

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of foot reflexology massage on sleeping habits of autistic children aged 6-12 years in Mashhad

Protocol summary

Study aim

The effect of foot reflexology massage on sleeping habits of children aged 6-12 years with autism

Design

A clinical trial with two intervention and control groups - 60 autistic patients - one month follow-up

Settings and conduct

Mashhad autism centers are located, which will be followed by routine treatment in the control group. In the intervention group, in addition to routine treatment, foot reflexology massage is performed by the parents at home on the thumb for 15 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed parental consent - 6-12 years old - Autism diagnosis by a psychiatrist - No stressful event (such as parental divorce, death of a family member,) during the past 3 months, - Lack of other physical and mental illnesses in the child such as hyperthyroidism, hyperactivity, arthritis - Children must have a sleep habits score greater than 41 based on the Child Sleep Habits Questionnaire - no special problems such as burns, skin and fungal problems, paralysis, Sensory Disorders, Topical Inflammation - Lymphatic and Intravenous and Vascular Disease in Foot - No Parental Addiction, Exclusion criteria: Non-massage by parents for more than three sessions - Arbitrary use of sedative drugs and sleep-deprivation drugs outside of the care protocol - Autistic children with autism Severe sleep disorders are according to a pediatric psychiatrist

Intervention groups

The control group will receive routine treatment. In the intervention group, in addition to routine treatment, foot reflexology massage is performed by the parents at home on the toe for 15 minutes. Sleep habits are assessed by the standard questionnaire of sleeping children in three occasions (beginning, 15th day and day of intervention).

Main outcome variables

Changing sleep habits, affecting sleep problems,

changing time or quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043999N1**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **retrospective**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

Abdolrahman Golbaf

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

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golbafar961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on sleeping habits of autistic children aged 6-12 years in Mashhad

Public title

The Effect Of Foot Reflexology On The Habits Of Sleep Children With Autism

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Informed Parental Satisfaction Age range 6 to 12 years
Diagnosis of autism by a psychiatrist No stressful event (eg parent divorce, death of a first-degree family member, parental dispute, unrealistic parenting) during the past 3 months, Absence of other physical and mental illnesses in the child such as hyperthyroidism, hyperactivity, arthritis Children must have a sleep habits score greater than 41 based on a child's sleep habits questionnaire. No specific problems such as ulcers, burns, skin and fungal problems, paralysis, sensory disorders, local-lymphatic and venous inflammation, and vascular disease in the foot.

Exclusion criteria:

No parent massage for more than three sessions
Arbitrary use of sedative drugs and sleep-deprivation drugs outside the care protocols of the care centers, which may compromise the results of the study. The occurrence of a stressful event during the study. Autistic children with severe sleep disorders according to the pediatrician

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Then, the intervention and control groups are randomly assigned to the coin toss.

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad - Ph.D., Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

City

mashhad

Province

Razavi Khorasan

Postal code

95671-63941

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.020

Health conditions studied

1

Description of health condition studied

AUTISM

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

The score of sleep habits in the standard questionnaire of children's sleep habits

Timepoint

Sleep habits are assessed by the standard questionnaire of sleeping children in three occasions (beginning, 15th day and day of intervention).

Method of measurement

Evaluation of Sleep Habits by the Standard Child Sleep Questionnaire (CSHQ)

Secondary outcomes

1

Description

Baby sleep habits score

Timepoint

Sleep habits are assessed by the standard questionnaire of sleeping children in three occasions (beginning, 15th day and day of intervention).

Method of measurement

Evaluation of sleeping habits using standard child sleep questionnaire (cshq)

2

Description

Baby Bed Time Resistance Score

Timepoint

Evaluation takes place three times (first, fifteenth and day of intervention)

Method of measurement

Standard Child Sleep Questionnaire (cshq)

3

Description

Delayed sleep time score

Timepoint

Evaluation is done on three occasions (first, 15th day of intervention)

Method of measurement

Standard Child Sleep Questionnaire (cshq)

Intervention groups

1

Description

Intervention group: In addition to routine practice, foot reflexology massage is performed by parents at home for 15 minutes each night for one month before bedtime.

Category

Rehabilitation

2

Description

Control group: In control group no action is taken and only autistic children in this group will be monitored

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The Autism Center is takapo

Full name of responsible person

Nasim Jalalian

Street address

street Imam Reza - Imam Reza 48 - Autism Center is takapo

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Behnam Vashani

Position

Instructor of Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available