

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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)

##### Phone

+98 83 3828 2101

##### Email address

f.sharifi@kums.ac.ir

##### 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**

Kermanshah

**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 Rajaei Health Center

##### Full name of responsible person

foruzan sharifipour

##### Street address

Dolat Abad

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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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fnajafi@kums.ac.ir

#### 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

Midwifery

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## Person responsible for scientific inquiries

### Contact

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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