

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 2026

The effect of sensory based interventions on hand function of children with Autism Spectrum Disorders

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate sensory based interventions on hand function of children with Autism Spectrum Disorders. **Design:** Participants are selected from children with Autism, aged 4-14 years old, in Occupational Therapy Clinics in Tehran. 50 children are randomly assigned into control or intervention group by coded envelop. **Setting and conduct:** Evaluations are done two times before intervention and immediately after the end of intervention by a trained Occupational Therapist who is blind to type of group. **Participants:** children should get a Wechsler IQ score of 90. **Intervention:** After the baseline assessments, treatment sessions are given, 2 sessions per week, each session about 30-45 minutes for 8 weeks. Each session of treatment includes: A: Modulation of sensory defensiveness (in touch, vestibular, and proprioception) such as active movements on scooter board, Wilbarger protocol, deep touch pressure. B: Improvement of hypo responsivity such as fast brushing, up and down jumping on trampoline. **Main outcome measures:** Bruininks-Oseretsky Test of Motor Proficiency and Vineland Adaptive Behavior Scales

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710083551N8**

Registration date: **2017-10-18, 1396/07/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-18, 1396/07/26

Registrant information

Name

Parvin Raji

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 8798

Email address

praji@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for education, Tehran University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sensory based interventions on hand function of children with Autism Spectrum Disorders

Public title

The effect of sensory based interventions on hand function of children with Autism Spectrum Disorders

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Children aged 14-4 years old with diagnosis of autism; Get a score of 90 from the Wechsler intelligence test; Earn score 38-141 of the Short Sensory Profile (SSP) Questionnaire, which means that they have

difficulty in sensory processing. Exclusion criteria: No taking anti-seizure medication during the last six months; No intention to continue cooperation in research.

Age

From **4 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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

Tehran University of Medical Sciences, Poursina St, Ghods St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2017-09-27, 1396/07/05

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3592

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

Motor Proficiency

Timepoint

before intervention, immediately after the end of intervention

Method of measurement

Bruininks-Oseretsky Test of Motor Proficiency

Secondary outcomes

1

Description

Adaptive behavior

Timepoint

before intervention, immediately after the end of intervention

Method of measurement

Vineland Adaptive Behavior Scales

Intervention groups

1

Description

Control group: Sensory Integration intervention

Category

Rehabilitation

2

Description

Intervention group: Sensory Integration intervention+ Modulation of sensory defensiveness (in touch, vestibular, and proprioception) such as active movements on scooter board, Wilbarger protocol, deep touch pressure and Improvement of hypo responsivity such as fast brushing, up and down jumping on trampoline.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Occupational Therapy Clinics in Tehran

Full name of responsible person

Safoora Azizi

Street address

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for education, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Jalili

Street address

Vice chancellor for education, 7th floor, Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran

City

Tehran

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

Yes

Title of funding source

Vice chancellor for education, Tehran University of Medical Sciences

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**

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Assistant Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave, Tehran

City

Tehran

Postal code**Phone**

+98 21 7753 8798

Fax**Email**

praji@tums.ac.ir

Web page address

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Assisted Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 7753 8798

Fax**Email**

praji@tums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Assisted Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty, Picheshemiran, Enghelab Ave, Tehran

City

Tehran

Postal code**Phone**

+98 21 7753 8798

Fax**Email****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