

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Sep 2021

### The effect of multimedia education on the family- centered approach of telephoning (tele nursing) on quality of life and self-efficacy of patients with myocardial infarction

#### Protocol summary

##### Study aim

Determining the impact of multimedia education on quality of life and self-efficacy in patients with MI.

##### Design

Clinical trials with community based and pragmatic control group, with parallel groups, randomized

##### Settings and conduct

This intervention will be carried out in the CCU of the Ayatollah Kashani Hospital and the ICU. After obtaining the relevant permissions of the researcher during the week, go to section referring to the entry criteria, they will look at their units Selects the available sampling. After explaining the goals and methods of work, patients and patients will be informed of the consent of the name of the patient. Then, the questionnaire on quality of life and self-efficacy is completed by the peer reviewer. In the intervention group, a 10-person training session with a multimedia program called a 2 to 3 hour one-day workshop for the patient. Member family activist is held. At the end of the workshop, the training file will be given to patients and patients. In the intervention group, in addition to the workshop, telephone interviews are also conducted for 1 month by the doctor. There is no intervention in the control group and they receive all nursing routine care. Quality of life and self-efficacy of patients after a specified time (one month) will be measured and recorded using the Sherer General Self-efficacy Questionnaire and Quality of Life in Minnesota, respectively.

##### Participants/Inclusion and exclusion criteria

Detection of cardiovascular disease admission in CCU section possibility of telecommunication.

##### Intervention groups

In the intervention group, a training session is held with groups of 10 people per day for 2 to 3 hours for the patient or active member of the family. There is no intervention in the control group and they receive all

nursing routine care.

##### Main outcome variables

Quality of life; self-efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181122041720N2**

Registration date: **2019-06-22, 1398/04/01**

Registration timing: **prospective**

Last update: **2019-06-22, 1398/04/01**

Update count: **0**

##### Registration date

2019-06-22, 1398/04/01

##### Registrant information

##### Name

Shirin Madadkar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3338 2382

##### Email address

shirinmadadkar@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-11, 1398/04/20

##### Expected recruitment end date

2019-09-11, 1398/06/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of multimedia education on the family-centered approach of telephoning (tele nursing) on quality of life and self-efficacy of patients with myocardial infarction

**Public title**

The effect of multimedia education in the patients with myocardial infarction

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Definitive diagnosis of myocardial infarction Admitted to the ccu section Ability to make phone calls Computer access point

**Exclusion criteria:**

Disclaimer Death of the patient Extended hospitalization time

**Age**

From **45 years** old to **88 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be entered into the study with a simple sampling method based on the criteria for entering the study and will be based on the random numbers table in the groups (intervention and control).

**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**

National Ethics Committee for Biomedical Research

**Street address**

Rahmatieh, Islamic Azad University, Shahrekord

Branch

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8813733395

**Approval date**

2019-06-09, 1398/03/19

**Ethics committee reference number**

IR.IAU.SHK.REC.1398.001

**Health conditions studied****1****Description of health condition studied**

Myocardial infarction

**ICD-10 code**

122.0

**ICD-10 code description**

Myocardial infarction

**Primary outcomes****1****Description**

Quality of Life

**Timepoint**

Before the intervention and one month after the intervention

**Method of measurement**

Minnesota Questionnaire

**2****Description**

Self-efficacy

**Timepoint**

Before the intervention and one month after the intervention

**Method of measurement**

Scherer self-efficacy questionnaire

**Secondary outcomes**

empty

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

Intervention group: In an intervention group, a training session with groups of 10 persons was conducted through multimedia software called a 2 to 3 hour one-day workshop for the patient and active member of the family in the date and time coordinated in the training class available in the department. Gets At the end of the workshop, patient and family questions will be answered

in relation to the educational content provided. An educational file is also provided to patients and patients to be reviewed in the home. In the intervention group, in addition to the intervention workshop, the intervention is also conducted for 1 month (once a week) by the peer reviewer. Quality of life and self-efficacy of patients after a specified time (one month) were measured and recorded in each group using the Sherer General Self-efficacy Questionnaire and Minnesota's Quality of Life, respectively

**Category**

Rehabilitation

**2****Description**

Control group: There is no intervention in the control group and all nursing routine care is received. Quality of life and self-efficacy of patients after a specified time (one month) were measured and recorded using the Sherer General Self-efficacy Questionnaire and Minnesota's Quality of Life, respectively.

**Category**

N/A

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

Ayatollah Kashani Hospital and Hagar Shahrekord Hospital

**Full name of responsible person**

Shirin Madadkar

**Street address**

Nursing Street, Ayatollah Kashani Hospital and Hagar Shahrekord

**City**

Shahrekord

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**Phone**

+98 38 3336 1000

**Email**

Kashani@skums.ac.it

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

Islamic Azad University

**Full name of responsible person**

Dr. Hossein Sazegar

**Street address**

Rahmatieh, Islamic Azad University of Shahrekord

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info@skums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Research Deputy of Islamic Azad University, Shahrekord Branch

**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**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Shirin Madadkar

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

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**

Not applicable

**Data Dictionary**

Not applicable