Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 intervetions 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)

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+98 21 2286 9884

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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

Pajoohan. 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

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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

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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

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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

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Other areas of specialty/work
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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
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