Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of simple and hot stone slow-stroke back massage on pain, anxiety and sleep quality after surgery: A randomized clinical trial study

Protocol summary

Study aim
Determining the effect of simple back stroke massage and with hot stones on the amount of pain, anxiety and sleep quality after surgery

Design
Clinical trial with control group, with parallel groups, single-blind, randomized, on 99 patients. Random allocation software will be used for randomization.

Settings and conduct
Study place: hospitals affiliated to Mashhad University of Medical Sciences in Mashhad that have surgical departments (Imam Reza, Qaim,....). Design: clinical trial with control group, with parallel groups, single-blind, randomized, on 99 patients. Random allocation software will be used for randomization. The analyzer is not aware of groups.

Participants/Inclusion and exclusion criteria
People age between 18 and 75 years old that having an orthopedic surgery that can tolerate the massage position (orthopneic) or recovery without increasing pain. Withdrawal from continuing cooperation, patient discharge, Change of condition and critical condition of the patient.

Intervention groups
One group will receive simple superficial back stroke massage and one group will receive hot stone massage. In the control group, patients receive the usual hospital care and education.

Main outcome variables
Pain, anxiety, sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211023052847N2**
Registration date: **2023-01-17, 1401/10/27**
Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**
Update count: **0**

Registration date
2023-01-17, 1401/10/27

Registrant information

Name
seyedeh zahra aemmi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3741 2080

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aammiz1@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-05, 1401/11/16

Expected recruitment end date
2024-02-05, 1402/11/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of simple and hot stone slow-stroke back massage on pain, anxiety and sleep quality after surgery: A randomized clinical trial study

Public title

The effectiveness of simple and hot stone slow-stroke back massage on pain, anxiety and sleep quality after surgery: A randomized clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 75 years old Having an orthopedic surgery that can tolerate the massage position (orthopneic) or recovery without increasing pain. Not using massage in the last three months. Non-use of sleeping pills, benzodiazepines, sedatives and narcotics by the patient, other than painkillers prescribed by the doctor. Absence of severe neuropathy in the patient Being healthy and not having wounds or skin disease or surgery in the back area Obtaining permission from the patient's doctor. Not suffering from mental retardation and mental illnesses, lack of cognitive, emotional or verbal impairment. Not suffering from another acute disease that causes pain and anxiety. No history of arthritis, joint rheumatism or joint diseases in the shoulder and back area. Having full consciousness and the ability to communicate verbally and visually and the ability to speak, read and write.

Exclusion criteria:

Withdrawal from continuing cooperation Patient discharge Change of condition and critical condition of the patient

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

By random allocation software, they are divided into three groups: simple back massage, hot stone and control

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyzer will not know about the groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Daneshgah

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-10-30, 1401/08/08

Ethics committee reference number

IR.MUMS.REC.1401.310

Health conditions studied

1

Description of health condition studied

Patients after orthopedic surgery

ICD-10 code

ICD-10 code description

orthopedic

Primary outcomes

1

Description

Pain

Timepoint

Before the intervention and again half an hour after the intervention, the pain questionnaires will be completed for all three groups.

Method of measurement

Pain (Visual Analogue Scale)

2

Description

Anxiety

Timepoint

Before the intervention and again half an hour after the intervention, the anxiety questionnaires will be completed for all three groups.

Method of measurement

Anxiety (Spielberger state and trait Anxiety Questionnaire)

3

Description

Sleep quality after surgery

Timepoint

Before the intervention and again the day after the

intervention, the sleep quality questionnaires will be completed for all three groups.

Method of measurement

Sleep quality (Pittsburgh Sleep Quality Index)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A simple back stroke massage will be performed by a nurse skilled in this field on the first or second day after the surgery, in the morning and in the afternoon, for 10-15 minutes each time.

Category

Treatment - Other

2

Description

Intervention group: A hot stone massage will be performed by a nurse skilled in this field on the first or second day after the surgery, in the morning and in the afternoon, for 10-15 minutes each time.

Category

Treatment - Other

3

Description

Control group: Patients receive usual hospital care and education.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals of Mashhad University of Medical Sciences in Mashhad that have surgical departments (Imam

Full name of responsible person

Seyedeh Zahra Aemmi

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Ibn Sina

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9137913199

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-Mobarhan

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Aemmi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Article publish

When the data will become available and for how long

Unlimited

To whom data/document is available

Researcher

Under which criteria data/document could be used

Use by researchers

From where data/document is obtainable

Database

What processes are involved for a request to access data/document

Email to the author

Comments