

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of tele rehabilitation on the pattern of sensory processing, social competence and occupational performance of autism children

Protocol summary

Study aim

checking the effect of tele rehabilitation on the pattern of sensory processing, social competence and occupational performance of autism children

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, control group: 16 autistic children, intervention group: 16 autistic children

Settings and conduct

In the first phase, the sensory diet intervention protocol is written for 4 sensory processing patterns. In the second phase, the samples are divided into two groups: in-person and tele occupational therapy. The interventions of both group are done during 8 weeks. (12 sessions/ each session: 30 minutes) the sessions of tele occupational therapy are in the form of video/audio conference. A special sensory diet is given to each child during the sessions.

Participants/Inclusion and exclusion criteria

(1) diagnosis of autism spectrum disorder by a child psychiatrist and diagnosis of level one and two of autism spectrum disorder by an occupational therapist (Gilliam Autism Rating Scale, third edition) (2) age range: 4-10 years, (3) not having neurological disorders such as epilepsy and other psychiatric disorders

Intervention groups

Intervention group: receiving a sensory diet through tele occupational therapy/Control group: receiving a sensory diet through face-to-face occupational therapy

Main outcome variables

Tele occupational therapy, sensory processing, social competency, occupational performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221128056651N1**

Registration date: **2022-12-16, 1401/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-16, 1401/09/25**

Update count: **0**

Registration date

2022-12-16, 1401/09/25

Registrant information

Name

Simin Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 9884

Email address

siminotdehghani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tele rehabilitation on the pattern of sensory processing, social competence and occupational performance of autism children

Public title

The effect of tele rehabilitation on the pattern of sensory

processing, social competence and occupational performance of autism children

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 (1) diagnosis of autism spectrum disorder by a child psychiatrist and diagnosis of level one and two of autism spectrum disorder by an occupational therapist (Gilliam Autism Rating Scale, third edition) (2) age range: 4-10 years, (3) not having neurological disorders such as epilepsy and other psychiatric disorders
Exclusion criteria:

Age
From **4 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Children with autism spectrum disorder (level 1 and 2) will be selected by available sampling from the autism rehabilitation centers in Tehran. Children who have the entry criteria will be selected. Then, a demographic information questionnaire will be completed and a written consent form will be received from all people who have the entry criteria. the occupational therapist provides an pocket for the caregivers to choose a card from. The arrangement of the cards will be random and card A represents the intervention group and card B represents the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The initial and final tests will be done by another occupational therapist who is proficient in the tests.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pajoochan. Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yaman Street, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-12-13, 1401/09/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.570

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sensory processing pattern, social competency and occupational performance

Timepoint

Before and after the intervention and one month after the intervention

Method of measurement

Sensory Profile 2 Test, Social Responsiveness Scale 2, and Canadian occupational Performance Measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving sensory diet through tele occupational therapy

Category

Rehabilitation

2

Description

Control group: receiving sensory diet through face-to-face occupational therapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran autism rehabilitation centers/Arman Shayan Occupational Therapy Clinic

Full name of responsible person

Doctor Mehdi Alizadeh

Street address

Arman Shayan Superspecialized Rehabilitation Center, Behnam Street, Ariashahr, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

2188639921

Phone

+98 21 4402 2820

Email

Mehdii.alizadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Administrator of Research and Technology

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yaman Street, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Fax

+98 21 2243 9981

Email

Mpajouhesh@sbmu.ac.ir

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Navid Mirzakhani Araghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Shahid Beheshti Rehabilitation Faculty, in front of Bu Ali Hospital, Imam Hossein Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 7754 2057

Fax

+98 21 7754 2057

Email

Mirzakhany@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Simin Dehghani

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 23, 6th Street, Abuzar Ghafari Street, Khaje Abdullah, Shariati, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1661638175

Phone

+98 21 2286 9884

Fax**Email**

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Simin Dehghani

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 23, 6th Street, Abuzar Ghafari Street, Khaje
Abdullah, Shariati, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1661638175

Phone

+98 21 2286 9884

Fax**Email**

siminotdehghani@gmail.com

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information related to the main outcome, can be shared by printing the article.

When the data will become available and for how long

Access will start 6 months after the results are published.

To whom data/document is available

The data will be available to the researchers working in academic and scientific institutions and the families of clients.

Under which criteria data/document could be used

Everyone has the right to submit a request.

From where data/document is obtainable

Applicants can contact the researcher through E-mail.

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

After receiving the e-mail and checking the applicant's request, information will be sent to him/her.

Comments