Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Group-based Music Therapy with Group-based Social Skills Training on Sensory Processing and Social Skills of Children with Autism Spectrum Disorder

Protocol summary

Study aim

To evaluate the effectiveness of a structured group-based music therapy program in improving sensory processing patterns and social skills in children aged 6–12 years with Autism Spectrum Disorder, compared to group-based social skills training without music.

Design

Two-arm, parallel-group, randomized trial of 20 participants with open-label intervention and blinded data analysis, single-center.

Settings and conduct

The trial will take place at the Occupational Therapy Department of Imam Hossein Hospital in Tehran, Iran. Children will be recruited from outpatient clinics. It is an open-label trial for participants and therapists, but outcome assessment will be blinded, with an independent analyst conducting all analyses without knowing group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Children aged 6–12 years - Clinical diagnosis of ASD based on DSM-5 by a qualified child and adolescent psychiatrist - Stable physical health - Basic communication abilities for group participation - Informed consent from parent/legal guardian Exclusion criteria: - Uncontrolled neurological disorders (e.g., epilepsy) - Significant hearing or vision impairment - Severe behavioral problems preventing group participation - Participation in intensive music therapy in the past 6 months - Family unwillingness to attend scheduled sessions

Intervention groups

Group-based music therapy program, 14 sessions (30–45 minutes each), including structured welcome and closing songs, rhythmic exercises, instrument playing, singing, and movement-based activities designed to stimulate sensory processing and promote social interaction.

Main outcome variables

Sensory processing profile score — measured with the Children's Sensory Profile-2 Social responsiveness score — measured with the Social Responsiveness Scale-2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250325065158N1**
Registration date: **2025-10-08, 1404/07/16**
Registration timing: **prospective**

Last update: **2025-10-08, 1404/07/16**
Update count: **0**

Registration date

2025-10-08, 1404/07/16

Registrant information

Name

Benyamin Hamid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Group-based Music Therapy with Group-based Social Skills Training on Sensory Processing and Social Skills of Children with Autism Spectrum Disorder

Public title
Effects of Group-Based Music Therapy on Sensory Processing and Social Skills of Children with Autism Spectrum Disorder
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 6-12 years Clinical diagnosis of Autism Spectrum Disorder based on DSM-5 by a registered child and adolescent psychiatrist Stable physical health Basic communication abilities for group participation Informed consent from parent/legal guardian
Exclusion criteria:
Uncontrolled neurological disorders (e.g., epilepsy) Significant hearing or vision impairment Severe behavioral problems preventing group participation Participation in intensive music therapy in the past 6 months
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to either the intervention or control group in a 1:1 allocation ratio using block randomization. A total of five blocks, each containing four participants, will be used to ensure balanced group sizes throughout enrollment. Within each block, two participants will be allocated to the intervention group and two to the control group, with the order of assignments randomized using a computer-generated random number list in Excel. The randomization sequence will be prepared prior to enrollment by an independent researcher not involved in recruitment, assessment, or intervention delivery. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes (SNOSE), which will be opened only after confirming participant eligibility and completing baseline assessments.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the use of parent-reported outcome measures, blinding of participants and assessors is not feasible; however, data entry and statistical analysis will be conducted by personnel blinded to group allocation. Questionnaire scores will be entered into the dataset by researchers who are unaware of group allocation. Groups will be coded as “Group A” and “Group B” during analysis to ensure blinding of the data analyst.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences HQ., Erabi St., Daneshjoo Blvd., Velenjak
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Approval date
2025-09-14, 1404/06/23
Ethics committee reference number
IR.SBMU.RETECH.REC.1404.420

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
Sensory processing patterns
Timepoint
Before intervention, immediately and 2 weeks after intervention

Method of measurement
Children's Sensory Profile - 2

2

Description
Social Skills
Timepoint
Before intervention, immediately and 2 weeks after intervention
Method of measurement
Social Responsiveness Scale - 2

Secondary outcomes

1

Description
Symptoms of Autism Spectrum Disorder
Timepoint
Before intervention, immediately, and 2 weeks after intervention
Method of measurement
Gilliam Autism Rating Scale - 3

Intervention groups

1

Description
Intervention group: This group-based intervention will be delivered by a qualified music therapist over 14 sessions, each lasting 30–45 minutes, twice per week, in a therapy room equipped with simple musical instruments (e.g., drums, tambourine, xylophone, bells, small percussion). The overall approach combines improvisational music therapy with structured activities, focusing on improving social interaction, joint attention, communication skills, and sensory regulation. Each session will begin with a fixed “hello” song and end with a fixed “goodbye” song to provide structure and predictability for the children. Session 1: Introduction and rapport-building — instrument introduction, hello song with child’s name, free exploration of instruments, goodbye song. Session 2: Musical turn-taking — “passing the beat” in a circle, imitating rhythms, turn-taking with different instruments.Session 3: Call-and-response singing — therapist sings short phrases for the child to repeat, incorporating names and emotions. Session 4: Rhythmic synchrony — group drumming to a steady beat, gradually increasing rhythmic complexity. Session 5: Musical storytelling — creating a simple story with sound effects (e.g., rainstick for rain, drum for thunder).Session 6: Emotions in music — playing musical excerpts with different moods (happy, sad, angry) and discussing feelings. Session 7: Instrument choice and leadership — each child chooses an instrument and leads a short group improvisation. Session 8: Sensory regulation through music — alternating stimulating (fast, loud) and calming (slow, soft) music to teach self-regulation. Session 9: Duet improvisations — therapist pairs with each child for short improvisations focusing on matching and responding. Session 10: Group composition — creating a short song together on a theme such as friendship or the group experience. Session 11: Performance preparation — rehearsing favorite songs/activities for a final sharing session. Sessions 12–14: Group sharing and closure — short performance for parents or peers, feedback, and formal goodbye.
Category
Rehabilitation

2

Description
Control group: Participants in the control group will receive a structured social skills training program, delivered in 14 group sessions of 30–45 minutes each, held twice per week over seven weeks. Sessions will be conducted by a certified occupational therapist in a quiet therapy room with minimal sensory distractions. Each session will follow a consistent format of greeting, targeted activities, and closing summary. Session 1 will focus on introductions, rapport building, and establishing group rules. Session 2 will address greeting skills through role-play and eye contact practice. Session 3 will target turn-taking using games and “talking stick” activities. Session 4 will develop active listening through “repeat back” tasks and short story comprehension. Session 5 will encourage sharing via cooperative play and group art projects. Session 6 will teach expressing feelings using emotion cards and charades, while Session 7 will focus on understanding others’ emotions through perspective-taking and facial expression matching. Session 8 will practice asking for help in various scenarios, and Session 9 will promote giving compliments through structured peer feedback. Session 10 will teach joining group activities politely, and Session 11 will address problem solving using social scenarios and brainstorming. Session 12 will reinforce following group plans through a cooperative project with assigned roles. Session 13 will review and practice all skills through rotating activity stations, and Session 14 will provide closure with group reflection, feedback, and a certificate ceremony. Activities will include role-plays, cooperative games, storytelling, and group projects, supported by visual aids and scenario cards.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
UN agencies and international organizations
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable