Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of family- centered care based on Newman's systemic model on the quality of life in patients with diabetes type 2

Protocol summary

Study aim
Determining the impact of family-centered care based on Betty Newman's systemic model on the quality of life of patients with type 2 diabetes

Design
A randomized controlled clinical trial

Settings and conduct
The research population is all patients with type 2 diabetes referring to Imam Reza (AS) health center in Esfrain city.

Participants/Inclusion and exclusion criteria
Diagnosing type 2 diabetes according to the internist's opinion Having a history of type 2 diabetes for more than one year The ability of the patient to understand and speak Persian Possibility of direct contact with the patient In the critical phase of the disease

Intervention groups
After explaining the objectives of the research and obtaining the research consent, a demographic and quality of life questionnaire was filled out for all patients, and then the Newman evaluation form was completed for them during an interview with all patients in the intervention group. After the data were analyzed, nursing diagnoses based on Nanda It will be determined for patients in the intervention group.In the intervention group, introduce a first-class family member (spouse, parents, children, siblings) who had the most interaction and communication with him. Family-centered care for the intervention group is performed in 2 months, first, the educational needs of the patient with diabetes are determined through the Newman form and based on nursing diagnoses. Then the active member of the family in the intervention group will be trained about diabetes based on the nursing diagnosis.One month after the completion of the training, the quality of life questionnaire will be filled again by the patients of the test and control groups, and the quality of life measured in both the test and control groups before and after the intervention will be compared.

Main outcome variables
Quality of life based on Newman's systemic model

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200504047296N1**
Registration date: **2023-05-29, 1402/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-12, 1402/03/22**
Update count: **1**

Registration date
2023-05-29, 1402/03/08

Registrant information

Name
Somayeh Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3723 9195

Email address
somayerahimi90@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-21, 1402/02/31

Expected recruitment end date
2023-08-21, 1402/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of family- centered care based on Newman's systemic model on the quality of life in patients with diabetes type 2

Public title
The effect of family - centered care based on Newman's systemic model on the quality of life in patients with diabetes type 2

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient's condition: diagnosis of type 2 diabetes according to internal specialist's opinion Having a history of type 2 diabetes for more than one year The patient's ability to understand and speak Persian Conditions of one of the patient's family members: having literacy to read and write Willingness to participate in patient accompanying meetings Hearing the patient's words from him Living with the patient

Exclusion criteria:
In the critical phase of the disease

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In the first stage, sampling is done in a purpose-based manner, and the eligible samples are selected based on the study entry criteria, then they are randomly assigned to two test and control groups by block method with blocks of 4 people. The simple random method causes the inequality of people in two groups, which reduces the statistical power of the test used. Therefore, by using the block method with random allocation, the people assigned to two groups are equal to each other. To avoid predicting the allocation of people in the group, blocks of different sizes (blocks of 4 people and 6 people) are determined. Then, by entering the information of the number of blocks, groups and total samples to reliable sites such as "https://www.sealedenvelope.com/simple-randomiser/v1/lists", the order of people is assigned to groups, similar to the information below. be.

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 Islamic Azad Isfahan (Khorasgan) Branch University of Medical Sciences

Street address
East J St.-Arghavanieh-- University Blvd

City
Isfahan

Province
Isfehan

Postal code
81551-39998

Approval date
2023-04-17, 1402/01/28

Ethics committee reference number
IR.IAU.KHUISF.REC.1402.020

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11.8

ICD-10 code description
Type 2 diabetes mellitus with unspecified complications

Primary outcomes

1

Description
Quality of Life

Timepoint
At the beginning of the study and three months after the intervention

Method of measurement
Summarized clinical questionnaire of the quality of life of diabetic patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention in this study

includes teaching the diet plan of diabetics - teaching the general principles of diabetic foot care - teaching prevention methods - giving awareness and information about the disease - allowing the patient to express his feelings - regular blood sugar control - exercising the feet - Daily walk, regular use of diabetic medication - Regular examination of the skin of the limbs - Recommendation for regular examination by an ophthalmologist - Regular blood sugar control - Training on warning signs and prevention methods - Regular blood pressure control - Training on diet plan for diabetic patients - Previous blood sugar control Sleep-recommendation to exercise before going to sleep-not consuming caffeinated substances before going to sleep-providing a calm environment for sleeping-teaching the patient about the disease and how to control and prevent complications in the form of face-to-face meetings and preparation of educational pamphlets. The sessions are tailored to the educational needs of the patients and are at least 6 sessions of 30 minutes. A meeting will be held every week. The nursing diagnoses related to each patient will be determined based on the completion of the Newman evaluation form by the participating members of the intervention group, and the care plan will be designed and implemented based on the nursing process. that nursing diagnoses based on Nanda Nursing Diagnosis (Nursing Diagnosis Institute of North America) along with related nursing care will be implemented for each patient privately.

Category

Lifestyle

2

Description

Control group: The control group will only complete the quality of life questionnaire and demographic characteristics. The duration of the intervention lasts a maximum of 2 months, and one month after the end of the intervention, the quality of life questionnaire will be completed again.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

پایگاه بهداشتی امام رضا

Full name of responsible person

سمیه رحیمی

Street address

EMAM RESA

City

Esfarayen

Province

North Khorasan

Postal code

9661876981

Phone

+98 58 3722 3504

Email

SOMAYERAHIMI90@GMAIL.COM

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maasoumeh barkhordari

Street address

Shohada Gomnaam Blvd , Alam square , Professor Hasabi Blvd , Yazd

City

Yazd

Province

Yazd

Postal code

۱۴۷۷۸۹۳۷۸۰

Phone

+98 35 3187 1000

Email

INFO@IAUYAZD.AC.IR

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

SOMAYERAHIMI

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Taleghani Street, Central Building, Esfrain Faculty of Medical Sciences

City

Esfarayen
Province
North Khorasan
Postal code
9661876981
Phone
+98 58 3722 3504
Email
SOMAYERAHIMI90@GMAIL.COM

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
SOMAYE RAHIMI
Position
NURSE
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Imam Reza Street - Esfrain Faculty of Medical Sciences
City
Esfarayen
Province
North Khorasan
Postal code
9661876981
Phone
+98 58 3722 3504
Email
SOMAYERAHIMI90@GMAIL.COM

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
SOMAYE RAHIMI
Position
NURSE
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Imam Reza Street - Esfrain Faculty of Medical Sciences
City
Esfarayen
Province
Yazd
Postal code
9661876981
Phone
+98 58 3722 3504
Email
SOMAYERAHIMI90@GMAIL.COM

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
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
Not applicable
Title and more details about the data/document
The results of the data will be published in general and without identification code.
When the data will become available and for how long
After the decision of the journal to accept and publish the results in the form of an article
To whom data/document is available
magazine's editor in chef
Under which criteria data/document could be used
Checking the quality and scientific validity of the study
From where data/document is obtainable
SOMAYE RAHIMI
What processes are involved for a request to access data/document
After receiving the request, the editor of the magazine will decide which part of the information can be published, and after removing any identification code, the desired data will be sent by email.
Comments