

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Examining the efficacy of the Program for the Education and Enrichment of Relational Skills (PEERS) in improving the social function of adolescents with autism spectrum disorder

Protocol summary

Study aim

-Translation and localization of the Program for the Education and Enrichment of Relational Skills (PEERS) for children and adolescents with autism spectrum disorder (ASD) - Investigating the effectiveness of the PEERS in improving the social functioning of patients with ASD - Preparing a manual for teaching communication skills to adolescents with ASD and their caregivers

Design

A clinical trial with the control group, randomized, on 30 patients. The Simple randomization method is used.

Settings and conduct

Day center of Roozbeh hospital

Participants/Inclusion and exclusion criteria

Age between 12 and 18 years Diagnosis of ASD verbal IQ above 70 No present comorbidity with acute phases of bipolar or psychotic disorders

Intervention groups

The experimental intervention will include 14 sessions of training and strengthening social skills for adolescents with ASD, as well as parallel group sessions for a member of their family. This program is a social skills intervention and addresses elements of social functioning for adolescents such as two-way conversation skills, making friends, using appropriate humor, managing rejection, bullying, or gossiping. Social skills are taught using cognitive behavioral therapy techniques.

Main outcome variables

Improving social interaction and communication in adolescents with ASD

General information

Reason for update

Acronym
PEERS

IRCT registration information

IRCT registration number: **IRCT20230610058443N1**
Registration date: **2023-07-18, 1402/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

Registration date

2023-07-18, 1402/04/27

Registrant information

Name

Najmeh Tavakolian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9151

Email address

tavakoliann@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the efficacy of the Program for the Education and Enrichment of Relational Skills (PEERS) in improving

the social function of adolescents with autism spectrum disorder

Public title

Effect of Program for the Education and Enrichment of Relational Skills (PEERS) for adolescents with Autism Spectrum Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed diagnosis of autism with ADOS Verbal IQ above 70 Informed consent for 14 weekly sessions and doing tasks A family member who is cooperative to participate in parallel sessions No present comorbidity with acute phases of bipolar or psychotic disorders

Exclusion criteria:

Not participating in more than 3 sessions emergence of acute psychiatric symptoms (aggression, psychosis, suicidal thoughts)

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is performed. It is an individual randomization unit. The number of groups was set at 2. Group 1 case name and group 2 placebo name were determined. Then the software determined which number is in the case group and which number is in the placebo group. The numbers were matched with an Excel file containing the patients' names, thus identifying the case and control groups. Forty adolescent patients with autism spectrum disorder are numbered from 1 to 30 in the Excel file. Then, 30 patients were entered into the Random Allocation software. The number of groups is set at 2. Group 1 case name and group 2 control name are determined. Then the software determined which number is in the case group and which number is in the control group. The numbers are matched with an Excel file containing the patients' names, thus identifying the case and control groups.

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 Tehran university of medical sciences

Street address

Roozbeh hospital, south Kargar, Tehran

City

Tehran

Province

Tehran

Postal code

1333715914

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.833

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

Social Interaction and relationship in adolescents with ASD

Timepoint

before intervention and 14 and 28 weeks after intervention

Method of measurement

Social Skills Improvement System, Social Responsiveness Scale, Friendship Quality Scale, The Quality of Play Questionnaire, Test of Adolescent Social Skills Knowledge.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 14 weekly sessions (90 min) of PEERS and parallel sessions for family members

Category

Treatment - Other

2

Description

Control group: waiting list. Adolescents with ASD who do not receive any nonpharmacologic treatment during the implement of PEERS for intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Najmeh Tavakolian

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotuhi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Research Center for Cognitive and Behavioral 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

Najmeh Tavakolian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Subspecialist

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Person responsible for updating data

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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