Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

comparison of aromatherapy with Citrus aurantium and lavender on sexual satisfaction of lactating women referred to health care centers

Protocol summary

Study aim

Determine the effect of aromatherapy with Citrus aurantium and lavender on the sexual satisfaction of lactating women

Design

This randomized triple-blind clinical trial study was performed on 210 qualified lactating woman referred to health care centers of Kermanshah. Participants were randomly assigned to three groups (70 in each group) including two interventional and one control group with a placebo and each participant is assigned a code.

Settings and conduct

Place of study is health care centers of Kermanshah and participants receive three times a day and each time,inhaled 2 to 3 drops of essence(lavender or Citrus aurantium) or placebo solution that are poured on forearm area of the hand for 40 days.Study is triple-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Placing in breastfeeding(3-6 months postpartum), lack of psychological problemsorsystemic disease known to affect sex performance, lack of sexual problems in husband according wife's comment, absence of stressful events in the last 6 months, having a health record in health care centers, married and living with apermanent husband, use a reliable method of contraception,lack of using any medication that has an effect on sexual response, lack of disorder of olfactory or sensitivity to herbal medicines. Exclusion criteria: quitting the study, occurrence of side effects of medication and sensitivity to essential oils during the study, occurrence of major emotional event, occurrence of pregnancy during the study,occurrence of mental health problems or serious illness during the study, divorce or death or illness of the husband during the study.

Intervention groups

Intervention group 1: intervention with Lavender aroma
Intervention group 2: intervention with Citrus aurantium aroma Intervention group 3: intervention with placebo (control group)

Main outcome variables

The main outcome is the mean of total sexual satisfaction after intervention in study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160427027633N3**
Registration date: **2017-12-17, 1396/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-17, 1396/09/26**
Update count: **0**

Registration date

2017-12-17, 1396/09/26

Registrant information

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Name of organization / entity
Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-12-24, 1395/10/04

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of aromatherapy with Citrus aurantium and lavender on sexual satisfaction of lactating women referred to health care centers

Public title

comparison of aromatherapy with Citrus aurantium and lavender on sexual satisfaction of lactating women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

willingness to participate in the study having health dossier in health care centers literacy sufficient to complete of the questionnaire married and lives with her husband permanently use a reliable method of contraception exposure during lactation (6-3 months postpartum) lack of mental health problems or known systemic disease affecting a person's sexual function lack of drug dependence lack of sexual problems in husband according wife's comment lack of addicted husband the absence of stressful events in the last 6 months (divorce of parents, death of family members, etc.) the absence of diseases, , lack of stress factors (Parent divorce in the past six months), l the lack of any effective drug on a person's sexual response (Antihypertensive drugs, Thiazide Diuretics, Antidepressants, Antihistamines, Barbiturates, Narcotics, Diazepins, Amphetamines, Cocaine) lack of disorder of olfactory or sensitivity to herbal medicines according wife's comment and other disorders related to nose (fracture, deviated septum, rhinitis and sinusitis

Exclusion criteria:

dissuasion of participating in the study incidence of side effects and sensitivity to essential oils during the study emotional major event such as a death of One of the relatives in particular loss of child proof of pregnancy occurrence during the study the incidence of mental health problems or serious illness during the study living away from his husband catching the debilitating diseases such as cancer that person will have to leave the study surgery during the intervention divorce,death or illness of husband during the intervening period of study

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Simple randomization method is used for random allocation (hiding allocation). In this way, 210 cards matched in appearance are prepared and 70 of them have the number or code 1 that specifies the group "Intervention based on essence of Citrus aurantium " and on 70 others of them the number or code 2 which specifies the group "Intervention based on essence of lavender " and on the other 70 Of them, the number or code 3, which specifies the control group, means "routine actions" 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, 2, or 3 in the type of intervention that will be assigned.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, to hide the allocation of aromas (essence of Citrus aurantiumor lavender) and placebo (Firouz baby oil) Opaque envelopes sequentially numbered are used.Each envelope contains a glass of essence of Citrus aurantiumor lavender 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 1 to 210. Therefore, in this study, participant and researcher blindness are used. Blindness of data analyzer also runs. Thus, individuals in two groups of intervention (Citrus aurantium or lavender) and the placebo group (Firouz babyoil) are characterized by code (for example, codes 1, 2 and 3) and data analyzer is not aware of the subject code. So the study is triple-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 Avenue, Research Deputy of Kermanshah University of Medical Sciences

City

Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2017-07-19, 1396/04/28
Ethics committee reference number
KUMS.REC.1396.189

Health conditions studied

1

Description of health condition studied
sexual satisfaction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
sexual satisfaction
Timepoint
Before and 40 days after the intervention
Method of measurement
Lindaberg's Sexual Satisfaction Questionnaire

Secondary outcomes

1

Description
Side effects
Timepoint
40 days after start the intervention
Method of measurement
Researcher made questionnaire

Intervention groups

1

Description
Interventions 1: intervention with Lavender aroma: They received three times a day and each time, 2 to 3 drops of solution are injected into the forearm area of the hand for 40 days in an inhaler.
Category
Treatment - Drugs

2

Description
Interventions 2: intervention with Citrus aurantium aroma: They received three times a day and each time, 2 to 3 drops of solution are injected into the forearm area of the hand for 40 days in an inhaler.
Category
Treatment - Drugs

3

Description
Intervention 3:control with Firuze baby oil aroma: They received three times a day and each time, 2 to 3 drops of solution are injected into the forearm area of the hand for 40 days in an inhaler.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kermanshah City Health Center
Full name of responsible person
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Sponsors / Funding sources

1

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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
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
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Foruzan Sharifipour
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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