

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### The Effect of Telephone Nursing Follow-up on Quality of Life and HbA1C in Older People with Diabetes Referring to hospital

#### Protocol summary

##### Study aim

Determining the effect of telephone follow-up by a nurse on the quality of life and blood glycosylated hemoglobin in the elderly with diabetes hospitalized in hospitals affiliated to Shahid Beheshti University of Medical Sciences in 1401

##### Design

Semi-experimental study with control group, with parallel groups, randomized

##### Settings and conduct

People are randomly divided into intervention and control groups. The research tools will be a specific questionnaire for the quality of life of the elderly and a device for measuring glycosylated hemoglobin. Diet, exercise and drug therapy training will be given to the elderly in the hospital. People in the intervention group will be followed up by phone through a nurse for three months. The research tools will be completed immediately and one month after the intervention by the research units.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to speak Persian Confirmation of diabetes by a doctor People over 60 years old Telephone access at home No speech and hearing problems Glycosylated hemoglobin more than 7 and treated with oral hypoglycemic drugs Not suffering from the advanced form of diseases of vital organs and known mental disorders Non-entry criteria: Insulin therapy Suffering from diabetic ketoacidosis or hyperosmolar non ketonic hyperglycemic syndrome

##### Intervention groups

In the intervention group, trainings with the content of diet for diabetic patients, doing aerobic and stretching exercises, and drug therapy for the elderly will be conducted through lectures along with educational videos. There will be no educational intervention in the control group.

##### Main outcome variables

Changes in the amount of glycosylated hemoglobin

Quality of life score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230217057440N1**

Registration date: **2023-03-23, 1402/01/03**

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

Last update: **2023-03-23, 1402/01/03**

Update count: **0**

##### Registration date

2023-03-23, 1402/01/03

##### Registrant information

##### Name

Elahe Asadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8832 2352

##### Email address

www.elaheasadi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-28, 1401/12/09

##### Expected recruitment end date

2023-07-02, 1402/04/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
The Effect of Telephone Nursing Follow-up on Quality of Life and HbA1C in Older People with Diabetes Referring to hospital

**Public title**  
Telephone Nursing Follow-up on Quality of Life

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Have the ability to speak Persian Their diabetes has been confirmed by an internist or endocrinologist The age of people is more than 60 years Willingness to participate in research. Have access to a telephone at home Do not have speech and hearing problems have glycosylated hemoglobin more than 7 and be treated with oral hypoglycemic drugs Absence of suffering from the advanced form of diseases of the vital organs of the body and known mental disorders  
**Exclusion criteria:**  
diabetes control to insulin therapy Suffering from diabetic ketoacidosis or hyperglycemic hyperosmolar non-ketonic syndrome

**Age**  
From **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **90**  
More than 1 sample in each individual  
Number of samples in each individual: **1**  
In this study, each person participating in the study is the same as the number of people included in the study, and each person provides a sample for the study.

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this interventional study, all the centers covered by Shahid Beheshti University of Medical Sciences will be classified into four clusters based on geographical region, and one hospital will be randomly selected within the clusters. In this way, a total of four hospitals will be considered, two hospitals will be randomly assigned to select the samples of the intervention group (45 people) and two hospitals will be assigned to select the samples of the control group (45 people) (using cards lottery). Inside the hospitals, according to the characteristics of the research units, the samples will be selected by available sampling method. In other words, it will be a multi-stage cluster sampling method.

**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 Shahid Beheshti University of Medical Sciences  
**Street address**  
No. 2661, College of Nursing and Midwifery, in front of Shahid Rajaei Heart Hospital, Vali Asr St., Niayesh Intersection, Tehran., Iran.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985717443

**Approval date**  
2022-09-06, 1401/06/15

**Ethics committee reference number**  
IR.SBMU.PHARMACY.REC.1401.119

**Health conditions studied**

**1**

**Description of health condition studied**  
Diabetes  
**ICD-10 code**  
E11.6  
**ICD-10 code description**  
Type 2 diabetes mellitus with other specified complications

**Primary outcomes**

**1**

**Description**  
Glycosylated hemoglobin change rate  
**Timepoint**  
Measurement of glycosylated hemoglobin at the beginning of the study and three months after the beginning of the training  
**Method of measurement**  
Measuring Glycosylated Hemoglobin Using Blood Sample with High Performance Liquid Chromatography Method

**2**

**Description**  
The Quality of life score  
**Timepoint**

The Quality of life score at the beginning of the study and three months after the beginning of the training

#### Method of measurement

Measuring the Quality of Life Score with a Specific Questionnaire for Measuring the Quality of Life of the Elderly

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: At the beginning of the study, completion of the quality of life questionnaire for the elderly, training on the content of the diet of diabetic patients, aerobic and stretching exercises and drug therapy for the elderly in the form of lectures along with educational videos, telephone follow-up for 12 weeks (in the first month of each week Twice and once a week during the second and third months), one month after the end of the last telephone follow-up, the people of the intervention group will complete a special questionnaire measuring the quality of life of the elderly.

#### Category

Lifestyle

### 2

#### Description

Control group: No educational intervention was done

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Selected centers related to Shahid Beheshti University of Medical Sciences in Tehran

##### Full name of responsible person

Abbas Abbaszadeh

##### Street address

No. 2661, College of Nursing and Midwifery, in front of Shahid Rajaee Heart Hospital, Vali Asr St., Niayesh Intersection, Tehran., Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 8865 5366

##### Email

aabbaszadeh@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Abbas Abbaszadeh

##### Street address

No. 2661, College of Nursing and Midwifery, in front of Shahid Rajaee Heart Hospital, Vali Asr St., Niayesh Intersection, Tehran., Iran.

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+98 21 8865 5366

##### Email

elaheasai@sbmu.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 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

Abbas Abbaszadeh

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Nursery

##### Street address

No. 2661, College of Nursing and Midwifery, in front of Shahid Rajaee Heart Hospital, Vali Asr St., Niayesh Intersection, Tehran., Iran.

##### City

Tehran

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1985717443  
**Phone**  
+98 21 8865 5366  
**Email**  
aabaszadeh@sbmu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Abbas Abbaszadeh  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No. 2661, College of Nursing and Midwifery, in front of Shahid Rajaei Heart Hospital, Vali Asr St., Niayesh Intersection, Tehran., Iran.  
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**Email**  
aabaszadeh@sbmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Abbas Abbaszadeh  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Nursery  
**Street address**  
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aabaszadeh@sbmu.ac.ir

## 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

The information related to the main outcome, including the quality of life score and the change in the amount of glycosylated hemoglobin in the blood, can be shared.

### When the data will become available and for how long

The access period starts 6 months after the results are published.

### To whom data/document is available

Study data will be available to researchers working in academic and scientific institutions and people who are also engaged in industry.

### Under which criteria data/document could be used

Secondary analyzes are performed on the primary data of the present study by the groups requesting the study data.

### From where data/document is obtainable

Corresponding author and research team  
aabaszadeh@sbmu.ac.ir ADDRESS: Vali Asr St., Niayesh Intersection, Tehran, in front of Shahid Rajaei Heart Hospital, College of Nursing and Midwifery

### What processes are involved for a request to access data/document

Through correspondence with the responsible author, within three working days, the data will be provided to the requesting person via email.

### Comments