Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the Comparative Effectiveness Between Achillea wilhelmsii Consumption and Counseling with Mindfulness-Based Cognitive Therapy (MBCT) Approach on Hot Flashes, Quality of Life and Sleep in Menopausal Women

Protocol summary

Study aim

Determining and comparing the effect of Achillea wilhelmsii and counseling with mindfulness-based cognitive therapy approach on hot flashes, quality of life and sleep in postmenopausal women

Design

The first group is 25 people treated with Yarrow Capsules. The second group is 25 people in the control group without treatment. They will receive only the routine care of the health center, and the third group is 25 people in the counseling group. Considering the effect size of 0.4, the sample size in each group was 22 people .According to the probability of falling, a total of 75 people will be included in the study.

Settings and conduct

After receiving permission to conduct the research and presenting it to Kerman University of Medical Sciences, the researcher refers to health centers under the auspices of Torbat Heydariyeh University of Medical Sciences and this clinical trial study will be a random sampling method. Menopausal women under the auspices of Torbat Heydariyeh health centers . will be obtained through the Apple system.

Participants/Inclusion and exclusion criteria

Inclusion criteria Be literate and grow All women are 65-45 Have at least 20-20 hot flashes a day For one year after the last menstrual period Exclusion criteria: Absence from two sessions of medical counseling

Intervention groups

The first group is 25 people treated with Yarrow capsules the morning .The second group is the control group without treatment, they will receive only the routine care of the health center, and the third group is the counseling group.

Main outcome variables

Sleep quality: Quality of life: Flushing:

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210201050212N1**
Registration date: **2021-07-28, 1400/05/06**
Registration timing: **prospective**

Last update: **2021-07-28, 1400/05/06**
Update count: **0**

Registration date

2021-07-28, 1400/05/06

Registrant information

Name

omolbanin lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5222 7100

Email address

o.lotfi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Comparative Effectiveness Between Achillea wilhelmsii Consumption and Counseling with Mindfulness-Based Cognitive Therapy (MBCT) Approach on Hot Flashes, Quality of Life and Sleep in Menopausal Women

Public title

The effect of yarrow on menopause

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be literate All Women are 65-45 Have at least 3- 20 hot flashes a day For one year after the last menstrual period

Exclusion criteria:

Absence from two sessions of medical counseling Have a physical or mental illness Have a regular exercise program Taking psychotropic drugs Have a severely stressful event over the past month Has taken less than 80% of his medication Has used soy or phytoestrogens more than once in the past week Over the past week with a specific illness that is severely stressful or causing pain During the study, he had to use a special medication that caused sleep disturbances as well as hot flashes Have changed your sleeping place and place during the last week Used sleeping pills or hypnotics He has used psychedelic, sedative and anti-anxiety drugs Be addicted to drugs such as cigarettes and alcohol Use medications that cause sleep disturbances or insomnia History of yarrow or any of its components, people with allergic asthma, seizures, liver disease or cancer Take any estrogen-based medication to treat menopausal complications (osteoporosis, hot flashes) or other interfering medications such as tibolone with a night shift job. Menopause due to bilateral removal of the ovaries or undergoing chemotherapy Treatment for mental disorders or hot flashes in the last 60 days Hormone Therapy Use of hormonal contraceptives Taking selective estrogen receptor modulators or aromatase inhibitors over the past two months Have severe depression Have a severe current illness Suicide attempt in the last 3 weeks Having bipolar disorder or other mental disorders throughout life Uncontrolled blood pressure Taking tamoxifen, raloxifene, antidepressant, clonidine in the last two months

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permutation will be performed using the block method: For random assignment, triple blocks with three patients and a table of single-digit random numbers are used, so that for a random number, a triple block, and for a random number, two triple blocks, and so on, the numbers zero, seven, and eight are used. No, we will. ABC for digit 1 ACB for figure 2 BAC for digit 3 BCA for figure 4 CAB for digit 5 CBA for figure 6 And we ignore the numbers 0, 7, 8 and 9. The reason for using the random permutation block method is that the number of people in the groups is equal.

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 Kerman University of Medical Sciences

Street address

No.9,Kashini Ave

City

Totbat e heydarieh

Province

Razavi Khorasan

Postal code

9516817311

Approval date

2021-06-14, 1400/03/24

Ethics committee reference number

IR.KMU.REC.1400.174

Health conditions studied

1

Description of health condition studied

Investigation of the comparative effectiveness between Achillea wilhelmsii consumption and counseling with mindfulness-based cognitive therapy (MBCT) approach on hot flashes, in menopausal women

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Comparative study of the effect of Achillea wilhelmsii and counseling with mindfulness-based cognitive therapy approach on quality of life in postmenopausal women

ICD-10 code
ICD-10 code description

3

Description of health condition studied
Comparative study of the effect of Achillea wilhelmsii and counseling with mindfulness-based cognitive therapy approach on sleep quality in postmenopausal women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Flush score
Timepoint
Measure hot flashes before the study and at the end of the first and second months
Method of measurement
Flushing severity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Achillea wilhelmsii capsule (2 mg daily in the morning and evening for 2 months) which contains Achillea wilhelmsii which has phytoestrogenic properties and is produced by Kerman School of Pharmacy
Category
Lifestyle

2

Description
Intervention group: Counseling group:Eight sessions of 120 to 150 minutes. With 45 minutes a day of exercise, which can be accompanied by a one-day program of mindfulness guided in week 6. In the first 4 sessions, the focus is on inner experiences and in the second half on the challenges of life. Mindfulness training will be short.
Category
Behavior

3

Description
Control group: Does not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Torbat Heydariyeh Health Center
Full name of responsible person
Lotfi Omolbanin
Street address
No.9,Kashani Ave
City
Torbat Heydariyeh
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9516817311
Phone
+98 51 5222 7100
Email
olotfi1398@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Abbas Pardakhti
Street address
No.9,Kashani Ave
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Torbat Heydarieh
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9516817311
Phone
+98 51 5222 7100
Email
olotfi1398@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Omolbanin Lotfi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
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No.1,GHarani Ave,Torbat Heydariyeh University of Medical Sciences
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Person responsible for updating data

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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