

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The Effect of Smartphone-Based Educational Program on Self-Efficacy of Patients Undergoing Heart Valve Surgery and the Family Caregivers' Burden: Parallel Randomized Clinical Trial

#### Protocol summary

##### Study aim

Determining the impact of the designed educational program based on smartphones on the self-efficacy of patients undergoing heart valve surgery and the care burden of family caregivers.

##### Design

A parallel randomized clinical trial including a sample size of 60 people will be conducted in a randomized block fashion in two intervention and control groups. The random allocation sequence and the list of blocks will be obtained by the statistical consultant and with the help of the website <https://www.sealedenvelope.com>.

##### Settings and conduct

In the intervention group, in addition to heart valve replacement clinic training, training is done using an Android application. The control group will only use hospital and clinic training.

##### Participants/Inclusion and exclusion criteria

Patients have undergone mechanical heart valve replacement surgery for the first time. The age range of people is between 18 and 65 years. Have an Android smartphone. People who have hearing, visual and touch disorders or who are not able to speak Persian language.

##### Intervention groups

The smartphone-based application is installed by the researcher for the patient and caregiver in the intervention group, and they are taught how to use the application in a session. Both groups will use the routine training programs of the heart clinic. The control group will not receive additional training and will only benefit from clinic training.

##### Main outcome variables

Self-Efficacy ; burden of care

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210714051889N1**

Registration date: **2023-03-11, 1401/12/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-11, 1401/12/20**

Update count: **0**

##### Registration date

2023-03-11, 1401/12/20

##### Registrant information

##### Name

mohammad zarei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3872 0878

##### Email address

zarei.mohammad72@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-30, 1401/11/10

##### Expected recruitment end date

2023-03-21, 1402/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Smartphone-Based Educational Program on

Self-Efficacy of Patients Undergoing Heart Valve Surgery and the Family Caregivers' Burden: Parallel Randomized Clinical Trial

#### Public title

The Effect of Smartphone-Based Educational Program on Self-Efficacy of Patients Undergoing Heart Valve Surgery and the Family Caregivers' Burden

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The age range of people should be between 18 and 65 years. Have an Android smartphone. Patients undergo mechanical valve surgery for the first time.

##### Exclusion criteria:

Suffering from known physical and mental diseases that affect the quality of life, such as dialysis, or other known mental problems, such as depression and schizophrenia, which require special medication or diet (according to the patient's self-report). People who have participated in another educational program during the research.

People who have hearing, visual and touch disorders or who are not able to speak Persian language. People who underwent valve repair or biological valve.

#### Age

From **18 years** old to **65 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

Randomization will be done by block method. First, the random allocation sequence and block list will be obtained by the statistical consultant. The website <https://www.sealedenvelope.com> is used to generate a random sequence for block-type randomization so that there is no limit on the number of blocks for random allocation. In this research, the block method with a volume of 4 is used to create a random allocation sequence. According to the total number of samples required for the study, which was 60 family members and patients (30 patients and family members in the test group (A) and 30 family members and patients in the control group (B)), in 15 quadruple blocks including Two groups A and B will be randomly selected through the site. Based on the list of randomized blocks of four prepared, a trained nursing expert outside the research group is responsible for registering participants and assigning patients randomly, after the entry of each patient, according to the 15 blocks of four prepared in the first stage, each patient is Randomly placed in group A (intervention) or B (control group). For example, after randomly selecting the BBAB block, the patients were placed in the control, control, intervention and control groups in the order of their entry. And the sampling

process is done consecutively in the same way until the sampling is completed, and the code of each patient was also assigned to his family member. People are assigned to the desired group in the order of their entry into the study and randomly through randomized blocks.

#### 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

Ethics committee in research of the Faculties of Pharmacy, Nursing and Midwifery, Shahid Beheshti Un

##### Street address

Resalat Highway, Kerman Street, Shahid Mousavi Street

##### City

tehran

##### Province

Tehran

##### Postal code

1634678694

#### Approval date

2022-10-31, 1401/08/09

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.166

## Health conditions studied

### 1

#### Description of health condition studied

of Patients Undergoing Heart Valve Surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Self-efficacy of patients undergoing heart valve surgery

#### Timepoint

Before the intervention and eight weeks after the intervention

#### Method of measurement

Patient's demographic information questionnaire and Sullivan Cardiac Self-Efficacy Questionnaire (SCSES) are completed by the patient. Sullivan's self-efficacy

questionnaire has 16 questions, which evaluates the level of confidence and self-efficacy of patients in the field of compliance with general care, control of disease symptoms, and compliance with medication orders. The questionnaire is scored on a 5-point Likert scale, including completely = 4, very much = 3, almost = 2, a little = 1 to not at all = 0.

## 2

### **Description**

Caring burden of family caregivers

### **Timepoint**

Before the intervention and eight weeks after the intervention

### **Method of measurement**

The caregiver demographic information questionnaire and the CBI care burden questionnaire are completed by the caregiver. The care burden questionnaire has 24 statements, which was created in 1989 by Novak and Guest to measure the objective and mental burden of care and measures the burden of mental care with more emphasis. This questionnaire has five subscales and includes time-dependent caregiving burden, evolutionary caregiving burden, physical caregiving burden, social caregiving burden, and emotional caregiving burden. ), it measures partially correct (score 2), correct (score 3) and completely correct (score 4), therefore, the scores obtained from this questionnaire are from zero to 96.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The intervention is in the form of providing an application (Android application) that can be installed on the phone, which provides information about heart valve failure and dysfunction, familiarity with drugs and the necessity of using them, the importance of the role of self-efficacy in the patient, and the beneficial effects of self-care and emphasis. on the importance of the role of caregivers and reducing the burden of care and how to take proper care of oneself and its dimensions and the importance of how to manage symptoms and signs in emergency situations and the importance of making changes in lifestyle for the patient and caregiver (including following a proper diet, mobility and exercise, It includes medication adherence, smoking cessation, weight control) and other educational information. The smartphone-based application is installed by the researcher for the patient and caregiver in the intervention group, and a session is taught on how to use the application (in order to prevent access to the application by the control group during the intervention, a special password is required to enter the program given to a phone). At the same time, the intervention group will use the routine training programs of the heart clinic. During the implementation of the intervention until

the re-completion of the questionnaires, the researcher was in contact with the caregivers and the patient through telephone calls and questions and answers with the participants through the formation of a group in the available social network (if the participants are satisfied). And while following up by phone, their questions will be answered. After 8 weeks from the end of the intervention, the questionnaires will be given to the intervention group again.

### **Category**

Other

## 2

### **Description**

Control group: At the same time, the control group will benefit from the clinic's routine training in the form of face-to-face training and hospital pamphlets. The relevant questionnaires are designed face-to-face or press-line and are completed by the research sample (including the patient and his caregiver) and face-to-face training sessions are arranged in one to two sessions according to the needs of the individual and then to answer questions no. The phone will be provided to them.

### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Modares and Imam Hossein Hospital

##### **Full name of responsible person**

MOHAMMAD ZAREI

##### **Street address**

South Rodaki Street, Shahid Ali Mazaheri Alley, Moghadam Alley 2, No. 12, Unit 1

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##### **Province**

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##### **Postal code**

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##### **Phone**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Dr. Afshin Zarghi

##### **Street address**

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**Web page address**

<https://research.sbmu.ac.ir>

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

MOHAMMAD ZAREI

**Position**

Bachelor's degree nursing student majoring in special care nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Position**

Master's degree student in nursing majoring in special care nursing

**Latest degree**

Bachelor

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available