

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of family-centered education on family burden and anxiety of caregivers of elderly with type 2 diabetes

Protocol summary

Study aim

Determining the effectiveness of family-centered education on the care burden and anxiety of caregivers of the elderly with type 2 diabetes

Design

Clinical trial on diabetic and caring elderly, has an intervention and control group, simple randomization of even and odd with a sample size of 46 people in each group

Settings and conduct

The study site was at diabetic clinic of Khatam Al Anbia Hospital, Behshahr. Participants were selected by simple random method, and divided into two groups, intervention group and control group. The pre-test questionnaire was given to both groups and completed. Intervention group got four sessions of 45-minutes training based on an educational booklet, but the control group received routine care. Finally, both groups were given a post-test after one month that the intervention group's education was done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Able to read and understand Persian language questionnaire. 2-The caregiver has not previously attended relevant training sessions Exclusion criteria: 1-patient or family member cannot participate in all educational sessions 2-Caregivers and patients do not want to continue working together

Intervention groups

Explanation about diabetes, personal care training, drug management, diet management, daily life activities and ways to reduce the burden of care caregivers and caring for a diabetic elderly

Main outcome variables

Care burden; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200613047750N1**

Registration date: **2020-08-29, 1399/06/08**

Registration timing: **retrospective**

Last update: **2020-08-29, 1399/06/08**

Update count: **0**

Registration date

2020-08-29, 1399/06/08

Registrant information

Name

Mosa Kohsari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3215 7139

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered education on family burden and anxiety of caregivers of elderly with type 2 diabetes

Public title

Effectiveness of family-centered education in diabetes type 2

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Caregiver must be the next of kin of the patient and take full care of the patient (at least four days of a week).

Have the ability to read and comprehension of Farsi

Caregiver must not take care of any other patient than the diabetic patient The patient does not have a stroke, severe heart problems or be a dialysis patient. The caregiver must not suffer from mental, neurological or physical disorders The caregiver must not be a member of medical staff.

Exclusion criteria:

Patient or family member cannot participate in all educational sessions Caregivers and patients do not want to continue working together

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Random distribution to intervention and control groups: In this study, 46 number 1 and number 2 were placed in envelopes. During sampling, each participant got an envelope randomly. Then, number 1 were recognized as intervention group and participants with number 2 were named the control group

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

Babol University of Medical Sciences

Street address

Gorgan, Janbazan St., 560 Army Hospital

City

Behshahr

Province

Mazandaran

Postal code

4916795478

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.317

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.6

ICD-10 code description

Type 2 diabetes mellitus with other specified complications

Primary outcomes

1

Description

Care burden

Timepoint

Before starting the intervention and One month after the end of the intervention

Method of measurement

Caregiver burden inventory

2

Description

Anxiety

Timepoint

Before starting the intervention and One month after the end of the intervention

Method of measurement

Spielberger Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family caregivers for type 2 diabetics who have been trained for 4 Meeting-45-minute sessions based on a textbook. Training includes activities in the field of personal care, drug management, diet management, daily life activities and ways to reduce the burden of caregivers

Category

Behavior

2

Description

Control group: Family caregivers for type 2 diabetics who have received routine training

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Musa Koohsari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Musa Koohsari

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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