Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of sensory integration approach on stereotyped behaviors of children with autism spectrum disorder

Protocol summary

Study aim
Determining the effectiveness of the sensory integration approach in reducing stereotypical behaviors in children with autism spectrum disorder

Design
A concealed, randomized, double-blind, parallel group clinical trial with 60 participants randomly assigned into two equal groups. Randomization was performed using the Rand function in Microsoft Excel.

Settings and conduct
The study is conducted at special education centers for children with autism spectrum disorder in Ahvaz. The intervention includes 11 face-to-face sensory integration sessions delivered by an occupational therapist. Effectiveness is evaluated using questionnaire results completed by the teacher, and participants are followed throughout the study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Diagnosis of autism spectrum disorder with mild to moderate severity; age between 4 to 10 years; enrollment in special education centers for children with autism spectrum disorder in Ahvaz city; willingness and consent of parents to participate in the study; regular use of Risperidone and Ritalin medications as reported by parents. Exclusion Criteria: Concurrent diagnosis of severe psychiatric disorders such as psychosis, severe bipolar disorder, personality disorder, or uncontrolled epilepsy; diagnosis of blindness or deafness.

Intervention groups
In the intervention group, children receive a sensory integration therapy program consisting of targeted sensory-motor activities aimed at improving sensory processing and reducing stereotypical behaviors. The control group receives standard care without any specific intervention. Both groups are followed concurrently throughout the study.

Main outcome variables
Change in the severity of stereotypical behaviors in children with autism spectrum disorder, based on the results of the Garth questionnaire.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250720066558N1**
Registration date: **2025-08-15, 1404/05/24**
Registration timing: **prospective**

Last update: **2025-08-15, 1404/05/24**
Update count: **0**

Registration date
2025-08-15, 1404/05/24

Registrant information

Name
Marzie Zakernejad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3550 7191
Email address
komeili_h@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-16, 1404/08/25

Expected recruitment end date
2026-02-04, 1404/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of sensory integration approach on stereotyped behaviors of children with autism spectrum disorder

Public title
Investigating the Effect of Sensorimotor Exercises on Repetitive Behaviors in Children with Autism

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of autism spectrum disorder with mild to moderate severity Enrollment in exceptional education centers for children with autism spectrum disorder in Ahvaz Willingness and consent of the parents of these individuals to participate in the study Regular use of Risperidone and Ritalin medications according to parents' report

Exclusion criteria:
Concurrent diagnosis of severe psychiatric disorders such as psychosis, severe bipolar disorder, personality disorder, or uncontrolled epilepsy Diagnosis of blindness or deafness

Age
From **4 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate 60 participants into two groups of 30 each, a randomization method using blocks of 4 was employed. In this method, each block consisted of 4 individuals, evenly divided between the two groups (two participants in the intervention group and two in the control group). First, all possible combinations of this type of allocation (such as AABB, ABAB, ABBA, etc.) were entered into Excel software. Then, 15 blocks were randomly selected from these combinations so that a total of 60 participants were evenly and randomly assigned to the two groups. To generate random combinations, the Rand Between and Index functions in Excel were used, determining each individual's placement in the intervention or control group. Finally, the results were manually saved to ensure no changes occurred in the allocation after determination.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Jundishapur University of Medical Sciences

Street address
No. 17, Nazem Street, Shariati Street End, Jomhouri Alley

City
اهواز

Province
Khouzestan

Postal code
6197870008

Approval date
2025-07-15, 1404/04/24

Ethics committee reference number
IR.AJUMS.REC.1404.197

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
Change in the severity of stereotyped behaviors in children with autism spectrum disorder based on the GARS questionnaire score

Timepoint
Before and after the intervention (after 11 sessions of the sensory integration approach)

Method of measurement
Gilliam Autism Rating Scale (GARS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention is conducted over 11 consecutive weeks, with 11 sessions using tools such as a soft brush, massager, and ball pool, each session lasting 45 minutes. Sessions are held twice a week by the occupational therapist of the education center under the supervision of the principal investigator. After 11 sessions, the severity of stereotyped behaviors in both groups is reassessed using the GARS tool. The effectiveness of this intervention is evaluated by analyzing the final questionnaire results.

