

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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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

AgeFrom **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

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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

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

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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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