Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Diabetes Education by Peer Coaching on Diabetes Control and Management

Protocol summary

Summary

An unblinded randomized clinical trial in which women with type 2 diabetes are divided into one of the two following categories: • Intervention group: diabetic patients who received education through peer coaches. • Control group: diabetic patients who received routine care includes attending small group class on diabetes, diabetes class or education through national media) Research population is all women with type 2 diabetes who refer to the municipality clinics in Tehran and (Two clinics depend on endocrinology and metabolism research center and health centers in 22 districts of Tehran) for receiving primary care of diabetes (management and education). Intervention: all patients according to the type of receiving drugs contacting with a peer for 6 months. Essential information will be obtained at the beginning of the project (pre-intervention) and 3, 6 and 12 months after intervention. Intervention will be continued for 6-month. All patients in the intervention group, should have two telephone talks with peers, two times face to face meetings and receive three SMS (during one month). If essential they also receive two face-to-face. If necessary, they will have a clinic visit. Meetings, phone talk or SMS, will be made based on the patient and peer agreement. All peers should be record every meeting or call history including contact time, contact type, contact duration, and the subject of talk. Patients will be joint to the peers, according to the gender. The first meeting takes place by telephone and introduction session between the peer and patient will be held. Then specific clinical goals, including HbA1c, FBS, lipid profile (LDL, HDL, TG, Cholesterol) and high blood pressure, self-care skills such as using a glucometer and proper strategies during hypoglycemia, taking drugs, changing lifestyle, healthy eating, physical activity and stress will be discussed. Peers and patients may have talked about family, job or hobbies on holidays. There is not any educational intervention between patient and peer at 6 month to 12 month of the intervention. They just continue their relationship by telephone talking. at least all information will be recorded and measured at 12 month. Cluster sampling is done in which Tehran divided into five geographic zones, including north-south-east-west and Center. In each zone 1 area will be selected randomly. Since each municipality area has different districts, two districts of each area will be considered to select intervention groups and two districts of each area will be considered to select control group. In this way the possibility of contact between members of the two groups will be decreased.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501128175N3**
Registration date: **2015-09-18, 1394/06/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-18, 1394/06/27

Registrant information

Name

Neda Mehrdad

Name of organization / entity

Faculty of NURSING & Midwifery,Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source
Endocrinology and Metabolism Research InstituteTehran University of medical Sciences,Tehran, Iran

Expected recruitment start date
2015-04-09, 1394/01/20
Expected recruitment end date
2016-04-08, 1395/01/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Diabetes Education by Peer Coaching on Diabetes Control and Management

Public title
Effect of Diabetes Education by Peer Coaching on Diabetes Control and Management
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria Individuals eligible for attending in the study are women with type 2 diabetes who have HbA1c ≤ 8% in the last 6 months. Patients should not plan to migrate out of Tehran during the period of study and research team could easily have been in contact with them. Additionally, following criteria is essential: • Ability to speak in Persian • Age between 20 and 60 years old • To have HbA1c ≤ 8% in the last 6 months • Not be pregnant • Patients with a life expectancy of less than a year and has a serious illness and disease with reduced cognitive capacity approved by the health center staff will be recruited. • Patients who are currently enrolled in a diabetes education programs are not included in the study. exclusion criteria • To have HbA1c equal and above 9% during the study • Become pregnant during the study
Age
From **73 years** old to **33 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **492**
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
lEthics Committee of Endocrinology and Metabolism Research Institute of Tehran University of Medic
Street address
Shariati Hospital, North Karegar St.
City
Tehran
Postal code
1411413137
Approval date
2014-12-28, 1393/10/07
Ethics committee reference number
EC-00378

Health conditions studied

1

Description of health condition studied
type 2 Diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HbA1c
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
HPLC

Secondary outcomes

1

Description
Fasting Blood Suger
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
Glocose Oxidase

2

Description
Total Cholestrol

Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
CHOD-Pap

3

Description
Triglyseridi
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
Gpo-pap

4

Description
LDL
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
photometery

5

Description
HDL
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
photometery

6

Description
Body Mass Index
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
weight (kg) / height (m)2

7

Description
Blood Pressure
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
Manometer (mmhg)

8

Description
Waist to Hip Ratio
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
waist hip ratio measurement

9

Description
Food intake
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
The three-day recall questionnaire

10

Description
Levels of physical activity
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
International Physical Activity Questionnaire (IPAQ

11

Description
self-care activity
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
summery of diabetes self-care activities- SDSCA

12

Description
Quality of Life
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
Diabetes Quality of Life (DQOL) Questionnaire

13

Description
Depression
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
Beck Depression Inventory

14

Description
Social Capital
Timepoint
Before the intervention and at 3, 6 and 12 months after intervention
Method of measurement
Social Capital Integrated questionaire

Intervention groups

1

Description

An unblinded randomized clinical trial in which women with type 2 diabetes are divided into one of the two following categories: • intervention group: diabetic patients who received education through peer coaches. Research population is all women with type 2 diabetes who refer to the municipality clinics in Tehran and (Two clinics depend on endocrinology and metabolism research center and health centers in 22 districts of Tehran) for receiving primary care of diabetes (management and education). Intervention: all patients according to the type of receiving drugs contacting with a peer for 6 months. Essential information will be obtained at the beginning of the project (pre-intervention) and 3, 6 and 12 months after intervention. Intervention will be continued for 6-month. All patients in the intervention group, should have two telephone talks with peers, two times face to face meetings and receive three SMS (during one month). If essential they also receive two face-to-face. If necessary, they will have a clinic visit. Meetings, phone talk or SMS, will be made based on the patient and peer agreement. All peers should be record every meeting or call history including contact time, contact type, contact duration, and the subject of talk. Patients will be joint to the peers, according to the gender. The first meeting takes place by telephone and introduction session between the peer and patient will be held. Then specific clinical goals, including HbA1c, FBS, lipid profile (LDL, HDL, TG, Cholesterol) and high blood pressure, self-care skills such as using a glucometer and proper strategies during hypoglycemia, taking drugs, changing lifestyle, healthy eating, physical activity and stress will be discussed. Peers and patients may have talked about family, job or hobbies on holidays. There is not any educational intervention between patient and peer at 6 month to 12 month of the intervention. They just continue their relationship by telephone talking. at least all information will be recorded and measured at 12 month.

Category

Lifestyle

2

Description

An unblinded randomized clinical trial in which women with type 2 diabetes are divided into one of the two following categories: • control group: diabetic patients who received routine care includes attending small group class on diabetes diabetes class or education through national media)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology & Metabolism Research Institute of Tehran University of Medical Sciences

Full name of responsible person
Dr Neda Mehrdad

Street address
Shariati Hospital, North Karegar St.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Endocrinology & Metabolism Research Institute of Tehran University of Medical Sciences

Full name of responsible person
Dr Hossein adibi

Street address
Shariati Hospital, North Karegar St.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Endocrinology & Metabolism Research Institute of 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
Endocrinology and Metabolism Research Institute Tehran University of medical Sciences,Tehran, Iran

Full name of responsible person
Mahnaz Sanjari

Position
PhD Candidate in Nursing Education

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Endocrinology & Metabolism Research Institute of Tehran University of Medical Sciences
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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