

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jan 2020

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 address7th 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 sourceVice 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

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ati.kargosha@yahoo.com

Web page address

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan