

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of lavender and chamomile herbal tea on anxiety and depression in postmenopausal women: A randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of lavender and chamomile herbal tea on anxiety and depression in postmenopausal women referring to community health centers in Larestan in 1399

Design

The present study is a clinical trial study with a control group and two intervention groups that will be performed in parallel, without blinding, randomly on 96 postmenopausal women.

Settings and conduct

All postmenopausal women referring to community health centers in Larestan city

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age over 45 years 2. Do not use alternative therapies such as hormone therapy 3. Achieve mild to moderate depression score (score 14 to 28) 4. Having informed consent to participate in research 5. Ability to swallow and no oral and digestive problems that do not interfere with herbal tea. 6. Having the necessary vigilance to complete the questionnaires 7. Depression and anxiety disorders are not caused by physical problems such as hypothyroidism. 8. Candidates should not participate in other treatment programs that interfere with the present study. 9. Regular use of herbal tea according to the treatment plan Exclusion criteria: 1- Unwillingness of samples to participate in research 2- History of allergy to herbal medicines 3- Addiction to drugs, alcohol and painkillers 4- Consumption of neuropsychiatric drugs 5- Having severe depression or anxiety

Intervention groups

The intervention includes the use of 2 grams of dried leaves of lavender and 2 grams of dried leaves of chamomile in each intervention group, which is boiled in 2 times in the morning and evening (Dried flowers of lavender and chamomile are placed in 300 ml of boiling

water for 10-15 minutes) and consumed daily with the candy in the form of 2 cups of lavender tea and 2 cups of chamomile tea.

Main outcome variables

Beck Depression questionnaire and Spielberger Anxiety questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090304001742N6**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **prospective**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

mohammadrafi bazrafshan

Name of organization / entity

shiraz university medical science

Country

Iran (Islamic Republic of)

Phone

+98 917 382 1959

Email address

mrbazr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lavender and chamomile herbal tea on anxiety and depression in postmenopausal women: A randomized clinical trial

Public title

Comparison of the effect of lavender and chamomile herbal tea on anxiety and depression in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 45 years Do not use alternative therapies such as hormone therapy Achieve mild to moderate depression score (score 14 to 28) Having informed consent to participate in research Ability to swallow and no oral or digestive problems that do not interfere with drinking. Having the necessary vigilance to complete the questionnaires Depression and anxiety disorder are not the result of physical problems such as hypothyroidism. Candidates should not participate in other treatment programs that interfere with the present study. Regular use of tea according to the treatment plan

Exclusion criteria:

Reluctance of samples to participate in research History of allergy to herbal medicines Addiction to drugs and alcohol and painkillers Taking psychiatric drugs Having severe depression or anxiety

Age

From **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the list of community health centers in Larestan city that postmenopausal women refer to for health services is written on paper. In the next step, the name of each center is placed in a separate envelope and a simple envelope is selected at random. . Assisting the researcher to refer to the selected health center by using available sampling and applying the conditions for entering and leaving the study, sampling postmenopausal women. The selected samples are placed in each of the intervention groups or the control group according to the randomized blocks according to

the inclusion in the study. Thus, according to the sample size of this study, which is estimated at 96 people, 8 blocks of 12 are used. This means that in each block, 4 people are in the intervention group of lavender tea, 4 people are in the chamomile tea intervention group and 4 people are in the control group. Sampling continues until 8 blocks are completed. Finally, 32 people in each group are selected in randomized blocks.

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**

Ethics committee of Larestan University of Medical Sciences

Street address

Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City, Larestan county, Fars province, Iran

City

Larestan

Province

Fars

Postal code

7431889629

Approval date

2020-06-30, 1399/04/10

Ethics committee reference number

IR.LARUMS.REC.1399.006

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

Anxiety and depression in postmenopausal women

ICD-10 code

F32.0

ICD-10 code description

Depression

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

Anxiety and depression

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Spielberger Anxiety Questionnaire - Beck Depression Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes the use of 2 grams of dried leaves of lavender, which is boiled twice in the morning and evening (Dried lavender flowers are placed in 300 ml of boiling water for 10-15 minutes) and consumed daily with candy in the form of 2 cups of lavender herbal tea.

Category

Treatment - Drugs

2

Description

Intervention group: includes the use of 2 grams of dried leaves of Chamomile, which is boiled twice in the morning and evening (Dried Chamomile flowers are placed in 300 ml of boiling water for 10-15 minutes) and consumed daily with candy in the form of 2 cups of Chamomile herbal tea.

Category

Treatment - Drugs

3

Description

Control group: In this study, the control group did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Larestan community health centers

Full name of responsible person

Dr. Mohammad-Rafi Bazrafshan

Street address

Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City, Larestan county

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Dr Mohammad Hossein Karimi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Larestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Mohammad-Rafi Bazrafshan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants' information can be shared after it becomes unrecognizable

When the data will become available and for how long

Access begins a year after the publication of results

To whom data/document is available

People who are working in the academic and scientific institutions

Under which criteria data/document could be used

It needs the agreement of Larestan University of Medical Sciences

From where data/document is obtainable

Dr. Mohammad Rafi Bazrafshan, Associate Professor, Larestan School of Medical Sciences, Email: m.bazrafshan@larums.ac.ir, Contact Phone: 07152247110, Mobile Number: 09173821959

What processes are involved for a request to access data/document

Written and formal request to the vice chancellor for research of Larestan University of Medical Sciences

Comments