Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of culturally adapted play therapy with parental involvement versus routine care on stereotyped behaviors, communication skills, and social interactions in children with autism spectrum disorder

Protocol summary

Study aim

Determining the effect of culturally adapted play therapy with parental involvement on stereotyped behaviors, communication skills, and social interactions in school-aged children with autism

Design

A quasi-experimental study, with a pretest-posttest control group design, parallel groups, single-blind, and randomized, conducted on 40 patients. Randomization was performed using a simple random drawing method.

Settings and conduct

Study setting: Urmia Autism Association. Study population: Children with autism. Blinding: Single-blind. Blinding procedure: The data analyst was blinded to the group allocation (intervention or control) and the actual identity of the participants.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged 7 to 12 years with Autism Spectrum Disorder (low according to GARS criteria); with a prior psychiatric diagnosis of autism, residing in Urmia or nearby cities; parents with at least a lower secondary education and willingness to participate; no counseling services received during the study; and informed parental consent. Exclusion Criteria: Children aged 7 to 12 years with Autism Spectrum Disorder (moderate to severe according to GARS criteria); Inability of parents to read and write.

Intervention groups

Intervention group: The culturally adapted play therapy group. In this group, in addition to routine care, a family-centered culturally adapted play therapy intervention was conducted in 6 sessions of 2 hours each (on average, three sessions per week). Control group: The routine care group. In this group, only the standard care provided by the Autism Association was administered.

Main outcome variables

Stereotyped behaviors; communication skills; and social interactions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131112015390N10**
Registration date: **2025-12-31, 1404/10/10**
Registration timing: **retrospective**

Last update: **2025-12-31, 1404/10/10**
Update count: **0**

Registration date

2025-12-31, 1404/10/10

Registrant information

Name

Naser Parizad

Name of organization / entity

Urmia University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date
2021-06-05, 1400/03/15
Actual recruitment end date
2021-09-01, 1400/06/10
Trial completion date
2022-03-01, 1400/12/10

Scientific title
Comparing the effectiveness of culturally adapted play therapy with parental involvement versus routine care on stereotyped behaviors, communication skills, and social interactions in children with autism spectrum disorder

Public title
Examining the Effect of Culturally Adapted Play Therapy with Parental Involvement on Children with Autism
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
School-aged children (7 to 12 years old) diagnosed with Autism Spectrum Disorder (ASD) Children with moderate to severe levels of autism according to the GARS (Gilliam Autism Rating Scale) criteria Parental willingness to participate in the study Previous diagnosis of autism made by a psychiatrist Residents of Urmia city or surrounding towns under Urmia's jurisdiction Parents with at least a lower secondary education Obtaining informed consent from parents for participation in the study
Exclusion criteria:
Children with low levels of autism according to the GARS (Gilliam Autism Rating Scale) criteria Inability of parents to read and write
Age
From **7 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **36**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the simple randomization by drawing method, 20 children were assigned to the control group and 20 children to the intervention group. The names of all participants were written on pieces of paper and placed in a box. Then, the papers were drawn one by one until the desired sample size for the intervention group was reached, and the remaining names in the box were assigned to the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The dataset was coded and anonymized by a member of the research team who was not involved in the analysis phase. The groups were replaced with neutral codes (such as A and B), and any variables that could reveal the nature of the intervention or group assignment were removed. The analyst had access only to the coded raw data and the predetermined statistical analysis protocol. Accordingly, without being aware of the study conditions or group assignments, the analyst performed all stages of the analysis, from assessing normality to conducting comparative tests.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Orjans Suburb, Resalat Blvd.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2021-03-07, 1399/12/17
Ethics committee reference number
IR.UMSU.REC.1399.399

Health conditions studied

1

Description of health condition studied
Stereotyped Behaviors, Communication Skills, and Social Interactions in Children with Autism
ICD-10 code
F84.0
ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Stereotyped behaviors score
Timepoint
before the start of the intervention, immediately after the intervention, and three months after the intervention
Method of measurement

Gilliam Autism Rating Scale

2

Description
Social interactions score
Timepoint
Before the start of the intervention, immediately after the intervention, and three months after the intervention
Method of measurement
Gilliam Autism Rating Scale

3

Description
Communication skills score
Timepoint
Before the start of the intervention, immediately after the intervention, and three months after the intervention
Method of measurement
Gilliam Autism Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention involved a series of structured, family-centered play therapy sessions aimed at building trust and engagement between the therapist, mother, and child; enhancing eye contact, social interaction, emotional recognition, and communication skills through traditional Iranian games; encouraging active parental involvement; providing feedback on home assignments; and promoting the continuation of playful therapeutic exercises beyond the sessions.
Category
Behavior

2

Description
Control group: This group only engaged in their usual recreational activities under parental supervision.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Hospital
Full name of responsible person
Mirreza Ghaemi
Street address
Kashani Street
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motahari-h-urm@umsu.ac.ir
Web page address
https://motahari.umsu.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber Gholizadeh
Street address
Deputy of Research and Technology, Urmia University of Medical Sciences, End of Jihad Street,
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Email
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Web page address
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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Naser Parizad
Position
Associate professor
Latest degree
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Other areas of specialty/work
Nursing
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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
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data of this study include the scores obtained from standardized questionnaires at three stages (pre-test, post-test, and three-month follow-up). Participant information was coded and anonymized by removing all identifying variables (such as name, national ID, or contact details). All quantitative data, after the anonymization process, will be available for sharing upon researchers' request and with the approval of the Ethics Committee of Urmia University of Medical Sciences. The data will be accessible only for research purposes and in full compliance with confidentiality and privacy protection principles.

When the data will become available and for how long

The release and access to the data of this study will begin after the publication of the research results in a reputable scientific journal. The data will remain available to interested researchers for five years after the publication of the article. Requests must be submitted formally, including the research purpose, to the Deputy of Research and Technology of Urmia University of Medical Sciences. Access to the anonymized data will be granted following review and approval by the Ethics Committee.

To whom data/document is available

Only researchers in the field of health and other related fields will be allowed to access the data if approved by the Vice President for Research and Technology and the corresponding author.

Under which criteria data/document could be used

Deidentified data will only be made available to researchers if there are scientific reasons and the need for statistical studies.

From where data/document is obtainable

Researchers can send their requests, along with the reasons, to the research project manager with the following information: Dr. Naser Parizad Associate Professor of Nursing Address: School of Nursing and Midwifery, Campus of Urmia University of Medical Sciences, 11th Kilometer of Serou Road, Urmia, West Azerbaijan, Iran Emails: nparizad@gmail.com

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

Researchers can get access to the data by providing reasons and guaranteeing citation to the article(s) resulting from the thesis project. They should send an email to the corresponding author of the research project (Dr. Naser Parizad). Email: nparizad@gmail.com

Comments