Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of family-based sensory diet program with and without tele occupational therapy on sensory processing pattern, social competency and occupational performance of children with autism spectrum disorder

Protocol summary

Study aim
Comparison of the effect of family-based sensory diet program with and without tele occupational therapy on sensory processing pattern, social competency and occupational performance of children with autism spectrum disorder

Design
A clinical trial with a control group, with parallel groups, single-blind, simple randomization using drawing method, control group: 16 autistic children, intervention group: 16 autistic children

Settings and conduct
The sensory diet intervention protocol is written for 4 sensory processing patterns. The samples in Tehran autism rehabilitation centers 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.The initial and final tests will be done by another occupational therapist who is proficient in the tests.

Participants/Inclusion and exclusion criteria
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)؛ age range: 4-10 years؛ not having neurological disorders such as epilepsy and other psychiatric disorders

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

Main outcome variables
sensory processing, social competency, occupational performance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221128056651N2**
Registration date: **2022-12-21, 1401/09/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-21, 1401/09/30**
Update count: **0**

Registration date
2022-12-21, 1401/09/30

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

Comparison of the effect of family-based sensory diet program with and without tele occupational therapy on sensory processing pattern, social competency and occupational performance of children with autism spectrum disorder

Public title

Comparison of the effect of family-based sensory diet program with and without tele occupational therapy on sensory processing pattern, social competency and occupational performance of children with autism spectrum disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

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) age range: 4-10 years

Exclusion criteria:

neurological disorders such as epilepsy and other psychiatric disorders

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

The occupational therapist provides a pack of envelopes for the caregivers to choose a card from them. The arrangement of the cards will be random. 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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.500

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

sensory processing pattern

Timepoint

immediately before and after the intervention and one month after the intervention

Method of measurement

sensory profile 2 test

2

Description

social competency

Timepoint

Before and after the intervention and one month after the intervention

Method of measurement

Social Responsiveness Scale 2

3

Description

occupational performance

Timepoint

Before and after the intervention and one month after the intervention

Method of measurement

Canadian occupational Performance Measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving sensory diet through tele occupational therapy/ In the first phase, the sensory diet intervention protocol is written for 4 sensory processing patterns. The samples in Tehran autism rehabilitation centers are divided into two groups: in-person and tele occupational therapy. In the second phase, The intervetions 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. Families are taught the necessary things: awareness of their child's sensory pattern, its effect on behaviors, familiarization with how to perform activities and necessary environmental adaptations by the therapist, or watch videos with the therapist's explanation.

Category

Rehabilitation

2

Description

Control group: receiving sensory diet through face-to-face occupational therapy/ In the first phase, the sensory diet intervention protocol is written for 4 sensory processing patterns by expert panel. The samples in Tehran autism rehabilitation centers are divided into two groups: in-person and tele occupational therapy. In the second phase, The intervetions are done during 8 weeks. (12 sessions/ each session: 30 minutes) the sessions of in-person group are done in Tehran autism rehabilitation centers . A special sensory diet is given to each child during the sessions. Families are taught the necessary things: awareness of their child's sensory pattern, its effect on behaviors, familiarization with how to perform activities and necessary environmental adaptations by the therapist, or watch videos with the therapist's explanation.

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

Dr Mehdi Alizadeh

Street address

Arman Shayan Superspecialized Rehabilitation Center, Behnam Street, Ariashahr

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

Vice President of Research and Technology

Street address

SBMU, Next to Taleghani Hospital, Yaman Street

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, infront of Bu Ali Hospital, Imam Hossein Square

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
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

Street address
4th floor, No. 23, 6th street, Abuzar Ghafari Street, Khaje Abdullah, Shariati, Tehran

City
Tehran

Province
Tehran

Postal code
1661638175

Phone
+98 21 2286 9884

Fax

Email
siminotdehghani@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Simin Dehghani

Position
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

Street address
4th floor, No. 23, 6th street, Abuzar Ghafari Street, Khaje Abdullah, Shariati, Tehran

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
Part of the data, such as the information related to the main outcome or the like, can be shared by printing the article.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
The data will be available to 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
Immediately after receiving the e-mail and reviewing the applicant's request, possible information will be provided to him/her.

Comments