Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Foot Reflexology Massage on Delirium and Physiological Indicators in Children Admitted to Pediatric Intensive Care Unit: A randomized clinical trial

Protocol summary

Study aim
Determining the effect of foot reflexology massage on delirium and physiological indicators in children admitted to the pediatric intensive care unit.

Design
The research is a randomized clinical trial with a control and test group, which is conducted on 74 children in PICU. Computerized randomization (www.randomizer.org) will be used.

Settings and conduct
This research will be done in Hazrat Ali Asghar hospital. Sampling will be done continuously and based on the study inclusion criteria. Using computer randomization (www.randomizer.org), the selected in the control and the intervention group. Informed written consent will be obtained from the children's parents as well as verbal consent from the child to participate in the research. Demographic data will be recorded from the child's medical record. Foot reflexology massage will be performed by a researcher who was trained in this field and according to the standard instructions, during 2 consecutive days. In all cases , first the child will be connected to cardiorespiratory monitoring and then the form of physiological indicators (blood pressure, heart rate, arterial blood oxygen saturation) Cornell delirium questionnaire for children, 5 minutes before the floor reflex massage. In intervention group, in addition to providing the usual care of the ward. Then, immediately after intervention, the Physiological Index Form of the Children's Cornell Delirium will be completed 2 hours later. In control group, the physiological indicators form will be completed 33 minutes later and the children's delirium kernel questionnaire will be completed 2 hours and 33 minutes after the initial assessment.

Participants/Inclusion and exclusion criteria
74 children hospitalized in the pediatric intensive care unit

Intervention groups
foot reflexology massage- control group

Main outcome variables
Delirium; physiologic parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230202057303N3**
Registration date: **2024-04-19, 1403/01/31**
Registration timing: **prospective**

Last update: **2024-04-19, 1403/01/31**
Update count: **0**

Registration date
2024-04-19, 1403/01/31

Registrant information

Name
Mona Alinejad naenie

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-29, 1403/02/10

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Foot Reflexology Massage on Delirium and Physiological Indicators in Children Admitted to Pediatric Intensive Care Unit: A randomized clinical trial

Public title

The effect of Foot Reflexology Massage on Delirium and Physiological Indicators in Children Admitted to Pediatric Intensive Care Unit: A randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Failure to score 4- and 5- on the Richmond Agitation Scale Age 6-12 years old Hospitalization in the pediatric intensive care unit for at least 3 days Absence of abnormalities such as corns, wounds, previous scars, burns, amputations, and skin diseases on the legs. Absence of vascular injuries in the lower limbs and absence of sensory-motor disorders (confirmed by a neurologist) in the legs Diagnosis of delirium by obtaining a delirium score of 9 and above based on the Cornell scale and a pediatric neurologist No previous experience of foot reflexology massage before the study Confirmation of the doctor's diagnosis by a pediatric specialist

Exclusion criteria:

Mechanical ventilation Taking a X Ray and performing an invasive procedure due to the occurrence of restlessness and disturbance in the massage Children's restlessness Lack of proper cooperation and resistance of the child and his parents at any time of the study Emergency conditions such as cardiopulmonary resuscitation or seizures Child suffering from acute heart or respiratory diseases Reduction of vital signs more than expected, such as: drop in blood pressure (below 25th percentile) and bradycardia (below 65 beats per minute)

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: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Using computerized randomization (www.randomizer.org), continuously selected children will be placed in the control group and the intervention group

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

Working Group/Committee of Ethics in Research of Iran University of Medical Sciences

Street address

Nursing and Midwifery Faculty, Rashid Yasmi St., Valiasr St.

City

Tehran

Province

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Postal code

1436944694

Approval date

2023-11-15, 1402/08/24

Ethics committee reference number

IR.IUMS.REC.1402.725

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium, not induced by alcohol and other psychoactive substances

Primary outcomes

1

Description

Delirium

Timepoint

5 minutes before the intervention - immediately after the intervention

Method of measurement

Cornell Assessment of Pediatric Delirium (CAPD)

Secondary outcomes

1

Description
Physiological Indicators
Timepoint
5 minutes before the intervention - immediately after the intervention
Method of measurement
Monitoring connected to the child

Intervention groups

1

Description
Intervention group: Foot Reflexology Massage- foot massage includes the steps of preparation, heating and relaxation. In the preparation phase, all children will be given towels and shampoo to wash their feet. The researcher will massage the hands together with a small amount of baby oil to make the soles of the feet slippery, while creating a suitable and even heat for the hand. The heating stage is actually a basic and general type of massage that is aimed at familiarizing the foot with the hands of the masseur. In the relaxation phase, the reflex points of the brain, pituitary, hypothalamus, heart, lungs, and solar plexus will be massaged on both feet for 10 minutes. This massage will be done on 2 consecutive days.
Category
Treatment - Other

2

Description
Control group: No intervention is received
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Asghar Children's Hospital
Full name of responsible person
Zahra Mazhary
Street address
Hazrat Ali Asghar Children's Hospital, Shahid Dastgardi Street (Zafar), after Mirdamad Bridge, Modares Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research and technology of Iran University of Medical Sciences
Full name of responsible person
Reza Falak
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Grant name
Deputy of research and technology of Iran University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research and technology of 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
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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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further 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
Not applicable
Data Dictionary
Not applicable