

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Majid Pourshaikhian

Name of organization / entity

Guilan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 13 3360 5768

Email address

m_pourshaikhan@gums.ac.ir

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

Street address

Next to Guilan Management and Planning Organization, Dr. Heshmat Hospital, 15 Khordad St.

Rasht

City

Rasht

Province

Guilan

Postal code

41939-76993

Phone

+98 13 3366 9064

Fax

+98 21 3366 8718

Email

heshmat@gums.ac.ir

Web page address

<http://www.gums.ac.ir/heshmat/default.aspx?tabid=416>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohamd Reza Naghipour

Street address

Deputy of Research and Technology of Guilan University of Medical Sciences, Siadati Ave., Namjoo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Phone

+98 13 3333 5821

Fax

+98 13 3333 6395

Email

research@gums.ac.ir

Web page address

<http://www.gums.ac.ir/research/Default.aspx?tabid=304>

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

Majid Pourshaikhian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School of Shahid Dr. Beheshti,
Hamidyan Shahrak, Shahid Dr. Beheshti Ave

City

Rasht

Province

Guilan

Postal code

41939-76702

Phone

+98 13 3360 5768

Email

pourshaikhian_m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Majid Pourshaikhian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School of Shahid Dr. Beheshti,
Hamidyan Shahrak, Shahid Dr. Beheshti Ave

City

Rasht

Province

Guilan

Postal code

41939-47002

Phone

+98 13 3360 5768

Fax

+98 13 3355 0097

Email

pourshaikhian_m@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Majid Pourshaikhian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School of Shahid Dr. Beheshti,
Hamidyan Shahrak, Shahid Dr. Beheshti Ave

City

Rasht

Province

Guilan

Postal code

39841-41469

Phone

+98 13 3360 5768

Fax

+98 13 3355 0097

Email

pourshaikhian_m@yahoo.com

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

