Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Aromatherapy with Achillea wilhelmsii C. Koch Essential Oil on Sleep Quality, Insomnia Severity, Stress, Anxiety, and Depression in Patients with Generalized Anxiety Disorder: A Randomized Controlled Trial

Protocol summary

Study aim
Evaluation of the Effectiveness of Aromatherapy with Essential Oil from the Aerial Parts of Yarrow (Achillea wilhelmsii C. Koch) on Sleep Quality, Insomnia Severity, Stress, Anxiety, and Depression in Patients with Generalized Anxiety Disorder.

Design
A phase 2, randomized, double-blind, parallel-group controlled clinical trial on 40 patients with Generalized Anxiety Disorder. The study groups consist of the intervention (yarrow essential oil inhalation) and control (placebo) groups, allocated in a 1:1 ratio. Block randomization with variable block sizes (4 and 6) using R software was used for randomization.

Settings and conduct
Randomized double-blind parallel trial, 40 GAD patients, Farabi sleep clinic, nightly yarrow oil inhalation vs placebo for 8 weeks; blinding of patients, assessor, analyst, and partial blinding of interventionist.

Participants/Inclusion and exclusion criteria
A total of 40 participants aged 18 to 60 years.

Intervention groups
Nature of the intervention: Inhalation aromatherapy. Intervention group: 2 drops of standardized essential oil from the aerial parts of yarrow (Achillea wilhelmsii) (with confirmation of chemical composition using GC-MS analysis) are dropped onto a cloth placed on the patient's sleeping pillow. This is done by the patient themselves before sleep, and they have received the necessary training beforehand. Control group (placebo): 2 drops of an odorless and inert carrier oil (pharmaceutical-grade oral paraffin) are used in the same manner. Time and duration: Sessions are conducted every night, 1 minute before the individual's usual bedtime, for 4 consecutive weeks (28 sessions in total). Usual care (medications prescribed by the psychiatrist) continues in both groups. The next period will be repeated in the same way, meaning for another 4 weeks the patients will receive the spray.

Main outcome variables
Sleep Quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221026056303N1**
Registration date: **2026-09-29, 1405/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-29, 1405/07/07**
Update count: **0**

Registration date
2026-09-29, 1405/07/07

Registrant information

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Nader Rajabi Gilan

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2028-09-22, 1407/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Aromatherapy with Achillea wilhelmsii C. Koch Essential Oil on Sleep Quality, Insomnia Severity, Stress, Anxiety, and Depression in Patients with Generalized Anxiety Disorder: A Randomized Controlled Trial

Public title
The Effect of Yarrow Essential Oil Aroma on Sleep and Mental Health in People with Generalized Anxiety Disorder: A Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of GAD by a psychiatrist. Generalized Anxiety Disorder (GAD-7) questionnaire score ≥ 10. Pittsburgh Sleep Quality Index (PSQI) score > 5 Age between 18 and 60 years Written informed consent to participate in the study. Having treatment stability (no change in the type or dosage of psychiatric medications) for at least the past month Obtaining a score of 8 or higher on the Insomnia Severity Index (ISI).
Exclusion criteria:
Having other major psychiatric disorders (psychotic disorders, bipolar disorder, active substance abuse). Having acute respiratory diseases (such as severe asthma) or allergic skin conditions on the face. History of known allergy to plants of the Asteraceae/Compositae family (chicory family). Pregnancy or breastfeeding. Concurrent use of other complementary sleep-affecting treatments (such as melatonin or other herbal treatments) that the individual is not willing to discontinue. Concurrent participation in new structured psychotherapy.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Randomization is performed using balanced block randomization with variable block sizes (4 and 6). This method ensures balance in the number of participants between the two groups over the enrollment period. Random sequence generation: The allocation sequence is generated by an independent collaborator (e.g., the project statistician, who has no role in the enrollment and intervention procedures) using R software or the randomization.com website. Enrollment: The principal investigator or research assistant enrolls the participant after confirming eligibility criteria and obtaining informed consent. Intervention assignment: After enrollment, the investigator contacts the independent collaborator who holds the allocation sequence (or the online allocation system) and provides the new participant's identification code. Based on the predetermined sequence, the independent collaborator informs the investigator of the corresponding intervention package number. Allocation concealment: Sealed opaque envelopes or a system of pre-numbered packages are used. Each envelope/package contains the relevant code and substance (essential oil/placebo) and is opened only after the participant's definitive enrollment and by the investigator. This mechanism prevents prediction of allocation and avoids bias.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is conducted as a double-blind trial: Participant blinding: Participants do not know whether they are in the actual intervention group or the placebo group. The appearance, packaging, and method of use are identical in both groups. Patients are aware that they are participating in the study and receiving a new herbal medicine, but they remain blinded to group allocation (intervention vs. control). Outcome assessor blinding: The person who completes the questionnaires or conducts interviews at baseline and at the end of the study is unaware of the participant's group allocation. Interventionist researcher: Due to the distinctive odor of yarrow essential oil, full blinding of the interventionist may not be feasible. To reduce bias, a "partial blinding" approach is applied: The interventionist has no role in outcome assessment. They are instructed to refrain from asking about or discussing the intervention's effects with the participant. Preparation and coding of the intervention and placebo packages were performed by a neutral third party. Data analyst blinding: The statistician is unaware of the meaning of the group codes (A and B) until the primary analysis is complete.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Faculty of Medicine, Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences, Zakaria Razi Blvd., between Shahmoradi and Hafez Blvd., Kermanshah, Iran.
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Province
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Postal code
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Approval date
2026-06-15, 1405/03/25
Ethics committee reference number
IR.KUMS.MED.REC.1405.093

