Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Designing an Evaluation and Intervention Protocol to Improve the Skills of Initiating and Maintaining the Topic of Conversation based on the Combination of Script Therapy and Normal Peer- Mediated Intervention Methods and Investigating its Effectiveness in Children with Autism Spectrum Disorder Level 1

Protocol summary

Study aim
The objective of this study is to develop an assessment and intervention program to enhance topic initiation and maintenance skills by integrating Script Therapy and Peer-Mediated Intervention, and to evaluate its effectiveness in children with Level One Autism Spectrum Disorder using a single-subject research design.

Design
This is a Phase 2, open-label, non-randomized clinical trial using a single-subject design with 5 participants. Each participant serves as their own control, with individual comparisons performed between the baseline and intervention phases.

Settings and conduct
This study will be conducted in a controlled environment at the Clinic of the Faculty of Rehabilitation, University of Iran (Tehran), utilizing a single-subject design. Following repeated baseline assessments of conversational initiation and maintenance skills to establish a stable trend, a combined Script Therapy and Peer-Mediated Intervention will be implemented. Progress will be evaluated using identical tools across both phases to compare each participant's improvement relative to their own baseline.

Participants/Inclusion and exclusion criteria
ASD Participants: ASD Level 1 diagnosis, age 8-15, literate; MLU between 2-5 words and vocabulary > 50 words; social initiation and maintenance deficits (per parent/teacher reports); informed consent. Typically Developing Peers: Age 8-15, same gender, no previous acquaintance, typical language skills; informed consent

Intervention groups
Participants in this group receive a combined program to enhance their conversational topic initiation and maintenance skills, utilizing a single-subject research design. This intervention includes the instruction of written scripts and interactive exercises with peers in controlled environments.

Main outcome variables
Initiation and topic maintenance of conversation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250723066608N1**
Registration date: **2026-06-26, 1405/04/05**
Registration timing: **prospective**

Last update: **2026-06-26, 1405/04/05**
Update count: **0**

Registration date
2026-06-26, 1405/04/05

Registrant information

Name
Roya Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 939 084 6059

Email address
royamohammadi895@yahoo.com

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2027-05-20, 1406/02/30
Expected recruitment end date
2027-11-20, 1406/08/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing an Evaluation and Intervention Protocol to Improve the Skills of Initiating and Maintaining the Topic of Conversation based on the Combination of Script Therapy and Normal Peer- Mediated Intervention Methods and Investigating its Effectiveness in Children with Autism Spectrum Disorder Level 1

Public title
Intervention to Improve the Skills of Initiating and Maintaining the Topic of Conversation based on the Combination of Script Therapy and Normal Peer-Mediated Intervention Methods and Investigating its Effectiveness in Children with Autism Spectrum Disorder Level 1
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Participant with autism spectrum disorder: - According to the Gilliam Autism Severity Rating Scale, third edition (GARS-3), have a level 1 autism spectrum disorder - Based on the demographic information questionnaire and date of birth, be between the ages of 8 and 15 - Has reached the level of academic skills and, according to the parent and teacher report, is literate and can read script. - In terms of language skills, be at least at the advanced level of language, in other words, have a vocabulary of more than 50 words and an average length of utterance in words (MLUw) between 2 and 5 - Has difficulty in initiating and maintaining social interaction skills, as reported by parents and teachers - The participant and his / her family must consent to participate in the research Peer participants: - Based on the demographic information questionnaire and date of birth, be between the ages of 8 and 15 - Be of the same sex as the participant with autism spectrum disorder (this will be determined in the third phase of the study, according to the selected participants. In fact, male participants will be matched with a male partner and female participants with a female partner) - Has no prior knowledge of the participant with autism spectrum disorder - Be interested in interacting with participants with autism spectrum disorder - The participant and his / her family must consent to participate in the research. - Be natural in the speech and language skills. - Have reached the level of academic skills and are literate and able to follow the instructions and training necessary to implement interventions.
Exclusion criteria:
Participant with autism spectrum disorder: Presence of attention deficit hyperactivity disorder (ADHD) diagnosed by a psychiatrist Peer participant: Diagnosis of other neurodevelopmental disorders such as ADHD diagnosed by a psychiatrist
Age
From **8 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **5**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences(IUMS)
Street address
Tehran - Intersection of Tous and Yadegar Imam Streets - Faghani Brothers Alley - Corner of Memarian Alley - Number 24 - Unit 3 - Fourth Bell 24
City
Tehran
Province
Tehran
Postal code
1343916118
Approval date
2025-05-25, 1404/03/04
Ethics committee reference number
IR.IUMS.REC.1404.281

Health conditions studied

1

Description of health condition studied
Level 1 autism spectrum disorder
ICD-10 code
F84.0
ICD-10 code description

Autistic disorder

Primary outcomes

1

Description
score of topic Initiation of conversation
Timepoint
Before the start of the intervention - every month during the intervention - 4 and 8 weeks after the intervention
Method of measurement
Conversational skills assessment checklist

