

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 2026

The effect of foot reflexology massage on sleep quality of school-age children with chronic lung diseases admitted to selected hospitals affiliated to Tehran University of Medical Sciences in 1400

Protocol summary

Study aim

1. Determining the quality of sleep in school-age children with chronic lung diseases in selected hospitals affiliated to Tehran University of Medical Sciences in 1400

Design

The clinical trial has a control and intervention group and is a blind end. It is performed on 36 children with name and fibrocystic.

Settings and conduct

Foot reflexology massage for school-age children diagnosed with chronic lung disease will be admitted at hospitals affiliated to Tehran universities. children will be randomly divided into two groups of odd and even considering the last number of their case number. How to enter is voluntary and with the written consent of parents. sleep quality is evaluated first by the related questionnaire and then again after the massage is given. Performing non-invasive complementary medicine procedure in 3 sessions of 30 minutes.

Participants/Inclusion and exclusion criteria

Entry requirements: The children studied did not have foot ulcers, foot fractures or foot surgery. They are between 6-12 years old. The children under study must be hospitalized in the desired hospitals. No entry conditions: Having diseases such as nephrotic syndrome, diabetic foot ulcers and leg edema, etc. Hospitalized in wards other than the lung wards .

Intervention groups

This study examines the quality of sleep in school-age children with name and fibrocystic by performing reflective foot massage. The reflexology massage of the sole of the foot in this study is performed by performing a non-invasive complementary medicine procedure in 3 sessions of 30 minutes. foot Massage will be held in hospitals affiliated to Tehran universities, and then the quality of sleep will be assessed with a questionnaire. Massage is done every evening. Each foot is massaged 5

times. Massage with baby oil will be done .

Main outcome variables

quality of sleep with CSHQ

General information

Reason for update

Acronym

ماساژ بارتابی کف پا

IRCT registration information

IRCT registration number: **IRCT20210722051954N1**

Registration date: **2021-11-09, 1400/08/18**

Registration timing: **retrospective**

Last update: **2021-11-09, 1400/08/18**

Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name

Elnaz Moghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3865 1750

Email address

el.moghani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology massage on sleep quality of school-age children with chronic lung diseases admitted to selected hospitals affiliated to Tehran University of Medical Sciences in 1400

Public title
The effect of foot reflexology massage on sleep quality of school-age children with chronic lung diseases

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The children did not have foot ulcers The children were between the ages of 6-12. The studied child had no history of foot surgery Days and nights were intended for the child's parents
Exclusion criteria:
 Occurrence of any situation for the patient and his active family member that necessitates interventional measures or has a clear effect on quality of life, such as physical, psychological, family and economic crisis The presence of the patient and his active family member in another educational program related to the quality of the child's sleep (except for the routine program of the center) Any underlying disease (other than the diseases considered in this study) that restricts the patient's breathing, such as injury, burn and chest dressing, chest fracture, and... Any conditions that exclude the possibility of intervention (foot massage), including foot fractures, wounds and foot dressings and... Children did not have other chronic diseases that prevent reflexology massage

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: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sampling is one of the statistical sampling methods in which people in the community have an equal chance of being selected. In this method, the required people or objects are randomly selected from the list of statistical population that has been numbered and prepared for this purpose. According to the law of probability, selected individuals must have the same characteristics as the community from which they were selected. Children were assigned to the intervention and

control groups using a random division method (for example, the last number of even files of the intervention group and the last number of individual files of the control group). For example, the file number is mentioned as 04-34-86, considering that the number 6 is even, then in the present study, it will be included in the intervention group, and vice versa.

Blinding (investigator's opinion)
Single blinded

Blinding description
The children in the control group and their families are unaware of the assignment of the study groups. Principles will be done for the intervention group according to the principles that the researcher has passed the relevant course. How to do the work varies according to the pressure on the sole of the foot and is not recognizable to the children family.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
 Ethics Committee of Islamic Azad University of Medical Sciences, Tehran
Street address
 No11.ladan6 ave .vakil abad blvd.
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9179653968
Approval date
 2021-07-29, 1400/05/07
Ethics committee reference number
 IR .IAU.TMU.REC.1400.067

Health conditions studied

1
Description of health condition studied
 asthma
ICD-10 code
 J45
ICD-10 code description
 Asthma

2
Description of health condition studied

cystic fibrosis
ICD-10 code
E84
ICD-10 code description
Cystic fibrosis

Primary outcomes

1

Description

Sleep quality score in the sleep quality questionnaire

Timepoint

Before the intervention and Immediately after the intervention

Method of measurement

Sleep quality questionnaire called CHSQ

Secondary outcomes

empty

Intervention groups

1

Description

In this study, foot reflexology massage was performed by performing a non-invasive complementary medicine procedure in 3 sessions of 30 minutes. Every day, the evening of massage for school-age children diagnosed with chronic lung diseases is hospitalized in hospitals affiliated to Tehran universities. Each leg is massaged 5 times in each session.

Category

Rehabilitation

2

Description

Control group: foot massage without pressure on specific points

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar

Full name of responsible person

Elnaz Moghani

Street address

No 11.Ladan 6 Ave. Vakil Abad Blvd.

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Phone

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Email

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Recruitment center

Name of recruitment center

Mofid

Full name of responsible person

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Recruitment center

Name of recruitment center

Bahrami

Full name of responsible person

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Recruitment center

Name of recruitment center

Pediatric Medical Center

Full name of responsible person

Elnaz Moghani

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Shirin Hejazi

Street address

Sattari Blvd. Islamic Azad University.

City

Tehran

Province

Tehran

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1477893855

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Email

Fnm.eexam@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Islamic Azad University

Proportion provided by this source

20

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**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Elnaz Moghani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Elnaz Moghani

Position

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Other areas of specialty/work

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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 includes the age of the participants and

the type of disease and how it is performed and the reportable result.

When the data will become available and for how long

2021/11/19

To whom data/document is available

Nursing students and other related fields

Under which criteria data/document could be used

Related research

From where data/document is obtainable

send email to researcher or professor

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

Submit the desired title of the researcher and state the field of study

Comments