Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of aromatherapy with Rose petal aqueous extract on sexual function of postmenopausal women

Protocol summary

Study aim
The effect of aromatherapy of rose petals on sexual function of postmenopausal women

Design
The clinical trial has intervention and control groups; parallel groups; randomized; in each group 57 people are assigned using the random permutation block method.

Settings and conduct
The intervention group received 2-3 drops of 10% rosemary solution three times a day for 6 weeks on the forearm by inhalation and the placebo group received distilled water solution like the intervention group.

Participants/Inclusion and exclusion criteria
Age between 45 and 60 years, natural menopause, more than 12 months passed since the last menstrual period, living with a spouse and having sexual activity, body mass index 18.5 to 29.9, achieving the quorum score in the DASS_21 questionnaire, achieving the quorum FSFI questionnaire scores at the level of moderate sexual dysfunctio

Intervention groups
Intervention group: improvement of sexual function in postmenopausal women with rosehip extract Control group: improvement of sexual performance in postmenopausal women without using rosehips with distilled water

Main outcome variables
The main outcome in this study is the improvement of sexual performance, the score given by the research units from the response to the FSFI sexual performance index questionnaire, which examines the dimensions of sexual desire, psychological stimulation, arousal, moisture, orgasm, satisfaction and pain.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220621055245N1**
Registration date: **2022-07-16, 1401/04/25**
Registration timing: **prospective**

Last update: **2022-07-16, 1401/04/25**
Update count: **0**

Registration date
2022-07-16, 1401/04/25

Registrant information

Name
nasrin vahdani Rashvanlouyi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3242 4581

Email address
vahdani.n.midwifery@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of aromatherapy with Rose petal aqueous extract on sexual function of postmenopausal women

Public title
The effect of aromatherapy with Rose petal aqueous

extract on sexual function of postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 45 and 60 years, menopause occurs naturally, more than 12 months have passed since the last menstruation, living with a spouse and having sexual activity, body mass index 18.5 to 29.9, absence of addiction and drug use, not using any drugs that affect Sexual function, not having a known systemic disease affecting sexual function, no disturbance in the sense of smell No history of using aromatherapy, no sensitivity to rosehip compounds, no problem of spouse in sexual relations, obtaining the quorum score in the DASS_21 questionnaire, obtaining the quorum score in the FSFI questionnaire at the level of moderate sexual dysfunction

Exclusion criteria:

Reluctance to enter the study Not having a sexual partner premature menopause People do not have the ability to understand Farsi language The presence of psychiatric problems History of hospitalization in psychiatric hospitals

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling in random categories will be proportional to the volume of floors, so that each of the comprehensive health service centers in Gonabad is considered as a floor and from each center is calculated according to the sample size and proportional to the number The population covered by each center, from the list of covered people, research samples will be randomly selected and randomly assigned to the aromatherapy or control group using permutation blocks.Random permutation blocks of sizes 2 and 4 will be used for randomization. The analyzer will determine the randomization list based on a web-based randomization program. The allocation will be concealed using opaque sealed envelopes with a random sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be done for the data analyzer. For the study groups, A and B codes are considered, and the data analyzer is not told the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Scienses

Street address

17 September South .Farabi .Farabi 3. No. 49

City

Bojunord

Province

North Khorasan

Postal code

9413653514

Approval date

2022-06-06, 1401/03/16

Ethics committee reference number

IR.GMU.REC.1401.032

Health conditions studied

1

Description of health condition studied

The effect of rosemary extract on postmenopausal women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function

Timepoint

At the beginning of the study, immediately after the intervention (two weeks after the start of the intervention) and one month after the intervention, participants in both groups will complete the sexual function index questionnaire again.

Method of measurement

FSFI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 2-3 drops of 10% rosehip solution (prepared at Pars Tek Rokh Company) are inhaled three times a day for 6 weeks on the forearm to ensure the correctness of the intervention, once a week. The participants will be contacted and a daily checklist will be given to the people to mark every day after the intervention and the complication form will be filled by the participants during the study in case of problems. Immediately after the end of the intervention (two weeks after the start of the intervention) and one month after the end of the intervention, the participants in both groups will complete the sexual performance index questionnaire again.

Category

Treatment - Drugs

2

Description

Control group: Distilled water solution is inhaled 3 times a day for 6 weeks on the forearm. In order to ensure the correctness of the intervention, the participants are contacted once a week and a daily checklist is given to the individuals to mark every day after the intervention, and the complication form during the study in case of any problem by the participation. will be filled. Immediately after the end of the intervention (two weeks after the start of the intervention) and one month after the end of the intervention, the participants in both groups will complete the sexual performance index questionnaire again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonabad Comprehensive Health Service Centers

Full name of responsible person

Nasrin Vahdani Rashvanlouyi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Postgraduate expert

Street address

Khorasan Razavi, Gonabad, Imam Khomeini St., Gonabad University of Medical Sciences

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Gonabad

Province

Razavi Khorasan

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6535149413

Phone

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Email

info@gmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad University of Medical Sciences

Proportion provided by this source

30

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

Gonabad University of Medical Sciences

Full name of responsible person

Nasrin Vahdani Rashvanlouyi

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Nasrin Vahdani Rashvanlouyi

Position
Master student of midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Participants are coded to increase access to them and their information, but at the time of publication, only the main outcome is published and the participants' information is not published at all.

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
Access is open to the public

Under which criteria data/document could be used
If people request, without mentioning the coding of information confidentially, without personal information, only the main and side consequences will be provided to the applicant.

From where data/document is obtainable
E-mail

What processes are involved for a request to access data/document
The applicant must first e-mail the message and state its use. Information will be sent within a week with conditions and restrictions for use.

Comments