

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of Swedish massage on anxiety, sleep quality and muscle strength on conscious patients admitted to intensive care units of Khatam Al-Anbia Hospital in Iranshahr during 2021

Protocol summary

Study aim

Investigating the effect of Swedish massage on anxiety, sleep quality and muscle strength on conscious patients

Design

The clinical trial with intervention and control groups, with parallel, non-blind, randomized groups will be performed on 60 patients. Block random allocation was used for randomization.

Settings and conduct

This research will be performed in the medical center of Khatam al-Nabia Hospital in Iranshahr. Prior to the intervention, the patient's background profile form will be completed by the researcher using the patient's file. Also, the Anxiety, Sleep Quality Interview Questionnaire and Muscle Strength Questionnaire using the relevant checklist will be completed at the beginning of the study and one week after the intervention. The patient's vital signs and state of consciousness and medications are checked and recorded daily.

Participants/Inclusion and exclusion criteria

Conditions of entry: age over 18, no fracture of upper and lower limbs, no amputation of any limb, no sensitivity to olive oil. Conditions of non-admission: transfer to the ward in less than the first 8 days of hospitalization, violation of the mentioned admission criteria and samples who did not receive a maximum of 2 days of intervention.

Intervention groups

Massage group: In this group, the patient will be lying on his back with a head angle of 30-45 degrees. Then olive oil (10 cc) will be used for massage. The Swedish massage will be performed once a day for 30-60 minutes each time for seven consecutive days. Sham group: In this group, in addition to routine care, the whole body will be under simple touch. In such a way that a simple touch will be done once a day for 30-60 minutes each time for seven consecutive days.

Main outcome variables

Anxiety; sleep quality; Muscle strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211124053171N1**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

saymeh mazarzai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3722 5140

Email address

s.mazarzai@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of Swedish massage on anxiety, sleep quality and muscle strength on conscious patients admitted to intensive care units of Khatam Al-Anbia Hospital in Iranshahr during 2021

Public title
Investigating the effect of Swedish massage on anxiety, sleep quality and muscle strength on conscious patients admitted to intensive care units

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years No fractures of the upper and lower limbs Absence of neuromuscular diseases (Guillain-Barre syndrome and myasthenia gravis and botulism poisoning and pesticides, etc.) No vascular disorders such as DVT Four Score score thirteen and above Do not amputate any of the limbs No skin disease Lack of sensitivity to olive oil Lack of chest tube Absence of coagulation disorders
Exclusion criteria:
 Transfer to the ward in less than the first eight days of hospitalization Four Score drops to less than 13 Create any of the disorders listed in the inclusion criteria Samples that do not answer 20% of the questionnaire questions Samples that have not received a maximum of 2 days of intervention

Age
From **18 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 that meet the inclusion criteria will be included in the study by available sampling method and then will be assigned to the intervention and sham groups using block random allocation. The selection of blocks is based on individual characteristics.

Blinding (investigator's opinion)
Not blinded

Blinding description

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

campus of Kerman University of Medical Sciences, The beginning of Haft Bagh Alavi axis

City

Kerman

Province

Kerman

Postal code

76169-13555

Approval date

2021-11-08, 1400/08/17

Ethics committee reference number

IR.KMU.REC.1400.493

Health conditions studied

1

Description of health condition studied

Patients admitted to the intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in Beck questionnaire

Timepoint

At the beginning of the study (before the intervention) and one week after the intervention

Method of measurement

Beck Anxiety questionnaire

2

Description

Sleep quality score in Spider-Halpern questionnaires

Timepoint

At the beginning of the study (before the intervention) and one week after the intervention

Method of measurement

Spider-Halper sleep quality questionnaire

3

Description

Muscle strength score on the MRC-SS scale

Timepoint

At the beginning of the study (before the intervention) and one week after the intervention

Method of measurement

MRC-SS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention will start from the second day of hospitalization and in this group, in addition to routine care, the whole body will be massaged. The method of massage in the intervention group is that first the mattress is placed so that the patient's mattress is not soaked in oil and the patient is given a position. Massage in such a way that the patient will be placed in a supine position with a head angle of 30-45 degrees and the coverage of the massage area will be removed and other parts of the body will be covered, and then after examining the whole body for massage prohibition, Do not have vascular disorders such as deep vein thrombosis (DVT) and fractures of the lower and upper limbs and skin diseases, wounds, infections, allergies to olive oil, in the absence of massage problems that include caressing movements, nodding, shaking and Exercises will be performed from 4 to 8 pm when the ward is more secluded and has less workload and patients are getting ready for bedtime. To perform the massage, olive oil will be used to the extent that it makes it slippery and easy to massage (10 cc). The Swedish massage will be performed once a day for 30-60 minutes each time for seven consecutive days. Swedish massage will be performed continuously with caressing and nodding movements, shaking and exercises on the upper and lower limbs and back, chest. After the massage, the patient's body will be cleaned with a towel to remove the remaining oil from the patient's body. The massage will be performed by the researcher himself / herself for female samples and also by the researcher colleague for male samples, both of whom will be trained in Swedish massage by a physiotherapist and will gain the necessary mastery in this procedure.

Category

Rehabilitation

2

Description

Control group: In this group, in addition to routine care, the whole body will be under simple touch. The method of touching in the sham group is that the patient is first given a position. The patient will be placed lying on his back with a head angle of 30-45 degrees and the coverage of the affected area will be removed and other parts of the body will be covered. If there is no touch problem will be done. A simple touch will be done once a day for 30-60 minutes each time for seven consecutive

days. Simple touch on the upper and lower limbs and back, chest will be done continuously.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al-Anbia Hospital in Iranshahr

Full name of responsible person

saima mazarzahi

Street address

Razi School of Nursing and Midwifery, Kerman
University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Mahlagha Dehghan

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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

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
Saymeh Mazarzai
Position
Student
Latest degree
Bachelor
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