

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Study and comparison the effectiveness of family-centered empowerment, collaborative care model and motivational interviewing techniques on blood sugar control and eating behaviors based on BASNEF model among patients with diabetes

Protocol summary

Study aim

Studying the effectiveness of behavior change techniques on the sugar blood control and nutritional behaviors

Design

In this single blind randomized clinical trial, with parallel form, subjects in all four groups are randomly assigned into the study. Samples will be selected using the multistage cluster sampling. At first, among 80 health houses, we will consider 3 health houses and 60 subjects will be included in each health house (30 in the control group and 30 in the intervention group). Finally, 180 patients will be considered to participate in the study.

Settings and conduct

The statistical population will be patients with type 2 diabetes referred to the rural health centers in Gorgan. In this study, a multi-stage cluster sampling will be used. Patients will be blinded to the type of intervention they will receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes diagnosed by a physician; Patients who have been registered and have records in health houses

Intervention groups

There are four groups. Intervention group 1: Collaborative care including four steps in the form of two phases of collaborative educational visits and collaborative follow-up visits. Intervention group 2: Family-based empowerment consisting of four stages of perceived threat, self-efficacy, self-esteem and evaluation; Intervention group 3: Motivational interviewing including four principles of express empathy, develop discrepancy, rolling with resistance, self-efficacy support. The control group: receiving common training in the health centers about diabetes.

Main outcome variables

Blood glucose: Nutritional behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140518017736N10**

Registration date: **2018-12-05, 1397/09/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-05, 1397/09/14**

Update count: **0**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

Seyed Kamaladdin Mirkarimi

Name of organization / entity

Golestan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 17 1553 2872

Email address

k.mirkarimi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study and comparison the effectiveness of family-centered empowerment, collaborative care model and motivational interviewing techniques on blood sugar control and eating behaviors based on BASNEF model among patients with diabetes

Public title
The effectiveness of family-centered empowerment, collaborative care model and motivational interviewing techniques on blood sugar control and eating behaviors

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with type 2 diabetes diagnosed by a physician
 Patients who have been registered and have records in health houses in Gorgan Not participating in other family-based empowerment training classes, collaborative care model and motivational interviewing Reading and writing literacy
Exclusion criteria:
 Consumption of medications which have possible interaction with type 2 diabetes

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a multi-stage cluster sampling method will be used. At first, 80 Health Houses will be selected and then, three health houses will be selected using the simple sampling method. Randomization will be done using SPSS (version 18) software.

Blinding (investigator's opinion)
Single blinded

Blinding description
There is no blinding process at present study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

4th Kilometer of Gorgan-Sari Road

City

Gorgan

Province

Golestan

Postal code

4917818183

Approval date

2016-12-18, 1395/09/28

Ethics committee reference number

IR.GOUMS.REC.1395.211

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Blood sugar

Timepoint

Pre-intervention, 2, 6 and 12 months after intervention

Method of measurement

Fasting blood sugar test and HbA1C for measuring blood sugar

2

Description

Nutritional behaviors

Timepoint

Pre-intervention, 2, 6 and 12 months after intervention

Method of measurement

Standardized questionnaire of food frequency for measuring eating behaviors

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Collaborative Care. It consists of four stages: 1) motivation, 2) preparation, 3) engagement and 4) evaluation. These four steps will be conducted in the form of two phases of collaborative educational visits and collaborative follow-up visits. Interventions for all visits will be conducted for 2 groups of 15 (30 in total) independently (each session duration is 60-45 minutes on average).

Category

Behavior

2

Description

Intervention group 2: Family-based Empowerment. It consists of four stages of perceived threat, self-efficacy, self-esteem and evaluation. All stages are delivered through two 30-45 minute sessions. Each group has 15 people (2 groups of 15).

Category

Behavior

3

Description

Intervention group 3: Motivational Interviewing. It consists of four basic principles: expressing empathy, developing discrepancy, rolling with resistance and self-efficacy support. Each group consists of 10 patients. The training will be delivered through 5 30-45 minute sessions.

Category

Behavior

4

Description

Control group: This group only receives common training about diabetes in the health centers through 5 30-45 minute sessions. Each group has 15 patients (2 groups of 15)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratories

Full name of responsible person

Alireza Dehghan

Street address

Laboratory Unit, 5 Azar Hospital, 5 Azar street,
Gorgan city, Golestan Province

City

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Province

Golestan

Postal code

4917848183

Phone

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ak.mirkarimi@gmail.com

2

Recruitment center

Name of recruitment center

Health House

Full name of responsible person

Vahid Maghsoudloo

Street address

Amir Abad, Kafshgiri and Hashem Abad villages,
Gorgan city

City

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Province

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Postal code

4917848183

Phone

+98 17 3216 0330

Email

Maghsoudlo-v@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Seyyed Kamaladdin Mirkarmi

Street address

No 19, 2 Floor, Shaghayegh building, 3rd Sima Alley,
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k.mirkarimi@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Seyyed Kamaladdin Mirkarimi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcomes of the study will provide for decision makers and authorities of Health Deputy

When the data will become available and for how long

The study will be conducted in November 1397 and results will be presented after one year

To whom data/document is available

All academic researchers will have access to the results

Under which criteria data/document could be used

In addition to publishing results in valid journals, the results will be available to officials working in the provincial health center

From where data/document is obtainable

Dr Seyyed Kamaladdin Mirkarimi, Assistant Professor, Department of Public Health, Golestan University of Medical Sciences, Mobile number 09112731646 and email k.mirkarimi@goums.ac.ir

What processes are involved for a request to access data/document

Results, questionnaire and study tools will be available to

all researchers (after publication of the paper) through the telephone and email

Comments