

# 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

##### City

Larestan

##### Province

Fars

##### Postal code

7431895639

##### Phone

+98 71 5224 7110

##### Fax

+98 71 5224 7111

##### Email

m.bazrafshan@larums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Larestan University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Hossein Karimi

##### Street address

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

##### City

Larestan

##### Province

Fars

##### Postal code

7431889629

##### Phone

+98 71 5225 5512

##### Email

m.bazrafshan@larums.ac.ir

#### 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  
**Street address**  
Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City, Larestan county  
**City**  
Larestan  
**Province**  
Fars  
**Postal code**  
7431889629  
**Phone**  
+98 71 5225 5512  
**Email**  
m.bazrafshan@larums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Larestan University of Medical Sciences  
**Full name of responsible person**  
Larestan University of Medical Sciences  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City, Larestan county  
**City**  
Larestan  
**Province**  
Fars  
**Postal code**  
7431889629  
**Phone**  
+98 71 5225 5512  
**Email**  
m.bazrafshan@larums.ac.ir

## Person responsible for updating data

### 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  
**Street address**  
Sina Building (Larestan University of Medical Sciences), Behind Larestan Grand Bazaar, Karmandan St., North Ghadir Blvd., New City, Larestan county  
**City**  
Larestan  
**Province**  
Fars  
**Postal code**  
7431889629  
**Phone**  
+98 71 5225 5512  
**Email**  
m.bazrafshan@larums.ac.ir

## 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