

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### localization of the Program for the Education and Enrichment of Relational Skills (PEERS) for adults with Autism Spectrum Disorder and Investigating the effect of PEERS on Their Social Functions A Randomized Control Trial.

#### Protocol summary

##### Study aim

Translation and localization of Program for the Education and Enrichment of Relational Skills (PEERS) in young adults Study of Effectiveness of PEERS in social functioning of patients

##### Design

This is a mixed method study and will be conducted in two steps. In first step, Persian translation and validation will be done. For the second step, a randomized clinical trial will be done in a sample of 18-30 year old patients diagnosed with ASD. Randomized allocation will be done and control group will be in waiting list

##### Settings and conduct

Adult ASD patients admitted in outpatient autism Clinic in Tehran

##### Participants/Inclusion and exclusion criteria

Inclusion: Confirmed diagnosis of autism with AQ higher than cutoff verbal IQ>70 Informed consent for 15 weekly session and doing tasks A family member who is cooperative to participate in parallel sessions vineland adoptive behavior score>85 not being treated in any other interventions except for standard care no present comorbidity with acute phases of bipolar or psychotic disorders Exclusion: Emergence of acute psychiatric symptoms (suicidal idea, aggression, psychosis) not participating in more than 3 sessions

##### Intervention groups

Intervention: 16 session (90 min) of PEERS and parallel session for caregiver or friend Control: Waiting list

##### Main outcome variables

Communicative skills Social interactions Empathy Emotional Intelligence Lonliness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110630006923N3**

Registration date: **2021-03-13, 1399/12/23**

Registration timing: **prospective**

Last update: **2021-03-13, 1399/12/23**

Update count: **0**

##### Registration date

2021-03-13, 1399/12/23

##### Registrant information

##### Name

Elham Shirazi

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2209 5680

##### Email address

eshirazi@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

localization of the Program for the Education and Enrichment of Relational Skills (PEERS)for adults with Autism Spectrum Disorder and Investigating the effect of PEERS on Their Social Functions A Randomized Control Trial.

## Public title

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

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Confirmed diagnosis of autism with AQ higher than cutoff verbal IQ>70 Informed consent for 15 weekly session and doing tasks A family member who is cooperative to participate in parallel sessions vinland adoptive behavior score>85 not being treated in any other interventions except for standard care 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 **16 years** old to **30 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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 Iran University of Medical Sciences

##### Street address

Hemmat Highway, Iran University of medical

sciences, school of medicine

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Approval date

2021-01-31, 1399/11/12

#### Ethics committee reference number

IR.IUMS.REC.1399.1158

## Health conditions studied

### 1

#### Description of health condition studied

Autism Spectrum Disorder

#### ICD-10 code

F84

#### ICD-10 code description

Pervasive developmental disorders

## Primary outcomes

### 1

#### Description

Social Skills

#### Timepoint

pre and post intervention

#### Method of measurement

Social Skills Rating System (SSRS)

### 2

#### Description

empathy

#### Timepoint

pre and post intervention

#### Method of measurement

Empathy Qoutient

### 3

#### Description

Emotional intelligent

#### Timepoint

pre and post intervention

#### Method of measurement

Bar-On's measure of emotional and social intelligence

### 4

#### Description

Lonliness

#### Timepoint

pre and post intervention

#### Method of measurement

Social and Emotional Loneliness Scale for Adults (SELSA-S)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 16 sessions (90 min) of PEERS and parallel sessions for family members or friends

#### Category

Treatment - Other

### 2

#### Description

Control group: waiting list

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Roozbeh Adult developmental disorders clinic

##### Full name of responsible person

Javad Alaghband-rad

##### Street address

South Kargar, Roozbeh Hospital

##### City

Tehran

##### Province

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##### Postal code

13337159140

##### Phone

+98 21 5541 9151

##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences, Deputy of Research

##### Full name of responsible person

Seyyed Abbas Motevallian

##### Street address

Iran University of Medical Sciences Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

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##### Phone

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##### Email

shirazi\_elham@yahoo.com

#### Grant name

high quality article grant

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical Sciences, Deputy of Research

#### 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

Elham Shirazi

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran

##### City

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##### Postal code

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##### Phone

+98 21 86701

##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr Elham Shirazi

##### Position

Associate Professor, Board of Subspeciality of Child and Adolescent Psychiatry

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**Tehran Institute of Psychiatry, Shahid Mansouri St,  
Niayesh St, Sattarkhan St, Tehran, Iran.**City**

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**Web page address****Phone**

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**Fax****Email**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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

**Title and more details about the data/document**

Clinical study report and consent

**When the data will become available and for how long**

6 months after publication of results

**To whom data/document is available**

Researchers in Academic Institutions

**Under which criteria data/document could be used**

only for research purposes

**From where data/document is obtainable**

Dr Elham Shirazi, Principal Researcher

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

After receiving the requests, it will be answered in a month

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Elham Shirazi

**Position**

Associate Professor, Board of Subspeciality of Child and Adolescent Psychiatry

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

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