

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effectiveness of family centered play-based interventions on sensory pattern and occupational performance of children with autism spectrum disorder

Protocol summary

Study aim

The effectiveness of the intervention on the sensory pattern and occupational performance of children with autism spectrum disorder

Design

A clinical trial ,a control group with randomized one way blinded identical groups. Numbered envelopes for randomization.

Settings and conduct

Samples from Arman shayan Rehabilitation . Assessments are in the form of a questionnaire and an interview. During the intervention sessions, the researcher teaches parents how to play the selected games that are appropriate to the assessments along with the necessary considerations appropriate to the child's sensory conditions and needs to play at home in the presence of the child. Parents are then asked to play games at home. The duration of the intervention is 3 days a week for 8 weeks. During the week, the researcher communicates with the family by virtual environment. It should be noted that this book has been translated into Persian. The intervention group will receive these games in addition to the usual rehabilitation programs supervised by the project manager, and the control group will receive only the usual rehabilitation services according to their schedule during these 8 weeks. At the end of the intervention period, the final evaluation is performed again to assess the effectiveness of the intervention.

Participants/Inclusion and exclusion criteria

Children with ASD at the age of 3 to 6 years Existence of sensory processing disorder No history of seizures or epilepsy No accompanying physical problems Gars score below 80 Parents of children with at least a diploma literacy level

Intervention groups

intervention group teaching sensory plays in addition to

usual treatments control group just usual treatment

Main outcome variables

Occupational performance , Sensory processing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211114053055N1**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **prospective**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

Registration date

2022-02-02, 1400/11/13

Registrant information

Name

Negar Baharian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2290 7189

Email address

baharian.negar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of family centered play-based interventions on sensory pattern and occupational performance of children with autism spectrum disorder

Public title

Effectiveness of family centered play-based interventions on sensory pattern and occupational performance of children with autism spectrum disorder

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with autism spectrum disorder at the age of 3 to 6 years Existence of sensory processing disorder No history of seizures or epilepsy No accompanying physical problems GARS score below 80 (Autism level 1 and 2) Parents of children must have at least a diploma level of education.

Exclusion criteria:

Lack of parents or child cooperation at any stage of the study

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

We will have envelopes A and B for the number of people we have in the study (48). Each of the eligible participants will enter the intervention group by selecting envelope A and the control group by selecting envelope B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Eligible families are given the necessary explanations about the study and are assured that their information will be kept with the study team. Participants' families will be explained that assessments will be performed for their child, and they may then be taught games to play at home, reassuring them that there will be no harm or danger to any of them. The study process will not be relevant to their child

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

Street address

Department of Occupational Therapy, Tehran University of Medical Sciences, Corner of Safi Alisha, Above Pich Shemiran, Enghelab St.

City

TEHRAN

Province

Tehran

Postal code

11489-65111

Approval date

2021-12-05, 1400/09/14

Ethics committee reference number

IR.TUMS.FNM.REC.1400.160

Health conditions studied**1****Description of health condition studied**

Autism Spectrum Disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes**1****Description**

Occupational performance

Timepoint

After two months and after the end of the intervention

Method of measurement

Canadian Occupational Performance Measure

2**Description**

sensory processing

Timepoint

After two months and after the end of the intervention

Method of measurement

Canadian Occupational Performance Measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the researcher teaches the parents how to play the selected games that are in accordance with the evaluations performed and the reported sensory pattern of the child, along with the necessary considerations in accordance with the conditions and sensory needs of the child to play at home in the presence of the child. This training will be in person and with visual instructions and written explanations for home implementation. It should be emphasized that the presence of the child in weekly training sessions and troubleshooting is mandatory, and although in addition to meeting sensory needs, strengthening mutual attention and engaging children is one of the primary goals of all selected games, but corrections and adaptations to conditions and environment The game is tailored to the needs of each child in order to play the games more correctly and completely at home and the cooperation of as many children as possible is suggested to the parents by the researcher. Parents are then asked to play games at home. The duration of the intervention is 3 days a week for 8 weeks. During the week, the researcher communicates with the family by phone or video and follows the process of how the games are played at home and gives feedback to the family. The accuracy of the games will be measured by the parents through a checklist prepared by the researcher in consultation with the research team. The games will be selected from the book of early intervention games written by Ms. Barbara Sher.

Category

Rehabilitation

2

Description

Control group: During the intervention, the control group will receive their other rehabilitation programs (including speech therapy, etc.) according to the previous procedure. The primary and secondary evaluations of this study will be performed for them as well.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Arman Shayan Rehabilitation Clinic

Full name of responsible person

Negar Baharian

Street address

Arman Shayan Rehabilitation Complex, in front of Tarbiat Park, Ayatollah Kashani Highway, Behnam St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available