

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of oral capsule of Ocimum basilicum leaf extract on sleep quality in menopausal women

Protocol summary

Study aim

Determination of the effect of oral capsule of ocimum basilicum leaf extract on sleep quality in postmenopausal women

Design

A randomized controlled clinical trial with 60 randomized, triple-blind, placebo-controlled trials on 60 postmenopausal women who were randomly assigned to each group using a random number table.

Settings and conduct

Mashhad Health Centers

Participants/Inclusion and exclusion criteria

Minimum literacy, post menopause, sleep quality scores above 5, 40 to 65 years, no history of sleep disorder requiring medical intervention (per person), no smoking and alcohol use, no smoking Hormone therapy for the past 6 months, no depression, stress or anxiety, no medical illnesses, no mental illnesses, no infectious and feverish illnesses, no simultaneous use of sleeping herbal remedies, Non-use of sleep-inducing chemical drugs, No use of anticoagulants, Anxiolytic drugs, No shift work the night

Intervention groups

Intervention group used oral capsule of ocimum basilicum leaf extract and control group received placebo containing starch.

Main outcome variables

Quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200104046001N1**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **prospective**

Last update: **2020-01-10, 1398/10/20**

Update count: **0**

Registration date

2020-01-10, 1398/10/20

Registrant information

Name

fatemeh zahra karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1512

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral capsule of Ocimum basilicum leaf extract on sleep quality in menopausal women

Public title

Effect of Ocimum basilicum on sleep quality in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least literacy Being a postmenopausal patient(Have at least 12 months spontaneous abstinence, with no association with pregnancy, lactation, or other medical, pharmaceutical, or serum FSH levels> 40IU / L.) Having a sleep quality score above 5 Age 40 to 65 years No history of sleep disorder requiring medical intervention (according to the person) Lack of allergy to Ocimum basilicum Exclusion criteria: Smoking and alcohol Hormone therapy in the past 6 months Having severe depression, stress, or severe anxiety(A score of less than 19 under the stress scale, a score of less than 10 under the anxiety scale, or a score of less than 14 under the DASS-21 Depression Scale) Medical illness(Such as, asthma, restless leg syndrome, kidney failure, liver disease,, chronic illness, seizure, Parkinson's disease, epilepsy, arthritis) Mental illness(Delirium, Schizophrenia, Alzheimer's) Infectious and feverish diseases(Respiratory tract infection, urinary and hepatitis, influenza, arthritis) Use herbal sleep medicines that affect sleep(Lavender, Spring Orange, Basil Lemon, herbal tea of Ocimum basilicum) Concomitant use of sleep-inducing chemical drugs(Clonidine, antidepressants, tamoxifen, raloxifene, anticonvulsants such as gabapentin, sedative) Use of anti-coagulants, anxiolytic drugs Having a night shift Age From 40 years old to 65 years old Gender Female Phase 3 Groups that have been masked • Participant • Investigator • Data analyser Sample size Target sample size: 60 Randomization (investigator's opinion) Randomized Randomization description Originally from Mashhad 5 and Samen districts, their names are written on paper. Two centers are selected by lot and each center has two centers that meet the conditions of staff cooperation and presence of postmenopausal women. After attending these centers, the menopausal women are selected after being given access to the research unit selection checklist, followed by oral capsules of basil leaf extract and placebo, administered by a pharmacy consultant professor at the Medicinal Plant Pharmacology Center of Mashhad University of Medical Sciences, Mashhad, Iran. The packaging is completely identical and only a drug consultant is aware of it will be provided with the researcher based on the code and Individuals with inclusion criteria who fall into groups according to the random number table Blinding (investigator's opinion) Triple blinded Blinding description	In order to blind the basil leaf extract and placebo capsule to the researcher in similar forms and in identical cans, each researcher has a code that the pharmacy consulting professor is aware of. Individuals with inclusion criteria are randomly assigned to the groups using the random number table, so by the end of the study unit, the researcher and the statistical analyst will not know the codes for the basil leaf extract and placebo. Placebo Used Assignment Parallel Other design features Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics Committee of Mashhad University of Medical Sciences-School of Nursing and Midwifery Street address School of Nursing and Midwifery,Doctora Crossroads,Daneshgah Street, City Mashhad Province Razavi Khorasan Postal code 9137913199 Approval date 2019-11-12, 1398/08/21 Ethics committee reference number IR.MUMS.NURSE.REC.1398.070 Health conditions studied <u>1</u> Description of health condition studied sleep disorder ICD-10 code G47 ICD-10 code description Sleep disorders Primary outcomes <u>1</u> Description sleep quality Timepoint Before the study and immediately after the intervention Method of measurement Pittsburgh Sleep Quality Questionnaire
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Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Oral Extract of Ocimum Basilicum Leaf Extract Made in the Pharmacology Department of Mashhad University of Medical Sciences, each capsule contains 500 mg of Basil Leaf Extract.research units consume one capsule daily before bedtime for one month

Category

Treatment - Other

2

Description

Control group: Control group: Use placebo with similar capsules and cans that Made in the Pharmacology Department of Mashhad University of Medical Sciences, each capsule contains 500 mg of Starch.research units consume one capsule daily before bedtime for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

samen health center

Full name of responsible person

محمد مهدی ایزدپناه

Street address

24,Akhund Khorasani,Gonbad sabz Square

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Province

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2

Recruitment center

Name of recruitment center

shahid ghodsi health center

Full name of responsible person

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Next to Blood BankEnd of Sanabad Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

DR. Bahreini

Street address

School of Nursing and Midwifery,Doctora Crossroads,Daneshgah Street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

حمیده حسینی

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

Fatemeh zahra karimi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Hamideh hosseini

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Latest degree

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Other areas of specialty/work

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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

Not applicable

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