

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3220 3966

###### Email address

gholizade.zahra.1278@gmail.com

##### 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**

Shahrazad Ghiasvandian

**Street address**

Nosrat St., Tohid Sq

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**Province**

Tehran

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**Email**

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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**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

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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

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Zahra Gholizadeh

**Position**  
Master student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nursery

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