

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparing the effects of therapeutic massage done by nurses and patients companion on reducing anxiety, vital signs and the blood cortisol level in males hospitalized in coronary care unit .

Protocol summary

Summary

This study aimed to compare the effects of massage therapy (done by the nurse and by the patient's companion) on the anxiety, vital signs and the level of the serum cortisol of the male patients hospitalized in the CCU. a randomized controlled clinical trial study will be conducted. a convenience sample of the patients will be randomly allocated to within the 3 groups randomly by using a dice. The dice numbers of 1 and 2 will be allocated within the first group, the dice numbers of 3 and 4 in the second group and the dice numbers 5 and 6 in the control group. The first and second group will receive a session of total body massage therapy for about 60 minutes. Massage therapy for the first group will be done by the nurse and for the second group by the patients' companion. The patients' vital signs, anxiety and serum cortisol levels will be checked immediately before and after the massage therapy session. Data analysis will be done by SPSS software. Parametric and non parametric statistical tests will be used to analyse the data.

General information

Acronym

Massage therapy

IRCT registration information

IRCT registration number: **IRCT201112048296N1**

Registration date: **2012-02-11, 1390/11/22**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2012-02-11, 1390/11/22

Registrant information

Name

Rahman Rajabi Beheshtabad

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-03-19, 1391/12/29

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of therapeutic massage done by nurses and patients companion on reducing anxiety, vital signs and the blood cortisol level in males hospitalized in coronary care unit .

Public title

Comparing the effects of therapeutic massage done by nurses and patients companion on reducing anxiety, vital signs and the blood cortisol level in males hospitalized in coronary care unit .

Purpose

Supportive

Inclusion/Exclusion criteria

A) Inclusion criteria: 1. Male patients hospitalized in CCU
2. Being literate. 3. Being conscious 4. Stay in ward more than 3 days 5. Willing to participate B) Exclusion criteria:
1- Discharge from the ward 2- Loss of consciousness 3 - Having cardiac arrest during the past 72 hours 4- Receiving warfarin 5- Having known mental disorder 6- having cardiac pacemaker 7- Bradycardia (pulse rate less than 60) 8- Severe dyspnea 9- Having burn more than 25% of BSA 10- Having known infectious disinvest or hepatitis and jaundice 11- Fever 12- Having amputated limb 13- Having known adrenal gland disorder 14- Having bone fractures in the past 2 months 15- Having known skin problem 16- Deep vein thrombosis 17- Having dialysis fistula.

Age

To 75 years old

Gender

Male

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kilometer 5, Ghotb ravandi bilvard

City

Kashan

Postal code

88141/87159

Approval date

2012-01-31, 1390/11/11

Ethics committee reference number

3614/1/5/29/پ

Health conditions studied

1

Description of health condition studied

Angina pectoris

ICD-10 code

I20

ICD-10 code description

Angina pectoris

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger questionnaire

2

Description

Serum cortisol

Timepoint

Before and after intervention

Method of measurement

Blood tests

3

Description

Vital signs

Timepoint

Before and after the intervention

Method of measurement

Blood pressure (sphygmomanometre), temprature (medical termometer), pulse and respiration (by the researcher, in 1 min.)

Secondary outcomes

empty

Intervention groups

1

Description

The first group (massage by the nurse): The patient's vial signs will be assessed on 30 minutes before the massage will be done. Then the Spielberger questionnaire will be completed by the patient and a blood sample will be taken. Now, total body massage will be conducted by the nurse for about 60 min. Then, the patient's vital signs will be assessed and blood sample will be taken and Spielberger questionnaire will be completed again.

Category

Behavior

2

Description

group II (massage by the patient's companion): The patient's vital signs will be assessed on 30 minutes before the massage will be done. Then the Spielberger questionnaire will be completed by the patient and a blood sample will be taken. Now, total body massage will be conducted by the patient's companion for about 60 min. Then, the patient's vital signs will be assessed and blood sample will be taken and Spielberger questionnaire will be completed again.

Category

Behavior

3

Description

Group III (control group): This group does not receive massage therapy, but will receive the routine care. The patient's vital signs will be assessed on 30 minutes after being in bed. Then the Spielberger questionnaire will be completed by the patient and a blood sample will be taken. assessing the patient's vital signs, blood sampling and Spielberger questionnaire will be repeated after 75 minutes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan University of Medical Sciences

Full name of responsible person

Rahman Rajabi

Street address

Kashan University of Medical Sciences

City

Kashan

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Dr. Mohsen Adib-Hajbaghery

Street address

Nursing Faculty, Kashan university of Medical sciences

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam ali Hamidi

Street address

Vice chancellor for research, Kashan University of Medical Sciences

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Rahman Rajabi

Position

Graduate student

Other areas of specialty/work

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City**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty