

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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. having Type 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 $1 + 2k$ ($k = 3$), 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

Name

zahra najafpour dobakhshari

Name of organization / entity

Country

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 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

AgeFrom **30 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget 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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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

Name of organization / entity

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Full name of responsible person

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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

Health Service Management

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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