

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of smartphone based self-help intervention on depression, anxiety, stress and quality of life in patients with Acute Coronary Syndrome

Protocol summary

Study aim

determining the effect of smartphone-based self-help intervention on depression, anxiety, stress and quality life in patients with acute coronary syndrome

Design

clinical trial with control group, randomized, not blinded, with 64 participants. random numbers sequence generated by computer software was used for randomization.

Settings and conduct

The present study will be done on patients with acute coronary syndrome attending to Amiralmomenin Hospital of Gerash city. participants will be selected based on inclusion criteria and informed consent form will be obtained from them. first, depression, anxiety, stress and quality of life will be evaluated with standard questionnaires and then, participants will be assigned to intervention or control group, randomly. for intervention group, smartphone based self-help intervention will be done in 6 session during 3 weeks. control group will receive routine cares. study variables will be evaluated immediately after and 3 weeks after intervention in both groups.

Participants/Inclusion and exclusion criteria

inclusion criteria include acute coronary syndrome confirmed by cardiologist, passed at least 24 hours from hospitalization, willingness to participate in the study, age between 30 to 65 years, ability to read and write in persian, ability to use smartphone and accessibility to internet and not participated in psychological interventions in past 3 months.

Intervention groups

intervention group will receive smartphone-based self-help intervention in six session during 3 weeks (2 sessions each week). control group will receive routine cares and no education or care will be presented to them by the research team.

Main outcome variables

depression, anxiety, stress; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054627N1**

Registration date: **2022-05-15, 1401/02/25**

Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**

Update count: **0**

Registration date

2022-05-15, 1401/02/25

Registrant information

Name

Faezeh setoudeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

faezehsotoudeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of smartphone based self-help intervention on depression, anxiety, stress and quality of life in patients with Acute Coronary Syndrome

Public title
evaluating the effect of self-help intervention on mental health and quality of life

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
acute coronary syndrome confirmed by cardiologist passed at least 24 hours from hospitalization willingness to participate in the study age between 30 to 65 years ability to read and write in persian ability to use smartphone and accessibility to internet not participated in psychological interventions in past 3 months
Exclusion criteria:

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants in this study will be assigned to intervention or control group based on blocking randomization methods. For randomization, the sample size (64 persons) will be divided into 16 block. each block size will be 4 persons and 2 of them will be assigned to the control group and 2 of them will be assigned to intervention group. assigning participants in each block to intervention or control group will be based on random numbers generated by random allocation software. this random numbers sequence will be produced in a way that, 2 participants in each block assign to control group and 2 participant assign to intervention group.

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

Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information.

Street address

Fatemeh (P.B.U.H) School of Nursing and Midwifery, Namazi hospital, Namazi square.

City

Shiraz

Province

Fars

Postal code

۷۱۹۳۶ - ۷۱۹۳۶

Approval date

2022-04-03, 1401/01/14

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.008

Health conditions studied

1

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Quality of life scores in Ferrans and Powers Quality of Life Index

Timepoint

before, immediately after and 3 weeks after interventions

Method of measurement

Ferrans and Powers Quality of Life Index

2

Description

Depression scores based on Depression, anxiety and stress scale (DASS-21)

Timepoint

before, immediately after and 3 weeks after interventions

Method of measurement

Depression, anxiety and stress scale (DASS-21)

3

Description

Anxiety scores based on depression, anxiety, stress scale (DASS-21)

Timepoint

Before, immediately after and 3 weeks after interventions

Method of measurement

depression, anxiety, stress scale (DASS-21)

4**Description**

strss score based on depression, anxiety, stress scale (DASS-21)

Timepoint

Before, immediately after and 3 weeks after interventions

Method of measurement

depression, anxiety, stress scale (DASS-21)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: intervention group will receive smartphone-based self-help intervention within 3 weeks. educational contents includes 6 main topics which will be sent to participants usnig whats app messenger. participants will be asked to read these contents and use them in their routine life. generally, reading and using each topic requires 40-80 minutes in week and timing for reading and using educational contents will be based on participants preferences. educational contents will be sent to participants weekly and two topics each week. first topic incudes information about acute coronary syndrome and its possible effects on mental heal and quality of life, and also information about self-care such as physical activity, diet, prescribed medications and times to visit physician. in second topic, paticipants will receive information about coping with negative thoughts and tensions related to acute coronary syndrome. third topic will be about modification of Thought patterns and Cognitive thinking. fourth topic will focus on increasing participants resilience and coping skills. in fifth topic, information about sleep hygine and relaxing technics will be discussed. sixth topic includes information about importance of self-care and personal developement.

Category

Lifestyle

2**Description**

Control group: control group will receive only routine cares (such as physician visit, educations provided by physician and nurses). this group will not receive any education or intervention from the researchers.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gerash Amiralmomenin teaching hospital

Full name of responsible person

Faezeh Setoudeh

Street address

Amiralmomenin teaching hospital, Vahdat Blvd, Shahid Beheshti Square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahtab Memarpour

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Administration Building of Shiraz University of Medical Sciences, Zand St.

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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

Shiraz 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**

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Molazem

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Fatemeh (P.B.U.H) School of Nursing and Midwifery,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Zahra Molazem

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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

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

Not applicable