

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of violet flower and evening primrose flower on the anxiety of menopausal women

Protocol summary

Study aim

Comparison of the effect of violet flower and evening primrose flower on the anxiety of menopausal women

Design

Clinical trial with a control group, with parallel groups, a blind strain, randomized on 72 patients. Sealed Envelope software will be used for randomization.

Settings and conduct

This study will be conducted in all health and treatment centers of Khomein city as a clinical trial. After the intervention, the level of anxiety of postmenopausal women in two intervention groups and one control group is measured and recorded. Only the analyzers do not know how the samples are placed in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, Having at least reading and writing literacy, Menopause, Age 40-65 years; Exclusion criteria: Preventing the patient from taking herbal medicines, Being admitted to the hospital, The occurrence of a severe stressful event

Intervention groups

Intervention group: In the first intervention group (violet flower syrup), women for one month will consume 5 ml of violet flower syrup twice a day. In the second intervention group (evening primrose flower), postmenopausal women will consume 1 gram of evening primrose flower syrup twice a day for one month. Control group: They do not receive this intervention during this period. In the first 15 days, the researcher will follow up by phone and check the checklist weekly to ensure the correct use of drugs. The second questionnaire of the scale of depression, anxiety and stress-21 will be completed by the individual after the first 15-day period of use. And the third questionnaire will be completed by all three groups on the 30th day after taking the second course of medicine.

Main outcome variables

anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051142N9**

Registration date: **2023-02-28, 1401/12/09**

Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**

Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

Aida Arjloo

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3402 0115

Email address

golmehrsherafati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2023-04-03, 1402/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of violet flower and evening primrose flower on the anxiety of menopausal women	
Public title	Comparison of the effect of violet flower and evening primrose flower on the anxiety
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Willingness to participate in the study Having at least reading and writing literacy Menopause (at least 12 months of spontaneous cessation of menstruation) Age 40-65 years
Exclusion criteria:	Preventing the patient from taking herbal medicines Being admitted to the hospital The occurrence of a severe stressful event before entering the intervention (death of relatives, separation from spouse, sick person in the family, dismissal and bankruptcy)
Age	From 40 years old to 65 years old
Gender	Female
Phase	N/A
Groups that have been masked	Data analyser
Sample size	Target sample size: 72
Randomization (investigator's opinion)	Randomized
Randomization description	Menopausal women are assigned to two intervention groups and one control group based on the randomization sequence that will be generated in advance, which is unpredictable and its arrangement is completely random. To allocate the samples, the block randomization method with the size of 3 and 6 blocks will be used, so that by using the software for generating random numbers in the block method, a randomization sequence will be generated according to the sample size required for the three groups. First, all the modes in which the 3 letters A, B and C can be put together in blocks of 3 and 6 are generated, then a block is randomly selected by placing it among the blocks and the layout pattern in that block will be used to allocate women. Finally this block will be placed in the main container and another block will be selected again. Blocks of 3 and 6 will all be in the same container. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.
Blinding (investigator's opinion)	Single blinded
Blinding description	The data analyzer will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of faculty of medical sciences, Aligudarz Azad university
Street address	Daneshgah square, Velayat Blvd., Aligudarz, Lorestan province
City	Aligudarz
Province	Lorestan
Postal code	۷۴۷۷۸۹۳۷۸
Approval date	2022-11-22, 1401/09/01
Ethics committee reference number	IR.IAU.AGZ.REC.1401.002
Health conditions studied	
<u>1</u>	
Description of health condition studied	Anxiety
ICD-10 code	F06.4
ICD-10 code description	Anxiety disorder due to known physiological condition
Primary outcomes	
<u>1</u>	
Description	Anxiety rate
Timepoint	Before the intervention and twice after the start of the first intervention (on the 15th and 30th days of the intervention), the level of anxiety of each patient is measured.
Method of measurement	At the beginning and end of the study, the demographic questionnaire, the Spielberger questionnaire, and the depression, anxiety and stress scale-21 form are completed by the menopausal women of all three groups, and their anxiety level is determined based on this

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the first intervention group (violet flower syrup), women will consume 5 ml of violet flower syrup twice a day (in the morning after waking up and at night before going to bed) for one month. At the beginning and end of the study, the Spielberger questionnaire, and the depression, anxiety and stress scale-21 form are completed by the menopausal women of all three groups, and their anxiety level is determined based on this.

Category

Other

2

Description

Intervention group 2: In the second intervention group (evening primrose flower), postmenopausal women will consume 1 gram of evening primrose flower syrup twice a day (once in the morning and once at night with a glass of water) for one month. At the beginning and end of the study, the Spielberger questionnaire, and the depression, anxiety and stress scale-21 form are completed by the menopausal women of all three groups, and their anxiety level is determined based on this.

Category

Other

3

Description

Control group: In this period, they do not receive this intervention and only fill the Spielberger questionnaire and the depression, anxiety and stress-21 scale form at the beginning and end of the study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health and treatment centers of Khomein city

Full name of responsible person

Zeynab Beheshti

Street address

University campus, Daneshgah Blvd., Khomein

City

Khomein

Province

Markazi

Postal code

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+98 86 4633 7801

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golmehrsherafati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Khomein branch

Full name of responsible person

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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

Islamic Azad University, Khomein branch

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

Islamic Azad University, Khomein branch

Full name of responsible person

Zeynab Beheshti

Position

Assistant 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

Contact

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

since the spring of 2023

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

In order to reduce the anxiety level of menopausal women

From where data/document is obtainable

Vice chancellor for education and research, Khomein Azad university

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

These documents will be available on the website of Khomein Azad university.

Comments