Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 بازتابی 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.

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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

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No 11.Ladan 6 Ave. Vakil Abad Blvd.

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Recruitment center

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Recruitment center

Name of recruitment center

Pediatric Medical Center

Full name of responsible person

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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
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1477893855
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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
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Elnaz Moghani
Position
Nurse
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Person responsible for updating data

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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