Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

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 ungina, 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
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Iran (Islamic Republic of)
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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 appling 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.
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Khouzestan
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
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Shahram molavi nejad
Position
Senior Lecturer in Nursing, Faculty of Nursing and Midwifery
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Person responsible for updating data

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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