Health conditions studied

1

Description of health condition studied
Generalized Anxiety Disorder (GAD)
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Sleep quality
Timepoint
Changes in the total score of the Pittsburgh Sleep Quality Index (PSQI) from baseline to the end of the fourth and eighth weeks of the intervention.
Method of measurement
Through changes in scores on the Pittsburgh Sleep Quality Index (PSQI) questionnaire.

Secondary outcomes

1

Description
Changes in the anxiety scale score
Timepoint
from baseline to the end of the fourth and eighth weeks.
Method of measurement
Anxiety Scale Questionnaire

2

Description
Changes in the stress scale score
Timepoint
from baseline to the end of the fourth and eighth weeks
Method of measurement
Stress Scale Questionnaire

3

Description
Changes in the depression scale score
Timepoint
from baseline to the end of the fourth and eighth weeks.
Method of measurement
Depression Questionnaire

4

Description
Changes in the PSQI subscales (such as sleep onset latency, sleep duration, and sleep efficiency).
Timepoint
from baseline to the end of the fourth and eighth weeks
Method of measurement
Pittsburgh Sleep Quality Index (PSQI) questionnaire

5

Description
Changes in the Insomnia Severity Index (ISI) questionnaire score
Timepoint
from baseline to the end of the fourth and eighth weeks.
Method of measurement
Severity Index (ISI) questionnaire

Intervention groups

1

Description
Intervention group: Two drops of standardized essential oil from the aerial parts of yarrow (Achillea wilhelmsii) (with chemical composition confirmed by GC-MS analysis) are dropped onto a cloth placed on the patient’s pillow. The patient applies this themselves before bedtime after receiving the necessary training beforehand.
Category
Treatment - Drugs

2

Description
Control group (placebo): Two drops of an odorless, inert carrier oil (pharmaceutical-grade oral paraffin) are administered in the same manner.Time and duration: Sessions are conducted every night, 1 minute before the participant’s usual bedtime, for 4 consecutive weeks (28 sessions in total). Usual care (medications prescribed by the psychiatrist) continues in both groups. The subsequent period will be repeated in the same manner; that is, for another 4 weeks, patients will receive the spray.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Farabi hospital, Kermanshah

Full name of responsible person
Ali Zakiei

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Sponsors / Funding sources

1

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Ali Zakiei

Position
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Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No permission to publish from the management of the patient recruitment center.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Publishing an article in international journals
When the data will become available and for how long
Non-consent to publication
To whom data/document is available
Non-consent to publication
Under which criteria data/document could be used
Non-consent to publication
From where data/document is obtainable
Non-consent to publication
What processes are involved for a request to access data/document
Non-consent to publication
Comments