Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effectiveness of social stories and cognitive rehabilitation on social skills, executive functions, verbal and non-verbal communication skills and stereotypical behaviors of children with high-functioning autism

Protocol summary

Study aim

Determining the effectiveness of social stories and cognitive rehabilitation on social skills, executive functions, verbal and non-verbal communication skills, and stereotypical behaviors in children with high-functioning autism.

Design

A clinical trial with a control group and two intervention groups, single-blind, randomized, phase 3 will be conducted with 15 participants in each group, using SPSS software for analysis.

Settings and conduct

After selecting the samples and placing them in two intervention groups and a control group, the intervention will be implemented in the researcher's office in Isfahan, in the form of 14 individual sessions for each member of the intervention group, and a one-way blinding method will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 6 to 11 years; Higher than average intelligence quotient; Diagnosis of high-functioning autism based on assessment by a therapist from counseling centers; Absence of sensory impairments. Exclusion criteria: Receiving simultaneous rehabilitation; Undergoing medical or psychiatric treatments that interfere with the intervention process.

Intervention groups

Intervention One: 12 recorded social stories will be listened to and acted out, and questions will be asked to understand the situation. Intervention Two: An emotion-based rehabilitation package for emotional abilities and mental states will be administered. Intervention Three: Control group samples, who will not receive any intervention.

Main outcome variables

Improving the quality of life for children with autism and their families; Developing effective educational programs for children with autism in schools and rehabilitation centers; Preventing long-term social and behavioral problems in children with autism; Facilitating the social participation of children with autism in public and educational environments.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250308064990N1**
Registration date: **2025-05-06, 1404/02/16**
Registration timing: **prospective**

Last update: **2025-05-06, 1404/02/16**
Update count: **0**

Registration date

2025-05-06, 1404/02/16

Registrant information

Name

Sara Masoumi Torkamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 3176

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-21, 1404/02/31

Expected recruitment end date

2025-09-22, 1404/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of social stories and cognitive rehabilitation on social skills, executive functions, verbal and non-verbal communication skills and stereotypical behaviors of children with high-functioning autism

Public title

Comparing the effectiveness of social stories and cognitive rehabilitation in children with high-functioning autism

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 6 to 11 years. Having an intelligence quotient higher than average. High-functioning autism diagnosis based on the assessment of therapists at counseling centers. Lack of sensory deficits such as deafness and blindness. Informed consent and willingness to cooperate of children and their families.

Exclusion criteria:

Receiving simultaneous rehabilitation Absence for more than two sessions. Undergoing medical and psychiatric treatments that intervene in the educational process.

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population is children with high-functioning autism in Isfahan, who will be selected through purposive sampling (based on research criteria) and then placed in the first and second experimental groups and the control group by simple random assignment, so that everyone has an equal chance of being selected.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since the placement of participants in each of the three groups is random, only the rehabilitation method used in that group will be described.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University - Ahvaz Branch

Street address

Faculty of Nursing and Midwifery, Islamic Azad University, Ahvaz Branch, Farhang Shahr

City

Ahvaz

Province

Khouzestan

Postal code

61349-37333

Approval date

2024-12-27, 1403/10/07

Ethics committee reference number

IR.IAU.AHVAZ.REC.1403.373

Health conditions studied

1

Description of health condition studied

Impairment in social skills, executive functioning, communication skills, and stereotypical behaviors in children with high-functioning Autism Spectrum Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Social Skills

Timepoint

Measuring social skills before the start of the intervention and measurement after the completion of 14 intervention sessions on the effectiveness of social stories and cognitive rehabilitation on two intervention groups.

Method of measurement

Bellini and Hopf's Social Skills Profile of Autism

2

Description

Executive Functioning

Timepoint
Measuring executive functioning before the start of the intervention and measurement after the completion of 14 intervention sessions on the effectiveness of social stories and cognitive rehabilitation on two intervention groups.
Method of measurement
Brief Executive Functions Questionnaire

3

Description
Verbal and Nonverbal Communication Skills
Timepoint
Measuring verbal and nonverbal communication skills before the start of the intervention and measurement after the completion of 14 intervention sessions on the effectiveness of social stories and cognitive rehabilitation on two intervention groups.
Method of measurement
Bishop's Children's Communication Checklist

4

Description
Stereotypical Behaviors
Timepoint
Measuring Stereotypical Behaviors before the start of the intervention and measurement after the completion of 14 intervention sessions on the effectiveness of social stories and cognitive rehabilitation on two intervention groups.
Method of measurement
Gilliam Autism Rating

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Effectiveness of social stories: 12 social stories (one social story per session) will be recorded and played by the researcher, re-read, related pictures will be shown, and then acted out and questions will be asked to understand the situation. The stories will be explained to parents so that the necessary points can be observed in similar situations. This intervention will be carried out in 14 sessions, 60 minutes each, 2 sessions per week.
Category
Rehabilitation

2

Description
Intervention group 2: Effectiveness of cognitive rehabilitation: Emotion-based cognitive rehabilitation package, which teaches basic emotions to the individual at 10 different levels and provides feedback based on the individual's response. At the end of the session, the situations will be explained to the subject's parents. In each session, the subject will be asked questions about the content taught. This intervention will be carried out on the intervention group over 14 sessions of 60 minutes (three sessions per week).
Category
Rehabilitation

3

Description
Control group: Control group samples will not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sara Masoumi Torkamani Psychology Center
Full name of responsible person
Sara Masoumi Torkamani
Street address
Second floor, No. 622, Shahid Yazdani Alley, Kh. Vahid.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University - Ahvaz Branch
Full name of responsible person
Marzieh Talebzadeh Shoushtari
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Phone
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Email
talebzadehmarzieh@gmail.com
Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University - Ahvaz Branch

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
Islamic Azad University - Ahvaz Branch

Full name of responsible person
Sara Masoumi Torkamani

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Psychology

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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
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
All data can potentially be shared after individuals have been anonymized.

When the data will become available and for how long
The access period begins 6 months after the publication of the results.

To whom data/document is available

All researchers working in academic and scientific institutions, specialists in psychology with related fields to the research topic, students, and researchers in this area.

Under which criteria data/document could be used

Results and data of the research aimed at improving the living and social conditions of children with high-functioning autism

From where data/document is obtainable

Specialized websites, reputable journals related to the research, and the email address of the researcher.

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

After completing the research, presenting the final results, and defending it, the information will be published. Considering the time required for the publication of information, it will be accessible from reputable related information sources.

Comments