

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of self- directed learning and support group on quality of life in menopause women

Protocol summary

Summary

Menopause causes a decrease in quality of life. Therefore, it is necessary to develop effective intervention program to improve quality of life after menopause. Support group is indicated as one of the most acceptable methods for providing information on the needs of the menopause. Women participating in such groups help each other through discussions by sharing of personal experiences and current information on menopause. Self- directed learning (SDL) is used in health interventions. SDL has become synonymous with self-managed learning, lifelong learning and independent learning. The aim of this research is to evaluate the effect of self-directed learning & support group on quality of life after menopause. In a randomized control trial and single blind study, 155 postmenopausal women from Saadatmandy treatment & health center, Tehran, Iran, who have inclusion criteria of this study, will be randomly assigned to three groups (two interventions groups, one control group). Data will be gathered with the menopause quality of life questionnaire (MENQOL) at baseline and 1 month after termination of the program.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010022324N6**

Registration date: **2011-01-06, 1389/10/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-06, 1389/10/16

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

keshavarz@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Tehran University of Medical Sciences

Expected recruitment start date

2010-08-21, 1389/05/30

Expected recruitment end date

2010-12-02, 1389/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self- directed learning and support group on quality of life in menopause women

Public title

The effect of self- directed learning and support group on quality of life in menopause women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Healthy Iranian married women who have not had a hysterectomy, ability to read and write, Muslim, ceasing menstruation for 2-7 years, not using cigarette, Body mass Index (BMI) below of 30 Kg/m², not

belonging to health care staff, have not used hormone replacement therapy during the preceding 6 months. Exclusion criteria: not willing to continue participation in per stage of study, not answering at least to one question in questionnaire, irregularly participating in weekly meetings, Happening unpleasant events during study , suffering from physically or emotional disease during study, using hormone replacement therapy during study.

Age

From **40 years** old to **67 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **165**

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**

School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address

Rashid Yasami St. Valiasr Ave, P.O Box: 19395-4798

City

Tehran

Postal code**Approval date**

2010-07-18, 1389/04/27

Ethics committee reference number

1744273

Health conditions studied**1****Description of health condition studied**

quality of life

ICD-10 code

Z73.9

ICD-10 code description

Problem related to life-management difficulty, unspecified

Primary outcomes**1****Description**

quality of life score

Timepoint

after 3 month

Method of measurement

Menopause specific quality of life (MENQOL) questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Support group: four meetings, each meeting will be 120 min. Each meeting includes two sections (each section 60 min) which will be designed every week.

Category

Lifestyle

2**Description**

Self directed learning group will be given four Guide books during four weeks.

Category

Lifestyle

3**Description**

No intervention in control group

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Robat Karim Saadatmandy health and treatment center

Full name of responsible person

Dr Mohammad Hossain Moghadam

Street address**City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Street address

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave

City

Tehran

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

Yes

Title of funding source

School of Nursing and Midwifery, Tehran 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

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

MSc in midwifery, academic member, associated professor

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

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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