

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of the education program on quality of life in menopausal women in intervention and control groups

Protocol summary

Summary

Objective: this study assesses The effect of the education program on quality of life in menopausal women Design: single-blind randomized clinical trial that will be conducted on 100 menopausal health centers in Hamadan city. They will be randomly assigned to intervention and control groups with regard to Allocation concealment (50 in intervention group and 50 in control group). Setting and conduct: the eligible women who refer to health centers in 2016 will be enrolled. Inclusion criteria consisted of women: married and menopause women; quality of life score ≥ 50 ; had no history of physical and mental disorders ; and had not used hormone replacement therapy. Exclusion criteria consisted of women who ; unwillingness to continue cooperation and in duration of intervention be disorder. intervention: The education program twice in week for 3 weeks will be given and in control group the education program not will be prescribed . Main outcome measures: the two groups will be compared in terms of the quality of life by MENQOL before the intervention, immediately after the intervention and 3 months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510186888N13**
Registration date: **2016-02-10, 1394/11/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-10, 1394/11/21

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

shobeiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-01-30, 1394/11/10

Expected recruitment end date

2016-04-29, 1395/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the education program on quality of life in menopausal women in intervention and control groups

Public title

The effect of the education program on quality of life in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria consisted of women: married and menopause women; quality of life score ≥ 50 ; had no history of physical and mental disorders ; and had not used hormone replacement therapy. Exclusion criteria consisted of women who ; unwillingness to continue

cooperation and in duration of intervention be disorder.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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

Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Postal code

Approval date

2015-04-11, 1394/01/22

Ethics committee reference number

UMSHA.REC.1394,7

Health conditions studied

1

Description of health condition studied

Quality of life in menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Quality of life

Timepoint

before the intervention, immediately after intervention, 3 months after the intervention

Method of measurement

MENQOL Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention: The education program twice in week for 3 weeks will be given . the quality of life will be measured by MENQOL before the intervention, immediately after the intervention and 3 months after the intervention.

Category

Treatment - Other

2

Description

Control: in control group the education program not will be prescribed .the quality of life will be measured by MENQOL before the study, immediately after the study and 3 months after the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Medical and Health Center

Full name of responsible person

Nahid Mohammadi, M.Sc. of Health, Instructor

Street address

No. 11, Takhti Street, Shohada Medical and Health Center, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Saied Bashirian

Street address

No. 307, Fahmideh Street, Hamadan University of
Medical Sciences

City

Hamadan

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, 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

Fatemeh Shobeiri

Position

Ph.D. in Maternal and Child Health

Other areas of specialty/work

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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