Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 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
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Iran (Islamic Republic of)
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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

1

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
۱۴۷۷۸۹۳۷۸۰
Approval date
2022-11-22, 1401/09/01
Ethics committee reference number
IR.IAU.AGZ.REC.1401.002

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Zeynab Beheshti
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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
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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
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