Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative Effectiveness of Family-Oriented Interventions vs. Subtain Academy Center Services on Enhancing Non-Verbal Skills in Children with ASD Aged 3-5 Years

Protocol summary

Study aim

This study aims to compare the effectiveness of two intervention methods—family-oriented intervention and services at the Subtain Academy Center —in enhancing the non-verbal skills of children aged 3-5 with ASD.

Design

A randomized, single-blind, parallel-group controlled clinical trial on 60 patients

Settings and conduct

Families with non-verbal autistic children aged 3-5 years who visit Al-Sibtain Educational Center during the study period will be screened for eligibility. Qualified participants will be enrolled in the study and randomly assigned to either intervention or control groups using block randomization. The study will follow a single-blind design where assessors of non-verbal skills and data analysts will remain blinded to the intervention type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Families with a child between 3 and 5 years old who has received a clinical diagnosis of autism; the child exhibits impaired nonverbal communication skills; The child has no other documented medical or psychological conditions according to their medical records; The child has toilet problems based on parent report. Exclusion criteria: The child has a high level of verbal skills; Child's primary language is not Arabic; Lack of Parental Adherence to the Study Protocol.

Intervention groups

The intervention group will receive a 47-session program over three months, integrating three core components: Pre-Linguistic Milieu Teaching, Video Self-Modeling, and a structured toilet-training protocol. The control group will receive 94 therapy sessions based on the Assessment of Basic Language and Learning Skills-Revised (ABLLS-R) curriculum, targeting language, social, and play skills.

Main outcome variables

pointing; vocal communication; eye gaze; functional play; and using the toilet independently

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180716040486N2**
Registration date: **2025-10-04, 1404/07/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-04, 1404/07/12**
Update count: **0**

Registration date

2025-10-04, 1404/07/12

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-17, 1404/06/26

Expected recruitment end date

2025-10-22, 1404/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative Effectiveness of Family-Oriented Interventions vs. Subtain Academy Center Services on Enhancing Non-Verbal Skills in Children with ASD Aged 3-5 Years

Public title
Enhancing Non-Verbal Skills in Children with ASD

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Families with a child who had received a clinical autism diagnosis from a child psychiatrist. The child's age is between 3 and 5 years. The family resides within a 30-kilometer radius of the Al-Sibtain Academy in Iraq The child exhibits impaired nonverbal communication skills, as determined by assessments conducted by an experienced speech and language pathologist. The child does not exhibit irritability. The child has no other documented medical or psychological conditions according to their medical records. The child has toilet problems based on parent report. The child exhibits communication difficulties and is in the pre-linguistic stage, as assessed using the Communication Matrix.

Exclusion criteria:
Lack of Commitment to Study Protocol: The family demonstrates an unwillingness or inability to commit to the time demands of the study, including attending training sessions, completing daily record forms, and participating in all assessment points (pre, post, and follow-up). Primary Language Other than Arabic: The child's primary household language is not Arabic. Having high Level of Existing Verbal Skills: The child demonstrates fluent verbal communication (e.g., uses phrase or sentence spontaneously for communication).

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

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To ensure balanced group sizes and comparability across key prognostic factors, participants will be allocated to the study groups using a stratified block randomization method. An independent statistician, uninvolved in recruitment or intervention, will generate the allocation sequences. The randomization will be stratified by age and baseline non-verbal ability to ensure balance within these subgroups. For each resulting stratification cell, a computer-generated sequence will be created using a block size of 6, ensuring that within every block of 6 participants, 3 will be assigned to the intervention group and 3 to the control group. To guarantee strict allocation concealment, these sequences will be implemented and stored within a central, web-based randomization module (Medidata.com). Upon enrollment of an eligible participant, the site coordinator, blinded to the sequence, will enter the participant's stratification details into the system, which will then automatically reveal the ensuing group assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will employ a single-blind (assessor-blind) design to minimize detection bias. Outcome assessors, responsible for coding video-based primary outcomes, and the data analyst will remain fully blinded to group allocation. To ensure the integrity of the blinding protocol, assessors will be trained specifically for this role and will have no contact with participants or other study staff. All video recordings of assessments will be edited by an independent research assistant to remove any auditory or visual cues (e.g., mentions of intervention-specific strategies, identifiable backgrounds) that could reveal group assignment. The assessors will analyze these blinded videos using a standardized coding protocol that is focused solely on observable behaviors. Furthermore, to test the integrity of the blinding procedure, assessors will be asked to guess the allocation of a random subset of participants upon study completion; a success rate approximating 50% will indicate effective blinding. In the event of accidental unblinding, the affected assessments will be re-allocated to another blinded coder. While participants and interventionists cannot be blinded due to the nature of the interventions, parents will be kept unaware of the study’s specific hypotheses to mitigate potential performance bias.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of School of Nursing and Midwifery & Rehabilitation, TUMS

Street address
Faculty of Nursing and Midwifery, Dr. Mirkhani Street (East Nusrat), Tohid Square.

