

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

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**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

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10053

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**Web page address**

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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**

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**Comments**