

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparing the effect of acupressure and reflexology on sleep condition in the patient after coronary artery bypass graft surgery

Protocol summary

Study aim

Comparison of the effect of foot reflexology massage with acupressure on patients' sleep after coronary artery bypass graft

Design

Patients are divided into 3 groups of 20 Acupressure and Reflexology and Control Using random numbers provided with computer software and Permuted Block Randomization By the Statistics Advisor, they will be randomly assigned. 10 blocks that has 6 member. In each block, there are 2 people from each group.

Settings and conduct

The intervention begins on the third night after the operation and 4 consecutive nights around 19-21 o'clock 2 to 3 hours before bedtime for the intervention group do Foot massage and acupressure. On the third to seventh day after the operation, the sleep quality questionnaire is completed again. The location of the study is Imam Reza Hospital in Mashhad.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The age of adults over 18 years of age, those undergoing coronary artery bypass grafting, their vital signs are stabilized (blood pressure, temperature, pulse, respiration), lack of communication problems Hearing impairment, vision or speech, not using anti-depressant drugs and antihistamines, Exclusion criteria: infection or ulcer in the palms of the feet, hands and forehead, amputation of the extremities, replacement or repair of the valve.

Intervention groups

The intervention begins on the third night after the operation and 4 consecutive nights 2 to 3 hours before bedtime. In reflexology group 5 minutes general massage and 10 minutes of specialized massage is done for each foot. in acupressure 7 points are stimulated that for every point 5 seconds pressure and 1 second rest until it reaches 3 minutes. The whole intervention takes 21 minutes. In control group, only applying ointment to feet is done.

Main outcome variables

sleep condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110906007494N29**

Registration date: **2019-06-06, 1398/03/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-06, 1398/03/16**

Update count: **0**

Registration date

2019-06-06, 1398/03/16

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effect of acupressure and reflexology on sleep condition in the patient after coronary artery bypass graft surgery

Public title
the effect of acupressure and reflexology on sleep condition in the patient has heart surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The age of adults over 18 years of age Do coronary artery bypass graft surgery
Exclusion criteria:
 Drug use Having communication problems (hearing impairment, vision or speech) Having severe neuropathy in the patient Having valve replacement or repair Having infection or ulcer on the soles of the feet, hands and forehead Having history of acute arthritis or rheumatoid arthritis End extremities amputation Using antidepressants and antihistamines Their vital signs have not been stabilized (blood pressure, temperature, pulse, respiration)

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
Patients eligible for 3 groups of 20 people of acupressure and reflexology and control Using random numbers provided with computer software and Permuted Block Randomization By the Statistics Advisor, they will be randomly assigned.10 blocks that has 6 member. In each block, there are 2 people from each 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 Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.MAZUMS.REC.1398.050

Health conditions studied

1

Description of health condition studied

sleep condition

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sleep condition

Timepoint

determination sleep condition at third day after surgery and at fourth until seventh day after surgery in control and massage group

Method of measurement

SMHSQ questionnaire (St. Marys Hospital Sleep Questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Foot reflexology massage will be done for 30 minutes (15 minutes each foot)5 minutes general massage and 10 minutes special massage. for every person from third day after surgery started and continued for 4 nights.

Category

Lifestyle

2

Description

Intervention group: acupressure performed on 7 point of body like forehead, radial, ulnar, solar plexus with 3 to 5 kg pressure for 5 seconds pressure and 1 seconds relax until it reaches 3 minutes. it takes 21 minutes for 4 consecutive nights.

Category

Lifestyle

3

Description

Control group: Not done any massage or acupressure

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital of Holy Mashhad

Full name of responsible person

Seyed Milad Hoseini Matankolaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

University researches Assistance

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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

Sari 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Bagheri Nasami

Position

Ph.D. Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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