Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 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 psycological 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 psycological 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 devided 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

۱۳۱۱۹ - 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, prescibed 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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۵۸۶۶۶ – ۷۴۴۱۷
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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
Street address
Administration Building of Shiraz University of Medical Sciences, Zand St.
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Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
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

Academic

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
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Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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