

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Aromatherapy Massage With Mint Essential Oil on Level of Consciousness and Physiological Parameters of Patients with Traumatic Brain Injuries at Intensive Care Units

Protocol summary

Summary

The present study aimed to evaluate the effect of aromatherapy massage with mint essential oil on the level of consciousness and physiological parameters in patients with traumatic brain injuries. The study population included all patients admitted with a diagnosis of brain injury. Inclusion criteria: 8 to 12 level of consciousness based on non-response overview scale (FOUR); aged 18-40 years; hemodynamic stability; the absence of sensory disorders in patients. The sample consisted of 38 patients. Targeted sampling method was used to select eligible individuals by taking into account inclusive and exclusive criteria. The selected individuals were randomly assigned to control(19) and experimental(19) groups. In the experimental group, the patients underwent 20 minutes of massages on hands and feet with 4% diluted mint and sweet almond essential oils for three consecutive days. Nonaromatic oil massage was performed in the control group using the same techniques and procedures carried out in the intervention group. Expected outcomes include changes in the level of consciousness after the intervention and changes in physiological variables, including: HR, RR, o2 SAT and systolic and diastolic blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062622772N3**
Registration date: **2016-09-20, 1395/06/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-20, 1395/06/30

Registrant information

Name

Abbas Balouchi

Name of organization / entity

Zabol University of Medical science

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Recruitment status

Recruitment complete

Funding source

Vice Cancellor for research of Zabol University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Aromatherapy Massage With Mint Essential Oil on Level of Consciousness and Physiological Parameters of Patients with Traumatic Brain Injuries at Intensive Care Units

Public title

Effect of Massage With Mint Essential Oil on Level of Consciousness and Vital Signs in Patients with Brain Damages

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : 8 to 12 level of consciousness based on non-response overview scale (FOUR); less than six-month and more than 48-hour hospitalization; minimum age of 18 and maximum age of 40; no history of chronic disease (diabetes, cardiovascular disease, epilepsy and renal disease) and endocrine disorders (Cushing's syndrome and hypo/hyperthyroid); no history of sensory-nervous disorders, coma or previous head injury; no evidence of increased intracranial pressure (ICP) and symptoms of fat embolism; no evidence of drug addiction; absence of ulcers, inflammation, infection, skin diseases and fractures in the areas undergoing massage. Exclusion criteria: Transfer patients to other health centers; Deterioration of the patient's condition and the need for cardiopulmonary resuscitation.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Random sample assignment: Initially to create a random sequence, the coin toss method was used. In a manner that one of the study groups is considered tails and the other heads, the coin toss is repeated as many times as the sample volume (38 patients) and each member of group is assigned a random coin toss. Then to conceal any trace of random assignment, and to avoid any prediction of future assignment by researchers and participants, with respect to study's sample volume, a number of aluminum foiled envelopes (so that the contents are not visible) are readied and each of random sequences are recorded on a card, then the cards are put into the envelopes in order. To keep the random sequence the envelopes are also numbered in the same order. Finally the envelopes are sealed and put into boxes in order. At the registration, for each of participants who are eligible to enter the study, an envelope is opened in order of their entrance and their assigned group is revealed. The creation of random sequence and assignment concealment is performed by a non-researcher and a researcher who is not aware of sample conditions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zabol University of Medical Science

Street address

Shahid Rajae st-Research and technology Deputy of Zabol University of Medical science

City

Zabol

Postal code

9861663335

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

zbmu.1.REC.1394.130

Health conditions studied

1

Description of health condition studied

Traumatic brain injuries

ICD-10 code

S06.0, S06

ICD-10 code description

Intracranial injury

Primary outcomes

1

Description

Systolic Blood Pressure

Timepoint

Immediately before intervention and within 5 minute after intervention then at 1,2,3 and 4 hours after intervention.

Method of measurement

Monitoring devices

2

Description

Diastolic Blood Pressure

Timepoint

Immediately before intervention and within 5 minute after intervention then at 1,2,3 and 4 hours after intervention.

Method of measurement

Monitoring devices

3

Description

Heart Rate

Timepoint

Immediately before intervention and within 5 minute after intervention then at 1,2,3 and 4 hours after intervention.

Method of measurement

Monitoring devices, pulse oximetry

4

Description

Respiratory rate

Timepoint

Immediately before intervention and within 5 minute after intervention then at 1,2,3 and 4 hours after intervention.

Method of measurement

Observation chest in a minute

5

Description

Arterial Oxygen Saturation

Timepoint

Immediately before intervention and within 5 minute after intervention then at 1,2,3 and 4 hours after intervention.

Method of measurement

Monitoring devices, pulse oximetry

Secondary outcomes

1

Description

Level of consciousness

Timepoint

Immediately before intervention and within 5 minute after intervention then at 1,2,3 and 4 hours after intervention.

Method of measurement

FOUR scale

Intervention groups

1

Description

Experimental group: Aromatherapy massage with mint oil. Prior to intervention, the author warmed up his hands. Then, he spread 4% diluted mint oil and sweet almond oil on his hands and he rubbed the patients' hands from wrist to fingers and feet from ankles to toes with stroking movements. The massage was carried out as pressuring with the entire palm. Intervention lasted for 20 minutes for three consecutive days (10-minute hand massage and 10-minute foot massage).

Category

Treatment - Other

2

Description

Control group: Nonaromatic oil massage. Prior to intervention, the author warmed up his hands. Then, he spread sweet almond oil on his hands and he rubbed the patients' hands from wrist to fingers and feet from ankles to toes with stroking movements. The massage was carried out as pressuring with the entire palm. Intervention lasted for 20 minutes for three consecutive days (10-minute hand massage and 10-minute foot massage).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-AL-momenin hospital

Full name of responsible person

Safiyeh Taheri

Street address

beginning of the road of Zabol-Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Zabol University of Medical Science

Full name of responsible person

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Shahid rajaie ST- Research Deputy of Zabol University of Medical Science

City

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Zabol University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty