

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Development and evaluation a theory-based intervention for medication and diet adherence in Patients with Type 2 Diabetes

Protocol summary

Study aim

Development and evaluation a theory-based intervention for improving medication and diet adherence in Patients with Type 2 Diabetes

Design

randomised trial with control group ,without blinded, design for 248 patients, Randomised

Settings and conduct

Patients with diabetes referred to the health centers of the South under the cover of Tehran University of Medical Sciences The study will be done in two phases. The intervention phase of the study includes the allocation of the target group in two groups of intervention and control, which In the intervention group will be done the educational intervention.

Participants/Inclusion and exclusion criteria

Younger than 65 years Patients with diabetes referred to the health centers of the South under the cover of Tehran University of Medical Sciences whose disease has been confirmed by doctors. Diagnosed with type 2 diabetes for more than six months. They have Score of medication and diet adherence low. To be satisfied with the study.

Intervention groups

The intervention group are patients with type 2 diabetes to receive theory-based educational interventions for improve diet and medication adherence

Main outcome variables

the improving medication and diet adherence in Patients with Type 2 Diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151208025431N4**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Elham Shakibazadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation a theory-based intervention for medication and diet adherence in Patients with Type 2 Diabetes

Public title

Effect of intervention on adherence in Diabetics

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Younger than 65 years Patients with diabetes referred to the health centers of the South under the cover of Tehran University of Medical Sciences whose disease has been confirmed by doctors. Diagnosed with type 2 diabetes for more than six months. They have Score of medication and diet adherence low. To be satisfied with the study.

Exclusion criteria:**Age**

To 65 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 248

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization stratified randomization Lottery

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of tehran University of Medical Sciences

Street address

Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-01-10, 1396/10/20

Ethics committee reference number

IR.TUMS.SPH.REC.1396.4200

Health conditions studied**1****Description of health condition studied**

type 2 diabet

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Adherence scale of medication

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the intervention

Method of measurement

Morisky questionnaire

2**Description**

Adherence scale of diet

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the intervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Task selfefficacy

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the interven

Method of measurement

questionnaire

2**Description**

Intention

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the interven

Method of measurement

questionnaire

3**Description**

Action planning

Timepoint

Adherence measurement at the beginning of the study

(before the intervention) and 1, 6 months after the interven

Method of measurement
questionnaire

4

Description

coping planning

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the interven

Method of measurement
questionnaire

5

Description

Coping selfefficacy

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the interven

Method of measurement
questionnaire

6

Description

Recovery selfefficacy

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the interven

Method of measurement
questionnaire

7

Description

Perceived social support

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 1, 6 months after the interven

Method of measurement
questionnaire

8

Description

HbA1C

Timepoint

Adherence measurement at the beginning of the study (before the intervention) and 6 months after the interven

Method of measurement
HbA1C

Intervention groups

1

Description

Intervention group: Theory-based interventions based on HAPA and needs assessment baseline

Category

N/A

2

Description

Control group: The control group will not intervene and only HbA1c Test were measured baseline and 6 months after the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

South Tehran Health Centers

Full name of responsible person

dr. Ghayumzadeh

Street address

No. 2, Alley, Shahid Abbas Shafiee, Vesal Shirazi Ave, Engelab Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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?
No
Title of funding source
School of Public Health, Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Soheila Ranjbaran
Position
Ph.D student
Latest degree
Ph.D.
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available