

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effects of foot reflexology massage on fatigue and pain in children with leukemia under Chemotherapy.

Protocol summary

Study aim

To determine the effect of foot reflexology massage on fatigue and pain of children with leukemia who undergo chemotherapy

Design

The clinical trial included three groups: Intervention1: (Foot Reflexology Massage) ,intervention2: (touch therapy) and Control group, Factorial.unblinded, Without randomization.Sample size:99child

Settings and conduct

The researcher obtains the necessary documentation.the oncology departments.Ali Asghar and Children's Medical Center Hospitals. children aged 4 to 14 years, with leukemia, undergoing chemotherapy. Intervention 1 (foot reflexology massage .Within 5 days.Between 17 and 19 hours, For both feet 30 minute) Intervention group two (Touch Therapy.Within 5 days.Between 17 and 19 hours, For both feet 30 minute) And the control group (receiving only routine care).

Participants/Inclusion and exclusion criteria

Inclusion criteria: There are no scars or physical problems in the feet and massage area. Any child who does not have a physical problems. (For example: Verbal, Visual, Mental, Hearing). Reflexology massage or similar treatments were not received during the study. Exclusion criteria: The child does not feel comfortable touching his or her feet and doing reflexive massage. The child is anxious by touching his or her feet and doing a reflexive massage. The child's illness is severe The doctor will not allow the intervention

Intervention groups

Group 1: Foot Reflexology for 5 days Group 2: Touch Therapy for 5 days Group 3: control Group(receiving only routine care)

Main outcome variables

Pain; fatigue; sleep; anxiety; vital signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N7**

Registration date: **2019-09-24, 1398/07/02**

Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**

Update count: **0**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4687 1192

Email address

shoghi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2019-05-15, 1398/02/25

Trial completion date

2019-05-15, 1398/02/25

Scientific title

The effects of foot reflexology massage on fatigue and pain in children with leukemia under Chemotherapy.

Public title

The effects of foot reflexology massage on fatigue and pain in children

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

There are no scars or physical problems in the feet and massage area Any child who does not have a physical problems. (For example: Verbal, Visual, Mental, Hearing) Reflexology massage or similar treatments were not received during the study.

Exclusion criteria:

The child does not feel comfortable touching his or her feet and doing reflexive massage. The child is anxious by touching his or her feet and doing a reflexive massage. The child's illness is severe The doctor will not allow the intervention

Age

From **4 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **99**

Actual sample size reached: **99**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences: next to Milad Tower: Hemat Highway: Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.525

Health conditions studied**1****Description of health condition studied**

Leukemia

ICD-10 code

D77

ICD-10 code description

Other disorders of blood and blood-forming organs in diseases classified elsewhere

2**Description of health condition studied**

Reflexology

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Fatigue

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

fatigue severity

Timepoint

Before intervention, day 3 and day 5 during five-day reflexology massage

Method of measurement

Child Fatigue Scale

2**Description**

Severity of pain

Timepoint

Before intervention, day 3 and day 5 during five-day reflexology massage

Method of measurement

visual analogue scale pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: Then oncology departments at hospitals, "Ali Asghar and Children's Medical Center Hospitals " among children 4 to 14 years old with leukemia who are undergoing chemotherapy. Methods: (Reflexology foot massage, for 5day, between 17and 19hours, 30minutes for both feet).

Category

Rehabilitation

2

Description

Intervention group two:Then oncology departments at hospitals, "Ali Asghar and Children's Medical Center Hospitals " among children 4 to 14 years old with leukemia who are undergoing chemotherapy. Methods: (Touch therapy, for 5day, between 17and 19hours, 30minutes for both feet)

Category

Rehabilitation

3

Description

Control group:Then oncology departments at hospitals, "Ali Asghar and Children's Medical Center Hospitals " among children 4 to 14 years old with leukemia who are undergoing chemotherapy. Methods:control group (receiving only routine care).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Soroor Sohrabi

Street address

Ali Asghar hospital: Shahid Dasgerdi street: Tehran

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2222 2041

Email

soroor.soh@gmail.com

2

Recruitment center

Name of recruitment center

Childrens medical center Hospital

Full name of responsible person

Tahereh khan Mohamadzadeh

Street address

Childrens Medical Center: Number 62: Keshavarz blvd: Dr. Qarib street, Tehran

City

Tehran

Province

Tehran

Postal code

1511419733

Phone

+98 21 6147 2917

Email

cmc.tums@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seid Kazam Malakuti

Street address

School of Nursing and Midwifery, Shahid Yasemi Street., North Kordestan Highway., Tehran.

City

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1996713883

Phone

+98 21 4365 1000

Email

PR@iums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Dr.Mahnaz Shoghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

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Full name of responsible person

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Position

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Latest degree

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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

Not applicable

Title and more details about the data/document

After Data coding in order to keep the confidentiality of the participants in the research

When the data will become available and for how long

The end of sampling till six months after article publishing.

To whom data/document is available

Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used

Systematic review and meta-analysis or secondary analysis citation.

From where data/document is obtainable

Dr. Mahnaz Shoghi, Email: shoghi.m@iums.ac.ir

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

After sending a request to academic email, we will send our data files up to one week.

Comments