2

Description
score of Maintaining the Topic of Conversation
Timepoint
Before the start of the intervention - every month during the intervention - 4 and 8 weeks after the intervention
Method of measurement
Conversational skills assessment checklist

Secondary outcomes

1

Description
Generalizing the topic initiation to non-instructional stimuli, new environments, and new people
Timepoint
after intervention
Method of measurement
Checklist for assessing the topic initiation and Topic Maintenance of conversation

2

Description
Generalizing the topicMaintenance to non-instructional stimuli, new environments, and new people
Timepoint
after intervention
Method of measurement
Checklist for assessing the topic initiation and Topic Maintenance of conversation

Intervention groups

1

Description
Intervention group: This study is conducted as a single subject design and there is no control group, in fact, each participant's performance is compared with himself. In the baseline phase, no intervention is carried out. In this phase, the participants' conversation initiation and maintenance skills are assessed three times to obtain a stable trend of their current performance and to serve as a basis for comparison for the intervention phase. In the intervention phase, participants undergo a combined prescription therapy and peer-mediated intervention. In the prescription therapy phase, written texts are used for training. In the peer-mediated intervention phase, normative peers act as models and facilitators in social interactions. This program consists of a three-month intervention that is implemented 3 times a week, each session lasting 45 minutes, in a controlled clinic environment.Assessment is performed using the assessment checklist developed in the first phase of this thesis at baseline, intervention, and treatment, and generalization of skills to new stimuli, new environments, and new people is also assessed after the intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Rehabilitation, Iran University of Medical Sciences
Full name of responsible person
Roya Mohammadi
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Mirdamad - Shah Nazari Street - Madagkaran Alley - Rehabilitation Faculty - Speech Therapy Clinic of the Rehabilitation Faculty
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Roya Mohammadi

Position

PhD candidate in speech therapy

Latest degree

Master

Other areas of specialty/work

Speech therapy

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Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the small sample size of the study (Single-Subject Design with 5 participants), publishing individual participant data would pose a significant risk of deductive disclosure and compromise the participants' anonymity. Therefore, IPD will not be made publicly 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

Study Protocol: Details (English): A comprehensive document detailing the study objectives, participant inclusion/exclusion criteria, a detailed description of the interventions, and the implementation steps of the single-subject design. Statistical Analysis Plan: A detailed plan of the data analysis methods, including visual analysis, trend analysis, level change assessment, and the specific criteria used for interpreting results in single-subject designs. Informed Consent Form: A blank template of the informed consent form, outlining participants' rights, description of the intervention, the voluntary nature of participation, and confidentiality measures. Clinical Study Report: A comprehensive report detailing the findings, performed analyses, and final conclusions based on the study objectives. Analysis Codes: The software scripts and commands used for data processing and generating the participants' progress graphs. Data Dictionary: A complete list of study variables, their definitions, measurement units, and the coding scheme

When the data will become available and for how long

Study design documents (including the statistical analysis plan, and blank informed consent form) will be available from the date of registration. Other result-related documents (including the clinical study report, analysis codes, and data dictionary) will be made available within 12 months following the study completion and the publication of final results in the thesis or related articles."

To whom data/document is available

researchers, academic faculty members, students in related fields, and scientific journal reviewers who intend to evaluate the methodology or replicate the study results for academic and educational purposes.

Under which criteria data/document could be used

Due to the small sample size of this study (single-subject design) and to ensure total participant confidentiality, de-identified individual participant data (IPD) will not be shared. However, for other documents (Protocol, statistical analysis plan, and analysis codes), the request conditions are as follows: 1. Request Mechanism: The requester must send a formal email to the principal investigator describing the specific purpose of the request. 2. Conditions of Use: The use of these documents is permitted solely for methodological analysis, verification of results, and comparison with other single-subject studies. 3. Permissible Analyses: Any statistical or visual analysis aimed at assessing research quality or replicating results is allowed. 4. Restrictions: Any commercial use or redistribution of the documents without written permission from the author is strictly prohibited

From where data/document is obtainable

Email: Send a formal request to the following email address: `royamohammadi895@yahoo.com` (Please mention "Document Request for Study" in the email subject). Corresponding Person's Details: Roya Mohammadi - PhD Candidate in Speech and Language Therapy at Iran University of Medical Sciences

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

The process for requesting and receiving documents is as follows: 1. Submission of Request: The requester must send a formal email to `royamohammadi895@yahoo.com`. This email should include the purpose of the request, the requester's name and academic affiliation, and a specific list of the requested files (e.g., protocol or analysis codes). 2. Review Process: The investigator (corresponding author) will review the request within 7 to 10 business days to ensure it aligns with scientific and non-commercial objectives. 3. Response and Delivery: Upon approval, the investigator will notify the requester via email and provide the requested documents as attachments. If the request is denied, the reason will be communicated to the requester. 4. Confirmation: The requester will confirm the receipt of the documents via a follow-up email. Estimated Timeline: On average, the entire process from the initial request to the final delivery of documents will take between 7 to 14 business days

Comments