

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of Home visit programe on self- management behaiviors and glycemic control in Patients with Type 2 Diabetes treated by Insulin referred to shahid Asghar shabani diabetes clinic in Isfahan 2018-19.

Protocol summary

Study aim

Determination of the effect of home visit program on self-management behaviors and blood glucose control indices in patients with type 2 diabetes mellitus treated with diabetes mellitus in Shahid Asghar Shaban Esfahan, 2018-19

Design

This is a randomized controlled clinical trial that was conducted in a three-stage and two-group method by selecting 64 samples of patients with type 2 diabetes in Isfahan. Before performing the intervention, the researcher sampled in an accessible month. In order to randomly assign samples to the two groups, the researcher wrote the sample names on small sheets after the end of the sampling, and started inserting the sheets out of the box without inserting them. In this way, the person (first, third, and ...) was assigned to the control group to the intervention group and the couple (second, fourth, and ...).

Settings and conduct

In this research, firstly, need assessment and sampling in the unit of education were carried out to the patient of the specialized clinic of Shahid Asghar Shabani Esfahan Diabetes Mellitus, and then home visit visits were held at the patients' homes.

Participants/Inclusion and exclusion criteria

1-There is a definite diagnosis of type 2 diabetes by a specialist 2. Being treated with insulin (pen or syringe). 3. Have a file in the center 4.Passed at least one year of diagnosis 5. The patient is 40 to 60 years old. 6.Lack of HbA1C control according to the doctor's opinion 7. The fasting blood glucose is greater than or equal to 126. Exit criteria: 1. A relative or neighbor is another participant in the study. 2. Getting complications of illness or any other reason (immigration, death, etc.)

Intervention groups

Teaching self-management behaviors by doing a home

visit schedule and Receive education by the control group

Main outcome variables

Self-management behaviors, blood glucose control (fasting glucose and glycosylated hemoglobin)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130801014242N3**

Registration date: **2019-10-06, 1398/07/14**

Registration timing: **retrospective**

Last update: **2019-10-06, 1398/07/14**

Update count: **0**

Registration date

2019-10-06, 1398/07/14

Registrant information

Name

Maryam Shirazi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2904

Email address

m_shirazi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-07-14, 1397/04/23
Actual recruitment start date
 2018-06-10, 1397/03/20
Actual recruitment end date
 2018-07-14, 1397/04/23
Trial completion date
 2018-09-06, 1397/06/15

Scientific title
 The effect of Home visit programe on self- management behaviors and glycemic control in Patients with Type 2 Diabetes treated by Insulin referred to shahid Asghar shabani diabetes clinic in Isfahan 2018-19.

Public title
 The effect of Home visit programe on self- management behaviors and glycemic control

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 1- There is a definite diagnosis of type 2 diabetes by a specialist Being treated with insulin (pen or syringe). Have a file in the center. At least one year has passed since they diagnosed their illness. Have the desire to participate in research and get home visits. No cognitive impairment. Ability to speak and understand fully the Persian language and have a reading and writing literacy The patient is 40 to 60 years old. Is located in Isfahan. HbA1C is considered to be uncontrolled according to the medical records of the patient and the doctor's opinion. The fasting blood glucose is greater than or equal to 126. Due to the distance to the center, it is not possible to get regular visits to the center (at least 1-2 times a month) to receive education. Be a lady The long-term complications of diabetes have not been diagnosed. Previously, they have not participated in home visits for diabetes.
Exclusion criteria:
 A relative or neighbor is another participant in the study. The patient's unwillingness to continue participating in the study If you have any complications of illness or any other reason (migration, death, etc.), the patient should be excluded from the investigator's access to the hospital for admission to hospital.

Age
 From **40 years** old to **60 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **64**
 Actual sample size reached: **64**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In order to randomly assign samples to the intervention and control groups, the researcher will write the names of the samples on small sheets after the completion of

the sampling and place them in the box and begin to remove the sheets without inserting them from the box. Individuals (first, third, ...) will be assigned to the control group to the intervention group and the couple (second, fourth, and ...).

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 Isfahan University Of Medical Sciences

Street address

Hezarjirib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

13133437

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.MUI.REC.1396.3.871

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Self Management Behavior

Timepoint

Before, After and 3 month After The Prevention

Method of measurement

DSMQ Self Management Questionnaire

2

Description

Glycemic Control

Timepoint

Before and 3 month After The Prevention

Method of measurement

Blood Sampling (FBS and HbA1C)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Performing a home visit program (3-5 sessions) for each client and training self-management behaviors during home visits and taking fasting blood sugar and HbA1c samples at baseline and three months after interventions.

Category

Behavior

2

Description

Control group: Sampling of fasting blood sugar and HbA1c at baseline and three months after sampling and then giving them educational booklets.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid Asghar shabani diabetes clinic in Isfahan

Full name of responsible person

Maryam Shirazi

Street address

Hezarjirib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

13133437

Phone

+98 31 3792 7585

Email

m_shirazi@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahnaz Norouzi

Street address

Hezarjirib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

13133437

Phone

+98 31 3792 7585

Email

norouzi@nm.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Shirazi

Position

Academic Member, Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Hezarjirib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

13133437

Phone

+98 31 3792 7585

Email

m_shirazi@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Shirazi

Position

Academic Member, Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Hezarjirib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

13133437

Phone

+98 31 3792 7585

Email

m_shirazi@nm.mui.ac.ir

Other areas of specialty/work

Nursery

Street address

Hezarjirib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

13133437

Phone

+98 31 3792 7585

Email

m_shirazi@nm.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Shirazi

Position

Academic Member, Instructor

Latest degree

Master