

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### Comparing the effect of follow-up care by telephone and short message services on patients' quality of life after cardiac valve replacement surgery

#### Protocol summary

##### Summary

This clinical trial study was done on patients admitted for valve replacement surgery. Inclusion criteria included; Having literacy of reading and writing, Lack of speech and hearing problems, Possible access to telephone and mobile phone (ability to use short message by the patient or the closest person to him/her, Cardiac valve replacement surgery for the first time and age between 15 and 75 years old. Samples were chosen before surgery according to inclusion criteria by convenience sampling (based on target) and after written consent. They were in three groups of telephone-care follow-up, Short message follow-up and control in the form of random allocation (ball bag). Totally in this study 99 people were assessed (Thirty three people in telephone follow-up group, Thirty three people in short message follow-up group and thirty three people in control group). One booklet was given to all the three groups before discharge and with the content which was derived from the booklet; Education was given with the presence of the samples. In the telephone follow-up group, there was call contact in the first month two times per week, and in the second and third months one time per week before noon. In the short message follow-up group, one message had been sent daily before noon. There was no follow-up in control group. In this study patient's quality of life assessed by Nottingham quality of life questionnaire before and 3 months after surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013031212797N1**

Registration date: **2013-08-19, 1392/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-08-19, 1392/05/28

##### Registrant information

###### Name

Fateme Ghafori

###### Name of organization / entity

Baqiyatallah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2245 1225

###### Email address

rbt@bmsu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Baqiyatallah University of Medical Sciences

##### Expected recruitment start date

2011-10-23, 1390/08/01

##### Expected recruitment end date

2012-01-21, 1390/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of follow-up care by telephone and short message services on patients' quality of life after cardiac valve replacement surgery

##### Public title

The effect of follow-up care by telephone and short

massage services on patients' quality of life after cardiac valve replacement surgery

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria; 1. Lack of suffering progressed form of diseases of vital organs (Motor disability, Rheumatoid Arthritis, Stroke and etc...) and psychopathy (Schizophrenia, Psychosis, Depression and...), 2. Having literacy of reading and writing, 3. Lack of speech and hearing problems, 4. Possible access to telephone and mobile phone (ability to use short massage by the patient or the closest person to him/her, 5. Cardiac valve replacement surgery for the first time, 6. age between 15 and 75 years old. exclusion criteria ; 1. Sample's unwillingness to cooperate at any stage of the research, 2. Appearance of physical and mental problems that lead to patient's disability at any stage of the research.

## Age

From **15 years** old to **75 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **99**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Baqiyatallah University of Medical Sciences Ethics Committee

##### Street address

Baqiyatallah University of Medical Sciences, Mollasadra Street, Tehran

##### City

Tehran

##### Postal code

#### Approval date

2011-11-29, 1390/09/08

#### Ethics committee reference number

28

## Health conditions studied

### 1

#### Description of health condition studied

Heart Valve Disorders

#### ICD-10 code

I39\*

#### ICD-10 code description

Endocarditis and Heart valve Disorders in Diseases Classified Elsewhere

## Primary outcomes

### 1

#### Description

Quality of Life

#### Timepoint

Before surgery, Three months after surgery

#### Method of measurement

Nottingham Quality of Life Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Short message Intervention: One message had been sent daily.

#### Category

Other

### 2

#### Description

Telephone Intervention: There was call contact in the first month two times per week, and in the second and third months one time per week.

#### Category

Other

### 3

#### Description

Control group : No follow - up.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baqiyatallah Hospital

##### Full name of responsible person

##### Street address

Baqiyatallah Hospital, Mollasadra Street, Tehran, Iran

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

Jamaran Hospital

**Full name of responsible person**

**Street address**

Jamaran Hospital, Jamaran Street, Tehran, Iran

**City**

Tehran

**3**

**Recruitment center**

**Name of recruitment center**

Shahid Rajayee Center

**Full name of responsible person**

**Street address**

Shahid Rajayee Center, Vali-asr Street, Tehran, Iran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Morteza Izadi

**Street address**

Baqiyatallah University of Medical Sciences,  
Mollasadra Street, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Baqiyatallah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Fateme Ghafori

**Position**

MSc.

**Other areas of specialty/work**

**Street address**

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fatemeghafor@yahoo.com

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Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Mahdi Sadeghi Sherme

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fatemeghafor@yahoo.com  
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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**  
empty

**Study Protocol**  
empty  
**Statistical Analysis Plan**  
empty  
**Informed Consent Form**  
empty  
**Clinical Study Report**  
empty  
**Analytic Code**  
empty  
**Data Dictionary**  
empty