Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of Rosmarinus officinalis L infusion on stress, anexiaty and depression in menopausal women

Protocol summary

Study aim
Determining the effect of rosemary tea on estress, anxiety and depression in postmenopausal women

Design
This study is a randomized placebo-controlled trial. Randomization of 108 participants will be conducted via simple randomization using a random number table. Participants will be allocated to groups based on the final digit of their assigned random number: digits from 0 to 4 will designate the intervention group, while digits from 5 to 9 will designate the control group. The study will employ a double-blind design.

Settings and conduct
This double-blind study will be conducted on 108 menopausal women referring to the 17 shahrivar Health Center and Health Center No. 4 in Ahvaz. Participants with specific scores for depression, anxiety, and stress (based on DASS-21) will be selected and randomly divided into an intervention group (rosemary tea, 54 people) and a control group (wheat bran placebo tea, 54 people). Questionnaires will be completed before the intervention, and 4 and 8 weeks after. Both groups will consume one tea bag (2.5 grams) daily for 8 weeks, with identical packaging and appearance of the teas to maintain blinding. Participants will record consumption information and physical status. Potential side effects will be followed up.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age: 50–60 years; Postmenopausal status (≥12 months amenorrhea); Mild-to-moderate stress, anxiety, and depression (via DASS scale); Minimum high school diploma. Exclusion Criteria: Rosemary hypersensitivity; Substance abuse or antidepressant use; Chronic physical illnesses; Current hormone therapy.

Intervention groups
The intervention group consumes rosemary tea daily for 8 weeks and the control group consumes wheat bran placebo tea; Both groups have similar packaging and appearance to maintain blinding

Main outcome variables
Reducing anxiety; reducing depression; Reduce stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260523069501N1**
Registration date: **2026-07-22, 1405/04/31**
Registration timing: **prospective**

Last update: **2026-07-22, 1405/04/31**
Update count: **0**

Registration date
2026-07-22, 1405/04/31

Registrant information

Name
Mahdis Bigdeli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3229 0604

Email address
bigdelisanam79@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-23, 1405/05/01

Expected recruitment end date
2026-11-22, 1405/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of Rosmarinus officinalis L infusion on stress, anexiaty and depression in menopausal women

Public title

Studying the effect of Rosmarinus officinalis L infusion on stress, anexiaty and depression in menopausal women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Menopause (at least 12 months have passed since the last menstrual period) mild to moderate symptoms of stress, anxiety and depression (according to the DASS scale score) Literacy of at least a diploma

Exclusion criteria:

Having an allergy to rosemary Addiction and use of antidepressants The occurrence of a disease or an accident or an event that causes problems with the consumption of rosemary in a person. Consuming any herbal tea with the same effective ingredient as rosemary. For example: lavender. Chamomile Basil leaves, saffron, lemon balm... Having any chronic and physical illness The occurrence of stressful events such as the death of relatives, etc. in the last 6 months People under hormone therapy

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple random sampling method, people are divided into two intervention groups (rosemary tea, 54 people) and control (placebo tea containing wheat bran, 54 people). The allocation of people to each of the two groups is done using a simple randomization method, so that a number is randomly selected for each person with the help of a random number table, if the selected number ends in 0 to 4, that person is assigned to the first group (intervention), and if it ends to 5 to 9, that person is assigned to the second group (control). Allocation of people to each of the groups is done in such a way that participants and researchers are unaware of the group assigned to the patient (double blind).It should be noted that tea bags are placed in cardboard envelopes in packs of 28 so that their contents are unclear. Also, the method of distribution is such that the participants receive a 28-pack at the beginning of the study period. At the end of the fourth week, they go to the health center to complete the questionnaire again and receive the second 28-pack.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to ensure impartiality in evaluating the effects of the intervention, the blinding process was implemented in two ways. In this regard, all study participants were unaware of the type of intervention they were receiving (rosemary tea or placebo). Also, the research executive team, including clinical assessors, data collectors, and other people who interacted directly with the participants, were not aware of the allocation of people to the intervention and control groups.In order to maintain this blinding situation, the rosemary tea and the placebo were designed and prepared in such a way that no distinction between them could be distinguished in terms of appearance and packaging. The responsibility of assigning the codes related to the intervention and placebo groups remained confidentially with a third party (such as a statistician or an independent pharmacist) to avoid any possible bias during the implementation and data collection process.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jundishapur University of AJUMS Medical Sciences

