Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of home care on glycosylated hemoglobin, quality of life, and readmission of patients with type 2 diabetes who have undergone surgery and are being discharged from selected training centers

Protocol summary

Study aim
Determining the effect of home care on quality of life, glycosylated hemoglobin and readmission of patients with type 2 diabetes undergoing surgery and discharged from selected educational hospitals in Isfahan 1398

Design
Randomized Clinical Trial.Double blind

Settings and conduct
for each patient in the intervention and control group, background and quality of life questionnaires will be completed and blood samples will be taken for glycosylated hemoglobin. The readmission questionnaire will be given to each patient to complete for each re-admission in three months priod and submit it to the researcher. In the intervention group, from the time of discharge, according to the protocol, visits will be planned and performed by the research team to determine and cover the educational, care and treatment needs of patients for 3 months. At the end of three months, for all patients in both intervention and control groups quality of Life Questionnaire will be completed .Blood samples will be taken for HbA1C testing.The research environment is patients' homes

Participants/Inclusion and exclusion criteria
1. The address of patients's residence is located in the geographical area of Isfahan. 2. Patients who speak Persian, 3. Patients who are able to communicate verbally 4. Patients with type 2 diabetes 5. Patients who consent to participate in the study 6. At the time of the research, they are being discharged from the surgical wards of selected hospitals (the discharge order is recorded in the file). 7. First-degree family members of the intervention group consented to participate in the study. 8. The age of the patients is 45 years and older. 9. Male patients must be married and living with their spouse during the intervention.

Intervention groups
One group: surgical patients being discharged

Main outcome variables
Quality of life, glycosylated hemoglobin and readmission

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190730044386N1**
Registration date: **2020-12-12, 1399/09/22**
Registration timing: **retrospective**

Last update: **2020-12-12, 1399/09/22**
Update count: **0**

Registration date
2020-12-12, 1399/09/22

Registrant information

Name
Parvaneh Abazari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-22, 1398/04/31

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
2019-07-22, 1398/04/31

Actual recruitment end date
2019-12-31, 1398/10/10
Trial completion date
2020-03-05, 1398/12/15

Scientific title
The effect of home care on glycosylated hemoglobin, quality of life, and readmission of patients with type 2 diabetes who have undergone surgery and are being discharged from selected training centers

Public title
The effect of home care on quality of life, re-admission and HbA1C of patients with diabetes
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Patients living in the geographical area of Isfahan Persian language Able to communicate verbally type2 diabetes Consent to participate in research inpatient in surgical wards with discharge order Consent the family to participate in the research at least 45 years old
Exclusion criteria:
Age
From **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation by blocking method will be done as follows: The researcher will divide the total sample size into smaller groups (groups of four) called blocks, considering that with a sample size of 70 and a quadruple block, an integer is not obtained, so we consider the number 72 and as a result we will have eighteen blocks. . The situations of placing people (four people) inside each block can be imagined and documented from the total number of samples from the intervention and control group {ACAC, ACCA, CCAA, CAAC, AACC, CACA)then assign a number to each of these blocks .ACAC = 1, ACCA = 2, CCAA = 3CAAC = 4, AACC = 5, CACA = 6)) We write the numbers on the balls of the same color and size and put them in the bag, and The three-year-old then pulls a ball out of the bag and, after recording the number on the ball, returns it to the bag and pulls out the next ball. In this way, during the sampling, according to the order of the blocks and the number taken out of the bag, sampling will be done. It is necessary to explain that the previous block must be completed to complete the next block.
Blinding (investigator's opinion)
Double blinded
Blinding description
In patient blinding, the researcher will explain the purpose of the study to both groups equally before randomly allocated the samples. Consent to participate in the study will be obtained from each participant in the study. Quality of life questionnaire for each of patients will be completed and a blood sample will be taken for glycosylated hemoglobin. Then, according to the block number (in which the four samples should be placed)patients will be randomly placed in intervention or control groups. Because sampling will be done on different days and in the morning and evening shifts, patients in the control and intervention groups will not be able to communicate with each other. In this study, blindness will also be performed for the statistical analyst. For this purpose, the letters A and B will be used to enter the data of the intervention and control group, and the analyst will not be aware of which letter belongs to which group under study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Fourth Floor,No 6,18th Alley,Friborg Street
City
Esfahan
Province
Isfehan
Postal code
8168783546
Approval date
2019-07-20, 1398/04/29
Ethics committee reference number
IR.MUI.RESARCH.REC.1398.210

