

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

Street address

Ferdowsi Ave

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861734184

Phone

+98 54 3222 3947

Fax

Email

m.Maghsoodloomahli@zbm.ac.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Mohammad Maghsoudloomahali

Position

Master of Science in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ferdowsi Ave

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861734184

Phone

+98 54 3222 3947

Fax

Email

m.Maghsoadloomahli@zbmu.com

Person responsible for updating data

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Mohammad Maghsoudloomahali

Position

Master of Science in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ferdowsi Ave

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

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