Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Nutrition Education on Healthy Eating Choice (Low-fat), Carbohydrate Counting and Physical Activity in Type 2 Diabetic Adults Using Theory of Planned Behavior (TPB)

Protocol summary

Summary

Nutritional behavior change in diabetics is critical and entails effective education. Thus the current research aims to do an educational intervention to promote healthy food options (low-fat), carbohydrate counting and physical activity in type 2 diabetic adults (25 to 59 years of age) using Theory of Planned Behavior (TPB). To do so, an elicitation study will be performed in 30 patients representing the main sample. Using face-to-face interview patients will mention advantages and disadvantages of performing the behavior, important groups or people who would approve or disapprove of and any conditions and factors that may prevent or help doing the behavior. Following content analysis regarding low-fat food options, carbohydrate counting and physical activity, the main questionnaire (valid and reliable) will be designed. Participants (n=142) will be randomly (using permutted block randomization) assigned into two equal (n=71) control and intervention groups all of which are diagnosed with Type 2 diabetes for at least past 2 years and have no debilitating complications to prevent them from participating in the study. Both groups will complete the main questionnaire and blood sample will be taken to determine triglyceride and LDL-cholesterol at baseline. After multiple regression analysis and structural equation analysis and recognizing changeable beliefs, focus group discussion (6 two-hour sessions including 7 to 12 patients in each) will be performed in the intervention which begins with a brief explanation by the trainer to make patients involved, while control won't get any intervention, except nutritional counseling, which both groups routinely get. At the end (about one and half months) question completeness and blood sampling will be done.

General information

Acronym

TPB (Theory of Planned Behavior), T2D (Type 2 Diabetes)

IRCT registration information

IRCT registration number: **IRCT2013040912961N1**
Registration date: **2013-07-26, 1392/05/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-26, 1392/05/04

Registrant information

Name

Reza Daryabeygi Khotbesara

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research- Tehran University of Medical Sciences

Expected recruitment start date

2013-07-01, 1392/04/10

Expected recruitment end date

2013-09-01, 1392/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nutrition Education on Healthy Eating Choice (Low-fat), Carbohydrate Counting and Physical Activity in Type 2 Diabetic Adults Using Theory of Planned Behavior (TPB)

Public title

Effect of Nutrition Education on Type 2 Diabetics' Healthy Food Options and Physical Activity Behaviors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: adults (25 to 59 years of age); taking usual lipid- and glucose-lowering drugs; had participated in routine nutrition classes for diabetics before the intervention; diagnosed with diabetes for at least past 2 years. Exclusion Criteria: complications (nephropathy, neuropathy and retinopathy) including cardiovascular disease that may prevent patients from participating in the study.

Age

From **25 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **142**

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

Vice-Chancellor for Research, Tehran University of Medical Sciences

Street address

4th fl, Main Organization of Tehran University of Medical Sciences, Qods corner, Keshavarz Blv, Tehran

City

Tehran

Postal code

Approval date

2013-06-22, 1392/04/01

Ethics committee reference number

3549/130/91/د

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Low-fat food choice behavior

Timepoint

before intervention and at the end, after intervention

Method of measurement

average Liker score- using questionnaire

2

Description

Low-fat food choice intention

Timepoint

before intervention and at the end, after intervention

Method of measurement

average Liker score- using questionnaire

3

Description

Subjective norm for low-fat food choice

Timepoint

before intervention and at the end, after intervention

Method of measurement

average Liker score- using questionnaire

4

Description

Attitude toward low-fat food choice

Timepoint

before intervention and at the end, after intervention

Method of measurement

average Liker score- using questionnaire

5

Description

Perceived behavioral control over low-fat food choice

Timepoint

before intervention and at the end, after intervention

Method of measurement
average Liker score- using questionnaire

6

Description
Carbohydrate counting behavior
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

7

Description
Carbohydrate counting intention
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

8

Description
Attitude toward carbohydrate counting
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

9

Description
Subjective norm for carbohudrate counting
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

10

Description
Perceived behavioral control over carbohydrate counting
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

11

Description
Physical activity behavior
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

12

Description
Physical activity intention
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

13

Description
Attitude toward physical activity
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

14

Description
Subjective norm for physical activity
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

15

Description
Perceived behavioral control over physical activity
Timepoint
before intervention and at the end, after intervention
Method of measurement
average Likert score- using questionnaire

16

Description
Education
Timepoint
During intervention
Method of measurement
feedback

Secondary outcomes

1

Description
Triglyceride
Timepoint
before intervention and at the end, after intervention
Method of measurement
mg/dl- colorimetric laboratory test

2

Description
LDL-cholesterol
Timepoint
before intervention and at the end, after intervention
Method of measurement
mg/dl- colorimetric laboratory test

3

Description
Age
Timepoint

before intervention (baseline)
Method of measurement
questionnaire

4

Description
Sex
Timepoint
before intervention (baseline)
Method of measurement
questionnaire

5

Description
Job
Timepoint
before intervention (baseline)
Method of measurement
questionnaire

6

Description
Level of education
Timepoint
before intervention (baseline)
Method of measurement
questionnaire

7

Description
Body mass index (BMI)
Timepoint
before and after intervention
Method of measurement
Weight divided by height squared

Intervention groups

1

Description
Education in intervention group will be based on focus group discussion. Patients will receive totally 6 two-hour session (about one and half months long), beside routine diabetic classes.
Category
Behavior

2

Description
No interventional education will be done in control group (except routine diabetic classes)
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Diabetes Society
Full name of responsible person
Dr Asadollah Rajab
Street address
No 46, Ramin Malakooti St, Patris Lomomba St, Sattarkhan St, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sceineces
Full name of responsible person
Vice-chancellor for research
Street address
4th fl, Main Organization of Tehran University of Medical Sciences, Qods corner, Keshavarz Blv, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sceineces
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

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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