Health conditions studied

1

Description of health condition studied
Diabetes Mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
HbA1C
Timepoint
At the beginning of the study and 3 months later
Method of measurement
Chromatography

Secondary outcomes

1

Description
Quality of life
Timepoint
At the beginning of the study and three months later
Method of measurement
Questionnaire

2

Description
Readmission
Timepoint
At the beginning of the study and three months later
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Home careInterventions in the test group include the following.A working team will be formed consisting of a nurse with 14 years of clinical experience (master's degree student in nursing) and her supervising professors (a PhD in nursing and an endocrinologist) a general surgeon and a dietitian.1- Quality of life questionnaire and background characteristics will be completed by patients at the beginning of the study2. Blood samples will be taken from patients to perform glycosylated hemoglobin test3- The first home visit will be done in the first 24 hours after discharge to determine and prioritize the patient's educational, care, treatment and support needs.4- Planning to cover the prioritized needs will be done in a meeting with other team members.5- The nurse will have scheduled visits to the patients' homes for 3 months to perform educational and care interventions, including changing the dressing , measuring blood sugar and teaching self management behaviors.The duration of home visits is estimated at least three hours per week in the first month, and in the second and third months,depending on the patient's needs, the frequency and duration of home care will vary.6- In addition to the scheduled visits, the nurse (researcher) telephone number will be provided to the family, who will contact the nurse in case of emergency and, if necessary, an additional home care session will be planned and performed.8-The medical needs of the patient will be covered by the team doctor in two ways. a- The nurse, in coordination with the doctor, will collect the necessary information in the patient's home and transfer it to the doctor.The doctor will then make the necessary treatment recommendations to the nurse based on the information received, and the nurse will follow the doctor's orders at home.B- If necessary, the doctor will personally visit the patient at home.8. The patient's nutrition pattern will be evaluated and information will be provided to the team dietitian.dietitian's recommendations based on the patient's needs will be taught to the patient and family at the nurse's next visit.13. The readmission questionnaire will be completed by the nurse each time the patient is readmitted for three months.14- At the end of the third month, a blood sample for HbA1C will be sent to the laboratory again.At the end of the third month, patients will complete the quality of life questionnaire again.
Category
Rehabilitation

2

Description
Control group:1- Quality of life questionnaire and background characteristics will be completed by patients at the beginning of the study2. Blood samples will be taken from patients to perform glycosylated hemoglobin test.3-Patients will be informed that they will be referred three months later to complete the Quality of Life Questionnaire and take a blood sample for HbA1C .4-.At the beginning of the study, the readmission questionnaire will be provided to patients. They will be taught how to complete the questionnaire and they will be asked to complete the questionnaire each time they are readmitted for three months.5- The nurse's phone number is provided to the patients so that they can contact them if they have any questions about completing the readmission questionnaire.6- The nurse will make a monthly phone call to the patients to remind them about completing the readmission questionnaire and that they will be referred to them by the end of the third month to test for glycosylated hemoglobin and complete the quality of life questionnaire. 7- Patients in the control group will not receive any care and treatment from the research team during the study period.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Selected Hospitals
Full name of responsible person
Parvaneh Abazari
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Sponsors / Funding sources

1

Sponsor
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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
70
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
Parvaneh Abazari
Position
Associate professor
Latest degree
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Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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