Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effect of Risperidone, Virtual Reality on Social Skills, and Behavioral difficulties in Children with Autism

Protocol summary

Study aim

Investigating and comparing virtual reality and Risperidone and the behavioral and social problems of children with autism. One of the problems of children with autism is social and behavioral disorders that parents are looking for. The aim of this study is to create a non-invasive solution to solve the social and behavioral problems of children with autism.

Design

Exprimental In this study, individuals who were diagnosed with autism were randomly divided into two intervention groups and one control group. The size of each group is 10 people.

Settings and conduct

Children with autism who came to the Center for Andisheh and Raftar. Virtual reality intervention sessions 6 months a week were two 45-minute sessions. The other group was treated with risperidone for 6 months. The control group did not receive any intervention. All parents of the clients completed the consent to participate in the research.

Participants/Inclusion and exclusion criteria

Diagnosis of autism according to the Gilliam test, clinical interview based on DSM-5. Age (in the age range of 4 to 12 years) Of course, this tool is applicable until the age of 16, but the researcher has chosen this age range because most of the clients are in this age range. The children who participated in this study participated in this study with the consent obtained from their parents.

Intervention groups

Children with autism who take virtual reality Children with autism who took Rsperidone.

Main outcome variables

Behavioral problems were measured before and after drug intervention and virtual reality intervention. Social problems were measured before and after drug intervention and virtual reality intervention.

General information

Reason for update

Acronym

Virtual Reality and Autism

IRCT registration information

IRCT registration number: **IRCT20191113045429N1**
Registration date: **2020-06-15, 1399/03/26**
Registration timing: **retrospective**

Last update: **2020-06-15, 1399/03/26**
Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Sakineh Soltani kouhbanani

Name of organization / entity

The Ferdowsi University of Mashhad

Country

Iran (Islamic Republic of)

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+98 51 3880 5892

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-11-14, 1398/08/23

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2019-11-14, 1398/08/23

Trial completion date

2019-11-14, 1398/08/23

Scientific title
Comparing the effect of Risperidone, Virtual Reality on Social Skills, and Behavioral difficulties in Children with Autism

Public title
Virtual Reality and Autism

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Having autism based on Gilliam test, clinical interview and DSM-5 components Minimum age 4 years and maximum age 12 years

Exclusion criteria:
parents dont agreed children who have comotbity disorder bisides autism

Age
From **4 years** old to **16 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **20**
More than 1 sample in each individual
Actual sample size in each individual: **20**
Each sample takes only one intervention. For example, 10 people who receive virtual reality intervention and 10 people who receive Risperidone medication.

Randomization (investigator's opinion)
Randomized

Randomization description
People with autism were randomly assigned to three groups (virtual reality,Risperidone therapy, and control group). Thirty names were written by chance, and the first 10 people were randomly selected from the Virtual Reality Process, and the second 10 people from the Risperidone group and the third 10 people from the group were waiting for the group to receive no intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Because the tool is built for the first time, the effectiveness of reducing social and behavioral problems is assessed

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ferdowsi University Of Mashhad

Street address
Azadi Ave.Ferdowsi University Of Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948974

Approval date
2019-11-14, 1398/08/23

Ethics committee reference number
IR.UM.REC.1398.129

Health conditions studied

1

Description of health condition studied
Autism Disorder

ICD-10 code
F84.0

ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Evaluates the behavioral problems of children with autism through a questionnaire.

Timepoint
The first group had two virtual reality training sessions per week, the second group received drug therapy every day, but pre-test and post-test measurements were performed only at the beginning and end of the intervention period (6 months).

Method of measurement
Behavioral Problems Questionnaire

2

Description
Evaluates the social problems of children with autism through a questionnaire.

Timepoint
The first group had two virtual reality training sessions per week, the second group received drug therapy every day, but pre-test and post-test measurements were performed only at the beginning and end of the intervention period (6 months).

Method of measurement
Social Problem Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Risperidone drug therapy is the first intervention in a group. The intervention lasted 6 months. The first group to receive drug treatment under the supervision of a psychiatrist received Risperidone medication. First, behavioral and social problems were taken before the test, and after 6 drug treatments, behavioral and social problems were taken twice, and this difference shows the effect of drug therapy on reducing behavioral and social problems.
Category
Treatment - Drugs

2

Description
In the second virtual reality intervention group, behavioral and emotional disorders were taken before the test, and two sessions a week, in which a 45-minute virtual reality training program was taught and lasted for 6 months. In this intervention model, a number of animation images that Communication skills training is done in a three-dimensional way for a child with autism, and at the end of 6 months of post-test intervention, behavioral and emotional disorders were performed.
Category
Treatment - Devices

3

Description
The control group did not receive any referrals. Only pre-tests completed behavioral and social problems and were placed on a waiting list, and after 6 months they completed the behavioral and social problem questionnaire again.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Andisheh Raftar Clinic
Full name of responsible person
Sakineh Soltani Kouhbanani
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Azadi Ave. Ferowsi University Of Mashhad
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice President For Research and Technology Of Ferdowsi University Of Mashhad
Full name of responsible person
Ahmad Reza Bahrami
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Private
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

Vice President For Research and Technology Of Ferdowsi University Of Mashhad

Full name of responsible person

Sakineh Soltani Kouhbanani

Position

Professer

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparing the effect of Risperidone, Virtual Reality and Risperidone on Social Skills, and Behavioral difficulties in Children with Autism

When the data will become available and for how long

1 year later in 2021

To whom data/document is available

every one

Under which criteria data/document could be used

Article

From where data/document is obtainable

s.soltani@um.ac.ir

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

s.soltani@um.ac.ir

Comments