Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effects of massage therapy and transcutaneous electrical nerve stimulation (TENS) on anxiety, fatigue and sleep quality of patients undergoing coronary artery bypass graft

Protocol summary

Study aim
Comparing the effect of massage therapy and transcutaneous electrical nerve stimulation (TENS) on anxiety, fatigue and sleep quality of patients undergoing coronary artery bypass surgery

Design
A clinical trial on 126 patients candidates for CABG surgery with a control group, double blind and randomized in a block of 6

Settings and conduct
This study is conducted on patients who are candidates for CABG surgery in Imam Hossein (AS) Shahrood Hospital. Massage techniques or TENS will be performed on the second to fourth days after CABG. Then the quality of sleep, fatigue and anxiety of the patients will be evaluated on the morning of the fifth day by an evaluation that is blind to the type of interventions and groupings.

Participants/Inclusion and exclusion criteria
Inclusion: Patients undergoing CABG surgery No previous use of alcohol, sedative and anti-anxiety drugs or narcotics Not using complementary medicine methods during the previous three months Absence of wounds, phlebitis, trauma and arthritis in the massage area exclusion: Previous diagnosis of sleep disorders Loss of consciousness and need for mechanical ventilation more than 24 hours after surgery Contraindications to TENS use such as pregnancy, epilepsy and skin disorders in the area where the electrodes are used Patients with severe communication disorder and unstable vital signs

Intervention groups
In the massage group, after the operation, classical massage will be performed for 30 minutes for each patient. In the TENS group, after the operation, TENS with a frequency of 60 Hz, an electric current of 4 to 7 mA and a pulse duration of 0.25 milliseconds will be performed for 30 minutes for each patient. In the control group, patients will only receive the standard care of the department.

Main outcome variables
sleep quality fatigue anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200206046395N4**
Registration date: **2024-06-15, 1403/03/26**
Registration timing: **prospective**

Last update: **2024-06-15, 1403/03/26**
Update count: **0**

Registration date
2024-06-15, 1403/03/26

Registrant information

Name
Mobin Mottahedi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-12, 1403/04/22

Expected recruitment end date
2025-07-13, 1404/04/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of massage therapy and transcutaneous electrical nerve stimulation (TENS) on anxiety, fatigue and sleep quality of patients undergoing coronary artery bypass graft

Public title

Comparing the effects of massage therapy and transcutaneous electrical nerve stimulation (TENS) on anxiety, fatigue and sleep quality of patients undergoing coronary artery bypass graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing CABG surgery No previous use of alcohol, sedative and anti-anxiety drugs or narcotics Not using complementary medicine methods during the previous three months Absence of wounds, phlebitis, trauma and arthritis in the massage area

Exclusion criteria:

Previous diagnosis of sleep disorders Loss of consciousness and need for mechanical ventilation more than 24 hours after surgery Contraindications to TENS use such as pregnancy, epilepsy and skin disorders in the area where the electrodes are used Patients with severe communication disorder and unstable vital signs

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

In the beginning, all the modes in which 3 letters A, B and C can be put together in a block of 6 are produced and a block is selected randomly and by placing among the blocks.The layout pattern in that block is used to allocate patients

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the study, it is not possible to blind the study participants. However, measures were taken in collecting information. After the intervention, the person collecting the information will not know the type of the participants' group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrood University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Haft Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

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Approval date

2024-06-02, 1403/03/13

Ethics committee reference number

IR.SHMU.REC.1403.043

Health conditions studied

1

Description of health condition studied

Chronic ischaemic heart disease, unspecified

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description

sleep quality

Timepoint

First, on the second day after the operation (before the intervention), the sleep quality of the patients will be evaluated. Then, after the end of the intervention period, on the morning of the fifth day after the operation, the quality of sleep will be evaluated again

Method of measurement

Richards–Campbell Sleep Questionnaire (RCSQ)

Secondary outcomes

1

Description
Anxiety
Timepoint
First, on the second day after the operation (before the intervention), the patients' anxiety will be evaluated. Then, after the end of the intervention period, on the morning of the fifth day after the operation, anxiety will be evaluated again
Method of measurement
The State-Trait Anxiety Inventory (STAI)

2

Description
Fatigue
Timepoint
First, on the second day after the operation (before the intervention), the fatigue of the patients will be evaluated. Then, after the end of the intervention period, on the morning of the fifth day after the operation, fatigue will be assessed again
Method of measurement
The multidimensional fatigue inventory (MFI-20)

Intervention groups

1

Description
intervention group: In the massage group, the classic massage procedure will be applied to the patient's hands without using any special equipment and will include the combination of 3 therapeutic massage methods: kneading, friction and petrissage. Massage will be done on both hands for 30 minutes, i.e. 15 minutes on each hand.
Category
Treatment - Other

2

Description
Intervention group: In the TENS group, the electrodes will be placed in the PC7 and LI4 regions. TENS with a frequency of 60 Hz, an electric current of 4 to 7 milliamp and a pulse duration of 0.25 milliseconds will be used for 30 minutes, so that the stimulation effect does not cause discomfort and muscle contraction in the patient.
Category
Treatment - Other

3

Description
Control group: In the control group, standard and routine care will be performed in the inpatient department after CABG surgery.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein (AS) Shahroud Hospital
Full name of responsible person
Mobin Mottahedi
Street address
Imam Hossein (AS) Shahrood Hospital, Imam St., at the end of 28 meters of Ayat A... Tawhidi, Shahrood
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Hossein Bagheri
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info@shmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Mobin Mottahedi

Position
Non-faculty instructor

Latest degree
Master

Other areas of specialty/work
Others

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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
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available