Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Lecturer

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Person responsible for updating data

Contact

Name of organization / entity
University of kerbala

Full name of responsible person
Zainab Sabah Sagheer Almasoudi

Position
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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
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-Muadhafeen 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