Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of foot reflexology massage on the rate of well-being and death anxiety in patient undergoing CABG

Protocol summary

Study aim
The effect of foot reflexology massage on the level of well-being and death anxiety in patients undergoing coronary artery bypass graft surgery

Design
66 patients were randomly assigned into two groups of 33 in a randomized massage and control group based on the Permuted Block Randomization computer program.

Settings and conduct
Foot reflex massage will be performed for 15 minutes from the second to the fourth day for 15 consecutive days.Massage is not performed for the control group, and the death anxiety questionnaire and the instrument of feeling well on the day before the operation and the fourth day after the operation are always filled with the intervention group. The study site is Fatemeh Zahra Hospital in Sari.

Participants/Inclusion and exclusion criteria
People over 18 years old, those undergoing coronary artery bypass surgery only, no pulmonary drainage and discharge more than 200 cc / h, their vital signs stabilized, no drainage Left ventricle less than 35%, no communication problems, no drug and alcohol use, no psychiatric treatment, no anxiety, depression and antihistamine 4 hours before Intervention, absence of severe neuropathy in the patient, absence of infection or ulceration of the feet, absence of extremity amputation،No history of arthritis or joint rheumatism, no valve replacement or repair, no need for intra-aortic pump balloons and no intubation for more than 24 hours,No previous experience of massage or acupuncture during the past 3 weeks, score above 45 on the Templar Death Anxiety Questionnaire

Intervention groups
For the intervention group, the reflective foot massage includes the general massage technique, which lasts about 5 minutes, and the specialized massage of the toe joints, which lasts 10 minutes. For the control group, the massage is not performed.

Main outcome variables
Death anxiety and feeling good

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N32**
Registration date: **2020-08-10, 1399/05/20**
Registration timing: **prospective**

Last update: **2020-08-10, 1399/05/20**
Update count: **0**

Registration date
2020-08-10, 1399/05/20

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-08, 1399/06/18

Expected recruitment end date
2021-01-08, 1399/10/19

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on the rate of well-being and death anxiety in patient undergoing CABG

Public title

The effect of foot reflexology massage on the rate of well-being and death anxiety in patient undergoing CABG

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and above Candidates for coronary artery bypass graft surgery Lack of pulmonary drainage and discharge more than 200 cc per hour Their vital signs are stable (blood pressure, temperature, pulse, respiration) No left ventricular ejection fraction less than 35% No communication problems (hearing, vision or speech disorders) Non-use of drugs and alcohol Lack of treatment for mental illness Do not take antihistamines, antidepressants or antihistamines 4 hours before the intervention Absence of severe neuropathy in the patient Absence of infection or sores on the soles of the feet No limb amputation No history of osteoarthritis or rheumatoid arthritis No valve replacement or repair No need for intra-aortic pump balloons and no intubation for more than 24 hours Lack of previous experience in massage or acupuncture during the last 3 weeks Get a score of 45 or higher from the Templer Death Anxiety Questionnaire, which indicates the presence of death anxiety

Exclusion criteria:

The patient's unwillingness to cooperate during the research The critical condition of the patient and the patient's return to the operating room The need to take antidepressants, antidepressants, and antihistamines while studying Death of the patient

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: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients are divided into two groups of 33 interventions and witnessed by random numbers provided with computer software and Permuted Block Randomization under the guidance of a statistical consultant. 66 envelopes have been designed in which the letters A (reflexology group) and B (control group) are embedded according to a computer program, and the envelopes from number one to 66 are prepared on the envelopes. He enters and has the criteria for admission. After obtaining written written consent, he enters the study and the sampling continues until patient number 66.

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

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

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2020-03-08, 1398/12/18

Ethics committee reference number

IR.MAZUMS.REC.1398.1394

Health conditions studied

1

Description of health condition studied

Well_being and death anxiety in patient undergoing CABG

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Well_being

Timepoint

For the intervention and control group, on the day before the operation and on the fourth day after the operation

Method of measurement

Subjective Well-being

2

Description
Death anxiety
Timepoint
For the intervention and control group, on the day before the operation and on the fourth day after the operation
Method of measurement
Templer questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Foot reflexology massage will be done for 30 minutes(15 minutes per foot) from the evening of the second day after the operation for 3 consecutive days (the second to the fourth day after the operation) using Firooz baby oil, made by Firooz company with number (ISO 9001 ISO 14001 OHSAS 18001) will be performed for each person.
Category
Lifestyle

2

Description
Control group: Do not get any massage
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Hospital in Sari
Full name of responsible person
Atieh Kalbadi Nejad
Street address
Juibar tree way,Mazandaran University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.Masoumeh Bagheri Nesami
Position
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Other areas of specialty/work

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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

no more 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