Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing The Effect Of Single And Combined Nature Based-Sound and Foot Reflexology On Level Of Consciousness And Physiological Indicatores Of Traumatic Comatose Patients

Protocol summary

Summary

Objective:The aim of present study is comparing the effect Of single and combined nature based sound and foot reflexology massag on level of consciousness and physiological indicatores of traumatic comatose patients 2) Design: The Study is a randomized clinical trial with both intervention group (Nature based sound ;Foot reflexology massage ;Combined nature based sound and foot reflexology massage)and control groupl .3) Setting and conduct: 120 traumatic comatose patiens admitted in the ICU of Hafte Tir and Rasool Akram hospitals in Tehran and Emam Hossein hospital in Shahrood and Kowsar hospital in Semnan will be randomly placed in the intervention group (Nature based sound ;Foot reflexology massage ;Combined nature based sound and foot reflexology massage)and control group4) Participants:Participants of this study are traumatic comatoes patients.5) Intervention: In the intervention group with sounds of nature, patients will listen to nature sounds through headphones twice a day for 30 minutes each morning and evening for 14 days. In the intervention group with foot reflexology massag,foot reflexology massag will do for patients twice a day for 30 minutes each morning and evening for14 days, In the intervention group with foot reflexology and nature sound,patients will receive both intervention(nature sound and foot reflexology) twice a day for 30 minutes each morning and evening for14 days. in The control group,patients will not receive any interventions.level of consciousness and apachi score for patients will be measured before and one week and two weeks after the study.Physiological indicatores will be measured during 5 to 10 minutes before intervention, immediately after the intervention, 25 to 30 minutes after the intervention, 2 hours after intervention.6) The primary outcome variable is level of consciousness and secondary outcome variable is physiological indicatores .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120125339N1**
Registration date: **2016-05-13, 1395/02/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-13, 1395/02/24

Registrant information

Name

Elahe Bahonar

Name of organization / entity

School of Nursing & Midwifery of Iran University

Country

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+98 912 532 1499

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Iran University of Medical Science

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-08-10, 1395/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing The Effect Of Single And Combined Nature Based-Sound and Foot Reflexology On Level Of Consciousness And Physiological Indicatores Of Traumatic Comatose Patients

Public title
Comparing The Effect Of Single and Combined Nature Based-Sound and Foot Reflexology On Level Of Consciousness And Physiological Indicatores Of Traumatic Comatose Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria include : Age Between 15 to 75 Years;Traumatic Comatose Patients with GCS Less Than 8;24 to 72 Hours After Admision At ICU;Lack of any brain injur;Lack of Hearing Impairment; ;Lack of Diabet And Arrhythmia;Lack of History Of Downing;Patients Undergoing Craniotomy and Propofol Will Be Enrolled In the Study 24 Hours After Craniotomy. Exclusion Criteria Include: Patients Who Do Not Tolerate The Procedure; If They Will Undergo Rapid Changes In Vital Signs ,Tachycardia(Heart Rate More Than 120), respiratory distress(Respiratory Rate More Than 24 Per Minute) Will Be Excluded From The Study.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not 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 and Health Services

Street address
Iran University Of Medical Sciences, Shahid Hemmat highway, Tehran, Iran

City
Tehran

Postal code

Approval date
2016-01-21, 1394/11/01

Ethics committee reference number
IR.IUMS.REC.1394 . 9311449001

Health conditions studied

1

Description of health condition studied
Trumatic Comatoes Patient

ICD-10 code
SO6.0،SO6.

ICD-10 code description
Injuries to the head

Primary outcomes

1

Description
level of consiosness

Timepoint
before intervention,one and two weeks after intervention

Method of measurement
glasco coma scale

Secondary outcomes

1

Description
Physiological Indicatores.

Timepoint
Physiological Indicatores will be measured during 5 to 10 minutes before intervention, immediately after the intervention, 25 to 30 minutes after the intervention, 2 hours after intervention.

Method of measurement
Check List

Intervention groups

1

Description
Intervention 1: In the intervention group with sounds of nature, patients will listen to nature sounds through headphones twice a day for 30 minutes each morning and evening for 14 days

Category
Rehabilitation

2

Description
Intervention 2: In the intervention group with foot reflexology massag,foot reflexology massag will do for patients twice a day for 30 minutes each morning and evening for14 days,
Category
Rehabilitation

3

Description
Intervention 3: In the intervention group with foot reflexology and nature sound,patients will receive both intervention(nature sound and foot reflexology) twice a day for 30 minutes each morning and evening for14 days
Category
Rehabilitation

4

Description
Control group: in The control group,patients will not receive any interventions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafte Tir
Full name of responsible person
Elahe Bahonar
Street address
Haftom Tir hospital, Rajaee st, Rey City,Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Elahe Bahonar
Street address
Rasol Akram Hospital, Niayesh st, Sattarkhan st,Tehran
City
Tehran

3

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Elahe Bahonar
Street address
Amin Blvd,Kowsar hospital,Semnan
City
Semnan

4

Recruitment center
Name of recruitment center
Emam Hossein Hospital
Full name of responsible person
Elahe Bahonar
Street address
Emam KHomeini Square، Emam St، Emam Hossein Hospital
City
SHahrood

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Iran University Of Medical Science
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
Iran University of Medical Sciences, Shahid Hemmat highway, Tehran
City
Tehran
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, Iran 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
School of Nursing & Midwifery of Iran University
Full name of responsible person
Elahe Bahonar
Position
Post Graduate Student in Nursing
Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

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