Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of educational intervention based on the theory of planned behavior on self-management behavior of patients with acute coronary syndrome (ACS)

Protocol summary

Study aim

Determining the effect of educational intervention based on the theory of planned behavior on self-management of patients with acute coronary syndrome (ACS)

Design

Patients will be divided into control and intervention groups . The sample size includes 63 in control & 63 in intervention group

Settings and conduct

The current study is an educational intervention that will be conducted on patients with ACS referred to the hospitals of Kerman University of Medical Sciences. Patients will be randomly divided into two control & intervention groups. Then, in addition to routine care, the intervention group will participate in training sessions based on the structures of the theory of planned behavior, and the control group will receive only routine care. The data collection tool will be a researcher-made questionnaire.data will be analyzed by SPSS26.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1. All conscious patients diagnosed with ACS 2. No participating in other studies or educational sessions similar to this research during the last 6 months 3. Having a smart phone and being able to work with it Exclusion criteria: 1. Not having minimum reading and writing literacy 2. Inability to take care of oneself 3. History of psychological disorder 4. Congenital heart disease 5. Inability to answer questions due to illness

Intervention groups

After randomly dividing the patients into two control and intervention groups, in addition to routine care, the intervention group will participate in training sessions based on the structures of the theory of planned behavior, and the control group will receive only routine care.

Main outcome variables

Attitude; Perceived norm; Perceived behavioral control; Behavioral intention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141109019862N9**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-11, 1401/09/20**
Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name
Sakine Sabzevari
Name of organization / entity
Kerman University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 34 3132 5219
Email address
s_sabzevari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of educational intervention based on the theory of planned behavior on self-management behavior of patients with acute coronary syndrome (ACS)

Public title
The effect of educational intervention based on the theory of planned behavior on self-management behavior in heart attack patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
All conscious patients, referred to this hospital, in whom the clinical and paraclinical diagnosis of ACS has been confirmed and are now ready to be discharged No participating in other studies or training sessions similar to this research during the last 6 months Having a smart phone and the ability to work with it
Exclusion criteria:
Lack of minimum reading and writing literacy Inability to self-care (dependence on others) for any reason except ACS based on Barthel's ADL tool (completely dependent (0-8 points), relative dependence (9-12 points), Complete independence (13-20 points)} is determined. History of psychological disorder (use of antipsychotic drugs) which is determined based on the self-report of the patient or the patient's companion Cardiovascular disease as a complication of another chronic disease Congenital heart disease Inability to answer questions due to the disease
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
The study is an educational intervention. By referring to the relevant ward, patients are selected based on the inclusion and exclusion criteria in the study and are placed in the control and intervention groups based on even and odd days, respectively. The control group receives the usual care of the ward. In addition to the usual interventions, the intervention group participates in training sessions designed based on the constructs of the theory of planned behavior.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Kerman University of Medical Sciences
Street address
Jahad Blvd. Ebn Sina Avenue, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
76177
Approval date
2022-09-04, 1401/06/13
Ethics committee reference number
IR.KMU.REC.1401.255

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome (ACS)
ICD-10 code
I24.9
ICD-10 code description
Acute ischemic heart disease, unspecified

2

Description of health condition studied
Self-management
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Attitude
Timepoint
At the beginning of the study (before the start of intervention) and 2 months after intervention
Method of measurement
A researcher-made questionnaire which reliability and validity have been confirmed.

2

Description
Perceived norm
Timepoint
At the beginning of the study (before the start of intervention) and 2 months after intervention
Method of measurement
A researcher-made questionnaire which reliability and validity have been confirmed.

3

Description
Perceived behavioral control
Timepoint
At the beginning of the study (before the start of intervention) and 2 months after intervention
Method of measurement
A researcher-made questionnaire which reliability and validity have been confirmed.

4

Description
behavioral intention
Timepoint
At the beginning of the study (before the start of intervention) and 2 months after intervention
Method of measurement
A researcher-made questionnaire which reliability and validity have been confirmed.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention is an educational intervention that has been prepared using reliable and up-to-date sources and has been approved by experts. Before the intervention, the overall score of each of the theoretical constructs as well as the overall score of the patients' self-management behavior is determined using a questionnaire. Then, in addition to routine care, the intervention group will participate in 5 training sessions (0.5 to 1 hour). After the implementation of the educational program for the intervention group and two months have passed, the questionnaire will be completed for them to determine the effect of the intervention on the patients under study.
Category
Other

2

Description
Control group: This group will only receive routine care. The questionnaire will complete twice by them. Once at the beginning of the study and the second time 2 months after filling the first questionnaire. At the end of the work and after filling the second questionnaire, in order to comply with ethics, educational materials are also provided to them.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital (Kerman)
Full name of responsible person
Dr Sakineh Sabzevari
Street address
Kosar Blvd, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
۷۶۱۸۷۵۱۱۵۱
Phone
+98 34 3211 5780
Email
shafahospital@kmu.ac.ir
Web page address
https://sh.kmu.ac.ir

2

Recruitment center
Name of recruitment center
Afzahipour hospital (kerman)
Full name of responsible person
Dr Sakineh Sabzevari
Street address
Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
+98 34 3132 8000
Email
Afzahipourhospital@kmu.ac.ir
Web page address
https://ah.kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person

Dr Sakineh Sabzevari

Street address
Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5700

Email
S_Sabzevari@kmu.ac.ir

Web page address
https://www.kmu.ac.ir

Grant name

Grant code / Reference number
با هزینه شخصی است

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
personal expenses

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr Skineh Sabzevari

Position
Associate professor, Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Medical Education

Street address
Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5219

Fax
+98 34 3132 5218

Email
s_sabzevari@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr Sakineh Sabzevari

Position
Associate professor, Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Medical Education

Street address
Haft Bagh Blvd, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7617796777

Phone
+98 34 3132 5219

Fax
+98 34 3132 5218

Email
S_Sabzevari@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr Sakineh Sabzevari

Position
Associate Professor, Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Medical Education

Street address
Haft Bagh Blvd

City
Kerman

Province
Kerman

Postal code
7617796777

Phone
+98 34 3132 5219

Fax
+98 34 3132 5218

Email
S_Sabzevari@kmu.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

A summary of the project in the form of an end of project report and article

When the data will become available and for how long

Completion of the plan

To whom data/document is available

Researchers in the field of health sciences

Under which criteria data/document could be used

Literature review, evidence-based medicine and nursing, modeling for similar diseases

From where data/document is obtainable

To published articles and contact authors

What processes are involved for a request to access data/document

Apply by email to the corresponding author

Comments