Category
Rehabilitation

2

Description
Control group: The control group participants will not receive any sensory integration intervention during the study period and will only receive the usual educational and rehabilitation services and programs of the center. After the completion of the study, if they wish, the sensory integration intervention will also be provided to this group.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Behesht School

Full name of responsible person
Marzie Zakernejad

Street address
No. 56, Hefari Boulevard, 8 Fath Street, National Drilling Town, Ahvaz.

City
ahvaz

Province
Khouzestan

Postal code

Phone
+98 61 3441 5030

Email
Khouz.pr@chmail.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Hossein Komeili Sani

Street address
Jundishapur University of Medical Sciences, Golestan St., Ahvaz, Iran

City
ahvaz

Province
Khouzestan

Postal code
6135733835

Phone
+98 61 3311 0000

Email
eduaum@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Marzie Zakernejad

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 17, Nazem Street, Shariati Neighborhood, by the river

City
Ahvaz

Province
Khouzestan

Postal code
6197870008

Phone
+98 61 3550 7191

Fax

Email
marzie.zakernejad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Marzie Zakernejad
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 17, Nazem Street, Shariati Neighborhood, by the river
City
Ahvaz
Province
Khouzestan
Postal code
6197870008
Phone
+98 61 3550 7191
Fax
Email
marzie.zakernejad@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Marzie Zakernejad
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 17, Nazem Street, Shariati Neighborhood, by the river
City
Ahvaz
Province
Khouzestan
Postal code
6197870008
Phone
+98 61 3550 7191
Fax
Email
marzie.zakernejad@gmail.com

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
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
De-identified individual participant data, including results for the primary outcome measure (GARS questionnaire scores), will be available upon reasonable request from qualified researchers after completion of data analysis. Other raw data will be shared only in aggregate form without any possibility of identifying participants.
When the data will become available and for how long
Access to de-identified individual participant data will be available starting 6 months after publication of the study results and will remain open for 3 years. Access will be granted only to qualified researchers upon submission of a reasonable request and approval by the principal investigator
To whom data/document is available
Data and study documents will be available only to qualified researchers affiliated with accredited academic institutions or recognized research centers, upon submission of a written request and approval by the principal investigator
Under which criteria data/document could be used
Access to anonymized data and study documents will be granted only to researchers affiliated with academic and scientific institutions. Requestors must submit a formal application describing the intended analyses. Use of the data and documents is limited to approved research purposes, and any further sharing or publication requires prior permission from the study's principal investigator. Compliance with ethical guidelines and confidentiality agreements is mandatory
From where data/document is obtainable
Applicants requesting study documents or data can submit their written requests via email to the principal investigator. If postal correspondence is required, they may contact the following postal address at Jundishapur University of Medical Sciences, Ahvaz. Contact details are as follows: Contact Person: Dr. Hossein Kemili Sani Email: hossein.kemili@ajums.ac.ir Postal Address: Golestan Street, Jundishapur University of Medical Sciences, Ahvaz, Postal Code 61357-14551, Iran Phone Number: +98 61 3333 1234 Fax Number: +98 61 3333 5678 Priority for receiving requests is via email, and if official documents or formal correspondence are needed, they will be handled through the postal address.
What processes are involved for a request to access data/document
Applicants must submit a written request via email or postal mail to the study coordinator. Upon receipt, the request will undergo an initial review by the research team to ensure completeness and validity. Then, the request will be forwarded to the ethics committee and relevant authorities for approval. This process typically takes 2 to 4 weeks. Once approved, de-identified

documents or data files will be sent to the applicant electronically. If printed copies or official documents are required, additional time will be needed depending on the delivery method

Comments