

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The comparison between the effectiveness of using virtual reality games and conventional intervention on social-communication skills of school-aged children with autism spectrum disorder

#### Protocol summary

##### Study aim

Comparing the effectiveness of joint attention interventions by virtual reality games and conventional treatment on the improvement of social-communication skills of children with autism

##### Design

Two arm, parallel group, double blind, randomized, sham controlled clinical trial of 32 participants. Randomization was computerized with concealed randomization sequence carried out by [www.sealedenvelope.com](http://www.sealedenvelope.com).

##### Settings and conduct

Eligible participants will be recruited selected from autism schools in Tehran City, Iran, using a convenience sampling method. The participants will randomly assign to the target and control groups. The study is double-blind and participants and assessors will be blinded to randomized group allocation. Both groups will receive the intervention in the speech and language therapy rooms of the schools. VR Sessions will occur 3 days per week, with at least 48 h between sessions. A total of 15 VR sessions are completed over a 5-week period. A follow-up appointment at the assessment site will be approximately one month after the end of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: A clinical diagnosis of autism spectrum disorder (ASD) Exclusion criteria: Inability to understand and follow simple instructions; History of seizures, epilepsy, migraines, vertigo, psychosis, or photophobia

##### Intervention groups

Children in the intervention group will receive joint attention interventions through virtual reality (VR) games with VR glasses, while children in the control group will use VR glasses only to watch a simple animation. Furthermore, both groups receive conventional speech and language therapy during the experiment.

##### Main outcome variables

social communication; initiating joint attention;

responding to joint attention; Visual pursuit; Eye contact

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221224056907N1**

Registration date: **2023-01-31, 1401/11/11**

Registration timing: **prospective**

Last update: **2023-01-31, 1401/11/11**

Update count: **0**

##### Registration date

2023-01-31, 1401/11/11

##### Registrant information

##### Name

Talieh Zarifian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0139

##### Email address

[ta.zarifian@uswr.ac.ir](mailto:ta.zarifian@uswr.ac.ir)

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-24, 1401/12/05

##### Expected recruitment end date

2023-04-04, 1402/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The comparison between the effectiveness of using virtual reality games and conventional intervention on social-communication skills of school-aged children with autism spectrum disorder

**Public title**

Effect of virtual reality games in autism spectrum disorder (ASD)

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Monolingual in Persian Parents consent for inclusion in the experiment A clinical diagnosis of autism spectrum disorder (ASD)

**Exclusion criteria:**

History of problems with virtual reality games History of seizures, epilepsy, migraines, vertigo, psychosis, or photophobia Obvious vision or hearing problem Severe stereotyped behaviors and hyperactivity Severe sensory or balance impairments Inability to understand and follow simple instructions Lack of proper psychomotor development

**Age**

From **7 years** old to **11 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **32**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The blocked randomization method is used to allocate participants to two groups. This allocation is done in several steps. First, using the online software application provided by sealedenvelope.com, a random sequence is generated with blocks of four. Then, to hide the random allocation, sequentially numbered, opaque sealed envelopes (SNOSE) are used in a random sequence.

Based on the sample size, 32 envelopes with aluminum foil inside (to prevent "hot lighting") are prepared. Each entry in the random sequence is noted on a card and is replaced in the envelope in a numbered envelope. Finally, the envelopes are sealed and placed in boxes, respectively. At the time of registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes is opened respectively and so the participant's assigned group is revealed. In this approach, the experts who check the inclusion and exclusion criteria and the experts who do the allocation process are independent.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study is double-blind and participants and assessors will be blinded to randomized group allocation. Children in the intervention group will receive joint attention tasks through virtual reality (VR) games with VR glasses, while children in the control group will use VR glasses only to watch a simple animation. Furthermore, both groups receive the conventional speech and language therapy during the experiment. The assessors are also not aware of which intervention participants have received and whether the assessments are pre- or post-intervention.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary IDs**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences

**Street address**

Kodakyar Ave., Daneshjo Blvd., Evin, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713871

**Approval date**

2022-12-21, 1401/09/30

**Ethics committee reference number**

IR.USWR.REC.1401.177

**Health conditions studied****1****Description of health condition studied**

Autism spectrum disorder

**ICD-10 code**

F84.0

**ICD-10 code description**

Autistic disorder

**Primary outcomes****1****Description**

Joint attention skills

**Timepoint**

Assessment of joint attention skills at the beginning of

the study (baseline, before the start of the intervention), at the end of the study and one month after the end of the study (follow-up)

**Method of measurement**

Floreo questionnaire; pre- and post-assessment game

**Secondary outcomes****1****Description**

Social-communication skills

**Timepoint**

Assessment of joint attention skills at the beginning of the study (baseline, before the start of the intervention), at the end of the study and one month after the end of the study (follow-up)

**Method of measurement**

Autism Classification System of Functioning: Social Communication (ACSF: SC)

**Intervention groups****1****Description**

Intervention group: Virtual reality games in order to make improvement joint attention through VR glasses, 15 sessions with an interval of 48 hours, three sessions per week, each session includes one or two virtual reality games, and the duration of each game is about five minutes. There is a three to five minute break between each game.

**Category**

Rehabilitation

**2****Description**

Control group: A simple animation through VR glasses, 15 sessions with an interval of 48 hours, three sessions per week, each session includes one or two animations with virtual reality characters, and the duration of each animation is about five minutes. There is a three to five minute break between each animation.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Aein Mehrvarzi School

**Full name of responsible person**

Mehdi Ghandazade

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<https://autismschool.ir/>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

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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****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tose'e Darman Sarv

**Full name of responsible person**

Hassan Yazdanian

**Position**

Research and development lead

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Engineering

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**Full name of responsible person**

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**Position**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

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**Person responsible for updating data****Contact****Name of organization / entity**

Tose'e Darman Sarv

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The results of this study will be published in peer-reviewed journals.

**When the data will become available and for how long**

After publishing results

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Data will be available only for research purpose.

**From where data/document is obtainable**

Through sending an email to:  
hassanyazdanian@gmail.com

**What processes are involved for a request to access data/document**

The requested data will be sent as soon as possible after receiving the email.

**Comments**