

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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)

###### Phone

+98 21 6692 7171

###### Email address

nmehrdad@tums.ac.ir

##### Recruitment status

**Recruitment complete**

## Funding source

Endocrinology and Metabolism Research Institute  
Tehran 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  $\leq$  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  $\leq$  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

IEthics 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 Sugar

#### Timepoint

Before the intervention and at 3, 6 and 12 months after  
intervention

#### Method of measurement

Glucose Oxidase

### 2

#### Description

Total Cholesterol

**Timepoint**

Before the intervention and at 3, 6 and 12 months after intervention

**Method of measurement**

CHOD-Pap

**3****Description**

Triglyceridi

**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**

photometry

**5****Description**

HDL

**Timepoint**

Before the intervention and at 3, 6 and 12 months after intervention

**Method of measurement**

photometry

**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)<sup>2</sup>

**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**

summary 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 questionnaire

## 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

##### Street address

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##### City

Tehran

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emri-research@tums.ac.ir  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Endocrinology & Metabolism Research Institute of  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr Neda Mehrdad  
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Associate Professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Maryam Aalaa  
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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*