

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparative investigation between the effectiveness of aromatherapy with *Lavandula angustifolia* with counselling based on Mindfulness-based Cognitive Therapy for sexuality (MBCT-S) on the sexual function of married women in reproductive age

#### Protocol summary

##### Study aim

Comparative investigation between the effectiveness of aromatherapy with *Lavandula angustifolia* and counselling based on Mindfulness-based Cognitive Therapy for sexuality (MBCT-S) on the sexual function of married women in reproductive age

##### Design

A clinical trial consisting of two intervention groups and a control group, with parallel groups, on 60 married women. Random allocation software is used for randomization.

##### Settings and conduct

Aromatherapy group: daily use of lavender essential oil  
Sexual counseling group with mindfulness-based cognitive therapy approach: 8 sessions of group counselling

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :Women 18-49 years ,Married ,Being sexually active  
Exclusion criteria :Happening of major stress during 3 month ago, Smelling disorder, Pregnancy, Sensitivity to lavender essential oil, Digestive disorders, Absence of the spouse

##### Intervention groups

1. Aromatherapy group: 2-3 drops of lavender essential oil are poured daily on a napkin daily and inhaled from a distance of 20 cm. 2. Sexual counseling group with mindfulness-based cognitive therapy approach: In 8 sessions of 120 minutes (one session per week), they will receive group sexual counseling with mindfulness-based cognitive therapy approach. 3. Control group: no intervention.

##### Main outcome variables

The rate of sexual function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170611034452N14**

Registration date: **2022-03-02, 1400/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-03-02, 1400/12/11**

Update count: **0**

##### Registration date

2022-03-02, 1400/12/11

##### Registrant information

##### Name

Atefeh Ahmadi

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5205

##### Email address

a.ahmadi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-05, 1400/10/15

##### Expected recruitment end date

2022-08-05, 1401/05/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparative investigation between the effectiveness of aromatherapy with Lavandula angustifolia with counselling based on Mindfulness-based Cognitive Therapy for sexuality (MBCT-S) on the sexual function of married women in reproductive age

**Public title**

Comparative investigation between the effectiveness of aromatherapy with Lavandula angustifolia with counselling based on Mindfulness-based Cognitive Therapy for sexuality (MBCT-S) on the sexual function of married women

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Married Being sexually active 18-45 years old women

**Exclusion criteria:**

happening of major stress during 3 months before intervention smelling disorders before intervention being pregnant before intervention Sensitivity to lavender essential oil before intervention Digestive disorders such as nausea, vomiting, stomachache and nausea before the intervention

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of sampling will be simple accident, In this way, the list of women of reproductive age will be obtained through the SIB system and will be contacted randomly. How to randomize using online software to generate random sequences(www.randomizer.org). To randomize the selection, Participants will be assigned a number from 1 to 60 respectively, Then using the block random allocation method With six blocks of ten, People will be divided into three groups of 20. In order to hide the random allocation process and avoid selective bias ,this action after preparing the final list and will be done by someone other than the principal investigator and the researcher will be obliged to act exactly accordingly.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committees of Kerman University Of Medical Sciences

**Street address**

Medical Science, Medical University Campus, Haft Bagh Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2021-12-15, 1400/09/24

**Ethics committee reference number**

IR.KMU.REC.1400.544

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

Women with sexual dysfunction

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The rate of sexual function

**Timepoint**

To assess the level of sexual function, in two stages, once before the intervention and once immediately after the intervention, the questionnaire (FSFI) is completed by the participants of all three groups.

**Method of measurement**

Female Sexual Function Index (FSFI)-Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:1. Treatment with lavender aroma : Standard lavender essential oil is purchased from Kashan Drug Pharmaceutical Company and after packaging in dark colored glasses containing 10 cc of essential oil is

provided to the patient. The aromatherapy group daily pours 2-3 drops of lavender essential oil on a napkin daily and inhales from a distance of 20 cm.

### Category

Treatment - Drugs

## 2

### Description

Intervention group2:.. Sexual counseling group with mindfulness-based cognitive therapy approach: Participants in 8 sessions of 120 minutes (one session per week) will receive group sexual counseling with mindfulness-based cognitive therapy approach. Counseling will be provided by a trained researcher. The number of participants in each session will be a maximum of ten people in accordance with health protocols. Due to the global prevalence of Covid-19 disease, if the prevalence of this disease is high at the time of intervention, counseling will be done virtually.

### Category

Behavior

## 3

### Description

Control group: .The third group, as a control group, will not receive any intervention other than the routine interventions of the health center. In order to comply with the ethical principles, all the contents of the counseling sessions will be provided to all members of the control group in the form of an educational booklet after the end of the research, and will be referred to counseling centers or gynecologists to investigate the problem.

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Roodan city health centers

#### Full name of responsible person

Zahra teimori ghotb

#### Street address

Rudan city health center, Velayat stree, Shohada boulevard, Rudan city

#### City

Rudan

#### Province

Hormozgan

#### Postal code

7991743385

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+98 76 4288 7179

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#### Email

Salamatkh.rudan@gmail.com

#### Web page address

<http://rnhn.hums.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Atefe Ahmadi

#### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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#### Province

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#### Postal code

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#### Phone

+98 34 3132 5205

#### Fax

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#### Email

international@kmu.ac.ir

#### Web page address

<http://www.kmu.ac.ir>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kerman 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

Kerman University of Medical Sciences

#### Full name of responsible person

Zahra Teimori Ghotb

#### Position

student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Midwifery

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Atefe Ahmadi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

**Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Atefe Ahmadi

**Position**

Assistant professor

**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**

There is no further information.

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

all collected deidentified IPD

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

people working in academic institutions

**Under which criteria data/document could be used**

with permission of the main authors and including their  
names in the new research

**From where data/document is obtainable**

atefeahmadi59@gmail.com

**What processes are involved for a request to access data/document**

sending an email to the corresponding

**Comments**