

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of empowerment model on quality of life and metabolic control in patients with type 2 diabetes

Protocol summary

Summary

Aim: Effect of empowerment model on quality of life and metabolic control in patients with type 2 diabetes.

Design: Double- Blind Clinical Trial. Method: patients will be allocated randomly to case and control groups. Data collection tools in this study includes investigation of laboratory indicators (for investigating the metabolic control), questionnaire of demographic information, questionnaire of empowerment evaluation of diabetic patients, and quality of life questionnaire, which will be completed before and after the intervention for both groups. Study population: patients with type 2 diabetes. Inclusion criteria: diagnosis of type 2 diabetes by doctor; minimum age of 18 and having a medical file in diabetes center of Shahroud. Exclusion criteria: not wanting to cooperate in any part of the study; inability to cooperate due to disease severity. In this study, with 95% confidence, power of 90% and by taking account of 10% attrition of sample units in each group, the calculated sample size for each group was 54 and consequently, a total sample size of 108 was obtained for two groups. Intervention: intervention for case group was by performing the empowerment education, and for control group was the center's routine education. Variables with main effect: metabolic control indicators and patients' quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082614484N1**

Registration date: **2014-03-17, 1392/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-17, 1392/12/26

Registrant information

Name

Mahdi Sadeghi

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 27 3334 1206

Email address

mahdisadeghi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council- Shahroud University of Medical Sciences

Expected recruitment start date

2013-10-30, 1392/08/08

Expected recruitment end date

2014-02-04, 1392/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of empowerment model on quality of life and metabolic control in patients with type 2 diabetes

Public title

Investigating the effect of education on quality of life and disease control in diabetic patients

Purpose

Health service research

Inclusion/Exclusion criteria

Main inclusion criteria: diagnosis of type 2 diabetes by the doctor; being at the minimum age of 18; and having a medical file in Diabetes center of Shahroud. Main exclusion criteria: not wanting to cooperate in any part of the study; inability to cooperate due to disease severity.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

people who completed the questionnaire were blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical Sciences

Street address

Shahroud, Hafte-Tir Square, Shahroud University of Medical Sciences 7th Tir Square, Shahroud, Iran.
Postal Code: 361473955

City

Shahroud

Postal code

Approval date

2013-10-07, 1392/07/15

Ethics committee reference number

920/07

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E10, E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

quality of life

Timepoint

Before the intervention, three months after the intervention

Method of measurement

questionnaire of empowerment evaluation of diabetic patients, and questionnaire of quality of life specific to diabetic patients

Secondary outcomes

1

Description

metabolic control

Timepoint

before the intervention and three months after the intervention

Method of measurement

Indicators of glycosylated hemoglobin and blood sugar, and fat

Intervention groups

1

Description

intervention will be performed by applying the empowerment method on patients (in four areas of medical regimen, nutrition, exercise and feet caring) for 3 month according to the mentioned steps in the model as follows: first stage (understanding the threat), Second stage (problem solving) and Third stage (evaluation).

Category

Other

2

Description

The control group will receive the routine education.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes center of Imam Hosein Hospital in Shahroud

Full name of responsible person

Mahdi Sadeghi

Street address

Shahroud, Imam Hosein Hospital, Diabetes center

City
Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Emamian

Street address

Shahroud, Hafte-Tir Square, Shahroud University of Medical Sciences, Vice chancellor for research

City

Shahroud

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, Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Mahdi Sadeghi

Position

instructor/M.Sc.

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