

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effectiveness of Sensory Integration Treatment in decreasing behavioral and communicative problems in autistic boys between 8-12 years old

Protocol summary

Summary

Objectives: The aim of this research is assessing effectiveness of Sensory Integration (SI) Treatment in decreasing behavioral and communicative problems in autistic boys between 8-12 years old. Design: This is a randomized clinical trial (RCT) with pre- and post test assessment. Setting and Conduct: One group will receive the SI therapies and other group no treatment. ADI-R test, which is a standard measure, will be used as pre- and post-test to assess the efficacy of SI. Participants: We design a in 24 children with autism described in DSM-4. The study population will be randomized into intervention and control groups. Intervention: The intervention group receive SI during 10 weeks (20 sessions-45 minutes), while the control group will not be under this treatment as their previous year. Main outcome measurement variables: We expect to see increasing the socialization abilities in the intervention group after SI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212079854N2**
Registration date: **2012-12-30, 1391/10/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-30, 1391/10/10

Registrant information

Name

Mojtaba Soltanlou

Name of organization / entity

University of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 21 6623 6219

Email address

soltanlou@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Beautiful Mind Rehabilitation Clinic, and Vice chancellor for research, Islamic Azad University - Tonekabon Branch

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-03-05, 1391/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Sensory Integration Treatment in decreasing behavioral and communicative problems in autistic boys between 8-12 years old

Public title

Sensory Integration in Autistic Children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: 8-12 years old; diagnosis of Autism by Psychiatrist based on DSM IV; no other treatment;
Exclusion: Other neurological disorder such as cerebral palsy; seizure; metabolic disorder; change in drugs during the intervention;

Age

From **8 years** old to **12 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of
Tonekabon

Street address

Educational complexity of Islamic Azad University of
Tonekabon, Vali Abad

City

Tonekabon

Postal code

586/46815

Approval date

2012-08-23, 1391/06/02

Ethics committee reference number

15920701882006

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

Social Interaction

Timepoint

Pre- intervention and 10 weeks after intervention

Method of measurement

ADI- R Questionnaire

Secondary outcomes

1

Description

communication problems and stereotyped behaviors

Timepoint

Pre- intervention and 10 weeks after intervention

Method of measurement

ADI- R Questionnaire

Intervention groups

1

Description

Sensory Integration Treatment in intervention group will be done for 20 sessions during 10 weeks. SI is a sensory-motor treatment which therapist will select the intervention based on client's response and is completely client center.

Category

Rehabilitation

2

Description

Control group includes autistic children who are not under any treatment when the study will be initiated and also will not receive any other during the research period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beautiful Mind Rehabilitation Clinic

Full name of responsible person

Mojtaba Soltanlou

Street address

No. 3, 16th Alley, Parvaneh St., Nasr bridge

City

Tehran

2

Recruitment center

Name of recruitment center

Peyke Honar Autism School

Full name of responsible person

Elham Vadi

Street address

West 44 Alley, Kalantari Sq., Yousef Abad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University -
Tonekabon Branch

Full name of responsible person

Dr Khalil Pour Shamsian

Street address

Educational complexity of Islamic Azad University of
Tonekabon, Vali Abad

City

Tonekabon

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Islamic Azad University -
Tonekabon Branch

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

University of Tabriz

Full name of responsible person

Mojtaba Soltanlou

Position

PhD Student of Cognitive Neuroscience

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty