

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

sehhatief@tbzmed.ac.ir

#### 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  
Sciences

**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

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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*