

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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 permuted 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

Country

Iran (Islamic Republic of)

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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
3549/130/91/3

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 Likert 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 carbohydrate 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

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Tehran University of Medical Sciences

Full name of responsible person

Vice-chancellor for research

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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 Sciences

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

Contact

Name of organization / entity

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Full name of responsible person

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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