

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of counseling on self-care and quality of life in postmenopausal diabetes women

Protocol summary

Summary

The aim of this study is to determine the effect of counseling on self-care and quality of life in postmenopausal diabetes women. This study is a randomized clinical trial study that implement in the experimental and control groups . Population of this study are postmenopausal diabetes women attending to Diabetes Research Center in Hamadan. Sampling is done through random permutation block. A sample of 40 patients in the intervention group and 40 in the control group will determined. Inclusion criteria are: age over 45 years, patients with type II diabetes, lack of women with premature menopause (menopause before 40 years). Exclusion criteria are: absence in more than one session of counseling session and no intention to continue the study. Intervention consists of four sessions of counseling on self-care that will conduct every week by a researcher. Control group only receive routine care. Comparison will done between two groups on the self-care and quality of life among diabetes women. Outcome of this research may improve post- menopausal diabetes' women' self-care and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120910426N9**

Registration date: **2016-01-18, 1394/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-18, 1394/10/28

Registrant information

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

parsa@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of Research Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling on self-care and quality of life in postmenopausal diabetes women

Public title

The effect of counseling on self-care and quality of life in postmenopausal diabetes women attending to Diabetes Research Center in Hamadan in 2015 -2016

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age over 45 years; Patients with type II diabetes; The lack of women with premature menopause (menopause before 40 years); passed at least one year and up to 10 years of menstruation (the physiological);

After at least one year of diabetes diagnosis; No history of myocardial infarction, liver diseases, mental health, thyroid or kidney; Failure Patients with advanced diabetes complications such as kidney failure, stroke, myocardial infarction, malignant tumor patients; The drug-treated diabetes (tablets or insulin). Exclusion criteria: not participate in more than one session of counseling class and wanting to continue to cooperate with investigation; The occurrence of stress-inducing events (such as near death, accident) during the study.

Age

From **45 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Avenue, Hamadan University of Medical Sciences

City

Hamadan

Postal code

6517838698

Approval date

2015-07-27, 1394/05/05

Ethics committee reference number

IR.UMSHA.REC.1394.207

Health conditions studied

1

Description of health condition studied

Diabetes Type II

ICD-10 code

E12

ICD-10 code description

Malnutrition-related diabetes mellitus

Primary outcomes

1

Description

Self care in Diabetes Type II

Timepoint

Before and 3 months after intervention

Method of measurement

Questionnaire of self-care

Secondary outcomes

1

Description

Quality of life

Timepoint

Before, immediately after and two months after intervention

Method of measurement

Questionare for quality of lifeof menopause women (MENQL)

Intervention groups

1

Description

Intervention group will receive self-care counseling for four sessions (one session a week)

Category

Lifestyle

2

Description

Control group have not receive any intervention during study however they will receive educational materials after the end of study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center of Hamadan

Full name of responsible person

Roya Ahmadi

Street address

Madani, Azadegan Street, Hamadan

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chanslor of Research in Hamadan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Shahid Fahmideh Street, Hamadan University of Medical Sciences, Vice Chanslor of Research

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chanslor of Research in Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Assistant Professor

Other areas of specialty/work

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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