

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of digital game program based on mother-child interaction on parenting stress in children with Autism Spectrum Disorder

Protocol summary

Study aim

Evaluation of the digital game program effects regarding mother-child interaction on parenting stress in the autistic children

Design

Single group clinical trial in 34 children with autism spectrum disorder

Settings and conduct

Available research units are randomly selected from high-functional autistic children, comprising the study intervention group, from 9 autism centers in Mashhad, Iran. The mothers of the selected children are asked to participate in a briefing session, in which the game installation link would be provided, and gameplays would be taught. Subsequently, they are asked to fill the Gilliam Garz and Parenting Stress Index Short Form (PSI-SF) questionnaires. Likewise, they are told to play various game stages with their children according to the compromised schedule at home. Finally, they must fill the required questionnaires immediately after the intervention conclusion and a month upon that.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with high-functional autism, children age 4-8 years, Children without any congenital disorders, Having IQ above 80 based on the patient's record, No visual and hearing impairments' according to the child's record, Parent desire to take part in the study. Exclusion criterion: Children have participated in similar game-based therapy programs

Intervention groups

Intervention: 8 sessions taking 10-20 minutes to play digital games

Main outcome variables

Parenting Stress Index Short Form, Gilliam Garz Questionnaire Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210328050783N1**

Registration date: **2021-06-22, 1400/04/01**

Registration timing: **retrospective**

Last update: **2021-06-22, 1400/04/01**

Update count: **0**

Registration date

2021-06-22, 1400/04/01

Registrant information

Name

Hanieh Esfahani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of digital game program based on mother-child interaction on parenting stress in children with Autism Spectrum Disorder

Public title

The effect of digital game program based on mother-child interaction on parenting stress in children with Autism Spectrum Disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Children with high-functional autism Children age 4-8 years Children without any congenital disorders Having IQ above 80 based on the patient's record No visual and hearing impairments' according to the child's record Parent desire to take part in the study

Exclusion criteria:

Children have participated in similar game-based therapy programs.

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

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 Mashhad University of Medical Sciences

Street address

Ibn Sina Ave; Doctora intersection

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Razavi Khorasan

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9137913199

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.004

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

Parenting stress

Timepoint

At the beginning of the intervention, Immediately after the intervention and one month after the intervention

Method of measurement

Parenting Stress Index Short Form

2

Description

Gilliam Garz Questionnaire Score

Timepoint

At the beginning of the intervention, Immediately after the intervention and one month after the intervention

Method of measurement

Gilliam Autism Diagnosis Test

Secondary outcomes

empty

Intervention groups

1

Description

This program developed for the Android platform includes eight games. Each game is designed for specific purposes, including Increasing attention and focus, problem-solving skills, vocabulary enhancement, increasing visual and hearing memory, teaching daily affairs skills, improving imitation skills, and improving interactions. Children and their mothers would play these eight games within eight weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shenava gosta

Full name of responsible person

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2**Recruitment center****Name of recruitment center**

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3**Recruitment center****Name of recruitment center**

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4**Recruitment center****Name of recruitment center**

Ava

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5**Recruitment center****Name of recruitment center**

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Full name of responsible person

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6**Recruitment center****Name of recruitment center**

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7**Recruitment center****Name of recruitment center**

Game Navid Zendegi5

Full name of responsible person

Dr. Nematullah Mokhtari

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
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Daneshgah Ave; across of Daneshgah 18 Ave
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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Monir Ramezani
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable