

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Development of a family- based sensory diet program on attention deficit, hyperactivity and impulsivity in elementary school students with attention deficit hyperactivity disorder

Protocol summary

Study aim

Determining the effect of family-based sensory diet program on attention deficit, hyperactivity and impulsivity in elementary school students with attention deficit hyperactivity disorder

Design

The study population will include 30 children with Attention Deficit Hyperactivity Disorder in Tehran, 6-12 years old. Hasti Therapy Clinic will be selected during the WISC-IV Children's Wechsler Scale to measure children's intelligence and the Connors Parent Form Scale for Attention Deficit Hyperactivity Disorder and will be randomly divided into two groups of 15 intervention and control. The intervention group will use 12 sessions of family-centered sensory diet program, 3 sessions per week and each session for 45 minutes, which is based on the Wilberger Sensory Protocol.

Settings and conduct

In the first session, with the aim of getting to know the family and the child, examining the child's sensory status, trainings on correcting environmental stimuli, the child's work environment, planning and scheduling the sensory regime will be done. In the next sessions of the intervention, parents will be given trainings to modulate sensory inputs and increase self-regulation, increase the level of consciousness, raise the level of attention using vestibular stimuli, profound sense, appropriate vision and controlled hearing. Each treatment session consisted of 5 to 6 exercises, and as the children progressed, the exercises became more difficult in the next sessions or other exercises will be used.

Participants/Inclusion and exclusion criteria

Having Attention Deficit Hyperactivity Disorder Age range 6-12 years.

Intervention groups

The control group of occupational therapy services and the intervention group will receive sensory diet programs

in addition to occupational therapy.

Main outcome variables

Changes in the symptoms of children with attention deficit hyperactivity disorder are expected

General information

Reason for update

Acronym

Attention Deficit Hyperactivity Disorder= ADHD

IRCT registration information

IRCT registration number: **IRCT20220214054020N1**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **retrospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

Name

Shila Shabdini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6690 1720

Email address

shila.shabdini@srbiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-25, 1400/12/06

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development of a family- based sensory diet program on attention deficit, hyperactivity and impulsivity in elementary school students with attention deficit hyperactivity disorder

Public title

"Effect of sensory diet on attention deficit/ hyperactivity"

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a diagnosis of inattention and hyperactivity.
Having a natural consciousness. Health of the visual and auditory system.

Exclusion criteria:

Family reluctance to participate in the study Lack of cooperation of the child to participate in the study Age conditions of the child outside the age range of 6-12 years

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

For simple randomization at sealedenvelope.com, the Simple Randomization Services section enters the research information, including the intervention description, sample size, and the researcher's e-mail address, which is issued a password for the research. The names of the samples are entered in the patient's field to perform the research and a random request is made from the site, and the site randomly places the sample in group A or B and sends the result to the researcher's email.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

, Islamic Azad University, Science and Research Branch, Tehran

Street address

No,92.,bagherkhan ST., satarkhan Ave

City

Tehran

Province

Tehran

Postal code

1441633571

Approval date

2021-06-24, 1400/04/03

Ethics committee reference number

IR.IAU.SRB.REC.1400.155

Health conditions studied**1****Description of health condition studied**

Attention deficit/hyperactivity Disorder

ICD-10 code

F90

ICD-10 code description

Disturbance of activity and attention

Primary outcomes**1****Description**

Measuring the rate of change in attention deficit, hyperactivity and impulsivity scores

Timepoint

The intervention group will use 12 sessions of family-centered sensory diet program, 3 sessions per week and each session for 45 minutes, for one month from the beginning of the program.

Method of measurement

Conners Behavior Scale of Parent Form

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Family-Based Sensory Diet: This program bases on the Wilberger (2018) treatment protocol and is a comprehensive sensory approach to treating sensory processing problems. This theory, officially known as the technique of deep pressure, deep sense and mouth touch, helps to organize the mind,

brain and body and increases attention, participation in daily activities, reduces tactile defense and increases body self-regulation. This protocol consists of three components: pulling the sensory brush to the body, compressing the joints, and sensory diet. Sensory diet is a set of sensory activities and inputs to the body and nervous system to maintain a person's level of arousal. Activities are selected according to the needs of the person and are included in his daily plan and increase the level of consciousness, increase the body's awareness about himself, the environment and others, attend activities, improve learning, play, sleep, interact with Peers and increase the level of efficiency. The intervention group will use 12 sessions of family-centered sensory diet program, 3 sessions per week and each session for 45 minutes, which was taken from Wilburger Sensory protocol.

Category

Rehabilitation

2

Description

control group: Since the children will be selected from rehabilitation centers and receive an occupational therapy program one or two sessions per week, it will not be ethically possible to eliminate occupational therapy. Occupational therapy routine includes attention and concentration exercises and structural activity exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasti center

Full name of responsible person

Shila shab dini

Street address

Satarkhan Allay-bagherkhan Allay-No92

City

Tehran

Province

Tehran

Postal code

1441633571

Phone

+98 21 6690 1720

Email

shilashab dini26@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Mohammad Parsa Azizi

Street address

Islamic Azad University Science and Research Branch, University Square, Shohada Hesarak Blvd., End of Shahid Sattari Highway

City

Tehran

Province

Tehran

Postal code

1477893855

Phone

+98 21 4486 5179

Email

shila.shab dini@srbiau.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Independent by researchers

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Mohammadparsa Azizi

Position

Association professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Islamic Azad University Science and Research Branch, University Square, Shohada Hesarak Blvd., End of Shahid Sattari Highway

City

Tehran

Province

Tehran

Postal code

1477893855

Phone

+98 21 4486 5179

Email

mp.azizi@srbiau.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Mohammadparsa Azizi

Position

Association professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Islamic Azad University Science and Research Branch,
University Square, Shohada Hesarak Blvd., End of
Shahid Sattari Highway

City

Tehran

Province

Tehran

Postal code

1477893855

Phone

+98 21 4486 5179

Email

mp.azizi@srbiau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shila Shabdini

Position

Phd student

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

No.92, Bagherkhan ST., Satarkhan Ave

City

Tehran

Province

Tehran

Postal code

1441633571

Phone

+98 21 6690 1720

Email

shila.shabdini@srbiau.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The individual identity of children with the disorder will not be revealed

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

Development of a family-based sensory diet program on attention deficit, hyperactivity and impulsivity in elementary school students with attention deficit hyperactivity disorder

When the data will become available and for how long

March 1400 to 6 months late

To whom data/document is available

Prior to publication, only researchers will be aware of the data

Under which criteria data/document could be used

Once published as an article, they will be available in reputable scientific journals

From where data/document is obtainable

researchers

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

Request data from researchers, receive confirmation of data dissemination from other researchers participating in the research and make the data available to the applicant

Comments