

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effectiveness of foot massage on physiological parameters among patients with acute coronary syndrome

Protocol summary

Study aim

Determine the effectiveness of foot massage on physiological parameters (heart rate, respiration, mean arterial pressure, pulse pressure, peripheral oxygen saturation) among patients with acute coronary syndrome.

Design

A quasi experimental design on non random in patient with acute coronary syndrome with minimum sample size of 30 for each group will be used; the total size 60 patient enrolled between December 2023 to September 2024.

Settings and conduct

The study was conducted in karbala heart center in Karbala Governorate, Iraq.

Participants/Inclusion and exclusion criteria

The Inclusion Criteria: All patient Those who are surgical diagnosed with acute coronary syndrome . patient between age 18 and over. Participants with Iraqi nationality. Conscious patient, able to communicate verbally, and able to make decision. Exclusion criteria: patient who declined to enroll in the study and who have discontinuing to intervention. Patients could have foot problems (such as callus, corn, fungal skin infection, previous scars, diabetic foot or known neuropathy). patient who have amputation in lower extremity.

Intervention groups

Data will be collected using the pre- and post-test methods. After assessing the physiological parameters the sample will be allocated into two groups: (Group 1)was applied for five minutes, each foot was massaged for five minutes. and followed four steps of foot massage, All of the four steps was given one minute and fifteen seconds of massage, which was five minutes in total, The physiological parameters of the client were documented before the massage and then the massage was implemented for five minutes. and re-recorded the Physiological parameters in the five and ten minutes after the end of five minutes of foot massage. and Group

2: control group without any intervention.

Main outcome variables

Reduce the physiological parameters.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240124060784N1**

Registration date: **2024-04-04, 1403/01/16**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-04, 1403/01/16**

Update count: **0**

Registration date

2024-04-04, 1403/01/16

Registrant information

Name

zainab sabah

Name of organization / entity

Kerbala university

Country

Iraq

Phone

+964 781 873 9384

Email address

zainab.sabah@s.uokerbala.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-31, 1402/11/11

Expected recruitment end date

2024-03-08, 1402/12/18

Actual recruitment start date

2024-02-10, 1402/11/21

Actual recruitment end date

2024-06-25, 1403/04/05

Trial completion date

2024-07-01, 1403/04/11

Scientific title

Effectiveness of foot massage on physiological parameters among patients with acute coronary syndrome

Public title

Effectiveness of foot massage on physiological parameters among patients with acute coronary syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All patient Those who are surgical diagnosed with acute coronary syndrome . Patient between age 18 and over Participants with Iraqi nationality. Conscious patient, able to communicate verbally, and able to make decision.

Exclusion criteria:

Patient who declined to enroll in the study and who have discontinuing to intervention. Patients could have foot problems (such as callus, corn, fungal skin infection, previous scars, diabetic foot or known neuropathy). Patient who have amputation in lower extremity

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Zainab Sabah Sagheer Almasoudi

Street address

Al-ibrahemia street

City

Karbala

Postal code

10053

Approval date

2023-09-26, 1402/07/04

Ethics committee reference number

4626

Health conditions studied**1****Description of health condition studied**

Acute coronary syndrome

ICD-10 code

NEC-I24.9

ICD-10 code description

Acute ischaemic heart disease, unspecified

Primary outcomes**1****Description**

The primary outcome variable is the physiological parameters change due to foot massage

Timepoint

Before intervention and after five , ten minutes from foot massage

Method of measurement

Physiological parameters chick list

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Foot massage was applied for five minutes, each foot was massaged for five minutes. and followed four steps of foot massage , All of the four steps was given one minute and fifteen seconds of massage, which was five minutes in total, The physiological parameters of the client were documented before the massage and then the massage was implemented for five minutes. and re-recorded the Physiological parameters in the five and ten minutes after the end of five minutes of foot massage . After putting a pillow under the patient's feet and positioning them in a supine position at a 30-degree angle to their head, and lubricated the hand with olive oil and began the massage by followed the four steps .1- With one hand, the sole of the foot was grasped, and the toes were checked to ensure they were directed upward. Then pressure was applied to the back of the foot by running the thumb slowly into each groove created by the tendons

connecting the ankle to the toes.2- While the other thumb was softly massaging the entire sole of the foot, one hand was used to hold the foot.3- The fingers were bent backward and forward while also being separately pulled to one side in a balanced manner.4- Between the thumb and toes, the base of each finger was grasped, pulled along, and bent outward. All participants continued to receive their conventional therapy.

Category

Treatment - Other

2**Description**

Control group: received no intervention ;instead they received pretest and post test assessment after five and ten minutes, as did the other groups ,and they will be compared to the other groups in the study.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

karbala heart center

Full name of responsible person

Karbala Health Directorate

Street address

Al- ibrahemia street

City

Karbala

Postal code

10053

Phone

+964 781 873 9384

Email

www.zainab.sabah@s.uokerbala.edu.iq

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of kerbala

Full name of responsible person

zainab sabah sagheer almasoudi

Street address

Al-ibrahemia street

City

Karbala

Postal code

10053

Phone

+964 781 873 9384

Email

www.zainab.sabah@s.uokerbala.edu.iq

Web page address

<https://nursing.uokerbala.edu.iq/wp/en/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

The author of the trial is the funding source

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**

University of Kerbala

Full name of responsible person

Zainab Sabah Sagheer Almasoudi

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Al-ibrahemia street

City

Karbala

Province

Karbala

Postal code

10053

Phone

+964 781 873 9384

Email

www.zainab.sabah@s.uokerbala.edu.iq

Web page address

<https://nursing.uokerbala.edu.iq/wp/en/>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of kerbala

Full name of responsible person

Zainab Sabah Sagheer Almasoudi

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Al-ibrahemia street
City
Karbala
Province
Karbala
Postal code
10053
Phone
+964 781 873 9384
Email
www.zainab.sabah@s.uokerbala.edu.iq
Web page address
<https://nursing.uokerbala.edu.iq/wp/en/>

Person responsible for updating data

Contact

Name of organization / entity
University of kerbala
Full name of responsible person
Zainab Sabah Sagheer Almasoudi
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Al-ibrahemia street
City
Karbala
Province
Karbala
Postal code
10053
Phone
+964 781 873 9384
Email
www.zainab.sabah@s.uokerbala.edu.iq
Web page address
<https://nursing.uokerbala.edu.iq/wp/en/>

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data will be the results of the acute coronary syndrome Patient with physiological parameters in Both the Control and Intervention Groups .

When the data will become available and for how long

God Willing, once the article is published, the data will be available after 6 months of publication. If the article will be published in a subscribed journal, the data will be available after one year because of the policy of the subscribed journals.

To whom data/document is available

with academic nurses and any researcher who is interested in the data.

Under which criteria data/document could be used

The data could be used after getting permission via email. Also, users need to acknowledge the owner.

From where data/document is obtainable

Users can ask for the data and permission via email. zainab al-masoudi is the corresponding author. He will contact whoever he requests the information from. her email is zainab . sabah@uokerbala.edu.iq zainab sabah works at the University of Kerbala/College of Nursing. The address is Al-Muadhfaeen district, Karbala, Iraq. What processes are involved for a request to access data/document

What processes are involved for a request to access data/document

Users can ask for the data and permission via email. zainab sabah is the corresponding author. He will contact whoever he requests the information from. His email is zainab . sabah@uokerbala.edu.iq Comments

Comments