

# 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

+98 81 1822 4396

##### 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 life of 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

#### Street address

Research Center for Chronic Diseases Home Care, Hamadan University of Medicine and Health Sciences, Shahid Fahmideh Street, Counterpoint of Mardom Park, Hamadan, Iran

#### City

Hamadan

#### Postal code

65178

#### Phone

+98 81 3838 0150

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parsa@umsha.ac.ir

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## Person responsible for scientific 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*