

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Sep 2026

Developing a parent training program to improve occupation of play in children with autism spectrum disorder and investigating its effect on children's play skills and parental self-efficacy

Protocol summary

Study aim

Investigating the effect of the parent training program on improving occupation of play in children with autism and parental self-efficacy

Design

A randomized controlled trial, with parallel-group, single-blind, involving 62 participants. The stratified randomization method will be used for randomization.

Settings and conduct

This study will be conducted in Isfahan. After sampling and preliminary evaluation, the samples are randomly divided into intervention and control groups. For the intervention group, a 12-session parent training program will be conducted by an experienced occupational therapist using occupational performance coaching principles. The control group will not receive any intervention. Outcome assessors and data analysts will be unaware of group allocations.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Child aged 3-6 with autism diagnosis; Receive a diagnosis of autism by a child psychiatrist; Obtaining a score of 54 and above on the Gilliam Autism Rating Scale; Being in level 1 or 2 of autism spectrum disorder; Exclusion criteria: Participating in another intensive treatment program; Severe child behavioral/emotional issues; Parental psychiatric diagnosis; Severe child medical problems

Intervention groups

Intervention group: The intervention group includes parents of children with autism who will receive the parent training program based on occupational performance coaching (OPC) for 12 sessions. Control group: The control group includes parents of children with autism spectrum disorder who will not receive any intervention.

Main outcome variables

Play skills Parental self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230628058613N1**

Registration date: **2023-10-06, 1402/07/14**

Registration timing: **prospective**

Last update: **2023-10-06, 1402/07/14**

Update count: **0**

Registration date

2023-10-06, 1402/07/14

Registrant information

Name

Ehsan Jamshidian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing a parent training program to improve occupation of play in children with autism spectrum disorder and investigating its effect on children's play skills and parental self-efficacy

Public title

Effect of parent training program to improve occupation of play in children with autism

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Parental consent to participate in the study by obtaining written consent Having a child in the age range of 3 to 6 years Receive a diagnosis of autism spectrum disorder by a child psychiatrist Obtaining a score of 54 and above on the Gilliam Autism Rating Scale Being in level 1 or 2 of autism spectrum disorder Availability of at least one parent who can continuously participate in educational and research workouts A stable course of the child's rehabilitation, medication, and school for at least one month prior to the start of the evaluations (no foreseeable change during participation in the study) Having at least a diploma in order to complete questionnaires and receive training

Exclusion criteria:

Participating in another intensive treatment program for more than 10 hours per week The presence of severe behavioral or emotional problems in the child Diagnosis of psychiatric disorders in parents based on structured clinical interview for DSM-5 disorders (SCID-5) The presence of severe medical problems, such as blindness, deafness, and epilepsy in a child Insufficient parental commitment for participation in the intervention

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the stratified randomization method is used and the participants are divided into different subgroups based on the child's level of play. Within each subgroup, a block randomization procedure with blocks of 4 was used to ensure equal representation of participants in each treatment group, and to minimize imbalances over time. This combination of stratified and block randomization is performed using R software, which increases accuracy and reduces human error. The software determines the appropriate blocks and allocates the samples, which ensures that the allocation process is truly random.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessors and the statistical data analyst will be unaware of allocating participants to the intervention and control groups. To ensure proper blinding, each participant will be assigned identifiers without specific information about groups. Also, any signs or symbols associated with the allocation group in the data and materials provided to the evaluator will be removed. The statistical analyst also faces only two groups ("Group 1" and "Group 2"), without knowing which one is related to the intervention group and which one is to the control group. The true identity of the groups will not be revealed until the statistical analyses are completed and before the results are presented. This blinding is done to avoid any bias or indirect influence in the evaluation and analysis process.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences

Street address

Occupational therapy department, University of social welfare and rehabilitation sciences, Kodakyar Ave., Daneshjo Blvd.,Evin

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Province

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Postal code

1985713871

Approval date

2023-08-22, 1402/05/31

Ethics committee reference number

IR.USWR.REC.1402.124

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

Play skills

Timepoint

At the beginning of the study and 3 and 4 months after the start of the parent education program

Method of measurement

Test of Playfulness (ToP)

Secondary outcomes

1

Description

Severity of autism symptoms

Timepoint

At the beginning of the study and 3 and 4 months after the start of the parent training program

Method of measurement

Autism Treatment Evaluation Checklist (ATEC)

2

Description

Parental stress

Timepoint

At the beginning of the study and 3 and 4 months after the start of the parent training program

Method of measurement

Parent Stress Index (PSI)

3

Description

Parental self-efficacy

Timepoint

At the beginning of the study and 3 and 4 months after the start of the parent education program

Method of measurement

Tool to Measure Parenting Self-Efficacy (TOPSE)

Intervention groups

1

Description

Intervention group: The intervention group in this study is parents of children with autism spectrum disorder who will receive the parent training program. This program is developed based on occupational performance coaching and will be held once a week for 12 sessions. The duration of each session will be 45 to 60 minutes.

Category

Rehabilitation

2

Description

Control group: The control group in this study is parents

of children with autism spectrum disorder who will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Parnian Autism Center

Full name of responsible person

Zahra Khalili

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2

Recruitment center

Name of recruitment center

Ordibehesht Autism Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Ehsan Jamshidian

Position
Ph.D. candidate

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

IDP: Once participants have been anonymized, we will share the data in an article. This article will discuss the effect of parent training program to improve occupation of play in children with autism and parental self-efficacy. The correlation of study findings will be examined with demographic information and made publicly available. Study protocol: We will present the study's methodology in a paper. Informed consent form: The details regarding informed consent form can be found in the proposal of this study. Clinical study report: We will disseminate the

clinical study report within a separate research paper.

When the data will become available and for how long

Access to the data will be possible from one month after the publication of the results.

To whom data/document is available

After publishing the paper, it will be accessible to researchers.

Under which criteria data/document could be used

The access depends on the journal in which we will publish the study results.

From where data/document is obtainable

Reach out to jamshidian.ot@gmail.com for any related information.

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

We cannot disclose data before it is published. Please be patient until the results are published.

Comments