

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Assessing the effect of self-management education on quality of life of patients with type 2 diabetes

Protocol summary

Summary

Objective: Determine the effect of self-management education on quality of life in patients with type 2 diabetes. Inclusion criteria: Patients who can understand and state Persian language; a definitive diagnosis of diabetes (type II) given by a doctor endocrinologist; similar research has not previously participated; there is a possibility of direct contact with the patient's home; disease is not known psychological and psychiatric drug use is not effective. Exclusion criteria: For some reason the patient needs to be hospitalized or emergency intervention so that the conditions of work with the researcher to los; during the study, the disease progresses in a manner that cannot work or if the patient dies; patients with physical limitations that prevent her colleagues is new. The sample size in this study, 98 patients (49 in each group) is. Patients in the intervention group self-management educational of four sessions on the topics of drug regimens, nutrition, physical activity, self-monitoring of blood glucose and foot care will be by researcher. Each session will be one hour. The intervals between training sessions a week. Training for ten-man group discussion with questions and answers, pamphlets and booklets will be provided training package includes. Diabetes quality of life brief clinical inventory questionnaire (DQOL- BCI) before and two months after the intervention by both the control and intervention is completed and evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040721637N1**

Registration date: **2015-06-08, 1394/03/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-08, 1394/03/18

Registrant information

Name

Asghar Salimi

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University Of Medical sciences

Expected recruitment start date

2015-07-12, 1394/04/21

Expected recruitment end date

2015-11-12, 1394/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of self-management education on quality of life of patients with type 2 diabetes

Public title

The impact of education on quality of life of diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients who can understand and state Persian language; a definitive diagnosis of diabetes (type II) given by a doctor endocrinologist; similar research has not previously participated; there is a possibility of direct contact with the patient's home; disease is not known psychological and psychiatric drug use is not effective. Exclusion criteria: For some reason the patient needs to be hospitalized or emergency intervention so that the conditions of work with the researcher to los; during the study, the disease progresses in a manner that cannot work or if the patient dies; patients with physical limitations that prevent her colleagues is new.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Science

Street address

The central building of Tehran university of medical sciences, Qods street, Keshavarz street, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-04-15, 1394/01/26

Ethics committee reference number

9111196031-1

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Quality of life

Timepoint

Before of intervention and two month after intervention

Method of measurement

Diabetes quality of life brief clinical inventory questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Self-management education is given through group discussion. The number of sessions, four one-hour sessions will be four weeks.

Category

Other

2

Description

Control group: Will receive routine educational program of center.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahroud Emam Hossein Hospital

Full name of responsible person

Masoumeh Ghasemi

Street address

Emam Hossein Hospital, Emam Street, Shahroud, Iran

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University Of
Medical science

Full name of responsible person

Masoud Younesian

Street address

The central building of Tehran university of medical
sciences, Qods street, Keshavarz street, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tehran University Of
Medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

School of Nursing and Midwifery, Tehran University of
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Full name of responsible person

Asghar Salimi

Position

Master Science Student of Nursing

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Person responsible for scientific

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty