Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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+98 31 3624 7599

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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

City
Tehran

Province
Tehran

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
Street address
Shahin Alley, Imam Khomeini St, Jomhoori Square
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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
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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