Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+98 21 4687 1192
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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
Tehran
Province
Tehran
Postal code
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

Street address

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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Latest degree

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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