# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 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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Hossein Rezai
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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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**Postal code**

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

**Street address**
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**
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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 scientific inquiries

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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**