Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity
Kerman University of Medical Sciences
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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

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
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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

Name of organization / entity

Kerman University of Medical Sciences

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
eople 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