

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Investigating the impact of the home visit program on the burden of care and self-efficacy of the Caregivers of veterans with diabetes

#### Protocol summary

##### Study aim

Determining the effect of the home visiting program on caregiving pressure and self-efficacy of caregivers of veterans with diabetes

##### Design

A single-blind randomized controlled clinical trial in which the randomization method is used by lottery from the list of samples

##### Settings and conduct

In the home of eligible veterans, entry into the study will take place in the presence of the main caregiver and with informed consent in Gorgan city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: caring for a veteran with 50% or more diabetes; complete and full-time care of the veteran; caregiver's absence of disease at the time of research; having at least the fifth primary level of care; not caring for another patient at the same time as caring for a veteran; not having stressful experiences in the past six months. Exclusion criteria: unwillingness to cooperate and continue studying; death of study caregiver or veteran; caregiver suffering from an acute illness or hospitalization while conducting research. A veteran suffering from an acute illness or being hospitalized while conducting research; the occurrence of a stressful event for the caregiver during the research; cancellation of 2 consecutive visit sessions.

##### Intervention groups

Trainings based on meeting care needs and according to people's abilities

##### Main outcome variables

care pressure; self-efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231018059763N1**

Registration date: **2024-01-19, 1402/10/29**

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

Last update: **2024-01-19, 1402/10/29**

Update count: **0**

##### Registration date

2024-01-19, 1402/10/29

##### Registrant information

###### Name

Mohammad Maghsoudloomahali

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3236 4770

###### Email address

mohammadmaghsoudloo5784@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-02-20, 1402/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the impact of the home visit program on the burden of care and self-efficacy of the Caregivers of veterans with diabetes

##### Public title

Investigating the effect of home visits on caregiving

pressure and self-efficacy

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Caring for a veteran with 50% or more of diabetes  
Providing full and full-time care for the veteran Not  
having a disease at the time of the research Having at  
least fifth grade education Not caring for another patient  
at the same time as caring for the veteran Not having  
stressful experiences during The past six months  
**Exclusion criteria:**  
Unwillingness to cooperate and continue studying Death  
of the study caregiver or veteran Caregiver suffering  
from an acute illness or hospitalization while conducting  
research A veteran suffering from an acute illness or  
being hospitalized while conducting research The  
occurrence of a stressful incident for the caregiver during  
the research Cancellation of 2 consecutive visit sessions

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: 30

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

**Randomization description**  
Simple randomization. First a list of eligible study entry  
samples that have submitted their consent by filling out  
the informed consent form is drawn then the first sample  
is placed in the intervention group and the next sample  
is placed in the control group and this continues until all  
the samples are completed and at the end we will have  
an equal group

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The samples in each group are unaware of the existence  
of the other group

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**

Ethics committee of zabol University of Medical  
Sciences

### **Street address**

Shahid bagheri Ave., Rajaei Ave.

### **City**

Zabol

### **Province**

Sistan-va-Balouchestan

### **Postal code**

9861663335

### **Approval date**

2023-10-14, 1402/07/22

### **Ethics committee reference number**

IR.ZBMU.REC.1402.080

## Health conditions studied

### 1

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

diabetes

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

E10-E14

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

Incl.: diabetes (mellitus)(nonobese)(obese): • adult-onset  
• maturity-onset • nonketotic • stable non-insulin-  
dependent diabetes of the young Excl.: diabetes mellitus  
(in): • malnutrition-related (E12.-) • neonatal (P70.2) •  
pregnancy, childbirth and the

## Primary outcomes

### 1

#### **Description**

"Care pressure score in the Novak and Ghost  
questionnaire ""automatic rate in the Scherer and  
colleagues questionnaire"

#### **Timepoint**

Before the intervention and 3 months after the end of  
the intervention

#### **Method of measurement**

Care pressure of Novak and Gost questionnaire and self-  
efficacy questionnaire of Sherer et al

## Secondary outcomes

empty

## Intervention groups

### 1

#### **Description**

The intervention consists of 4 home visits which address  
the needs of care and their education on diabetes the  
duration of each session is 40 minutes and each session  
addresses specific topics in the context of the situations  
that a person needs in relation to diabetes

#### **Category**

Behavior

## 2

### Description

Control group: In the control group, routine training (including control of disease complications, drug complications, insulin therapy, how to control blood sugar, diet, physical activities) will be provided to caregivers through educational pamphlets.

### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

General Administration of Martyr Foundation and Martyrs Affairs of Golestan Province

##### Full name of responsible person

Vaziri Esrafil

##### Street address

vila Ave, 5Azar Blvd

##### City

Gorgan

##### Province

Golestan

##### Postal code

4917758643

##### Phone

+98 17 3234 8551

##### Email

info@zbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zabol University of Medical Sciences

##### Full name of responsible person

Dr.Khadige Rezaei kheykhaei

##### Street address

Rajaei Ave

##### City

Zabol

##### Province

Sistan-va-Balouchestan

##### Postal code

98616615881

##### Phone

+98 54 3223 0768

##### Email

kh\_rezaeikahkha@zbm.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Zabol 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

Zabol University of Medical Sciences

##### Full name of responsible person

Mohammad Maghsoudloo mahali

##### Position

Master of Science in Nursing

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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Ferdowsi Ave

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Sistan-va-Balouchestan

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9861734184

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+98 54 3222 3947

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m.Maghsodloomahli@zbm.ac.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Position

Master of Science in Nursing

##### Latest degree

Bachelor

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mohammad Maghsoudloomahali

**Position**

Master of Science in Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

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9861734184

**Phone**

+98 54 3222 3947

**Fax**

**Email**

m.Maghsoadloomahli@zbmu.com

## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available