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1419733171

Approval date

2025-06-11, 1404/03/21

Ethics committee reference number

IR.TUMS.FNM.REC.1404.071

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder (ASD)

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

pointing

Timepoint

before intervention, immediately after intervention, and conducted 3 months after the intervention period as a follow-up

Method of measurement

The Communication Frequency Measurement Scale

2

Description

vocal communication

Timepoint

before intervention, immediately after intervention, and conducted 3 months after the intervention period as a follow-up

Method of measurement

The Communication Frequency Measurement Scale

3

Description

eye gaze

Timepoint

before intervention, immediately after intervention, and conducted 3 months after the intervention period as a follow-up

Method of measurement

The Communication Frequency Measurement Scale

4

Description

functional play

Timepoint

before intervention, immediately after intervention, and conducted 3 months after the intervention period as a follow-up

Method of measurement

Functional play scoring scale

5

Description

using the toilet independently

Timepoint

before intervention, immediately after intervention, and conducted 3 months after the intervention period as a follow-up

Method of measurement

percentage of correct urinations in the toilet record form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Parents in the intervention group will receive an intensive and structured training program consisting of 47 instructional sessions, each lasting approximately 60 to 75 minutes. This program will be implemented over a 3-month period (12 weeks) with a frequency of 3-4 sessions per week, conducted in the child's natural home environment either in person or via telepractice under the supervision of the researcher. The content of these sessions encompasses a hybrid protocol that teaches three core components: 1) Pre-Linguistic Milieu Teaching (PMT), aimed at enhancing non-verbal communication (such as the use of gestures, eye contact, and non-verbal vocalizations) through practical strategies including child preference assessment, environmental arrangement to create communicative opportunities, following the child's lead, descriptive talking, linguistic mapping, imitation, and establishing turn-taking routines—with parents required to achieve at least 95% mastery for each strategy; 2) Video Self-Modeling (VSM) for teaching functional play and correct use of 10 everyday objects (e.g., cup, spoon, telephone, toothbrush) by filming the child’s correct performance, editing the videos using computer software, and showing them to the child for learning purposes; and 3) a structured toilet-training protocol based on Applied Behavior Analysis (ABA) principles, which includes phases such as baseline assessment, diaper removal, offering fluids, scheduling bathroom visits (e.g., every 30 minutes), task analysis of bathroom steps, and systematic use of positive reinforcement (rewards) for successful voiding alongside neutral responses to accidents.

Category

Rehabilitation

2

Description

Control group: Parents in the control group will receive an alternative active intervention consisting of 94 sessions of the Assessment of Basic Learning Abilities-Revised (ABLA-R) program. This intervention will be administered at the Sebtain Academy Center with an intensity matching that of the intervention group, in order to control for non-specific factors including therapist contact, parental attention, and total intervention time. This structured, standardized program—implemented over an identical 3-month (12-week) period but at a higher frequency of approximately 8 sessions per week, with each session lasting 20–30 minutes—targets a comprehensive range of developmental domains through discrete trial teaching (DTT) methodology. The ABLA-R protocol includes systematically administered activities focusing on receptive language (e.g., responding to instructions, identifying objects and body parts), imitation (motor, vocal, and object-based actions), visual performance (puzzles, matching, sorting, patterns), expressive language (labeling, requesting, combining words), social interaction (greetings, turn-taking, sharing, eye contact), self-help skills (handwashing, using utensils, dressing, tooth-brushing), academic skills (color/shape identification, counting, tracing), and play/leisure (stacking, pretend play, exploring toys), with additional sessions dedicated to skill generalization across settings and people. Parents are trained to serve as the primary implementers, learning to deliver clear instructions, use prompting hierarchies, provide immediate reinforcement, and accurately record responses.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Subtain Academy for Autism and Neurodevelopmental Disorders

Full name of responsible person
Zahra Soleymani

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Faculty of Rehabilitation Sciences, Piche Shemiran, at the corner of Safi Alishah Street, Enghelab Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Zahra Soleymani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Speech therapy

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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

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not 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

Only part of the data, such as information related to the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Researchers who submit the requested form (via email) including the following: purpose of analysis, required assessments, ethical review (if applicable), and data security plan. Data requests will be approved only for: secondary analyzes (e.g., meta-analyses, subgroup analyzes by age/severity), methodological research (e.g., validation of assessment tools), and teaching/demonstration (with proof of academic affiliation).

From where data/document is obtainable

Primary Contact for Data Requests: Name: Zahra Soleymani Email: Soleymanislp@gmail.com Phone: 00982177533939 Mailing Address: Department of Speech therapy, School of Rehabilitation, corner of Safi Alishah St., Shemiran Intersection, Enghelab St., Tehran., Iran., Postal Code: 1148965111

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

To request data/documents, applicants should submit a formal request via email (Soleymanislp@gmail.com) including a completed Data Request Form, ethics approval (if applicable), and a research proposal. we will review the requests in 4–6 weeks, assessing scientific merit, feasibility, and privacy risks. If approved, applicants sign a Data Use Agreement (DUA) (1–2 weeks), after which data is shared via secure cloud links or encrypted email (1–7 days). The entire process typically takes 6–12 weeks, with post-access requirements like citations and progress reports.

Comments