

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparative assessment the effect of patient and family center education on quality of life and HbA1C in type 2 diabetic patients referring to diabetes clinic of Rafsanjan, 2018

Protocol summary

Study aim

Comparison the effect of patient and family center education on quality of life and HbA1C in type 2 diabetic patients referring to diabetes clinic of Rafsanjan, 2018

Design

Parallel group randomised trial, no blinded

Settings and conduct

The research population are patients with type 2 diabetes referred to the Diabetes Clinic of Rafsanjan. Sampling will be convenience. Allocation of samples will be done randomly by stratified method (minimization) and patients will assigned to three groups: patient-centered education groups (presence of the patient in educational sessions), family-centered education group (the presence of the patient and one of the family members in the training sessions) and control group. Educational intervention will conducted in two intervention groups for 12 weeks (6 session in first 6 weeks and 3 session in second 6 week).

Participants/Inclusion and exclusion criteria

Residents in Rafsanjan, type 2 diabetes, age over 40 years old and consent to participate in study are inclusion criteria. Having other forms of illness, in addition to diabetes and mental illness, are exclusion criteria.

Intervention groups

1. Family-centered education group 2. Patient-centered education group 3. Control group

Main outcome variables

Quality of life HbA1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N5**

Registration date: **2018-08-18, 1397/05/27**

Registration timing: **prospective**

Last update: **2018-08-18, 1397/05/27**

Update count: **0**

Registration date

2018-08-18, 1397/05/27

Registrant information

Name

Tabandeh Sadeghi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.sadeghi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative assessment the effect of patient and family center education on quality of life and HbA1C in type 2 diabetic patients referring to diabetes clinic of Rafsanjan,

2018

Public title

Comparison the effect of patient and family center education on quality of life and HbA1C in type 2 diabetic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Residents in Rafsanjan. Having type II diabetes. Age over 40 years old. Inform consent for participate in study.

Exclusion criteria:

Participate in another research project. Having other physical illnesses in addition to diabetes. Having psychiatric diseases.

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified Randomization by minimization method based on quality of life and HbA1C variables.

Blinding (investigator's opinion)

Not 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 Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-08-01, 1397/05/10

Ethics committee reference number

IR.RUMS.REC.1397.088

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Quality of life score

Timepoint

Pre intervention and 12 weeks post intervention

Method of measurement

SF36 questionnaire

2

Description

Mean of HbA1C

Timepoint

Pre intervention and 12 weeks post intervention

Method of measurement

Spectrophotometer device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patient-centered education group: patient will received educational intervention for 12 weeks (6 sessions in first 6 weeks and 3 sessions in second 6 weeks)

Category

Other

2

Description

Intervention group: family-centered education group: patient and one of family members will received educational intervention for 12 weeks (6 sessions in first 6 weeks and 3 sessions in second 6 weeks)

Category

Other

3

Description

Control group: no receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic of Ali Ebn Abitaleb Hospital

Full name of responsible person

Parisa Balaei

Street address

Mofateh Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0001

Email

aliebn@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0097

Email

vcrt@rums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Tabandeh Sadeghi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Parastar Ave

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Phone

+98 34 3425 5900

Fax

+98 34 3425 8497

Email

t.sadeghi@rums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Tabandeh Sadeghi

Position

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+98 34 3425 8497

Email

t.sadeghi@rums.ac.ir

Web page address

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Fax

+98 34 3425 8497

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t.sadeghi@rums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable