

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of maternal foot massage on the severity of symptoms of attention deficit hyperactivity disorder in children aged 6-12

Protocol summary

Study aim

Determine the effect of maternal foot massage on the severity of attention deficit / hyperactivity disorder symptoms in children aged 12-6 years

Design

A single blinded clinical trial with a control and intermediate group, with pre and post test designs, with 56 children with attention deficit hyperactivity disorder

Settings and conduct

A randomized clinical trial was conducted. A total of 56 patients referred to Isfahan University of Medical Sciences affiliated Clinics were randomly assigned to control and test groups. Test group was referred to Al-Zahra Hospital for learning massage therapy, and it was taken at home three times in the week is for one month and the control group is unaware of the massage and the study is single blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least six months have passed since diagnosis. There is no other psychiatric illness. Inclination to participate in the study and to be randomly assigned to the study groups. Do not simultaneously participate in another similar study. There is no specific problem, such as fractures, infections, or ulcers, and any factors that prevent full access to the legs Exclusion criteria: Use of therapeutic behavior along with drug therapy

Intervention groups

The intervention group learns massage in a one course and they do it three times a week for one month. The control group receives routine care.

Main outcome variables

The general score of severity of attention deficit / hyperactivity disorder symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042090N1**

Registration date: **2019-02-03, 1397/11/14**

Registration timing: **prospective**

Last update: **2019-02-03, 1397/11/14**

Update count: **0**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

Zahra Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3447 6269

Email address

z_asadi4838@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-09, 1397/11/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of maternal foot massage on the severity of symptoms of attention deficit hyperactivity disorder in children aged 6-12

Public title

The effect of foot massage on the severity of attention deficit / hyperactivity disorder symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least six months have passed since diagnosis. There is no other psychiatric illness. Willing to participate in the study. Do not participate in the same study at the same time. There is no specific problem, such as fractures, infections, or ulcers, and any factors that impede full access to the legs.

Exclusion criteria:

Use of therapeutic behavior along with drug therapy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and description of each method: Simple randomization: Children's files were numbered from 1 to 56, each number was recorded in a separate sheet and all the sheets were poured into the container after being placed in a container. After shaking the container, a sheet was removed, respectively, the first sheet was placed in the intervention group and the second sheet in the control group. Random unit: Individual Randomization Tool: Folded sheets in the bag

Blinding (investigator's opinion)

Single blinded

Blinding description

The group was not aware of the lack of simultaneous receiving of massage training in the control group. After the intervention, the massage program was given to the control group

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical

Sciences

Street address

Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery

City

Esfahan

Province

Isfahan

Postal code

8149868561

Approval date

2019-01-10, 1397/10/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.305

2

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

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City

Esfahan

Province

Isfahan

Postal code

8149868561

Approval date

2019-01-10, 1397/10/20

Ethics committee reference number

1397.305

Health conditions studied

1

Description of health condition studied

Attention-deficit hyperactivity disorder

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description

Severity of attention deficit / hyperactivity symptoms

Timepoint

Before the start of the study and 30 days after the intervention began

Method of measurement

Attention Deficit / Hyperactivity Disorder Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention :group was a group of test and the use of sweet almond oil for massage three times a week and twelve sessions.

Category

Behavior

2

Description

Control group: receives routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dependent clinic to the University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Research Deputy of Isfahan University of Medical Sciences

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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

Esfahan University of Medical Sciences

Proportion provided by this source

30

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

Esfahan University of Medical Sciences

Full name of responsible person

ZahraAsadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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

This file is secret

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

No - There is not 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

Protocol and data analysis will be published as an article

When the data will become available and for how long

After the finishing of research and publishing the article

To whom data/document is available

All the people that the result of the research is useful for them

Under which criteria data/document could be used

For using non-pharmacologic strategy in order to decreasing the sign of ADHD in pediatrics

From where data/document is obtainable

Zahra Asadi

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

Via E-mail

Comments