Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of early palliative care on quality of life and self-care behaviours in patient with type2 diabetes

Protocol summary

Study aim
Determining the effect of early palliative care on the quality of life and self-care behaviors of patients with Dodge type diabetes

Design
Clinical trial with a control group, without blinding, randomized, on 100 patients

Settings and conduct
The people in the intervention group are given the necessary information about palliative care, the palliative care plan is given to the people, and its implementation is followed up.

Participants/Inclusion and exclusion criteria
inclusion criteria : Diagnosis of type 2 diabetes Having one of the complications of diabetes (diabetic foot ulcer, neuropathy, nephropathy, etc.) Access and ability to use mobile phones to coordinate meetings، Not suffering from other life-threatening chronic diseases such as cancer, heart failure, etc. Ability to communicate in Farsi Internet access Exclusion criteria : Non-cooperation during intervention Partially deaf Cognitive and mental disorder

Intervention groups
In the intervention group, the necessary information about palliative care is given during group and individual meetings, and the palliative care program is designed based on the needs of each person, and the control group receives the usual care plan.

Main outcome variables
Quality of Life, Self-care behaviors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231107059976N1**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **registered_while_recruiting**
Last update: **2023-12-29, 1402/10/08**
Update count: **0**

Registration date
2023-12-29, 1402/10/08

Registrant information
Name
Zahra Gholizade
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
2023-12-22, 1402/10/01

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
The effect of early palliative care on quality of life and self-care behaviours in patient with type2 diabetes

Public title
The effect of early palliative care on quality of life and self-care behaviours in patient with type2 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:

Diagnosis of type 2 diabetes Access and ability to use mobile phones Ability to communicate in Farsi Access to internet

Exclusion criteria:

Non-cooperation during intervention Suffering from other life-threatening chronic diseases such as cancer, heart failure, etc Partially deaf Cognitive and mental disorder

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation law is used to allocate two groups. First, the sample size is determined, which becomes 100, then each sample is assigned a number from 1 to 100, and each number is recorded on paper and thrown into a lottery container, and group A is the test group and group B is the group Control is considered. Each paper is taken randomly and without replacement and placed in group A and then B.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Nosrat St., Tohid Sq.

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2023-11-05, 1402/08/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.418

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

(E10-E14)

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Quality of life score with Quality of life questionnaire for patients with diabetes

Timepoint

At the beginning of the study and 5 weeks after the end of the study

Method of measurement

Quality of life questionnaire for patients with diabetes

2

Description

The score of Self-care behaviors with the questionnaire of self-care behaviors of patients with diabetes

Timepoint

At the beginning of the study and 5 weeks after the end of the study

Method of measurement

Questionnaire of self-care behaviors of patients with diabetes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention is held 4 sessions weekly, the first 2 sessions are in groups, people are divided into 5 groups of 10 people, and group training sessions will be held between 60 and 90 minutes, after the training, there will be time to answer the clients' questions and group discussion. Taken. Thus, in the first session, the concept of diabetes and its symptoms, consequences and risks, the concept of palliative care and palliative care in diabetes are discussed. In the second session, the control of symptoms in the field of diet, medication, exercise and movement will be discussed and the needs of people in these areas will be examined. . In the third session, symptom management will be discussed regarding symptom control, relaxation methods, nutritional recommendations, foot care, and the consequences of diabetes. The third and fourth session will be held individually, the fourth session will be

about examining the patient's values and helping to make decisions about treatment and symptom control, and the care plan will be based on the needs of the client and his participation, with special attention to the symptoms. physical and psychosocial are regulated and the goals of care are determined, In the fifth session, the general review of life will be done by the researcher through the client's participation, and his needs will be determined in terms of improving the level of life in different areas. Then for 5 weeks follow-up will be done by the researcher to answer the questions and check the adherence to the care plan through text message or phone call.

Category

N/A

2

Description

Control group: Routine care is received during the study and After completing the study, the training files will be provided to the control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Zahra Gholizadeh
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Imam Khomeini Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahrzad Ghiasvandian
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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Zahra Gholizadeh
Position
Master student
Latest degree
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Other areas of specialty/work
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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)

Yes - There is 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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data related to the main outcomes of the study

When the data will become available and for how long

The access period starts six months after the publication of the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For scientific use for studies

From where data/document is obtainable

Gholizade.zahra.1278@gmail.com

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

Send a letter with the title of study data request

Comments