Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of a DIR/Floortime approach on sibling interaction and parental quality of life in families of children with autism spectrum disorder: A Randomized Clinical Trial

Protocol summary

Study aim

investigate the effect of the Floortime approach on sibling interactions and parental quality of life in families with children diagnosed with Autism Spectrum Disorder (ASD)

Design

Randomized controlled trial with parallel groups, single-blind, using block randomization, with random allocation performed by an independent statistician using computer software (e.g., R or SPSS).

Settings and conduct

A single-blind randomized controlled trial with two parallel groups involving parents of children aged 3–5 years with ASD, with an 8-week intervention consisting of weekly 3-hour sessions at the Comprehensive Autism Center and Talash Rehabilitation Clinic. Outcome assessors are blinded, and data are analyzed by an independent analyst.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children: definitive diagnosis of ASD Level 1 or 2 according to DSM-5; no acute physical problems; age 3–5 years. Mothers: ability to read and write; no chronic psychiatric or physical disorders; no musculoskeletal diseases. Siblings: Ages 7-12; no diagnosis of autism spectrum disorders, behavioral or psychiatric disorders; ability to follow simple instructions and maintain play interactions Exclusion criteria: Absence for more than 6 sessions; Initiation of a new treatment during the study.

Intervention groups

Intervention group: receives Conventional Occupational Therapy + Floortime training, including 24 individual practical sessions of 60 minutes each (three times per week) and daily home practice of 6–10 sessions of 20–30 minutes with parents and other siblings. Sessions are delivered and monitored by trained therapists. Control group: receives only Conventional Occupational Therapy similar to the intervention group, without Floortime training, with service hours recorded for comparison.

Main outcome variables

Parental quality of life, quality of sibling interactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251213068303N1**
Registration date: **2026-06-01, 1405/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-01, 1405/03/11**
Update count: **0**

Registration date

2026-06-01, 1405/03/11

Registrant information

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Babak Kashefimehr
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-23, 1405/03/02

Expected recruitment end date

2026-07-22, 1405/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a DIR/Floortime approach on sibling interaction and parental quality of life in families of children with autism spectrum disorder: A Randomized Clinical Trial

Public title

The effect of a DIR/Floortime approach on sibling interaction and parental quality of life in families of children with autism spectrum disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Child: having a definitive diagnosis of Autism Spectrum Disorder (ASD), Level 1 or 2, according to DSM-5, made by a child psychiatrist. Child: having no acute physical problems such as visual, balance and gait, hearing problems, epilepsy, etc. Child: age: 3-5 years. Mother: having the ability to read and write. Mother: having no diagnosed chronic psychiatric or physical disorders. Mother: having no diagnosis of chronic psychiatric disorders, including depression, anxiety, or other mood and mental disorders, as well as no musculoskeletal diseases. sibling: age: 7–12 years sibling: No diagnosis of Autism Spectrum Disorder or other neurodevelopmental disorders sibling: Absence of behavioral disorders such as aggression and psychotic disorders, and no definite psychiatric diagnosis based on DSM-5 sibling: Based on parental report or the therapist's initial observation, the sibling should be able to follow simple instructions and maintain play interactions for at least 15 minutes. The sibling should also have sufficient physical and sensory-motor abilities to participate in floor-based play activities (without motor limitations, visual impairments, hearing problems, etc.).

Exclusion criteria:

Attendance in at least 75% of the intervention sessions (18 out of 24 sessions); a maximum absence of 6 sessions is acceptable without withdrawal from the study. Initiation of a new treatment during the study.

Age

From **3 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using a Randomized Block Design to ensure that the groups are balanced in terms of the key variable (gender). It should be noted that the key background variables in this study are age, symptom severity, and gender. To control for the effect of age, only children with Autism Spectrum Disorder aged 3 to 5 years will be included in the study, while children aged 5 to 8 years will be excluded. To control for the effect of symptom severity, children with mild to moderate symptoms will be included, whereas children with severe symptoms will be excluded. To control for the effect of gender, blocking will be performed based on the child's gender (boy or girl). A random number generation software program (such as R or SPSS) will be used to allocate participants to either the intervention or control group. The randomization process will be conducted by an independent statistician who is not involved in the intervention or assessment procedures. Random Allocation: In this study, participants will first be selected through convenience sampling based on the inclusion criteria. After the initial assessments, they will be randomly assigned, using a Randomized Block Design, to either the intervention group or the control group (receiving routine occupational therapy interventions). The sealed envelope method will be used to conceal random allocation. Randomization will be carried out by an individual other than the therapist and assessor. Participants in both groups will be reassessed after completion of the interventions (at the end of the third month).

