Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of the self-management program based on Social cognitive theory on the anxiety and sleep quality of acute coronary syndrome in patients hospitalized in the coronary care unit of Hajar Hospital of Shahrekord

Protocol summary

Study aim
Determining the effect of self-management program based on social cognitive theory on anxiety and sleep quality of patients with acute coronary syndrome hospitalized in cardiac special care units of Hajarshahrkord hospital.

Design
A clinical trial with a control group with parallel and blinded Groups randomized on72patients randomization by block method

Settings and conduct
Cardiac Special Care Departments of HajarshahrKord Hospital After the patient is discharged from the Cardiac Special Care Department and after discharge from the hospital the educational intervention is in the form of virtual training through the social network and completing a randomized questionnaire.

Participants/Inclusion and exclusion criteria
Entry: informed written consent to participate in the study; definitive diagnosis of acute coronary syndrome based on the opinion of a specialist doctor or history of hospitalization in a special ward for acute coronary syndrome; Failure to enter: urgent clinical conditions of patients and emergence of acute complications

Intervention groups
The educational intervention will be done virtually and on the internal social network (ITA)The information gathering tool will be a questionnaire that includes 3 parts of demographic characteristics back anxiety and Pittsburgh sleep quality which will be available to the participants through the created virtual group A30-minute session will be held The control group will receive only the usual interventions The researcher will complete the research questionnaires for both the test and control groups immediately and eight weeks after the intervention.

Main outcome variables
Publication or presentation of articles in scientific research journals or scientific conferences clinical guidelines regarding the management of anxiety and sleep quality in patients with acute coronary syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240626062258N1**
Registration date: **2024-11-29, 1403/09/09**
Registration timing: **retrospective**

Last update: **2024-11-29, 1403/09/09**
Update count: **0**

Registration date
2024-11-29, 1403/09/09

Registrant information

Name
reyhaneh eskandarian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-19, 1403/07/28

Expected recruitment end date
2024-11-14, 1403/08/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the self-management program based on Social cognitive theory on the anxiety and sleep quality of acute coronary syndrome in patients hospitalized in the coronary care unit of Hajar Hospital of Shahrekord

Public title
The effect of self-management program based on social-cognitive theory on anxiety and sleep quality of cardiac patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Definite diagnosis of acute coronary syndrome based on the opinion of a specialist doctor or a history of hospitalization in a special department following acute coronary syndrome Obtain a minimum score of 8 from Beck's anxiety questionnaire Age over 18 years Willingness and written informed consent to participate in the study Able to read and write She/he has not participated in other research projects in this field Implementation of a self-management program based on cognitive-social theory after the patient's discharge from the cardiac intensive care unit, stabilization of the patient's condition and stabilization of hemodynamic symptoms. Access to the Internet and social network by the patient or her companion and the ability to work with the program
Exclusion criteria:
Incomplete completion of questionnaires Membership in the health team Urgent clinical conditions of patients and occurrence of acute complications
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The research samples will be easily selected from patients with acute coronary syndrome who are eligible to enter the study and give informed consent to participate in the study. Then, the samples will be placed in two groups of 36 people, test and control, by random block method in the form of blocks of four (2 test persons and 2 control persons) and 18 blocks that are chosen randomly.
Blinding (investigator's opinion)
Single blinded
Blinding description
None of the participants know whether they are in the control or intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Baharestan Street, Gallaher Street, Alley 2, No. 4, Unit 8
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8815969890
Approval date
2024-10-07, 1403/07/16
Ethics committee reference number
IR.SKUMS.REC.1403.086

Health conditions studied

1

Description of health condition studied
Acute Coronary Syndrome
ICD-10 code
-
ICD-10 code description

Primary outcomes

1

Description
Anxiety score in Beck's questionnaire
Timepoint
Before starting the study, immediately after the training and eight weeks after the training
Method of measurement
Beck index questionnaire

2

Description
Sleep quality score in the Pittsburgh Questionnaire
Timepoint
Before starting the study, immediately after the training and eight weeks after the training
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Within one or two days after the patient is admitted to the cardiac intensive care unit and his condition stabilizes, the researcher will guide the patient and his companions on how to access the virtual group and how to participate in the training program and provide practical explanations for 15 to 30 minutes. He will be present at the bedside of patients. Then, according to his access to the Ita social network, he will be a member in the virtual group. After obtaining the desired sample and his membership in the above-mentioned virtual groups, the link to the questionnaire will be designed and the necessary explanations about its completion will be sent on the platform of the virtual space. . Due to the anticipated lack of immediate access to the Internet for the participants, 3 days will be considered from the time of sending the questionnaires to complete and send them, and if they do not receive the message, they will be informed of this through a phone call. Also, in the created virtual groups, questions and answers will be open for group members. The intervention for the test group will be based on Bandura's social-cognitive theory. This intervention, which includes a self-management training program in three areas of cognitive, environmental and behavioral, was mentioned during 6 30-minute sessions virtually and via mobile phone in the form of a virtual group on the social network Ita, and after the patient became stable for The group test will be done. In general, the above-mentioned 6 intervention sessions will include two training sessions focused on individual characteristics, two sessions focused on behavioral training, and two sessions focused on the adjustment of environmental factors. At the end of the sixth session, the researcher will also use research questionnaires (Beck Anxiety Questionnaire and Pittsburgh Quality Questionnaire). will be uploaded in the virtual group and will be made available again to the people of the intervention group to complete it. In this stage, as in the first stage, the participants will be given 3 days from the time of sending the questionnaires to complete and send them, and all measures for Face-to-face and virtual response is also established as in the first stage. In the continuation of the research program, a follow-up program will be carried out, based on which, once a week for eight weeks, a telephone call will be made with the patients of the test group or their companions. The content of the phone call will be to strengthen education and verbal encouragement and ask questions about the patient's condition and answer the patients' questions and doubts. After completing the phone follow-up sessions and providing appropriate guidance and training, the anxiety and sleep quality questionnaire will be administered again in virtual groups. The loading will be completed by the patient or his companions, obviously, according to the previous two stages, a period of 3 days will be allocated to the participants to answer the questionnaires, and the researcher will be available to answer in person.
Category
Behavior

2

Description
Control group: The control group will only participate in the pre-test, post-test and follow-up stages, thus the patients in the control group will not receive the same intervention as what is considered for the test group, and they will only receive routine care provided by They receive what the hospital offers them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Shahrekord Hospital
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Sponsors / Funding sources

1

Sponsor
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Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord University of Medical Sciences

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
Shahre-kord University of Medical Sciences

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Reyhaneh Eskandarian

Position
Master's student

Latest degree
Bachelor

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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