Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Investigation of aromatherapy massage with Mint and sweet almond oil effects on physiological parameters and sleep quality of traumatic brain injury patients admitted in intensive care units

Protocol summary

Study aim

Investigation of aromatherapy massage with Mint and sweet almond oil effects on physiological parameters and sleep quality of traumatic brain injury patients admitted in intensive care units

Design

This study is a clinical trial with two groups , single blinded and randomized, with 30 patients in each group.

Settings and conduct

This study will be performed in Shahid Bahonar Hospital in Kerman. In the intervention group, the intervention will include hand and foot massage with peppermint oil mixed with almond oil for 20 minutes for 3 consecutive days. blindness is single blind and the statistician is blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria:Level of consciousness according to the Glasgow Coma scale 12-15,Less than six months and more than 48 hours of hospitalization ,Patient age in the range of 15 to 65 years,Exclusion criteria:A sudden drop in the level of consciousness,Transfer to another hospital,Discharge before the fourth day,Death of patients in both intervention and control groups during the study,At the same time, the patient participates in similar care programs such as massage therapy,History of chronic disease (diabetes, cardiovascular disease, epilepsy and kidney disease) and endocrine disorders (Cushing's syndrome and hypo / hyperthyroidism),A history of sensorineural disorders, coma, or previous head injury,Evidence of increased intracranial pressure (ICP) and symptoms of fat embolism,Wounds, inflammation, infection, skin diseases and fractures in the massage areas

Intervention groups

In the intervention group, hand and foot massage with mint oil mixed with sweet almond oil will be performed for 20 minutes and three consecutive days. For the control group, Vaseline massage will be performed with the same methods and techniques.

Main outcome variables

physiological parameters and sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N12**
Registration date: **2020-11-01, 1399/08/11**
Registration timing: **prospective**

Last update: **2020-11-01, 1399/08/11**
Update count: **0**

Registration date

2020-11-01, 1399/08/11

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of aromatherapy massage with Mint and sweet almond oil effects on physiological parameters and sleep quality of traumatic brain injury patients admitted in intensive care units

Public title
The effect of aromatherapy massage with Mint and sweet almond oil on physiological parameters and sleep quality of traumatic brain injury patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Level of consciousness according to the Glasgow Coma scale 12-15 Less than six months and more than 48 hours of hospitalization Patient age in the range of 15 to 65 years
Exclusion criteria:
A sudden drop in the level of consciousness Transfer to another hospital Discharge before the fourth day Death of patients in both intervention and control groups during the study At the same time, the patient participates in similar care programs such as massage therapy History of chronic disease (diabetes, cardiovascular disease, epilepsy and kidney disease) and endocrine disorders (Cushing's syndrome and hypo / hyperthyroidism) A history of sensorineural disorders, coma, or previous head injury Evidence of increased intracranial pressure (ICP) and symptoms of fat embolism Wounds, inflammation, infection, skin diseases and fractures in the massage areas
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to assign the participants to the intervention and control groups, block allocation is used. In this method, 4 blocks are used, in each block there are two people in the intervention group and two people in the control group. R software is used for random block allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blindness in this study is single blind, so that the statistician is not aware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran
City
kerman
Province
Kerman
Postal code
7616913555
Approval date
2020-10-20, 1399/07/29
Ethics committee reference number
IR.KMU.REC.1399.424

Health conditions studied

1

Description of health condition studied
physiological parameters
ICD-10 code
ICD-10 code description

2

Description of health condition studied
sleep quality
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Heart rate
Timepoint
Heart rate will be measured before intervention, 5 minutes after intervention, one hour after intervention, 2 hours after intervention, 3 hours after intervention, 4 hours after intervention and for three consecutive days.
Method of measurement
Monitoring device

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Systolic blood pressure will be measured before intervention, 5 minutes after intervention, one hour after intervention, 2 hours after intervention, 3 hours after intervention, 4 hours after intervention and for three consecutive days.
Method of measurement
Monitoring device

2

Description
Diastolic blood pressure
Timepoint
diastolic blood pressure will be measured before intervention, 5 minutes after intervention, one hour after intervention, 2 hours after intervention, 3 hours after intervention, 4 hours after intervention and for three consecutive days.
Method of measurement
Monitoring device

3

Description
respiratory rate
Timepoint
Breathing will be measured before intervention, 5 minutes after intervention, one hour after intervention, 2 hours after intervention, 3 hours after intervention, 4 hours after intervention and for three consecutive days.
Method of measurement
Observed by the researcher

4

Description
Arterial blood oxygen saturation
Timepoint
Arterial blood oxygen saturation will be measured before intervention, 5 minutes after intervention, one hour after intervention, 2 hours after intervention, 3 hours after intervention, 4 hours after intervention and for three consecutive days.
Method of measurement
Monitoring device

5

Description
sleep quality
Timepoint
Sleep quality will be measured before the intervention and the fourth day
Method of measurement
Richard Campbell sleep questionnaire

Intervention groups

1

Description
Intervention group: In the intervention group, hands and feet will be massaged with mint oil(Noorhan Company) mixed with sweet almond(Noorhan Company) oil for 20 minutes. The intervention will be performed for 20 minutes for three consecutive days (ten minutes of hand massage and 10 minutes of foot massage with each hand and each foot for 5 minutes). Prior to the intervention, physiological parameter forms (including blood pressure, arterial blood oxygen saturation, heart rate, and respiration) and sleep quality questionnaire will be completed. The researcher will warm his hands. Then, he will spread 5 teaspoons of mint oil mixed with sweet almond oil on his hands. He will then rub the patient's hands from the wrists to the fingers and toes from the ankles to the toes with caressing movements. The massage will be done with pressure with the palm of the hand. In the first stage of foot massage, each groove between the tendons that connect the ankle to the toes will be slightly pressed using the thumb or other toe. In the second stage, the feet and heels will be massaged. In the third step, the toes will be pulled back and forth separately. In the fourth step, the thumb and another finger of the massager will be pulled on the toes in an outward direction (from the base to the tips of the toes). The hand massage will be done on both the palm and the back of the hand. In the first stage, pressure and movements from the wrist to the fingers will be performed with direct pressure and moderate intensity. In the second stage, a semicircular stretch from the center of the hand to the surroundings will be performed with medium pressure. In the third step, small circular motions around the arm will be performed with gentle pressure. The palm will then be massaged. Information on physiological parameters will be recorded five minutes after the intervention and every hour for four hours after the intervention. The intervention will be repeated for three consecutive days in each group. On the morning of the fourth day, after the intervention, the sleep quality questionnaire will be completed again.
Category
Other

2

Description
Control group: In the control group, massage with Vaseline(kanz brand)will be performed using the same techniques and methods as in the intervention group, and the same amount of oil used for the intervention group will be weighed and we will use Vaseline in proportion to the weight of the oil.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
the kerman shahid bahonar hospital
Full name of responsible person
Mehdi Ahmadinejad
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Web page address
http://kmu.ac.ir/fa/vcrt

Grant name

Grant code / Reference number

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

Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Batool Tirgari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available