

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 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. 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 interventions 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 interventions 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**

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##### **Province**

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##### **Phone**

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##### **Fax**

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##### **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

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## 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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Position**

MSc student

**Latest degree**

Bachelor

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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**

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**

