

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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)

Phone

+98 56 3239 5680

Email address

mbroozgar@bums.ac.ir

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		Ethics Committee of Gonabad University of Medical Sciences	
Purpose	Supportive	Street address	Vice-chancellery for Research, Gonabad University of Medical Sciences, Imam Khomainsi St.,
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	City	Gonabad
Gender	Both	Postal code	
Phase	N/A	Approval date	2016-07-29, 1395/05/08
Groups that have been masked	No information	Ethics committee reference number	IR.GMU.REC.1395.54
Sample size	Target sample size: 120	Health conditions studied	
Randomization (investigator's opinion)	Randomized	1	
Randomization description		Description of health condition studied	
Blinding (investigator's opinion)	Not blinded	Diabetes Type 2	
Blinding description		ICD-10 code	
Placebo	Not used	E10	
Assignment	Parallel	ICD-10 code description	
Other design features		Insulin-dependent diabetes mellitus	
Secondary Ids		Primary outcomes	
empty		1	
Ethics committees		Description	
1		Family Behavior	
Ethics committee		Timepoint	
Name of ethics committee		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

Gonabad University of Medical Sciences

Full name of responsible person

Effat Datigerdi

Position

Nursing Student

Other areas of specialty/work

Street address

Birjand University of Medical Sciences, Ayatollah
Ghaffari Street,

City

Birjand,

Postal code

Phone

+98 56 3239 5680

Fax

Email

e.dastigerdi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Effat Datigerdi

Position

Nursing Student

Other areas of specialty/work

Street address

Birjand University of Medical Sciences, Ayatollah
Ghaffari Street,

City

Birjand,

Postal code

Phone

+98 56 3239 5680

Fax

Email

e.dastigerdi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

PhD Candidate in Translation Studies

Other areas of specialty/work

Street address

Birjand University of Medical Sciences, Ghaffari St.,

City
Birjand,
Postal code
Phone
+98 56 3239 5680
Fax
Email
hadirooz@gmail.com
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