Street address

Shahrivar Street, Golestan Boulevard

City

Ahvaz

Province

Khouzestan

Postal code

6177634848

Approval date

2026-06-27, 1405/04/06

Ethics committee reference number

IR.AJUMS.REC.1405.141

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Depression
Timepoint
Checking the depression score according to the DASS-21 questionnaire at the beginning of the study (before the start of the intervention) and 4, 8 weeks after the consumption of rosemary tea
Method of measurement
Questionnaire DASS-21

2

Description
Anxiety
Timepoint
Checking the anxiety score according to the DASS-21 questionnaire at the beginning of the study (before the start of the intervention) and 4, 8 weeks after the consumption of rosemary tea
Method of measurement
Questionnaire DASS-21

3

Description
Stress
Timepoint
Checking the stress score according to the DASS-21 questionnaire at the beginning of the study (before the start of the intervention) and 4, 8 weeks after the consumption of rosemary tea
Method of measurement
Questionnaire DASS-21

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group consists of menopausal women with moderate to mild levels of stress, anxiety, and depression as measured by the DASS-21 questionnaire; these participants will consume a rosemary infusion (2.5 g of dried rosemary leaves in 150 mL of boiling water) for 8 weeks, with DASS-21 scores being assessed at baseline (two sessions prior to the intervention), at 4 weeks, and at 8 weeks post-intervention
Category
Treatment - Other

2

Description
Control Group:The control group consists of menopausal women with moderate to mild levels of stress, anxiety, and depression as measured by the DASS-21 questionnaire; these participants will consume a wheat bran infusion (2.5 g of wheat bran powder in 150 mL of boiling water) for 8 weeks, with DASS-21 scores being assessed at baseline (two sessions prior to the intervention), at 4 weeks, and at 8 weeks post-intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health 17 shahrivar
Full name of responsible person
Mahdis Bigdeli
Street address
Gandomi Street, between Towhid and Rastagari Streets, East Imam Khomeini Avenue, Ahvaz, Iran
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Postal code
6155745474
Phone
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2

Recruitment center
Name of recruitment center
Health Services Center No. 4
Full name of responsible person
Mahdis Bigdeli
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abdollah Rafiei
Street address
Shahrivar Street, Golestan Boulevard
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Postal code
6135715794
Phone
+98 61 3311 0000
Email
eduaum@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mahdis Bigdeli
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Position
Midwife
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
Midwife
Latest degree
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Other areas of specialty/work
Midwifery
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bigdelisanam79@gmail.com

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

Yes - There is 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

The available data will consist of anonymized clinical datasets, including patient demographic characteristics (age, gender), baseline characteristics, clinical outcomes, depression, anxiety, and stress scores, as well as relevant diagnostic findings. All personally identifiable information (PII) will be strictly removed to ensure participant confidentiality. Documentation may include the study protocol and the statistical analysis plan.

When the data will become available and for how long

The data access period will commence 8 months after the publication of the study

To whom data/document is available

Data access will be restricted to researchers affiliated with academic or scientific institutions.

Under which criteria data/document could be used

De-identified data may be available to qualified researchers upon reasonable request and after approval from the corresponding author, solely for the purpose of scientific validation or further research. Access will be granted provided that such requests comply with ethical guidelines and patient confidentiality

From where data/document is obtainable

Requests for data or related documentation should be directed to the corresponding author via the email address provided in the study publication or registration details.

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

The process involves the following steps: 1) The requesting researcher submits a formal written request to the corresponding author, including a detailed research protocol and the intended use of the data. 2) The research team reviews the request for scientific merit and alignment with the original study's objectives. 3) Upon scientific approval, the request is reviewed to ensure it complies with ethical guidelines and data privacy regulations. 4) Once approved, a Data Use Agreement (DUA) may be signed, and de-identified data will be shared via a secure method.

Comments