

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of self-directed learning and support group styles on early menopause symptoms

Protocol summary

2013-06-02, 1392/03/12

Summary

The aim of this study is to determine the effect of self-directed learning and support group styles on early menopause symptoms. In this clinical trial, 186 eligible women were randomized block 3 and 6 bits (determined by computer application) and a 1:1:1 ratio to one of three groups self-directed learning, support and control groups will be assigned. After completing the baseline characteristics and pre-test, to self-directed learning group instructional booklet will given in three weeks. instructional booklet is contains information relating to the acceptance and compliance with the early symptoms of menopause. support group sessions for three weeks will be held. At the beginning of each session, the researcher will provide Informations about the headlines and topics discussed in each session about 15 minutes of each session. then will be asked from participants to discuss of their strategies and experiences in the field their subject about 30 minutes and in the remaining 15 minutes, the researcher will gather contents. One month after the intervention, early menopause symptoms in the three groups will be assessed by the Greene scale. In the software spss version 13, ANCOVA test will be used to comparing the post-intervention mean scores of early symptoms of menopause between the groups with controlling the pre-intervention scores.

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz university of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-09-23, 1392/07/01

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 styles on early menopause symptoms

Public title

The effect of self-directed learning and support group styles on early menopause symptoms:A randomized controlled trialed

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1- Being menopause 2- Being married

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305063027N25**

Registration date: **2013-06-02, 1392/03/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

3- Have at least secondary school education 4- age between 45 to 59 years old 5- At least 2 hotflashes per day. Exclusion criteria: 1- kidney, thyroid, heart - cardiovascular disease, diabetes, psychological and other systemic disease 2- taking estrogen or herbal medicines containing estrogen and phytoestrogens in the past three months 3- smoking, using of hubble-bubble and drinking Alcohol 4- severe stress such as the death of a family during the last 3 months 5- Surgical history of oophorectomy 6- Using of effective drugs on hot flashes including: clonidine, gabapentin, yohimbine.

Age

From **45 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **186**

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

Tabriz University of Medical Sciences Ethics Committee

Street address

Tabriz university of Medical Sciences, University St., Tabriz

City

Tabriz

Postal code

Approval date

2013-05-05, 1392/02/15

Ethics committee reference number

9217

Health conditions studied

1

Description of health condition studied

early menopause symptoms

ICD-10 code

95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Early menopause symptoms

Timepoint

Before intervention and 1 month after ending intervention

Method of measurement

Greene scale

Secondary outcomes

1

Description

Numbers of hotflashes

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Greene scale

Intervention groups

1

Description

Self- directed learning:Provide instructional booklet once a week for three consecutive weeks in the intervention group

Category

Lifestyle

2

Description

Support group:Training sessions once a week for three consecutive weeks for an hour in the intervention group

Category

Lifestyle

3

Description

Control :non intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr cooperative health centers

Full name of responsible person

Fahimeh Sehhatie Shafaie

Street address

Nursing and Midwifery faculty, Tabriz university of
Medical Sciences, Tabriz

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tabriz university of Medical
Sciences

Full name of responsible person

Dr. Kazem Shakouri

Street address

Golgasht st. Research Deputy of Tabriz university of
Medical Sciences, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Tabriz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Deputy, Tabriz university of Medical
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Full name of responsible person

Fahimeh Sehhatie Shafaie

Position

MSc on Midwifery

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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