Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone
+98 51 3859 1511

Email address
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
City
mashhad
Province
Razavi Khorasan
Postal code
9165633131
Phone
+98 51 3851 1801
Fax
+98 51 3851 1801
Email
jalalyan@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamid Reza Behnam Vashani
Street address
Taqi Abad - Ph.D., Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
City
mashhad
Province
Razavi Khorasan
Postal code
9567163940
Phone
+98 51 3859 1511
Fax
+98 51 3859 1511
Email
behnamhr@mums.ac.ir
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
Street address
Taghi Abad - PhD in Nursing and Midwifery, Mashhad University of Medical Sciences
City
MASHHAD

Province
Razavi Khorasan
Postal code
956716390
Phone
+98 51 3859 1511
Fax
+98 51 3859 1511
Email
BEHNAMHR@MUMS.AC.IR

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamid Reza Behnam Vashani
Position
Instructor, Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Taghi Abad - PhD in Nursing and Midwifery, Mashhad University of Medical Sciences
City
MASHHAD
Province
Razavi Khorasan
Postal code
9567163941
Phone
+98 51 3859 1511
Fax
+98 51 3859 1511
Email
behnamhr@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamid Reza Behnam Vashani
Position
Instructor, Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Taqi Abad - Ph.D., Faculty of Nursing and Midwifery
City
mashhad
Province
Razavi Khorasan
Postal code
9567163940
Phone
+98 51 3859 1511
Fax
+98 51 3859 1511
Email
behnamhr@mums.ac.ie

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