

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Determination of the impact of family-based education on quality of life of patients with type 2 diabetes

Protocol summary

Summary

Objective: Determining the family-oriented training on the quality of life of the patients with type 2 diabetes. The studied group was the patients with type 2 diabetes. The sample size is 40 patients in every group. The samples were selected using random sampling method and divided into control and test groups randomly. The training course includes three 1-hour and thirty minutes session in 3 successive days. The phone follow up continues until the post-test implementation three months after the intervention. The inclusion criterion for this study is the patients with type 2 diabetes with the minimum age of 18 years old. The exclusion criterion is the absence of the patient and his family from one of the training sessions. The training curriculum includes three successive sessions with the patient and one of his family members in the test group and the patient himself in the control group. To compare the test and control groups after three months, the effect of the training course on quality of life of the patients will be investigated using post-test. The primary outcome is the patient's quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092210899N1**

Registration date: **2013-02-01, 1391/11/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-01, 1391/11/13

Registrant information

Name

Zahra Ashrafi

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-06-25, 1391/04/05

Expected recruitment end date

2012-08-21, 1391/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of the impact of family-based education on quality of life of patients with type 2 diabetes

Public title

Impact of family education on quality of life of diabetic patient

Purpose

Other

Inclusion/Exclusion criteria

The inclusion criteria: the doctor and the diagnostic tests' results should confirm the disease diagnosis. At least, 6 months should have passed the diagnosis. The patient or one of his family members should be

educated. They should understand Persian language. The patient or his family members should not have received any formal education. The patient should not suffer type 1 diabetes. The minimum age of the patient should be 18 years old. The exclusion criteria: the patient and his family do not want to cooperate anymore. The patient and his family do not attend one of the training sessions. The patient and his family have attended other organizations' formal training.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The samples are allocated to groups control and interventional.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Tehran University of Medical Sciences

Street address

Sixth Floor, Central Organization of TUMS, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-06-22, 1391/04/02

Ethics committee reference number

409/130/91/ۛ

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10, E11,

ICD-10 code description

Insulin-dependent diabetes mellitus, Non-insulin-dependent diabetes mellitus, Malnutrition-related diabetes mellitus, Other specified diabetes mellitus, Unspecified diabetes mellitus

Primary outcomes

1

Description

Quality of life

Timepoint

Before and three months after intervention

Method of measurement

Quality of life questionnaire Darvishpour Kakhaki

Secondary outcomes

empty

Intervention groups

1

Description

The training course consists of three successive sessions with the patient and one of his family members in the test group and the formulated content would be taught in three 1-hour and thirty minutes sessions in 3 successive days. The training content includes: explaining the disease and its implications and the importance of having information to control the disease; the increase and decrease of blood sugar level (first session); how to take the medication; how to inject insulin (the way to calculate the doses, the way to fill the syringe and so on); how to use the urine sugar test strips and glucometer (second session); diet and exercise and their role in controlling diabetes; and preventing the disease complications (third session). Afterwards, phone follow up would continue every two weeks. In order to compare the test and control groups after three months, the effect of training course on quality of life will be investigated through posttest.

Category

Other

2

Description

In the control group, the training course includes three successive sessions with the patient. The formulated content would be taught in three 1-hour and thirty minutes sessions in three successive days and at the beginning of the first session pretest and at the end the posttest would be taken from the topics of interest to confirm the effect of the presented training. The training content includes explaining the disease and its implications and the importance of being informed to

control the disease, and reduce the symptoms and increasing of the blood sugar level (first session); how to take the medication, how to inject insulin (how to calculate the doses, how to fill the syringe and so on); how to use the urine sugar test strips and glucometer (second session); diet and exercise and their role in controlling diabetes; and preventing the disease complications (third session). Afterwards, phone follow up would continue every two weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Daryadokht Masror Rudsary

Street address

Nosrat St., Tohid Sq., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Sixth Floor, Central Organization of TUMS, Keshavarz Blvd, Tehran, Iran

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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

Vice chancellor for research, Tehran University of Medical Sciences

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

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Daryadokht Masror Rodsari

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Faculty member of Nursing and Midwifery

Other areas of specialty/work

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Web page address**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