

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparision of the effect of group education versus group counseling on self care of patient with diabetes type II

#### Protocol summary

##### Summary

The aim of the study is to compare the effect of group education and group counseling on self-care in patients with Type II diabetes . Inclusion criteria are patients 18 to 60 years old that last six months of diagnosis of diabetes. Exclusion criteria is participants who absent in more than a counseling or education session. Total of 110 diabetic patients randomly allocated into three groups. contro group has no education but intervention group 1, group education and intervention group 2, group counseling perform. counseling and education perform in 5 to 7 sessions of 1 to 1.5 hours. The primary outcome measures includ self-care and HbA1c. Primary outcome time points are beginning of the study and two months after intervention And Primary outcome method of measurement are Researcher made questionnaire Self Care and HBA1C Test. Primary outcome measures, time points and method of measurements is similar in three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014122220394N1**

Registration date: **2015-01-13, 1393/10/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-13, 1393/10/23

##### Registrant information

##### Name

Mahbobeh Firooz

##### Name of organization / entity

Mashhad Faculty of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 58 3723 2650

##### Email address

mahbobehfirooz@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-06-28, 1393/04/07

##### Expected recruitment end date

2015-01-20, 1393/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparision of the effect of group education versus group counseling on self care of patient with diabetes type II

##### Public title

Comparision of the group education versus group counseling on self care of patient with diabetes

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Including criteria: The last six months of diagnosis of diabetes; age 18 to 60 years. Exclusion criteria:

Participants who absent in more than a counseling or education session

##### Age

From **75 years** old to **33 years** old

##### Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: **110**

## 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

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Mashhad Faculty of Nursing and Midwifery, Ebn-e Sina St. Doktora Crossroads.

##### City

Mashhad

##### Postal code

##### Approval date

2014-06-28, 1393/04/07

##### Ethics committee reference number

922652

## 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

Self Care

#### Timepoint

Beginning of the study, two months after intervention

## Method of measurement

Researcher made questionnaire Self Care

### 2

#### Description

HbA1c

#### Timepoint

Beginning of the study, two months after intervention

#### Method of measurement

HbA1c test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

This was a 3-group randomized interventional trial. control group (without education) ); Includes patient with diabetes type II; interventions include: pretest( Researcher made questionnaire Self Care and HbA1c test); post tests include: two months after intervention.

#### Category

N/A

### 2

#### Description

intervention group1: patient with diabetes type II; interventions include: pretest( Researcher made questionnaire Self Care and HbA1c test), Attend in a 5 to 7 sessions of 1 to 1.5 hours group Educational about Self Care; post test two months after intervention.

#### Category

Prevention

### 3

#### Description

intervention group2 : patient with diabetes type II; interventions include: pretest( Researcher made questionnaire Self Care and HbA1c test), Attend in a 5 to 7 sessions of 1 to 1.5 hours group counseling about Self Care; post test two months after intervention.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Parsian Diabetes Clinic

##### Full name of responsible person

Ali Akbar Raof

##### Street address

Shahid Chamran St, Chamran 8 Ave.

##### City

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Mashhad University of  
Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Faculty of Nursing and Midwifery, Ebn-e Sina St,  
Doktora Crossing

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research, Mashhad 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**

Mashhad Faculty of Nursing and Midwifery

**Full name of responsible person**

Mahbobeh Firooz

**Position**

MS Nursing/Postgraduate student

**Other areas of specialty/work****Street address**

Ebn-e Sina St, Doktora Crossing

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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Seyed Reza Mazlom

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PhD

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## Person responsible for updating data

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**Web page address**

## 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*