

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The Effectiveness of Symbolic Play Training on the Improvement of Communication Skills in Autistic Children with High Performance: Single-subject Study

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of symbolic Play on communication skills of children aged 4-6 with high-performance autism disorders.

Design

In this study, single-subject experimental design using A-B method was used. This plan had three baseline, intervention and follow-up phases so the statistical population of this study included all children with autism spectrum disorder in Sabzevar who were selected by purposeful sampling method.

Settings and conduct

In this study, using the Autism Therapy Assessment Scale, the baseline was drawn for three sessions on the communication / speech / language scale. Information was completed by a pediatrician at the Autism Center. The content of the training sessions was adjusted to 36 sessions of 4 days per week for 1.5 hours. At the end of each of the 6 training sessions, the communication / speech / language scale was again completed by each child's instructor. For the follow-up phase four weeks after the last evaluation phase, the scale was completed again.

Participants/Inclusion and exclusion criteria

Inclusion criteria included a score of 85 or more on the Gilliam Autism Diagnosis Scale, age range 4 to 6 years, parental consent to participate in the study, lack of physical disabilities, visual and hearing impairments.

Intervention groups

Symbolic play of training sessions include several play situations based on the criteria provided by Karen Stagniti. Symbolic game skills therefore consist of 6 components: thematic play, sequences of imaginative play activities, object substitution, social interaction skills, independent role playing, playing with dolls.

Main outcome variables

Communication Skills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190630044053N1**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **retrospective**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

Registration date

2019-12-23, 1398/10/02

Registrant information

Name

mahbobe makarem

Name of organization / entity

The university of isfahan

Country

Iran (Islamic Republic of)

Phone

+98 51 4441 1676

Email address

makaremmahbobe@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-29, 1397/07/07

Expected recruitment end date

2018-12-03, 1397/09/12

Actual recruitment start date

2018-09-29, 1397/07/07

Actual recruitment end date

2018-12-03, 1397/09/12

Trial completion date

2019-02-06, 1397/11/17

Scientific title

The Effectiveness of Symbolic Play Training on the Improvement of Communication Skills in Autistic Children with High Performance: Single-subject Study

Public title

The Effectiveness of Symbolic Play Training in Autistic Children with High Performance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

score 85 or more on GARS of scale, parental satisfaction, lack of physical disability, blindness and deafness

Exclusion criteria:

lack of score 85 or more on GARS of scale, lack of parental satisfaction, physical disability, blindness and deafness

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **3**

Actual sample size reached: **3**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Single-subject Study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University

Street address

Hezar jarib Ave, Esfahan university, Esfahan

City

Esfahan

Province

Isfahan

Postal code

83111-84156

Approval date

2016-02-02, 1394/11/13

Ethics committee reference number

94/175471

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Communication Skills of score on in Autism Treatment Evaluation Scale

Timepoint

At the beginning of the study and during the intervention and its follow-up

Method of measurement

Autism Treatment Evaluation Scale

Secondary outcomes

empty

Intervention groups

1

Description

۴۳۸/۵۰۰۰ This study was conducted in the context of a single-subject experimental design using the B-A method. The statistical population included children with autism spectrum disorder in Sabzevar in 1397. Purposeful sampling was performed on 3 children with high functioning autism. Training sessions were organized in 36 sessions every 4 days for 1.5 hours. To measure the dependent variable before and after the intervention program, the Autism Therapy Assessment Checklist (ATEC) was completed by the trainers.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Roshd of Autism Center(sabzevar)

Full name of responsible person

mahbobeh makarem

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Mokhtar Malek Pour
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jcbs@ui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
University of Isfahan
Proportion provided by this source
10
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
The University of Isfahan
Full name of responsible person
Mokhtar Malek Pour
Position
Professor
Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

Part of the data, such as information about the main outcome, is possible.

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions and therapists in the field of autism

Under which criteria data/document could be used

data of validity and reliability

From where data/document is obtainable

Mahbobeh Makarem Department of Children with Special Needs, The University of Isfahan, Isfahan, Ave, Hezar jarib +98 915 170 2250

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

Send by email

Comments