

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Assessing the effect of educational intervention to improve adherence to the diet in patients with type 2 diabetes referred to health centers in south Tehran 2015 -2016 :health belief model

Protocol summary

Summary

1) Objectives :To determine the effect of educational intervention to improve adherence to the diet in patients with type 2 diabetes referred to health centers in south Tehran 2015 -2016 :health belief model. (2) Design :Clinical trial comparing the two groups.(3) Setting and conduct :The study involved two groups compared with the population studied, patients with type 2 diabetes who were referred to health centers in south Tehran. 216 samples were randomly divided into 2 groups were compared. (4) Participants including major eligibility criteria :Terms of Inclusion: patients diagnosed with diabetes, there is a desire to participate in the study, no known mental illness, spent at least one year from the definitive diagnosis of diabetes and major condition exclusion: unwillingness to participate in the study considered was.(5) Intervention : After determining the sample questionnaire is completed by both intervention and comparison groups. Then, according to data collected for the study group during the month, 6 training sessions for 45 to 60 minutes for group training and Q & A, as well as providing training package will take place after the impact of an educational intervention questionnaire 3 and 6 months after the training is completed for both intervention and comparison groups and using spss software version 11.5 is significantly lower than the 0.05 level will be analyzed. (6) main outcome measures (variables) : to improve adherence to the diet.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080212460N7**
Registration date: **2015-09-09, 1394/06/18**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-09, 1394/06/18

Registrant information

Name

Roya Sadedgi

Name of organization / entity

Tehran University of Medical Sciences

Country

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+98 912 327 5692

Email address

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Recruitment status

Recruitment complete

Funding source

Educational and Research vice chancellor of Tehran University of Medical Sciences

Expected recruitment start date

2015-10-05, 1394/07/13

Expected recruitment end date

2016-02-05, 1394/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of educational intervention to improve adherence to the diet in patients with type 2 diabetes referred to health centers in south Tehran 2015 -2016 :health belief model

Public title

Assessing the effect of educational intervention to improve adherence to the diet in patients with type 2 diabetes referred to health centers in south Tehran 2015-2016 :health belief model

Purpose

Other

Inclusion/Exclusion criteria

Terms of Inclusion : patients diagnosed with diabetes: there is a desire to participate in the study: no known mental illness: spent at least one year from the definitive diagnosis of diabetes and major condition exclusion : unwillingness to participate in the study considered was.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 216

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

The ethics committee of Tehran University of Medical Sciences

Street address

Poursina Ave.

City

Tehran

Postal code

Approval date

2015-07-28, 1394/05/06

Ethics committee reference number

IR.TUMS.REC.1394.457

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes

2

Description of health condition studied

Adherence to the diet

ICD-10 code

E12

ICD-10 code description

Malnutrition-related diabetes mellitus

Primary outcomes

1

Description

Adherence to the diet

Timepoint

Baseline and 3 and 6 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Health Belife Model constructs

Timepoint

Baseline and 3 and 6 months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention program will be conducted during one month including six educational sessions based on blended educational intervention program (Lecture, Group discussion, Question & Answer, Role playing, Educational film). The length of each session is about 45-60 minutes . The meetings will be tried on diabetes, its complications, and how to follow the diet, diabetic diet and be content to be discussed.

Category

Prevention

2

Description

In control group, education will be conducted based on routine plan of health centers.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

South of Tehran Health centers

Full name of responsible person

Mr.Javad Barzegari

Street address

NO.4 , Shafeei Alley , Quods Ave. , Enghelab Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Education vice chancellor of Tehran

Full name of responsible person

Dr. Mohammad Jalili

Street address

Main Building of Tehran University of Medical sciences
,Quods St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Education vice chancellor of Tehran

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research,of Tehran University of
Medical Sciences

Full name of responsible person

Dr.Masood Yonesiyan

Street address

Main building of Tehran University of Medical
Sciences ,Gouds St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research,of Tehran University of
Medical Sciences

Proportion provided by this source

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Roya Sadeghi

Position

phD/Academic staff

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work
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Phone

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