

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of applying of self-care program on quality of life in patients with unstable angina

Protocol summary

Study aim

Determining the effect of self-care program on quality of life in patients with unstable angina.

Design

Two arm parallel group randomised trial without blinded postoperative care and outcome assessment

Settings and conduct

After compiling the training program, patients were divided into two groups of intervention and control training sessions, six to eight sessions were held in the hospital training classes. Blinding has not been done.

Participants/Inclusion and exclusion criteria

Include criteria: The diagnosis of unstable angina, according to consulting doctor; Inclusion criteria: Having the ability to understanding and speaking Persian; Having the tendency to cooperate and participate in the study; Having at least reading and writing ability; having at least four self-care necessities. Exclusion criteria: no willingness to continue participating in the study; not participating in more than one sessions; The patient death during the study.

Intervention groups

Self-care program based on Orem's self-care model that includes a selection of information, attitudes and practices that Based on the needs of Unstable Angina ,patients in 4 to 6 sessions of 45 minutes taught them .control group will receive usual nursing cares .

Main outcome variables

This research is a quasi-experimental study. Each research group is containing 90 persons that have criterions of entering the study. These groups are divided to 2 groups of intervention and control . Each group are trained for a month (control group without researcher intermediation and based on department routine and test group with researcher intermediation according to Orem's model). After one month from education, they fill Seattle Angina Questionnaire. Study period for each group is one months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200802048268N1**

Registration date: **2020-08-06, 1399/05/16**

Registration timing: **retrospective**

Last update: **2020-08-06, 1399/05/16**

Update count: **0**

Registration date

2020-08-06, 1399/05/16

Registrant information

Name

Zeinab Ghaemnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3321 7444

Email address

zeinabg385@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-07-06, 1394/04/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of applying of self -care program on quality of life in patients with unstable ungina

Public title

Effect of self -care program on quality of life in patients with unstable ungina

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Include criteria: The diagnosis of unstable angina according to consulting doctor; The lack of a history of mental illness and physical disabilities based on patient records; The lack of a history of heart surgery in the last 6 months based on patient records; Residence in the city of ahvaz ; Lack of cognitive, hearing, and vision impairment; Lack of education in the department of medicine; Lack of formal training in unstable ungina patients; Having the ability and willingness to participate in the study; Ability to make phone calls

Exclusion criteria:

Exclude criteria: Lack of access with the patient by telephone and his family during the study (several times in a few days) ; Patient's unwillingness to continue participation in the study; Death due to illness or the occurrence of any event and the deterioration of the patient

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was performed by non-probability sequential method. Samples were allocated to two groups of intervention and control by block random allocation method. For this purpose, 6 predetermined blocks based on possible arrangements in two modes in blocks were used.

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

Ethics committee of Ahvaz university of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Science, Golestan Road, Ahvaz, Khuzestan, Iran.

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2016-10-04, 1395/07/13

Ethics committee reference number

IR.AJUMS.REC.1395.438

Health conditions studied

1

Description of health condition studied

Unstable Angina

ICD-10 code

I20.0

ICD-10 code description

Unstable angina

Primary outcomes

1

Description

Self-care training program

Timepoint

before intervention and 2 months after intervention

Method of measurement

Seattle Angina Questionnaire

Secondary outcomes

1

Description

physical function

Timepoint

before intervention and 1 months after intervention

Method of measurement

Seattle Angina questionnaire

2

Description

stable angina

Timepoint

before intervention and 1 months after intervention

Method of measurement

Seattle Angina Questionnaire

3

Description

Repeat pain

Timepoint

before intervention and 1 months after intervention

Method of measurement

Seattle Angina Questionnaire

4

Description

Satisfaction with treatment

Timepoint

before intervention and 1 months after intervention

Method of measurement

Seattle Angina Questionnaire

5

Description

Perception of pain

Timepoint

before intervention and 1 months after intervention

Method of measurement

Seattle Angina Questionnaire

Intervention groups

1

Description

Intervention group: 90 patients, will be divided randomly into two intervention and control groups, randomly. After getting written consent, they will complete demographic and Seattle Angina questionnaire will be completed. Then, self-care program education will be carried out based on Orem theory for intervention group and the control group will receive usual nursing cares. After one months, questionnaire of quality of life will be completed for both group and the results will be evaluated statistically. After the intervention, Self-care program based on Orem's self-care model that includes a selection of information, attitudes and practices that Based on the needs of Unstable Angina patients in 4 to 6 sessions of 45 minutes taught them. Seattle Questionnaire is a special questionnaire whose validity and reliability in Iran by Taheri Kharameh et al. In 2012 with 85% -59% and the reliability coefficient of retest (ICC) in two times and two weeks apart in all dimensions was 90% This questionnaire includes 19 questions that measure five dimensions of coronary heart disease. 9 questions of physical function, 1 question of angina stability, 2 questions of recurrence of pain, 4 questions of satisfaction with treatment, 3 questions of understanding quality of life by summing the scores of questions and converting to 0 scale. 100 is calculated. 0 will be the worst and 100 will be the best.

Category

Lifestyle

2

Description

Control group: control group will receive usual nursing cares.

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeni hospital, Golestan hospital

Full name of responsible person

Zeinab Ghaemnia

Street address

Faculty of Nursing and Midwifery, Jondishapour University of Medical Science, Golestan Road, Ahvaz, Khuzestan, Iran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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

No

Title of funding source

Ahvaz Jundishapur University of Medical Science

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

Khuzestan, Iran

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Senior Lecturer in Nursing, Faculty of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The research findings are completely limited in study and are likely to be met with a lower percentage of satisfaction in the current society.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available