

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Exploring the effect of extended reality training contents versus traditional methods such as flash cards, on basic recognition deficits in children with Autism Spectrum Disorder: A single-blinded randomized controlled trial

Protocol summary

Study aim

Exploring the effect of extended reality training contents versus traditional methods such as flash cards, on basic recognition deficits in children with Autism Spectrum Disorder

Design

Single-blinded randomized controlled trial with two parallel groups: one intervention group and one control group, and 32 participants

Settings and conduct

Children will receive extended-reality-based or flashcard-based training twice a week for 10 weeks at Sedighe-Mansour Autism Center in Hamedan, Iran

Participants/Inclusion and exclusion criteria

4 to 10 years old children with Autism Spectrum Disorder, level 2

Intervention groups

The intervention group will receive 20 sessions of half-hour training with extended reality goggles over 10 weeks, while the control group receives the same amount of training with standard-of-care methods such as flash cards.

Main outcome variables

Test grade in pre and post tests; eye contact

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040370N8**

Registration date: **2020-07-30, 1399/05/09**

Registration timing: **prospective**

Last update: **2020-07-30, 1399/05/09**

Update count: **0**

Registration date

2020-07-30, 1399/05/09

Registrant information

Name

Ensiyeh Jenabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0496

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2020-12-19, 1399/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploring the effect of extended reality training contents versus traditional methods such as flash cards, on basic recognition deficits in children with Autism Spectrum Disorder: A single-blinded randomized controlled trial

Public title

Exploring the effect of extended-reality training contents on basic recognition deficits in children with Autism

Spectrum Disorder

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Children 4 to 10 years old with Autism Spectrum Disorder, level 2 Autism disorder should be diagnosed by a pediatric psychologist Parents consent for inclusion in the experiment
Exclusion criteria:
 Sever behavioral or/and communication deficits that prevent understanding of simple explanations of the experiment or inversely effects the child's ability to perform the experiment contents

Age
From **4 months** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
 At first, a blind colleague will be given the names of the eligible participants and asked to encode the names and insert all males into one column in a Excel file and all females into one column in another Excel file (bock randomization). Then, using RAND function in Excel, a series of random numbers will be generated next to the unrecognizable encoded names in both files. Finally, when any of the generated random numbers are greater or equal to the mean of all numbers in their own column,"intervention" will be inserted next to them, and if they are lower than the mean, "control" will be inserted. In addition to allocation concealment, this will ensure that both groups have comparable number of males and females and also equal number of participants in general, and are yet totally randomized.

Blinding (investigator's opinion)
Single blinded

Blinding description
 A novel experimenter who is unaware of the experiment contents will give the pre and post tests. Also, a novel rater who is unaware of the experiment contents will examine the videos from an early, mid, and late session to find the percentage of making eye contact of each child.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Fahmiheh Street, Hamadan

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2020-07-10, 1399/04/20

Ethics committee reference number

IR.UMSHA.REC.1399.376

Health conditions studied

1

Description of health condition studied

Childhood Autism

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Test Grade

Timepoint

In a pretest session one week, a few days before starting the intervention, and again in the post-test session after finishing the intervention

Method of measurement

Percentage of correct answers to image recognition tests

Secondary outcomes

1

Description

Eye contact

Timepoint

During sessions 1, 10, and 20 of training

Method of measurement

Ratio of time that participant made eye contact to the duration of session

Intervention groups

1

Description

Intervention group: Children will receive half-hour training twice a week for 10 weeks with Nreal and Oculus Rift S goggles. The content will be engaging 3D basic objects such as animals and children will be encouraged to interact with them and surf around the virtual world. The researcher will guide the child through the training session, introducing the objects to them and asking them questions to make sure they are learning the concepts.

Category

Rehabilitation

2

Description

Control group: Children will receive half-hour training twice a week for 10 weeks with standard-of-care educational materials such as flashcards. The researcher will engage the child via games and reinforcements, making sure that they are learning the concepts, similar to that of the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sedighe-Mansor Center for Autism

Full name of responsible person

Fateme Malmir

Street address

Besat Sq., Jihad St., Azimi Alley

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

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Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Center for International Science and Technology Cooperation

Full name of responsible person

Mahdi Ghalenovi

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No.28, Attar St, Above of Vanak Square Valiasr St, Tehran, Iran

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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

Center for International Science and Technology Cooperation

Proportion provided by this source

50

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Data analysis is permitted with the author's permission.

From where data/document is obtainable

Hamadan University of Medical Sciences

What processes are involved for a request to access

data/document

Requests should be submitted to the corresponding

author via email. He will follow up with the inquiry

Comments