

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of telephone nursing consult (telenursing) on adherence to diet and medication regimen and incidence of clinical manifestations in myocardial infarction patients

#### Protocol summary

##### Summary

The objective of this study was to determine the effect of telephone nursing consult (telenursing) on adherence to diet and medication regimen and incidence of clinical manifestations in myocardial infarction patients. In this quasi-experimental study, 100 patients diagnosed with myocardial infarction were randomly allocated to experimental (n=50) or control (n=50) groups. At the beginning of the study, in an one-hour session, two groups were trained on the importance of treatment adherence, and training booklet was also given to the patients. Then the patients in the study group were under a nursing consultant with telephone for 12 weeks (in the 1st four weeks, twice a week and in the 2nd four weeks, once a week and in the 3rd four weeks, once every two weeks), while the control group did not receive any intervention. Before and after performing the interventions, diet adherence was measured by using diet adherence questionnaire, medication adherence by using Morisky medication adherence questionnaire, and the incidence of clinical manifestations by using a clinical manifestation form during the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201409148505N8**

Registration date: **2015-03-04, 1393/12/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-03-04, 1393/12/13

##### Registrant information

##### Name

Seyed Saeed Najafi

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1727 7445

##### Email address

najafisa@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2014-07-15, 1393/04/24

##### Expected recruitment end date

2014-09-15, 1393/06/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of telephone nursing consult (telenursing) on adherence to diet and medication regimen and incidence of clinical manifestations in myocardial infarction patients

##### Public title

The effect of telephone nursing consult (telenursing) on adherence to diet and medication regimen and incidence of clinical manifestations in myocardial infarction patients referring to cardiovascular clinic affiliated to Shiraz university of medical science, 2014

##### Purpose

Health service research

### **Inclusion/Exclusion criteria**

Inclusion criteria: Having a heart attack for the first time; passing at least 2 months after the heart attack; confirming a definitive diagnosis of a heart attack and being under treatment; not being afflicted with a severe and life threatening disease; having heart ejection fraction of 30% or more; having no hearing and speaking problem; having access to telephone and knowing how to use it. Exclusion criteria: Were unwillingness to cooperate and have phone calls for more than 3 consecutive times; needing a coronary artery bypass surgery.

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: **100**

### **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**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

7th floor, Central Building of Shiraz University of Medical Sciences, next to Red Crescent Organization, Zand Street, Shiraz

##### **City**

Shiraz

##### **Postal code**

71345-1978

##### **Approval date**

2014-07-14, 1393/04/23

##### **Ethics committee reference number**

ct-93-7089

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

myocardial infarction

#### **ICD-10 code**

I20,I21-I2

#### **ICD-10 code description**

Ischaemic heart diseases

## **Primary outcomes**

### **1**

#### **Description**

Diet adherence

#### **Timepoint**

Before and 3 months after intervention

#### **Method of measurement**

Questionnaire

### **2**

#### **Description**

Medication adherence

#### **Timepoint**

Before and 3 months after intervention

#### **Method of measurement**

Questionnaire

### **3**

#### **Description**

Clinical manifestations

#### **Timepoint**

During the study

#### **Method of measurement**

Clinical manifestations form

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention in the study group: In a one hour training session, the patients received face to face training about importance of treatment adherence and training booklet was also given to the patients. Then, the patients were under a sustained nursing consultant with telephone for 12 weeks (in the 1st four weeks, twice a week and in the 2nd four weeks, once a week and in the 3rd four weeks, once every two weeks). The maximum call duration was determined 15 minutes and patients could decide on the contact time from 8 am to 8 pm. The contents of phone calls were as follows: researcher self-introduction and general addressing of the patient's health condition, giving health advices and education about nutrition and

medication, questioning the extent of the patient's adherence to diet and medication and incidence rates of clinical manifestations, reinforcement of healthy behaviors and finishing phone calls with motivational words and arranging the next call. In the case of any question or problem, they could contact the researcher at any time.

**Category**

Other

**2**

**Description**

Control group: In a one hour training session, the patients received face to face training about importance of treatment adherence and training booklet was also given to the patients.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Cardiovascular clinics of Alzahra hospital

**Full name of responsible person**

Dr Kamran Aghasadeghi

**Street address**

Alzahra Hospital, Sibowyeh Blvd, Shiraz, Iran

**City**

Shiraz

**2**

**Recruitment center**

**Name of recruitment center**

Imam Reza polyclinic

**Full name of responsible person**

DR Kamran Aghasadeghi

**Street address**

Zand blvd, Namazi square, Next to Blood transfusion organization

**City**

Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Gholamreza Hatam

**Street address**

7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz

**City**

Shiraz

**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, Shiraz 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**

Shiraz University of Medical Science

**Full name of responsible person**

Maryam Shabani

**Position**

Master science student

**Other areas of specialty/work**

**Street address**

Hazrat-e-Fatemeh nursing and midwifery college, Namazi Hospital, Namazi Square, Shiraz, Fars

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

Seyed Saeed Najafi

**Position**

MS in nursing - Faculty member

**Other areas of specialty/work**

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Shiraz University of Medical Science

**Full name of responsible person**

Seyed Saeed Najafi

**Position**

MS in nursing - Faculty member

**Other areas of specialty/work**

**Street address**

No. 1132, street 1/23, Valiasr town, Rahmat blvd

**City**

Shiraz

**Postal code**

**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*