

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the nurse follow - up plan and its effect on self-care and metabolic control indices in diabetic patients

Protocol summary

Study aim

Evaluation the nurse follow - up plan and its effect on self-care and metabolic control indices in diabetic patients

Design

Clinical trial with control group, with parallel groups, randomized, on 65 patients

Settings and conduct

This study will be performed in Allameh Behloul Gonabadi Hospital as follows: In the intervention group: According to the ministry checklist, the patient's number will be called 3 to 7 days after discharge. The frequency of follow-up is determined as follows: 1. Green area: Follow the frequency of fish twice. 2. Yellow area: Frequency of follow-up once a week. 3. Red area: While advising to go to the hospital emergency department immediately, a follow-up by phone should be done up to 6 hours later. Follow-up of these patients is done twice a week after discharge from the hospital until they are in the green area. The control group will receive routine hospital training and follow-up. Of course, in order to maintain ethics, a normal follow-up will be done at least once in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of diabetes by a specialist Discharged from the hospital and referred to the hospital self-care and follow-up unit Age over 18 years Informed consent Access to phone or mobile Lack of speech, hearing and vision disorders and the ability to understand and answer questions Resident of Gonabad city No history of mental illness

Intervention groups

In the intervention group, the follow-up nurse project will be carried out. The control group will receive routine hospital care.

Main outcome variables

Self-care; Metabolic control indices of diabetic patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130428013152N3**

Registration date: **2021-05-22, 1400/03/01**

Registration timing: **prospective**

Last update: **2021-05-22, 1400/03/01**

Update count: **0**

Registration date

2021-05-22, 1400/03/01

Registrant information

Name

reza noori

Name of organization / entity

university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3513

Email address

noori.r@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the nurse follow - up plan and its effect on self-care and metabolic control indices in diabetic patients

Public title

Evaluation the nurse follow - up plan and its effect on self-care and metabolic control indices in diabetic patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of diabetes by a specialist doctor
Discharged from the hospital and referred to the self-care and follow-up unit of the hospital
Age over 18 years
Informed consent
Access to phone or mobile
No speech, hearing and vision disorders and the ability to understand and answer questions
Resident of Gonabad city
No history of mental illness

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by stratified random replacement blocks. Classes are based on three age groups (less than or equal to 45 years, 46 to 64 years, 65 years and more) and gender (male and female) that are created in a set of 6 classes. Randomization within each floor is done in the style of random replacement blocks with sizes 2 and 4. The list will be determined by the web analytics. In order to privatize the properties, opaque envelopes will be stamped using a random sequence

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The follow-up nurse project is being piloted at two medical universities.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Parastar Ave, Gonabad Town

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793918

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.GMU.REC.1400.013

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-care

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Diabetes Self-Care Questionnaire (F-SCODI)

2

Description

Fasting blood sugar

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Laboratory Kit

3

Description

Cholesterol

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Laboratory Kit

4

Description

Triglyceride
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Laboratory Kit

5

Description
Glycosylated hemoglobin
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Laboratory Kit

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Routine hospital care including discharge from the hospital and training during discharge by the patient nurse and return to the self-care clinic after 3 months
Category
N/A

2

Description
Intervention group: Follow-up nurse care plan including: performing safe discharge steps, introducing the patient to the follow-up nurse and sending his case summary. The patient's number is called the day after discharge. After contacting the patient and introducing yourself, based on the relevant checklist, the necessary follow-up is done and in any case where the patient needed further and supplementary training, recommendations are given. Also, if the patient needs support resources such as diabetes clinic, hospital self-care clinic, health centers, psychologist, addiction and smoking cessation centers, nutrition counselor and home care centers and referral until complete reassurance, the necessary follow-ups are done with the mentioned institutions. Frequency of follow-up is determined based on the severity of the disease and danger signs according to the instructions from three days to one year after discharge as follows: 1. Green area: Follow-up frequency of patients in the green area should be done twice as a fish. 2. Yellow area: Frequent follow-up of patients in the yellow area should be done once a week. Red area: While advising to go to the hospital emergency room immediately, a follow-up should be done by phone up to 6 hours later. Follow-up of these patients is done twice a week after discharge from the hospital until they are in the green area.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Behloul Gonabadi Hospital
Full name of responsible person
Elham Saberi Noghabi
Street address
Parstar Ave., Gonabad University of Medical Sciences
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Gonabad
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Razavi Khorasan
Postal code
9691793718
Phone
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Email
rnoori68@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Shahla Khosravan
Street address
Parstar Ave., Gonabad University of Medical Sciences
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Postal code
9691793718
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rnoori68@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Elham Saberi Noghabi

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Elham Saberi Noghabi

Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Reza Noori

Position

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Latest degree

Master

Other areas of specialty/work

Nursery

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Phone

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Email

Rnoori68@gmail.com

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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

All data related to the main consequences can be shared.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Data will be available to all researchers

Under which criteria data/document could be used

The data will be usable for further studies and improving patient care

From where data/document is obtainable

Elham Saberi Noghabi saberi.e@gmu.ac.ir

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

6 months after the publication of the results of the study, the applicant can submit a valid letter of introduction from an organization to the e-mail of Ms. Elham Saberi Noghabi and can request the data and the data file will be provided to her within two weeks.

Comments