Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of occupation-based self-determination interventions on social participation and goal-directed and autonomous behaviors of adolescents with autism spectrum disorder

Protocol summary

Study aim

Effect of occupation-based self-determination interventions on social participation and autonomous and goal-directed behaviors of adolescents with autism spectrum disorder

Design

A randomized, double blinded clinical trial with a parallel group design of 20 individuals. Randomization is simple with using a random number table.

Settings and conduct

In order to measure the degree of the self determination protocol (which has been compiled by the researcher) effectiveness on adolescents' with autism spectrum disorder (ASD) social participation, this study is designed. The study is double blinded (Consequence evaluators and statistical analyzers).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adolescents with autism spectrum disorder in the 13-18 age range; Autism spectrum disorder diagnosis. Exclusion criteria: Having other psychiatric diagnoses according to the demographic questionnaire; Autism spectrum disorder level 2 and 3 based on GARS-3 results; Consuming SSRIs.

Intervention groups

18 intervention sessions (two 45 minutes sessions for 9 weeks) will be performed for the intervention group. Meanwhile, the control group will have the regular Occupational therapy interventions (which involve consultation or visiting an occupational therapist in person).

Main outcome variables

Group; Social awareness, Social cognition, Social communication, Social motivation, Restricted interests and behavior, Social communication and interaction (Social responsiveness scale); Knowing self, Knowing values, Planing, Acting, Experiencing outcomes and learning (Self-determination student scale); Physicality, Information exchange, Relations (Assessment of communication and interaction skills); Grade; Number of children; Socioeconomic status; Age; Gender

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230131057291N1**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

Mohamad Naghavi kheslat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4413 5182

Email address

mohamad.naghavi97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-24, 1401/12/05

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of occupation-based self-determination interventions on social participation and goal-directed and autonomous behaviors of adolescents with autism spectrum disorder

Public title
Effect of Self-determination interventions on social participation of adolescents with autism spectrum disorder
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Adolescents with autism spectrum disorder in the 13-18 age range Autism spectrum disorder diagnosis
Exclusion criteria:
Autism spectrum disorder level 2 and 3 based on GARS-3 results Consuming Selective serotonin re-uptake inhibitors Having other psychiatric diagnoses according to the demographic questionnaire
Age
From **13 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with using a random number table. Once the exact number of participants is determined, a code will be allocated to each individual. Afterwards, with using a number table, a number will be chosen randomly before moving toward columns or rows in order to choose individuals for intervention or control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Consequence evaluators whose job is to evaluate participators using assessments, and statistical analyzer will not be aware of the randomization procedure.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committees of Iran University of Medical Sciences
Street address
Ring 1, No.7, West 6th alley, North Varzi Ave., West Ferdous Blvd.
City
Tehran
Province
Tehran
Postal code
1483793641
Approval date
2022-09-06, 1401/06/15
Ethics committee reference number
IR.IUMS.REC.1401.478

Health conditions studied

1

Description of health condition studied
Autism spectrum disorder
ICD-10 code
F84.0
ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
'Knowing self' score based on Self-determination student scale
Timepoint
Before intervention, after intervention, and 45 days after intervention
Method of measurement
Self-determination student scale

2

Description
'Knowing values' score based on Self-determination student scale
Timepoint
Before intervention, after intervention, and 45 days after intervention
Method of measurement
Self-determination student scale

3

Description
'Planing' score based on Self-determination student scale
Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Self-determination student scale

4

Description

'Act' score based on Self-determination student scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Self-determination student scale

5

Description

'Experiencing outcomes and learning' score based on Self-determination student scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Self-determination student scale

6

Description

'Social awareness' score based on Social responsiveness scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Social responsiveness scale

7

Description

'Social cognition' score based on Social responsiveness scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Social responsiveness scale

8

Description

'Social communication' score based on Social responsiveness scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Social responsiveness scale

9

Description

'Social motivation' score based on Social responsiveness scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Social responsiveness scale

10

Description

'Restricted interests and behavior' score based on Social responsiveness scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Social responsiveness scale

11

Description

'Social interaction and communication' score based on Social responsiveness scale

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Social responsiveness scale

Secondary outcomes

1

Description

'Physicality' score based on Assessment of communication and interaction skills

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Assessment of communication and interaction skills

2

Description

'Information exchange' score based on Assessment of communication and interaction skills

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Assessment of communication and interaction skills

3

Description

'Relations' score based on Assessment of communication and interaction skills

Timepoint

Before intervention, after intervention, and 45 days after intervention

Method of measurement

Assessment of communication and interaction skills

Intervention groups

1

Description
Intervention group: 18 session intervention (two 45 minutes sessions for 9 weeks) based on Field and Hoffman's Self-determination protocol which is provided by related occupations in order to improve adolescents' learning
Category
Rehabilitation

2

Description
Control group: Regular Occupational therapy interventions involving consultation and/or visiting an occupational therapist in person
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Khane-Omid 2 institution
Full name of responsible person
Saeid Hadigol
Street address
No.2, Deylaman Ave., Baradaran-e-Yaseri Ave., Jomhouri Ave.
City
Tehran
Province
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Postal code
0000000000
Phone
+98 920 978 0820
Email
NoEmail@none.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Zahra Kordloo
Street address
Iran university of medical sciences, Milad Tower, Hemmat hwy.
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2503
Email
Info@iums.ac.ir
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
Mohamad Naghavi kheslat
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All consequences information will be shared when the research is done.

When the data will become available and for how long
Research documentation will be shared 6 month after publishing the study.

To whom data/document is available
Universities and scientific institutes researchers and occupational therapist are permitted to access research documentation.

Under which criteria data/document could be used
In order to check the research details and understand its effectiveness on intervention group, research documentation is allowed to be used.

From where data/document is obtainable
Mohamad Naghavi Kheslat (researcher)
Mohamad.naghavi97@gmail.com

What processes are involved for a request to access data/document
After submitting the request, applicant's information and their request type will be checked. Requests will be checked and complied with within a week.

Comments