Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

A clinical trial on the effect of teaching versus non-teaching of supportive and obstructive behaviors to family caregivers on family behavior and self-care of patients with type 2 diabetes

Protocol summary

Summary

This study investigates the effect of teaching supportive and obstructive behaviors to family caregivers on family behavior and self-care of patients with type 2 diabetes. The study will be performed in the Diabetes Clinic of Birjand. Sixty patients with type 2 diabetes will be recruited via convenience sampling method. Major inclusion criteria comprised of obtaining maximally half total score on Self-Care Activities measure and on Family Behavior Checklist in the two subscales of supportive (less than 18) and obstructive (over 14) behaviors; living with family members; aged 30 to 60 years., etc. Family care-givers will be selected via convenience sampling method and according to the opinion of the diabetic patient. The caregivers will be randomly allocated into control (n=30) and intervention (n=30) groups through permutation blocks. For the intervention group, supportive and obstructive behavior training program will be provided in 7 sessions through lecture, Q & A, group discussion and movies.Additionally, there will be telephone follow-up for 2 months to respond to questions and provide consultation to the primary caregivers. The control group receives only the routine program of the Diabetes Center. Finally, after two months from the last intervention session, Self-Care Activities measure and on Family Behavior Checklist will be completed in both groups. Comparison of the results will show the effect of the intervention on family behavior and self-care of patients with type 2 diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053017756N15**
Registration date: **2017-07-04, 1396/04/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-07-04, 1396/04/13

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 3239 5680

Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-07-31, 1395/05/10

Expected recruitment end date

2017-10-02, 1396/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial on the effect of teaching versus non-teaching of supportive and obstructive behaviors to family caregivers on family behavior and self-care of patients with type 2 diabetes

Public title

The effect of teaching supportive and obstructive behaviors to family caregivers on family behavior and self-care of patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for patients: Type 2 diabetes; obtaining maximally half total score on Self-Care Activities measure and on Family Behavior Checklist in the two subscales of supportive (less than 18) and obstructive (over 14) behaviors; living with family members; time passed at least one year from diagnosis of diabetes; aged 30 to 60 years; having a record in the diabetes clinic of Birjand; receiving medical therapy (tablets or insulin); informed consent to participate; lack of any physical, mental and cognitive barriers for self-care behaviors. Exclusion criteria for the patients: lack of desire to continue to participate; occurrence of circumstances whereby understanding and support of family is influenced, such as mental illness, depression, and drug addiction; developing complications from diabetes such as kidney failure and blindness. Inclusion criteria for family care-givers: Informed consent to participate; no cognitive, emotional and physical barriers to perform supportive and communicative behavior; residing with the patient in the same place; undertaking the main task of caring Exclusion criteria for caregivers: developing cognitive, emotional and physical disorders impeding their support and communication; unwillingness to continue participation.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Gonabad University of Medical Sciences

Street address

Vice-chancellery for Research, Gonabad University of Medical Sciences, Imam Khomaini St.,

City

Gonabad

Postal code

Approval date

2016-07-29, 1395/05/08

Ethics committee reference number

IR.GMU.REC.1395.54

Health conditions studied

1

Description of health condition studied

Diabetes Type 2

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Family Behavior

Timepoint

Before intervention and 2 months after intervention is finished

Method of measurement

Family Behavior Checklist by Schafer et al.

2

Description

Self-care behavior

Timepoint

Before intervention and 2 months after intervention is finished

Method of measurement

Self-Care Activities (SDSCA) Measure by Toobert et al.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group will receive supportive and obstructive behavior training program in 7 sessions through lecture, Q & A, group discussion, and movies. There will also be telephone follow-up for 2 months to respond to questions and provide consultation for the primary caregivers. After two months from the last intervention session, Self-Care Activities measure and

Family Behavior Checklist will be completed in both groups.

Category

Behavior

2

Description

Control group: The control group receives only the routine program of Birjand-based Diabetes Center. After two months from the last interventional session, Self-Care Activities measure and on Family Behavior Checklist will be completed in both groups.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand Diabetes Center

Full name of responsible person

Dr Majid Shayesteh

Street address

Shirin Street,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Education and Research of Gonabad University of Medical Sciences

Full name of responsible person

Effat Datigerdi

Street address

Gonabad University of Medical Sciences, Asiayi Street,

City

Gonabad,

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Education and Research of Gonabad 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

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Full name of responsible person

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Position

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Position

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Other areas of specialty/work

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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