

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Development of serious game-based system for training social interaction to children with mild autism

Protocol summary

Study aim

Development of serious game-based system for training social interaction to children with mild autism

Design

A before and after study without a control group on 30 children with mild autism, without blinding. Without randomization and with available sampling method

Settings and conduct

A total of 30 children with mild autism who meet the conditions for entering the study will be selected and included in the study from among those referred to the Brain and Cognition Clinic of Iran University of Medical Sciences. During an orientation session, explanations will be provided to the children and their parents regarding the purpose of the study and the steps involved. During this session, the children's parents and therapists are asked to complete the social skills profile questionnaire for each child. The children must use the game for three months according to the doctor's prescription, and at the end, this questionnaire will be completed for them again.

Participants/Inclusion and exclusion criteria

Participants must be between 6 and 12 years old to enter the study. A specialist doctor has diagnosed and confirmed that the child has mild autism. Participants should be at least average in IQ. Participants must be at least at an intermediate level in terms of verbal and behavioral ability. Participants do not have disabilities in the upper limbs. Participants do not have any other mental or cognitive problems. The parents and guardians of the children have consented to participate in the study and completed the informed consent form.

Intervention groups

We ask the study participants to play the game as prescribed by the doctor after participating in the briefing session for 3 months, three days a week and at least 45 minutes each time at home. The control group will not be used in this study.

Main outcome variables

Autism social skills profile test scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230416057917N1**

Registration date: **2023-08-15, 1402/05/24**

Registration timing: **prospective**

Last update: **2023-08-15, 1402/05/24**

Update count: **0**

Registration date

2023-08-15, 1402/05/24

Registrant information

Name

Tahere Talebi Azadboni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4222 7642

Email address

tahere_22may@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development of serious game-based system for training social interaction to children with mild autism

IR.IUMS.REC.1402.281

Public title

Investigating the impact of serious game of training social interactions on children with mild autism

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 6 to 12 years
Diagnosis of mild autism by a specialist doctor
At least average IQ
Verbal and behavioral ability at least at an intermediate level
Lack of disability in the upper limbs of the body
Not suffering from other mental or cognitive problems

Exclusion criteria:

Adults with autism
Children with mild and severe autism

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

shahid hemmat highway, Tehran

City

Tehran

Province

Tehran

Postal code

14665354

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

mild autism

ICD-10 code

F84. 0

ICD-10 code description

utistic disorder

Primary outcomes

1

Description

Autism Social Skills Profile Test

Timepoint

At the beginning of the study and after three months

Method of measurement

The measurement of this variable is done using the standard autism social skills profile questionnaire. This 48-question questionnaire was created solely to plan treatment, determine the progress of treatment and to measure a wide range of social behaviors of children and adolescents with autism spectrum disorder in the age range of six to 17 years, and it is particularly sensitive to the changes caused by treatment. . The said questionnaire can be completed by the parent, teacher and any other adult who is familiar with the child's social behavior. It takes fifteen to twenty minutes to complete, and the questions are graded on a four-point Likert scale (never: one, rarely: two, often: three, and always: four). Higher scores indicate more positive social behaviors. This test has been translated and validated in Farsi. The test is performed by a neurologist and the parents of the sample children after the briefing session as the beginning of the study at the brain and cognition clinic affiliated to Iran University of Medical Sciences. At the end of the 3 months of the study, the participants will be tested again.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We ask the participants of the study to play parts of the game as prescribed by a specialist doctor after participating in the briefing session for 3 months, three days a week and at least 45 minutes each time at home. The results of each time the game is played, which is considered as points, will be recorded in the game along with the duration of the game. This game is a mobile game (based on Android) by the research team and after a systematic review of the

existing games and the impact They will be designed in such a way that the proposed game includes a series of small games and each of these small games will be related to one aspect of social skills.

Category

Treatment - Other

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

Brain and Cognition Clinic affiliated to Iran University of Medical Sciences

Full name of responsible person

tahere talebi

Street address

No. 33, Valiasr St., East Zaratasht

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8880 2063

Fax**Email**

bcclinic95@gmail.com

Web page address

<https://bcclinic.ir/>

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

Iran University of Medical Sciences

Full name of responsible person

Farahnaz Sadoughi

Street address

No. 4, Faculty of Management and Medical Information, Rashid Yasmi St, Valiasr St.

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 8879 4301

Email

sadoughi.f@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical 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**

Iran University of Medical Sciences

Full name of responsible person

Farahnaz Sadoughi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Informatics

Street address

No. 4, Faculty of Management and Medical Information, Rashid Yasmi St, Valiasr St.

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 8879 4301

Email

sadoughi.f@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

Farahnaz Sadoughi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Informatics

Street address

No. 4, Faculty of Management and Medical Information, Rashid Yasmi St., Valiasr St.

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 8879 4301

Email

sadoughi.f@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

Tahere Talebi Azadboni

Position

PhD. Student

Latest degree

Master

Other areas of specialty/work

Medical Informatics

Street address

No. 4, Faculty of Management and Medical Information, Rashid Yasmi St., Valiasr St.

City

Tehran

Province

Tehran

Postal code

1996713883

Phone

+98 21 8878 2919

Email

tahere_22may@yahoo.com

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The IPD after the end of the study will be reported in a non-identifiable way in the report of the intervention result in the thesis and extracted articles. The full report of the clinical study and its results will be reported in the form of the effect of serious play on the social interactions of children with mild autism at the end of the work.

When the data will become available and for how long

2024 , March

To whom data/document is available

Researchers interested in the subject of this study

Under which criteria data/document could be used

For use in selection or serious game design

From where data/document is obtainable

Professor Farahnaz Sadoughi

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

By email to sadoughi.f@gmail.com

Comments