Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparsion 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

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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

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

Public title

Comparsion 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)): Includs patient with diabetes type II; interventions includ: 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 includ: 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 includ: 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

Mashhad

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
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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
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Person responsible for updating data

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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