Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of educational intervention based on social marketing on medication adherence of patients with type 2 diabetes referred to health centers of Qazvin, year 1398

Protocol summary

Study aim
The effect of educational intervention based on social marketing on medication adherence of patients with type 2 diabetes referred to health centers of Qazvin, year 1398

Design
A randomized controlled trial with experimental and control groups

Settings and conduct
Study in health centers of Qazvin including 5 90-60 minute training sessions based on social marketing goals for experimental group with questionnaire

Participants/Inclusion and exclusion criteria
Inclusion criteria include: 1. havingType 2 diabetes 2. Ability to speak 3- At least 6 months have passed since the diagnosis of type 2 diabetes 4-History of drug treatment of type 2 diabetes 5. Residence in Qazvin 6. Voluntary participation 7. Failure to participate in similar educational interventions in the past year 8. Mobile phone use 9- Age 30-65 years Exclusion criteria 1- Patients' dissatisfaction with the study 2. Lack of proper physical conditions to answer questions 3. Gestational diabetes Type 1 diabetes 5. Hospitalization during the study period 6. Having uncontrolled underlying illnesses such as hypertension with a blood pressure of 130.90 mmHg with medication 7. Missing more than one session in training will be excluded

Intervention groups
Type 2 diabetic patients aged 30-65 years old in Qazvin Health Centers will be assigned a random number after random allocation based on random numbers Then, using the formula 1 + 2 k (k = 3), one of the patients will be assigned to the control group and one to the experimental group . One of the numbers will be assigned to the control group and the other to the experimental group. The intervention group will consist of lecture, pamphlet, texting and hands-on training sessions.

Main outcome variables
medication adherence, awareness, perceived barriers and benefits, abstract norms, self-efficacy, intention to behave

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190927044901N1**
Registration date: **2019-12-20, 1398/09/29**
Registration timing: **prospective**

Last update: **2019-12-20, 1398/09/29**
Update count: **0**

Registration date
2019-12-20, 1398/09/29

Registrant information

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zahra najafpour dobakhshari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-26, 1398/10/05

Expected recruitment end date
2020-06-25, 1399/04/05

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of educational intervention based on social marketing on medication adherence of patients with type 2 diabetes referred to health centers of Qazvin, year 1398

Public title
The effect of educational intervention on medication adherence of type 2 diabetic patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1-having To Type 2 Diabetes Ability to speak At least 6 months have passed since the diagnosis of type 2 diabetes History of drug treatment of type 2 diabetes Residence in Qazvin Voluntary participation 7. Failure to participate in similar educational interventions in the past year Mobile phone use Age 30-65 years
Exclusion criteria:
Patients' dissatisfaction with the study Lack of proper physical conditions to answer questions Gestational diabetes Type 1 diabetes Hospitalization during the study period Having uncontrolled underlying illness such as hypertension with 130/90 mm Hg with medication Missing more than one session in training will be excluded
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
In this two-stage cluster randomization study, we first select 4 centers from 12 health centers and then assign a number to each patient based on random numbers, then using the formula (k 2 + 1 (k = 3) Among the patients, one will be assigned to the control group and the other to the experimental group
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is a double-blind. The outcome is blinded by outcome assessor and data analyzer (double blind). Outcome assessors and data analysts are not aware of grouping. The outcome assessor and the data analyzer identify the groups as A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
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Qazvin - Shahid Bahonar Blvd. - Qazvin University of Medical Sciences
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Qazvin
Province
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Postal code
34199-15315
Approval date
2019-11-20, 1398/08/29
Ethics committee reference number
IR.QUMS.REC.1398.190

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Medication adherence
Timepoint
Before and 3 months after intervention
Method of measurement
Questionnaire based on variables of social marketing approach including 16 questions of awareness, 4 questions of perceived benefits, 7 questions of perceived barriers, 19 questions of self-efficacy, 8 questions of drug compliance, 4 questions of abstract norms, 7 questions of behavior intention, questions of demographic information

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: Intervention group consisting of 55 diabetic patients. Social marketing based training (including awareness, perceived barriers and benefits, abstract norms, self-efficacy, behavioral intention) will be conducted in 5 to 60-90 minute sessions in group. In the first session, your doctor will give a lecture to inform patients about diabetes and the symptoms and complications of diabetes. The second session is a group discussion with patients, where the perceived benefits and benefits of diabetes are understood and the appropriate solution is given. In the third session of the call for patients' families, the extent of family support is examined and the importance of family support is discussed. The fourth session examines the patient's skills needed to control the disease. In the fifth session, the patient is re-trained and practiced by a patient. Patients will be reminded of text messages and symptoms and symptoms of the disease. The educational pamphlet also includes information on diabetes, symptoms, complications, and ways to prevent and control the disease.

Category
Behavior

2

Description
Control group: There is no intervention for 55 patients in the control group and they only have routine health center training.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Qazvin Health Center

Full name of responsible person
Zahra Najafpur

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Sponsors / Funding sources

1

Sponsor

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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Zahra Najafpur

Position
MSc Student in Health Services Management

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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because the data is confidential and work for the master thesis will eventually become a training package
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available