Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Country
Iran (Islamic Republic of)

Phone
+98 51 3607 2695

Email address
esfahanih982@mums.ac.ir

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
City
Mashhad
Province
Razavi Khorasan
Postal code
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
Hamid Teirani nicneZhad

Street address
No.145; Rastegarmaghadam 1 Ave; Hedayat 32
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3607 2695
Fax
Email
Esfahanih982@mums.ac.ir

2

Recruitment center
Name of recruitment center
Naghme
Full name of responsible person
Majid Hadadi Aval
Street address
Isargaran4/1 Ave; Imam Hossein Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3607 2695
Email
Esfahanih982@mums.ac.ir

3

Recruitment center
Name of recruitment center
Parvaneha
Full name of responsible person
Mehri Lamse Khorasani
Street address
No. 3; Vahdat Haft Ave; Ershad Blvd6
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3607 2695
Email
Esfahanih982@mums.ac.ir

4

Recruitment center
Name of recruitment center
Ava
Full name of responsible person
Akram Najafian
Street address
No. 351; Danesh Amuz 13 Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3607 2695
Email
Esfahanih982@mums.ac.ir

5

Recruitment center
Name of recruitment center
Ruyesh
Full name of responsible person
Mohammad Hasan Fath Allah Zade
Street address
No. 45; Shahid Beheshti 33 Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3607 2695
Email
Esfahanih982@mums.ac.ir

6

Recruitment center
Name of recruitment center
Takapu
Full name of responsible person
Masoumeh Jalali
Street address
No. 17; Imam Reza 46 Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3607 2695
Email
Esfahanih982@mums.ac.ir

7

Recruitment center
Name of recruitment center
Game Navid Zendegi5
Full name of responsible person
Dr. Nematullah Mokhtari
Street address
Besat Blvd between Abuzar and Nasser Khosrow
City
Mashhad
Province

Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3607 2695

Email
Esfahanih982@mums.ac.ir

8

Recruitment center

Name of recruitment center
Kavush

Full name of responsible person
Ali Qanaee

Street address
Between Vakil Abad 55 and 57

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3607 2695

Email
Esfahanih982@mums.ac.ir

9

Recruitment center

Name of recruitment center
Armaghan nur

Full name of responsible person
Shahrbanoo Parku

Street address
No.15; Fallahi 34 Ave; Qasem Abad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3607 2695

Email
Esfahanih982@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Daneshgah Ave; across of Daneshgah 18 Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3841 1538

Fax
+98 51 3843 0249

Email
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
Ph.D.

Other areas of specialty/work
Nursery

Street address
Ibn Sina Ave., Doctora intersection

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Email
ramezanimn@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Monir Ramezani

Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ibn sina Ave; Doctora intersection
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
ramezanimn@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Monir Ramezani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ibn sina Ave; Doctora intersection
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
ramezanimn@mums.ac.ir

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