Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of foot reflexology on anxiety and physiological parameters in patient under coronary artery bypass graft surgery referred to Dr.Heshmat educational and remedial center in Rasht, 2020

Protocol summary

Study aim
Determining the effect of foot reflexology massage on anxiety and physiological parameters in patients under coronary artery graft surgery in Rasht, 2020.

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 66 patients. For randomization, block randomization method and the 2019 online randomization service was used.

Settings and conduct
The present study was performed at Dr. Heshmat Hospital in Rasht on patients undergoing coronary artery bypass graft surgery. On the first day of the patient's transfer to the cardiac surgery department, after obtaining his consent, anxiety levels and physiological indicators were measured in all three groups of test, control and placebo. The study is two-course and the person allocating the samples in the groups and the analyst are not aware of the placement of the samples in the groups.

Participants/Inclusion and exclusion criteria
Age: 20-80 years old; candidate for open heart surgery; full awareness; having a healthy lower limb

Intervention groups
Group A: foot reflexology massage of the important points of the sole of each foot for 15 minutes. Group B: Heel massage superficially without any pressure. Group C: No intervention on them

Main outcome variables
Anxiety level and physiological parameters (systolic, diastolic blood pressure, heart rate, respiration rate and arterial oxygen saturation percentage)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080825001083N10**
Registration date: **2020-05-29, 1399/03/09**
Registration timing: **prospective**

Last update: **2020-05-29, 1399/03/09**
Update count: **0**

Registration date
2020-05-29, 1399/03/09

Registrant information

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Majid Pourshaikhian

Name of organization / entity
Guilan University of Medical Sciences and Health Services

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-04, 1399/03/15

Expected recruitment end date
2020-10-06, 1399/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of foot reflexology on anxiety and physiological parameters in patient under coronary artery bypass graft surgery referred to Dr.Heshmat educational and remedial center in Rasht, 2020

Public title
The effect of foot reflexology on anxiety and physiological parameters in patient under coronary artery bypass graft

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient satisfaction to participate in the study Candidate of non-emergency open heart surgery Full awareness Having a healthy limb (especially the soles of the feet)

Exclusion criteria:
No history of open heart surgery No history of mental health problems, such as depression, according to medical history reports No heart pacemaker No alcohol or drug abuse No history of chronic pain Lack of previous history of reflexology Lack of visual and auditory disorders Do not take analgesic or sedatives for 3 h. before the intervention No history of mitral valve replacement or regurgitation Absence of the disorder during open heart surgery or recovery or hospitalization that has also affected the patient's anxiety Lack of a history of various psychological changes that have a significant impact on the results of anxiety levels in the patient.

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible individuals will be divided into three groups of foot reflexology massage, routine massage, and control using block-randomized sized six-block blocking. In order to produce the randomization list, the 2019 online randomization service (the Sealed Envelope Ltd) was used: https://www.sealedenvelope.com/simple-randomiser/v1/lists

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the present study, the double-blind method was used. Thus, the analyst and the person allocating the samples (to three groups A, B and C) do not know the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Opposite to 17 Shahrivar Hospital, Sayadati St., Namjoo St. Tel: 33336394

City
Rasht

Province
Guilan

Postal code
41446-66949

Approval date
2020-05-06, 1399/02/17

Ethics committee reference number
IR.GUMS.REC.1399.041

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Graft surgery

ICD-10 code
I25

ICD-10 code description
Ischemic Heart Disease

Primary outcomes

1

Description
Anxiety level in Spielberger's questionnaire

Timepoint
At the beginning of the study (before the intervention) and 10 minutes after the foot reflexology massage

Method of measurement
Spielberger's questionnaire

2

Description
Physiological parameters (systolic, diastolic blood pressure, heart rate, respiration rate and arterial oxygen saturation percentage)

Timepoint
Measurement of physiological parameters at the

beginning of the study (before the intervention) and 10 minutes after the reflex floor massage

Method of measurement

Monitoring system of vital signs made in Iran and Sazegar Gostar Company, VISTA model

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (A): Foot Reflexology massage. Before the massage, the researcher first washes his hands with warm water and smears them with sweet almond oil. He then massages the entire sole of the foot with special attention to the important reflection points of the sole of the foot. This intervention is performed for each leg for 15 minutes. First the right leg and then the left leg, which takes a total of 30 minutes. 10 minutes after the intervention, the consequences of the intervention (anxiety level and physiological parameters) are recorded.

Category

Treatment - Other

2

Description

Intervention group (B) or placebo group: Heel massage is performed superficially in patients without any pressure. 10 minutes after the intervention, the consequences of the intervention (anxiety level and physiological parameters) are recorded.

Category

N/A

3

Description

Control group (C): On the third day after coronary artery graft and after transfer to the surgical ward, the level of anxiety and physiological parameters are measured, without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Heshmat hospital

Full name of responsible person

Mehri Shahidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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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

Rasht University of Medical Sciences

Proportion provided by this source

50

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
Rasht University of Medical Sciences
Full name of responsible person
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Position
Assistant professor
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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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All study data can be shared after the samples are not identifiable.
When the data will become available and for how long
Immediately after the publication of the study results
To whom data/document is available
Data will be available to researchers working in academic and scientific institutions as well as health system managers.
Under which criteria data/document could be used
Send a request to the corresponding author's email address for accessing the study data.
From where data/document is obtainable
Corresponding author's email, Maji Pourshaikhian: pourshaikhian_m@yahoo.com
What processes are involved for a request to access data/document
Up to one week after sending the request to the email
Comments