranoid ideation, including deficits in Theory of Mind (ToM) and cognitive biases. The ToM is the complex mechanism of attributing information, intentions, or feelings to others that brings the ability to describe and predict their behavior, therefore influencing interactions within a social environment. It is part of the concept of social cognition that involves the perception, processing, and interpretation of social signals. Social cognition influences the daily living of patients with psychotic disorders and is directly associated with their work skills and interpersonal functioning. This has encouraged researchers to explore possible treatments that can improve social cognition. Results of several trials with different antipsychotics indicate that psychological treatments may hold more promise in improving social cognition. A growing body of literature has shown that performance on social cognitive tasks improves with different psychological interventions. Deficits in identifying emotions, lack of a hypothesis-testing attitude, and the presence of 'jumping to conclusions' in patients with psychosis make cognitive-behavioral therapy (CBT) a promising intervention, especially for those with incomplete remission with medications. Difficulties in implementing this treatment due to patient motivation or the spontaneity of real-world situations can be reduced by using virtual reality (VR). This newly developing technology provides a sense of immersion along with the possibility of timely feedback based on treatment strategy. Moreover, it also offers the opportunity to avoid safety search behaviors in a controlled and harmless environment. VR creates reactions similar to real situations and is safe to use with people with psychotic disorders despite concerns. Evidence supports it as a cost-effective, acceptable, and accessible treatment. This study aimed to evaluate the effect of VR assisted CBT on paranoia in patients with recent onset schizophrenia.

Who can participate?
Patients aged 18 to 70 years old who have a diagnosis of paranoid schizophrenia

What does the study involve?
This open-label, randomized, controlled trial will be conducted in the ARAS recent onset acute phase psychosis survey (ARAS) focusing on the first episode of psychosis in Iran. The intervention involves the creation of a VR social environment with human avatars representing different moods. The VR-based CBT will consist of 8 sessions over 4 weeks, each lasting 30 minutes, guided by a psychologist experienced in CBT. Patients will be exposed to virtual social situations to challenge suspicious thoughts and learn appropriate responses, aiming to reduce delusional symptoms and improve social relations. The effectiveness will be assessed using a questionnaire, comparing the VR-based CBT group with a control group receiving standard CBT treatment. No home exercises will be assigned between sessions to isolate the effects of virtual reality therapy.

What are the possible benefits and risks of participating?
Many patients are very fearful in real situations, preventing them from adopting safety behaviors and thus avoiding exposure. This intervention may lead patients to perform their exercises and feel less stress.
Intervention with virtual reality does not have any dangerous risks. Some patients may feel dizzy when using it, in which case the intervention will be stopped.

Where is the study run from?
Tabriz University of Medical Sciences (Iran)

When is the study starting and how long is it expected to run for?
January 2023 to June 2024

Who is funding the study?
Tabriz University of Medical Sciences (Iran)

Who is the main contact?
Dr Elham Monaghesh, monaghghesh1997@gmail.com

# Contact information

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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**
Nil known

# Study information

**Scientific Title**
VR-assisted cognitive behavioral therapy in patients with schizophrenia who experience paranoia

**Study objectives**
Virtual reality-assisted cognitive behavioral therapy improves the theory of mind and decreases paranoia in patients with schizophrenia

**Ethics approval required**
Ethics approval required

**Ethics approval(s)**
approved 24/05/2023, Student Research and Technology Committee (Tabriz University of Medical Sciences, Tabriz, -, Iran; +989149896585; src@tbzmed.ac.ir), ref: IR.TBZMED.REC.1399.584

**Study design**
Open-label randomized controlled trial

**Primary study design**
Interventional

**Study type(s)**
Treatment

## Health condition(s) or problem(s) studied
Paranoid schizophrenia

## Interventions
This study will be an open-label, randomized, controlled trial that will be conducted in the ARAS investigation phase of acute-onset psychosis. ARAS is a prospective group of the first episode of psychosis in Iran. Patients will be included in the study after giving written consent that will be obtained from the volunteers. It will be explained that everyone can leave the trial at any stage (without having to give a specific reason) without affecting their care.

First, with the formation of a focus group, the characteristics obtained in the previous stage will be voted on in a meeting with the presence of three experts in the field of psychiatry who have experience in treating paranoid patients, to prepare a suitable model with the determined characteristics under the supervision of experts. to be Then, based on the approved content, the appropriate scenario and virtual environment will be designed for avatar therapy. For this purpose, a virtual social environment will be created with Unity software and Unity assets. The scenario will be a social environment. For the patients to visualize the environment with real images and sounds and provide the complex environment with more immersion, several human avatars with different appearance characteristics will be designed, and the avatars with different moods such as neutral, angry, happy, surprised, sad and threatening with Patients will bump into, interact with, or pass by. Also, the avatars will speak pre-recorded sentences to communicate with the patient.

