

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 2026

### Comparison of relaxation training and Valerian on insomnia of menopause women

#### Protocol summary

##### Summary

Comparison of relaxation and Valerian on insomnia in menopausal women - random - no blindness - a placebo .  
Study population: qualified volunteers inclusion . Main inclusion criteria : 1 ) at least one year has passed since the last menstrual discontinued after natural menopause; 2 ) lack of mental and physical diseases such as musculoskeletal disorders or paralysis, and...; 3 ) lack of sedative drugs; 4) the lack of smoking and alcohol; 5 ) failure , liver disease , kidney and gastrointestinal; 6 ) no history of cancer; 7 ) not using hormone therapy within 3 months ; 8 ) not suffering from high blood pressure . Exclusion criteria included : 1 ) the creation of any physical illness and mental During the study period , causing obstructive sleep apnea; 2 ) the emergence of a significant change sleep conditions as unpredictable as travel , shift or taking any medications , and additional material during study; 3 ) Do not use Valerian maximum period of seven consecutive days during the study period 4 ) unwillingness to cooperate .  
volumes of sample : 129 subjects selected randomly from the population and divided them into three groups of 43 individuals qualified ( Group Valerians training relaxation and control) intervention study Group plant Valerian taken twice a day capsules of 530 mg Sedamin capsule before bed for a month , the group relaxation participate in classroom training 2 times per week for 2 hours and daily exercises for a month , the control group ( taking capsules of placebo containing 50 mg of starch is twice a day for a month . completing form : early intervention and 4 weeks later, both groups in the outcome of the study : comparing the educational effectiveness relaxation and lavender on menopausal insomnia

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014022516743N1**

Registration date: **2014-04-12, 1393/01/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-04-12, 1393/01/23

##### Registrant information

###### Name

Atefeh Kargosha

###### Name of organization / entity

Fatemeh College of Nursing And Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4258

###### Email address

kargosha@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shiraz University Of Medical Sciences

##### Expected recruitment start date

2014-03-20, 1392/12/29

##### Expected recruitment end date

2014-07-20, 1393/04/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of relaxation training and Valerian on insomnia of menopause women

**Public title**

Comparison of relaxation training and Valerian on insomnia of menopause women

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Main inclusion criteria : 1 ) at least one year has passed since the last menstrual discontinued after natural menopause; 2 ) lack of mental and physical diseases such as musculoskeletal disorders or paralysis, and...; 3 ) lack of sedative drugs; 4) the lack of smoking and alcohol; 5 ) failure , liver disease , kidney and gastrointestinal; 6 ) no history of cancer; 7 ) not using hormone therapy within 3 months ; 8 ) not suffering from high blood pressure . Exclusion criteria included : 1 ) the creation of any physical illness and mental During the study period , causing obstructive sleep apnea; 2 ) the emergence of a significant change sleep conditions as unpredictable as travel , shift or taking any medications , and additional material during study; 3 ) Do not use Valerian maximum period of seven consecutive days during the study period 4 ) unwillingness to cooperate.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 129

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University Of Medical Sciences

**Street address**

Shiraz University of Medical Science Building, Zand Ave, Shiraz

**City**

Shiraz

**Postal code**

7193613119

**Approval date**

2014-02-12, 1392/11/23

**Ethics committee reference number**

CT.92.6885

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

insomnia

**ICD-10 code**

F51.0

**ICD-10 code description**

Nonorganic insomnia

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

insomnia

**Timepoint**

Early intervention and after 1 month in all three groups

**Method of measurement**

Standardized questionnaire Petersburg

**Secondary outcomes**

empty

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

Valerian group, taken twice a day capsules of 530 mg

Valerian, oral capsule Sedamin before bed for a month

**Category**

Treatment - Drugs

**2****Description**

Relaxation training, participation in classes 2 times a day for the first week and then do the exercises at home

**Category**

Other

**3****Description**

Control group, placebo containing Starch 50 mg 2 times a day for a month

**Category**

Other

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**  
Motahari Clinic  
**Full name of responsible person**  
Mrs Halaj  
**Street address**  
Namazi square, Shiraz  
**City**  
Shiraz

2

**Recruitment center**  
**Name of recruitment center**  
Hazrat Zainab hospital  
**Full name of responsible person**  
Mrs Shahbazi  
**Street address**  
Defae Moghadas square  
**City**  
Shiraz

3

**Recruitment center**  
**Name of recruitment center**  
Hafez hospital  
**Full name of responsible person**  
Mrs Mahtab Tabrizian  
**Street address**  
Chamran Blvd, Shiraz  
**City**  
Shiraz

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**  
Vice chancellor for Research, Shiraz University of  
Medical Sciences  
**Full name of responsible person**  
Dr Gholam Reza Hatam  
**Street address**  
7th Flat, Central department of Shiraz University of  
Medical Sciences, Zand Street, Shiraz  
**City**  
Shiraz  
**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, Shiraz 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**  
Fatemeh (PBUH) College of Nursing and Midwifery  
**Full name of responsible person**  
Azam Jokar  
**Position**  
Faculty Member, MSc in Midwifery  
**Other areas of specialty/work**  
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**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

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ati.kargosha@yahoo.com

**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*