Blinding (investigator's opinion)

Single blinded

Blinding description

This study uses a single-blind design, meaning that outcome assessors will be unaware of participants' group allocation. To maintain blinding: * Independent assessors who are not involved in the intervention process will collect outcome data. * Parents and therapists are aware of the assigned group (due to the nature of the intervention, double blinding is not possible for them) but are prohibited from discussing group allocation with the assessors. * Raw data will be analyzed by an independent analyst who is blinded to group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Department of Occupational Therapy, Faculty of Rehabilitation Sciences, University of Tabriz, beside Vahdat Hall, 29 Bahman Boulevard

City
Tabriz

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East Azarbaijan

Postal code
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Approval date
2026-05-19, 1405/02/29

Ethics committee reference number
IR.TBZMED.REC.1405.109

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Parents' quality of life as measured by the WHOQOL-BREF questionnaire

Timepoint
Before the intervention (T0), and after completion of the interventions at the end of the third month (T1)

Method of measurement
WHO-QOL-BREF questionnaire

2

Description
Quality of sibling interactions

Timepoint
Before the intervention (T0), and after completion of the interventions at the end of the third month (T1)

Method of measurement
Sibling Relationship Questionnaire

Secondary outcomes

1

Description
Autism symptoms in the child

Timepoint
Before the intervention (T0)

Method of measurement
Gilliam Autism Rating Scale, third Edition

2

Description
Social Responsiveness Scale

Timepoint
Before the intervention (T0),and after completion of the interventions at the end of the third month (T1)

Method of measurement
Social Responsiveness Scale, Second Edition

Intervention groups

1

Description
Intervention group: 1) Conventional Occupational Therapy:This intervention will be provided to both groups with the same number and duration of sessions. Assessments will be conducted at two time points: before the intervention and immediately after completion of the intervention at the end of the third month. 2) DIR/Floortime: Parents will receive training in the Floortime-based intervention approach. This intervention includes teaching play-based interaction techniques, strengthening emotional connection, and responding to the child's developmental needs. The training program will include the following components: Individual practical sessions: Twenty-four 60-minute sessions, conducted three times per week, with the participation of the parents, child, and therapist to practice techniques in a real-life environment. Home practice: Floortime activities at home will be designed to facilitate the generalization of skills to the natural context and environment of daily life. According to general Floortime recommendations, the home practice dosage may increase to higher levels, up to several hours per day. However, in the present study, in order to enhance feasibility and treatment adherence under real family conditions, a minimum acceptable dose and a target dose will be defined. The minimum dose will consist of at least two daily sessions of 15–20 minutes each, while the target dose will consist of four daily sessions of 15–20 minutes each. In addition, parents may provide more practice time if feasible according to family capacity. The actual implementation time, including the number of sessions and total minutes per day, will be recorded daily, and treatment adherence will be reported as a procedural variable.

Category
Rehabilitation

2

Description
Control group: These interventions combine bottom-up and top-down features to improve the child's social skills. Bottom-up refers to sensory-motor strategies that are used in occupational therapy clinics. Top-down refers to features of behavioral and occupational analysis. This group does not receive any specific floortime training, but the number of hours of service received is recorded so that it can be compared with the intervention group. This treatment is provided to both groups with the same number of sessions. Assessments are conducted at two time points before the intervention and at the end of the third month after the intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Autism Center, Tabriz University of Medical Sciences

Full name of responsible person
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2

Recruitment center

Name of recruitment center
Talash Rehabilitation Clinic

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Babak Kashefi Mehr

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Participants' data will be presented as non-identifiable demographic data.

When the data will become available and for how long
The access period will begin 6 months after publication of the results and will continue for 1 year.

To whom data/document is available
Researchers and scientific institutions may access the data upon request from the author.

Under which criteria data/document could be used
For research purposes and with the approval of the corresponding author of the article.

From where data/document is obtainable
Corresponding author

What processes are involved for a request to access data/document
1. Identification of the institution or researcher 2. Approval of the corresponding author

Comments