After completing the design of the system, to evaluate it, the research samples in similar studies will be reviewed and then the evaluation will be done, and the research population will include patients with schizophrenia. The criteria for entering the study will include a diagnosis of paranoid schizophrenia and an age over 18 years. In addition to psychosis caused by organic causes, the exclusion criteria will be substance abuse and IQ lower than normal, and patients who do not cooperate with the completion of treatment sessions will be excluded from the study. To compare the effect of VR-based cognitive-behavioural therapy (CBT) and the standard method of CBT interventions, the samples will be equally divided into two intervention groups (treatment with VR) and a control group (treatment with the standard method). Randomization will be simple random sampling. Patients will be divided into two groups based on the received code. At the end, the effectiveness of each of the treatment methods in each group will be checked based on the PANNS questionnaire and a comparison will be made between the two groups.

The treatment based on virtual reality will consist of 8 sessions during 4 weeks. Each session will be about 30 minutes. A psychologist with experience in cognitive behavioral therapy will control the sessions. The first 10 minutes will be for educating and informing the patient about the therapy sessions, and then 10 minutes of these exercises will include cognitive behavioral therapy based on virtual reality. The remaining 10 minutes will be used to plan and reflect on the exercises. During virtual reality sessions, patients are tested to discover and challenge suspicious thoughts in social situations, in such a way that in virtual social situations, the patient is asked not to perform defensive behaviors and avoid things such as avoiding eye contact, observing distance from the avatar, stay away from them and refrain from communicating with the avatars to learn how to deal appropriately in stressful situations and to believe that their beliefs about threats and harm are incorrect and ultimately lead to a reduction in the symptoms of delusions and Improve social relations.

Also, no home exercises will be performed between sessions to evaluate the effects of virtual reality therapy without the influence of other factors. Control group patients will also receive standard CBT treatment.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Virtual reality

### Primary outcome(s)
The factors of paranoid thoughts from the aspect of suspicion and mistrust (related to thoughts of being harmed by others, being under control and feeling insecure) measured using the standard Positive and Negative Syndrome Scale (PANSS) for Schizophrenia at baseline and 1 week later

### Key secondary outcome(s))
The acceptance rate of VR and its usability will be measured using the relevant questionnaire at the end of intervention

### Completion date
25/06/2024

## Eligibility

### Key inclusion criteria
1. A diagnosis of paranoid schizophrenia
2. Aged 18 years old and over

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
70 years

### Sex
All

### Key exclusion criteria
1. Psychosis caused by organic causes defined in ARAS
2. Substance use
3. Lower than normal IQ
4. Patients who do not cooperate with the completion of treatment sessions

### Date of first enrolment
10/12/2023

### Date of final enrolment
30/12/2023

## Locations

### Countries of recruitment
Iran

### Study participating centre
**Tabriz University of Medical Sciences**
Tabriz University of Medical Sciences
Tabriz
Iran
-

## Sponsor information

### Organisation
Tabriz University of Medical Sciences

### ROR
https://ror.org/04krpx645

## Funder(s)

### Funder type
University/education

### Funder Name
Tabriz University of Medical Sciences

### Alternative Name(s)

Tabriz University of Medical Science Iran, Tabriz University of Medical Sciences, Tabriz, Iran, Tabriz Institution of Medical Sciences (TUOMS), Tabriz University of Medical Sciences - Iran, Tabriz University of Medical Sciences | Tabriz, Iran | TBZMED, Tabriz University of Medical Sciences (TUOMS), Iran, ., Tabriz University of Medical Sciences (TBZMED), ., , Danushgah-e 'lum-e Pezeshki-ye Tebriz, TUOMS Tabriz,Iran, TUOMS, TBZMED

### Funding Body Type
Government organisation

### Funding Body Subtype
Universities (academic only)

### Location
Iran

## 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 Dr Elham Monaghesh, monaghghesh1997@gmail.com. Data obtained from this study may be made available to qualified researchers. Shared data or samples are encrypted without PHI. Data requests can be submitted from 9 months after publication of the article and data will be accessible for up to 24 months. Extensions will be reviewed on a case-by-case basis. Access to experimental IPD can be requested by qualified researchers engaged in independent scientific research and will be provided after review and approval of a Research Plan and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA).

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |