Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

The effect of mobile health on self-care in older people with myocardial infarction

Protocol summary

Study aim
Determining effect of mobile health on self-care in older people with myocardial infarction

Design
The clinical trial has two parallel groups of intervention and control and block randomization is used. The sample size is 128 people

Settings and conduct
This study will be performed in the heart clinic of Boo Ali Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 60 years old and older; history of myocardial infarction for at least the last 6 months; education level at least a diploma; has the mental capacity to communicate; patient consent to participate in the study; having a smartphone (Android). Exclusion criteria: catching Heart failure; hearing or speech impairment that prevents communication; cognitive impairment such as Alzheimer's and amnesia; having debilitating diseases such as stroke and neurological diseases, etc.; occurrence of severe stressful event during the study or 3 months before; loss of smartphone; dissatisfaction with continuing the study.

Intervention groups
First, the health mobile application is installed on the phones of the intervention group and they are taught how to use it. Prior to the intervention, the baseline level of self-care will be assessed using the Self-care of Coronary Heart Disease Inventory (SC-CHDI) questionnaire uploaded to the health companion program. Health intervention includes two parts: monitoring and training. During this period, the control group will receive the usual care of Qazvin Heart Center (Bouali Hospital), which includes a low-fat low-fat diet educational pamphlet, a visit to a heart clinic two weeks after discharge, as well as advice not to consume salt and not to have sex for two weeks.

Main outcome variables
Level of self-care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210327050782N1**
Registration date: **2021-08-15, 1400/05/24**
Registration timing: **prospective**

Last update: **2021-08-15, 1400/05/24**
Update count: **0**

Registration date
2021-08-15, 1400/05/24

Registrant information

Name
Arash Ghiasvand mohammad khani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3367 4024

Email address
a.ghiasvand@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-21, 1400/05/30

Expected recruitment end date
2021-11-21, 1400/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of mobile health on self-care in older people with myocardial infarction

Public title

The effect of mobile health on self-care in older people with myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 years old and older A history of myocardial infarction for at least the last 6 months Has the mental capacity to communicate Patient consent to participate in the study Having a smartphone (Android) Have minimum ability to read and write

Exclusion criteria:

Catching Heart failure Hearing or speech impairment that prevents communication Cognitive impairment such as Alzheimer's and amnesia Having debilitating diseases such as stroke and neurological diseases, etc. Occurrence of severe stressful event during the study or 3 months before Loss of smartphone Dissatisfaction with continuing the study

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization method will be used in this study to randomize the samples. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers in cases where intermediate analyzes are needed during the sampling process. Number of samples Equal to each of the study groups. The size of all the blocks is equal and we will have 6 groups of 6 blocks (including 3 participants in the intervention group and 3 participants in the control group) in this two-group experiment. Random allocation software is also used for randomization tools. In addition to simple randomization, these random sequence generation software is able to generate random sequences by blocking method. To hide us from Allocation concealment We use the method used to perform a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequence Sequentially numbered, sealed, opaque envelopes in This method records each of the random sequences created on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

First, the health mobile application is installed on the phones of the intervention group and they are taught how to use it. Prior to the intervention, the baseline level of self-care will be assessed using the Self-care of Coronary Heart Disease Inventory (SC-CHDI) questionnaire uploaded to the accompanying health program.Health intervention includes two parts: monitoring and training. The monitoring section includes self-monitoring of the patient in the areas of drug use, examination of cardiac symptoms and nutrition, etc. The interactive and automated capability of this software is such that it provides reminders for timely consumption in the drug consumption section. In case of cardiac symptoms, patients can first receive a recommendation to go to the emergency room, stop the activity, etc. by entering their symptoms in the program. If there is a problem in the areas or have questions in these areas or training programs, they can refer to the question and answer section and send their question to the facilitators and receive the answer.The trainings provided in the health companion program are daily for 4 weeks. Educational content is provided to the elderly using specialized resources after simplification in the form of multimedia, Persian animations, text and audio in the accompanying health program. Different parts of this software help the user in various areas of self-care and receive the necessary information from the user in the form of artificial intelligence and forms and questionnaires. During this period, the control group will receive the usual care of Qazvin Heart Center (Bouali Hospital), which includes a low-fat low-salt diet educational pamphlet, a visit to the heart clinic two weeks after discharge, as well as advice not to consume salt and not to have sex for two It is the week.Immediately after the intervention and 1 month after, the software automatically measures the level of self-care of the participants and sends the results online to the software server and we access the data.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Qazvin University of

Medical Sciences

Street address

Beheshti Blvd.

City

Qazvin

Province

Qazvin

Postal code

13911/34156

Approval date

2021-08-03, 1400/05/12

Ethics committee reference number

IR.QUMS.REC.1400.200

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Self-care

Timepoint

(Before the intervention) and 30, 60 days after the intervention

Method of measurement

Self-care Questionnaire of Coronary Heart Disease Inventory (SC-CHDI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: first, the health mobile application is installed on the phones of the intervention group and they are taught how to use it. Prior to the intervention, the baseline level of self-care will be assessed using the Self-care of Coronary Heart Disease Inventory (SC-CHDI) questionnaire uploaded to the accompanying health program.Health intervention includes two parts: monitoring and training. The monitoring section includes monitoring the patient in the areas of medication use, cardiac symptoms, and nutrition. The interactive and automated capability of this software is such that in the drug consumption section, it provides reminders for timely use to the patient. In the event of cardiac symptoms, patients can first receive a recommendation to go to the emergency room, stop the activity or reduce the activity by entering their symptoms in the program. If there is a problem in the proposed areas or have a question in the same areas or training programs, they can refer to the question and answer section and send their question to the facilitators and receive the answer.The trainings provided in the health companion program are daily for 4 weeks. Educational content is provided to the elderly using specialized resources after simplification in the form of multimedia, Persian animations, text and audio in the accompanying health program. Different parts of this software help the user in various areas of self-care and receive the necessary information from the user in the form of artificial intelligence and forms and questionnaires.Immediately after the intervention and 1 month after, the software automatically measures the level of self-care of the participants and sends the results online to the software server and we access the data.It should be noted that the intervention group will also receive the usual care of the heart center.

Category

Lifestyle

2

Description

Control group: control group will receive the usual care of Qazvin Heart Center (Bouali Hospital), which includes a low-fat low-salt diet educational pamphlet, a visit to a heart clinic two weeks after discharge, as well as advice not to consume salt and not to have sex for up to two weeks.Immediately after participating in this study and one month later, the level of self-care will be asked of them and will be examined with other data.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali sina hospital heart clinic

Full name of responsible person

Arash Ghiasvand Mohammad Khani

Street address

Booali sina street

City

Qazvin

Province

Qazvin

Postal code

3413786165

Phone

+98 28 3333 2930

Fax

+98 28 3332 6033

Email

internationalaffairs@qums.ac.ir

Web page address

http://en.qums.ac.ir/Portal/home/?107188/Booali-Sina-Teaching-Hospital

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Mohammad Mehdi Imam Juma
Street address
Shahid Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
1531534199
Phone
+98 28 3333 6001
Fax
+98 28 3335 5162
Email
memamjomeh@qums.ac.ir
Web page address
http://en.qums.ac.ir/Portal/home/?548508/Contact-Us
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Arash Ghiasvand Mohammad Khani
Position
Master of Nursing in Geriatric nursing
Latest degree
Master
Other areas of specialty/work
Geriatrics
Street address
School of Nursing and Midwifery,Qazvin University of Medical Sciences, Shahid Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Fax
+98 28 3335 5162
Email
arashghisvand@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Arash Ghiasvand Mohammad Khani
Position
Master of Nursing in Geriatric nursing
Latest degree
Master
Other areas of specialty/work
Geriatrics
Street address
School of Nursing and Midwifery,Qazvin University of Medical Sciences, Shahid Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Fax
+98 28 3335 5162
Email
arashghisvand@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Arash Ghiasvand Mohammad Khani
Position
Master of Nursing in Geriatric nursing
Latest degree
Master
Other areas of specialty/work
Geriatrics
Street address
School of Nursing and Midwifery,Qazvin University of Medical Sciences, Shahid Bahonar Boulevard
City
Qazvin

Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Fax
+98 28 3335 5162
Email
arashghisvand@gmail.com

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
Yes - There is a plan to make this available
Title and more details about the data/document
After deleting the name and mobile number and address of the participants, the rest of the data can be published.
When the data will become available and for how long
Immediately after the publication of the results data can be published
To whom data/document is available
All researchers
Under which criteria data/document could be used
Unconditional
From where data/document is obtainable
Contact the following email to receive data : arashghisvand@gmail.com
What processes are involved for a request to access data/document
Unconditional
Comments