Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
Phone
+98 21 4293 3210
Email address
shakib@zums.ac.ir

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 questionaire

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
questionaire

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
questionaire

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
questionaire

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

questionaire

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

questionaire

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

questionaire

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

questionaire

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

questionaire

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

City

Tehran

Province

Tehran

Postal code

1417863181

Phone

+98 21 6695 0069

Email

Gayumzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeiyan

Street address

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

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

name@domian.com

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.
Other areas of specialty/work
Health Promotion
Street address
School of Public Health,Poursina Street, Keshavarz Boulevard, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Email
sph@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Eelham Shakibazadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
School of Public Health, Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Email
shakibazadeh@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Soheila Ranjbaran
Position
Ph.D
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
School of Public Health, Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Email
s-ranjbaran@razi.tums.ac.ir

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