Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Melissa Officinalis on stress, anxiety, depression and sleep quality of elderly women

Protocol summary

Study aim
Determining the effect of lemon balm on stress, anxiety, depression and sleep quality of elderly women

Design
90 elderly people are divided into two intervention and control groups by random division method

Settings and conduct
The intervention is carried out on the elderly who have sleep disorders and have stress, anxiety, and depression, who refer to the health centers of Rafsanjan city.

Participants/Inclusion and exclusion criteria
Entry criteria: age over 60 years old, gender: female, Pittsburgh score greater than 5, not using lemon balm continuously and regularly, not using other herbal medicines continuously and regularly, not using sedatives, not using alcohol and Psychedelic substances, no sensitivity to herbal medicines, no hypothyroid disease Exclusion criteria: not taking the medicine completely in two consecutive days, not wanting to continue participating in the study, starting to take other herbal medicines during the study, starting to take sedatives during the study. Sensitization, intermittent consumption of lemongrass during the study

Intervention groups
In both intervention and control groups, informed consent is obtained from the person or his family. Then, demographic and background information questionnaire, Pittsburgh sleep quality questionnaire and stress, anxiety and depression questionnaire are completed for the person. Next, lemongrass capsules containing 400 mg of lemongrass extract will be given to the elderly in the intervention group twice a day for one month. Also, placebo capsules containing 400 mg of starch powder will be given to the elderly in the control group twice a day for one month after matching the appearance with the capsules of the control group. How to use capsules and the importance of using them correctly are presented to both groups.

Main outcome variables
Stress-anxiety-depression and sleep

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150519022320N32**
Registration date: **2023-08-11, 1402/05/20**
Registration timing: **prospective**

Last update: **2023-08-11, 1402/05/20**
Update count: **0**

Registration date
2023-08-11, 1402/05/20

Registrant information

Name
Tayebeh Mirzaei

Name of organization / entity
Rafsanjan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 34 3425 5900

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Melissa Officinalis on stress, anxiety, depression and sleep quality of elderly women

Public title
Investigating the effect of Melissa Officinalis on stress, anxiety, depression and sleep quality of elderly women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
1. Age over 60 years 2. Gender: female 3. Pittsburgh score more than 5 4. Not using lemon balm continuously and regularly 5. Not using other herbal medicines continuously and regularly 6. Not using sedatives 7. Not using alcohol and Psychedelic substances 8. Lack of allergy to herbal medicines 9- Absence of hypothyroidism 10- Absence of epilepsy

Exclusion criteria:
1. Failure to take the medicine completely in two consecutive days 2. Unwillingness to continue participating in the study 3. Starting to take other herbal medicines during the study 4. Starting to take sedatives during study 5. Sensitization 6. Intermittent consumption of lemongrass while studying

Age
From **60 years** old to **85 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
With the purposeful sampling method, the elderly who meet the criteria for entering the study will be selected. Then the participants will be randomly divided into two intervention and control groups using the software.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Rafsanhan University of Medical Sciences

Street address
school of nursing and midwifery, Nurse Avenue, rafsanjan

City
Rafsanjan

Province
Kerman

Postal code
7718796755

Approval date
2023-08-08, 1402/05/17

Ethics committee reference number
IR.RUMS.REC.1402.067

Health conditions studied

1

Description of health condition studied
Stress-anxiety-depression and sleep disorder

ICD-10 code
F41.2

ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Stress-anxiety-depression and sleep disorder

Timepoint
All the participants completed the Pittsburgh questionnaires and the stress, anxiety and depression questionnaires before and after the intervention.

Method of measurement
Pittsburgh questionnaires and the stress, anxiety and depression questionnaires

Secondary outcomes

1

Description
Stress score, anxiety, depression and sleep quality

Timepoint
Sleep problems, stress, anxiety and depression of the participants are checked before and after the intervention

Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Teaching how to use 400 mg cucumber capsules (Meltropic) made by academic Jihad, which should be taken orally twice a day in the morning and evening, is explained to the elderly or one of their family members, and it should be taken for 4 weeks and during the period The drug is followed up through phone calls or forming a virtual group of participants to be notified if any side effects occur

Category
Treatment - Other

2

Description
Control group: Control group: They receive training on the use of 400 mg starch capsules twice a day, morning and night.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive health service centers of Rafsanjan city

Full name of responsible person
Dr.Tayebeh Mirzaei, KHalil Abadi

Street address
Faculty of Nursing, Nurse Blvd., Jomhury street, Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Dr.Reza Vazirinejad

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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
Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Dr.Tayebeh Mirzaei, KHalil Abadi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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