

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of *Salvia Officinalis* aromatherapy on sexual satisfaction and function in menopausal women

Protocol summary

Study aim

1. Determining and comparing the sexual function score of postmenopausal women in the control group before and after the intervention with placebo. 2. Determining and comparing the sexual function score of postmenopausal women in the intervention group before and after the intervention with the aroma of *Salvia Officinalis*. 3. Comparison of sexual function score of postmenopausal women before and after the intervention between the intervention and control groups. 4. Determining and comparing the sexual satisfaction score of postmenopausal women in the control group before and after the intervention with placebo. 5. Determining and comparing the sexual satisfaction score of postmenopausal women in the intervention group before and after the intervention with the aroma of *Salvia Officinalis*. 6. Comparison of sexual satisfaction score of postmenopausal women before and after the intervention between the intervention and control groups.

Design

Randomized clinical trial, two blinded, has a control group, with a parallel group design of 80 patients

Settings and conduct

This study will perform on menopause women referred to health centers. The intervention group 3 times in day and every time 2 drops of essential oil, for 6 weeks on the skin of the forearm, to inhalation to get. The control group also uses a placebo in the same way. in this study, participant and researcher blindness will be used.

Participants/Inclusion and exclusion criteria

Individuals who are most likely to benefit from the intervention are allowed to enter the study. People who may be harmed by the intervention are not included in the study.

Intervention groups

Intervention group (Intervention group with *Salvia Officinalis*): 3 times in day and every time 2 drops of essential oil, for 6 weeks on the skin of the forearm, to

inhalation to Get.

Main outcome variables

sexual function; sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160427027633N6**

Registration date: **2020-08-12, 1399/05/22**

Registration timing: **prospective**

Last update: **2020-08-12, 1399/05/22**

Update count: **0**

Registration date

2020-08-12, 1399/05/22

Registrant information

Name

Foruzan Sharifipour

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-04, 1399/06/14

Expected recruitment end date

2020-12-14, 1399/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Salvia Officinalis aromatherapy on sexual satisfaction and function in menopausal women

Public title

The effect of Salvia Officinalis aromatherapy on sexual satisfaction and function

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Insensitivity to Salvia Officinalis and almond oil Through at least one year since the last menstruation Not having a history of allergic rhinitis and known respiratory problems such as asthma The absence of physical and mental illness Non-occurrence of stressful incidents in the past six months Have enough literacy to fill out a questionnaire Non-use of drugs, tobacco and alcohol Earn a score of less than 28 in the Sexual Function Questionnaire

Exclusion criteria:

the appearance of any physical and psychological illness during the study Living away from the spouse and causing unexpected stressors (divorce, death and travel) Incidence of side effects and sensitivity to essential oil during the study Failure to run the program for a maximum of one week during the study

Age

From **45 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Simple randomization method is used for random allocation (hiding allocation). In this way, 80 cards matched in appearance are prepared and 40 of them have the number or code 1 that specifies the group "Intervention based on essence of Salvia Officinalis " and on 40 others of them the number or code 2 which specifies the group "Intervention based on almond oil " is written. Then, each eligible person for inclusion in the study randomly takes one of these cards with the codes written on it. In this way, the random allocation of patients to each group is determined without letting the participants to know the nature of the numbers 1 or 2 in the type of intervention that will be assigned.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, to hide the allocation of aromas (essence of Salvia Officinalis) and placebo (Almond oil) Opaque envelopes sequentially numbered are used. Each envelope contains a glass of essence of Salvia Officinalis or placebo. Medications were placed on the envelope in the randomized allocation sequence by the person not involved in the study. Investigating individuals to study and delivering envelopes are done by the researcher himself from Nos. 1 to 80. In this study, blindness is not possible for the participant. Therefore, in this study, researcher and data analyzer blindness (lack of knowledge of the subject code) will be used, so the study will be double-blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti

City

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Province

Kermanshah

Postal code

6715847141

Approval date

2020-07-13, 1399/04/23

Ethics committee reference number

1399.446.IR.KUMS.REC

Health conditions studied**1****Description of health condition studied**

sexual function

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

sexual satisfaction

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

sexual function

Timepoint

Before and after the end of the intervention period

Method of measurement

Female Sexual Function Index

2

Description

sexual satisfaction

Timepoint

Before and after the end of the intervention period

Method of measurement

Linda Berg sexual satisfaction Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention with Salvia Officinalis: 3times in day and every time 2 drops of essential oil for 4 weeks on the skin of the forearm, to inhalation to get.

Category

Treatment - Other

2

Description

Control group: Intervention with almond oil: 3times in day and every time 2 drops of essential oil for 4 weeks on the skin of the forearm, to inhalation to get.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Health Center

Full name of responsible person

foruzan sharifipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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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

60

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

Foruzan Sharifipour

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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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