Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of chamomile tea on anxiety and depression in postmenopausal women

Protocol summary

Study aim
The determine of the effect of chamomile tea on anxiety and depression in postmenopausal women.

Design
A two-group clinical trial with parallel groups is performed on 68 people. In both groups, the intervention is performed with chamomile tea or placebo. Study is one-blinded. Sampling done with simple method and random allocation was done.

Settings and conduct
The ethical aspects were investigated and confirmed by the Research Ethics Committee of AJUMS, and the necessary permissions were obtained. Participants who had the inclusion criteria enrolled in this one-blinded study and randomization was conducted in A or B groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Interested in participating in the study. Having at least elementary education. 45-60 years old. Amenorrhea for at least 1 year. Mild to moderate anxiety and depression symptoms (according to DASS scale). Exclusion criteria: Having allergy to chamomile. Major depression that need to special treatment. Person who have suicidal thoughts and self-harm. Having renal, liver, cardiac and thyroid disease, bleeding disorder and malignancies. degenerative, auto immune and psychological disorders. Using of anti-depression and sedative drugs in 3 months ago. Having a history of stressful events or tragic events in recent months such as the death of a spouse or close persons. Having a history of drug or alcohol abuse.

Intervention groups
This study have 2 groups. Group A: receives chamomile. Group B: receives placebo.

Main outcome variables
Anxiety and depression in postmenopausal women.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200818048452N1**
Registration date: **2020-11-05, 1399/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-05, 1399/08/15**
Update count: **0**

Registration date
2020-11-05, 1399/08/15

Registrant information

Name
Zohreh Zamanpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3621 0123

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-04-21, 1400/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of chamomile tea on anxiety and depression in postmenopausal women

Public title

The effect of chamomile tea on anxiety and depression in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Interested in participating in the study. Having at least elementary education. 45-60 years old. Amenorrhea for 1 year. Mild to moderate anxiety and depression symptoms (according DASS scale).

Exclusion criteria:

Having allergy to chamomile. Major depression that need to special treatment. Person who have suicidal thoughts and self-harm. Having renal, liver, cardiac and thyroid disease, Bleeding disorder and malignancies, degenerative, auto immune and psychological disorder. Using of anti-depression and sedative drugs in 3 months ago. Having a history of stressful events or tragic events in recent months such as the death of a spouse or close persons. Having a history of drug abuser or alcohol abuse.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using a random number table to create quadruple blocks in a one-to-one ratio that will be placed in two groups of 30 people to intervene and control.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants did not know each person was placed in which group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی اهواز

Street address

Esfand Ave., Golestan Blvd.,

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Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Approval date

2020-06-10, 1399/03/21

Ethics committee reference number

IR.AJUMS.REC.1399.228

Health conditions studied

1

Description of health condition studied

Anxiety and depression in postmenopausal women.

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety and depression in postmenopausal women.

Timepoint

Pre-intervention, 4 weeks after the start of the intervention, 8 weeks after the start of the intervention.

Method of measurement

Variables are measured by demographic questionnaire and DAAS-21 scale.

Secondary outcomes

1

Description

Anxiety and depression in postmenopausal women.

Timepoint

Pre-intervention, 4 weeks after the start of the intervention, 8 weeks after the start of the intervention.

Method of measurement

Variables are measured by demographic questionnaire and DAAS-21 scale.

Intervention groups

1

Description

Intervention group: For this patient if they had the inclusion criteria, after submitting a description and

obtaining informed consent, The DAAS-21 questionnaire and the demographic information form will be completed pre-intervention. Each patient consumes three sachets daily at least half an hour after each meal. In this way, 2.5 grams of dried German chamomile flowers made by Golestan factory are placed in 150 cc of boiling water every time. The duration of putting the tea in boiling water is the same for all people. Patients are followed up 4 weeks after the intervention and 8 weeks after the intervention and the DAAS-21 questionnaire is completed for them.

Category

Treatment - Other

2

Description

Control group: For this patient if they had the inclusion criteria, after submitting a description and obtaining informed consent, The DAAS-21 questionnaire and the demographic information form will be completed pre-intervention. In this group, the intervention is applied with the placebo that contains wheat germ powder. Each patient consumes three bags of placebo daily for at least half an hour after each meal. Each time, 2.5 grams of placebo, which is similar in shape and size to the chamomile tea bag made by Golestan factory, is placed in 150 cc of boiling water. The duration of putting the bag in the boiling water is the same for all participants. Patients are followed up 4 weeks after the intervention and 8 weeks after the intervention and the DAAS-21 questionnaire is completed for them. It should be noted that placebo contains wheat germ powder, which according to scientific articles and documents has no therapeutic effect on anxiety and depression.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Health Center No. 10

Full name of responsible person
Zohre Zamanpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
Zohreh Zamanpour

Position
Master of midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available