

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of Dyang's sensory stimulation and foot reflexology on the level of consciousness and physiological indicators in patients with disorders of consciousness

Protocol summary

Study aim

Determining the effect of Dyang's sensory stimulation and reflex foot massage on the level of consciousness and physiological indicators in patients with consciousness disorders

Design

A double-blind clinical trial with a control group and parallel groups has been randomized

Settings and conduct

In one group, foot reflex massage and in the other group, Dyang's sensory stimulation is performed for one week. The control group receives usual hospital care. Glasgow coma scale, physiological indicators at the beginning of the study and one week after the intervention with time intervals. Two hours after the last intervention, it will be done simultaneously in the intervention and control groups.

Participants/Inclusion and exclusion criteria

Age 18-65 Admission to ICU for more than 3 days
Consciousness level 3-7 based on the Glasgow Coma Scale in neurosurgery and neurological patients such as head trauma, stroke, cerebral hemorrhage, lesions and brain tumors Connection to the ventilator Absence of broken limbs Non-diagnosis of peripheral neuropathy, neuromuscular disorders, skin disorders and sensory disorders in the organs based on the relevant expert's opinion Not having vision and hearing disorders No history of drug addiction Not receiving frequent sedatives and induced coma at the time of the intervention until two hours later Not receiving narcotic drugs during the intervention until two hours later

Intervention groups

For intervention groups A and B, Dyang's sensory stimulation and foot reflex massage will be performed for one week and twice a day, respectively. The control group will receive usual hospital care.

Main outcome variables

level of consciousness; Physiological indicators (heart rate, breathing rate, systolic and diastolic blood pressure, temperature and percentage of oxygen saturation)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059339N1**

Registration date: **2023-09-11, 1402/06/20**

Registration timing: **prospective**

Last update: **2023-09-11, 1402/06/20**

Update count: **0**

Registration date

2023-09-11, 1402/06/20

Registrant information

Name

Fatemeh Asgari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5558 9392

Email address

fatimaasgari915@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-14, 1402/12/24

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Dyang's sensory stimulation and foot reflexology on the level of consciousness and physiological indicators in patients with disorders of consciousness

Public title
Comparison of Dyang's sensory stimulation and foot reflexology on the level of consciousness and physiological indicators in patients with disorders of consciousness

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-65 Admission to ICU for more than 3 days
Consciousness level 3-7 based on the Glasgow coma scale (50) in neurosurgery and neurological patients such as head trauma, stroke, cerebral hemorrhage, lesions and brain tumors Connection to the ventilator Absence of broken limbs Non-diagnosis of peripheral neuropathy, neuromuscular disorders, skin disorders and sensory disorders in the organs based on the relevant expert's opinion Not having vision and hearing disorders No history of drug addiction Not receiving frequent sedatives and induced coma at the time of the intervention until two hours later Not receiving narcotic drugs during the intervention until two hours later
Exclusion criteria:
The lack of consent of the patient's companions to continue participating in the research Discharge during intervention implementation process Transfer to another hospital death of the patient Performing surgery during intervention

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are made in blocks of four and six using Sealed Envelope Ltd software. 2017 available through www.sealedenvelope.com are assigned to three groups (two intervention groups and one control 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

Ethics Committee of the Faculty of Nursing and Midwifery, Kashan University of Medical Sciences

Street address

Kashan, Qotbe Ravandi Blvd., Nurse St., Kashan University of Medical Sciences, Faculty of Nursing and Midwifery

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2023-07-30, 1402/05/08

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.104

Health conditions studied

1

Description of health condition studied

patients with consciousness disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of consciousness and physiological indicators

Timepoint

At the beginning of the study and 7 days after the intervention

Method of measurement

Glasgow Coma Scale and Saadat Monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: foot reflexology

Category

Treatment - Other

2**Description**

Intervention group: Dyang's sensory stimulation

Category

Treatment - Other

3**Description**

Control group: Routine hospital care

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Fatemeh Asgari

Street addressIran, Kashan, Qotb Ravandi Blvd., Nurse St., Kashan
University of Medical Sciences, Faculty of Nursing and
Midwifery**City**

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

fatimaasgari915@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street addressIran, Kashan, Qotb Rawandi Blvd., Nurser St., Kashan
University of Medical Sciences, Research and
Technology Vice-Chancellor**City**

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

hamidi_gh@kaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Asgari

Position

Training instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street addressSchool of Nursing and Midwifery, Kashan university of
medical sciences, Parastar St., Qotbe Ravandi Blv,
Kashan, Iran**City**

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

fatimaasgari915@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Neda Mirbagher

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

salam_20012003@yahoo.co.uk

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Asgari

Position

Training instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

009855540021

Email

fatimaasgari915@gmail.com

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

Data of participants are confidential

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