Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The effect of Rosa damascena extract on anxiety and sexual function of primi parous breastfeeding women

Protocol summary

Study aim
Determining the effect of Rosa damascena extract on anxiety and sexual function in primiparous breastfeeding women

Design
This study will be a double-blind randomized controlled clinical trial with parallel, on 94 breastfeeding women with low sexual function score and high anxiety score. eligible participants will be randomised into intervention and control group using Stata software version 12. with a ratio of 1: 1

Settings and conduct
East Ahvaz Health Center No. 1, patients' height will be measured by a standard stadiometer and their weight will be measured by a digital scale. The nature of the drug and placebo will be revealed after analyzing the results. Each person will be assigned to a intervention group or placebo based on a random number table and the chances of individuals being in each group will be exactly the same.

Participants/Inclusion and exclusion criteria
1. Breastfeeding 2. At least 6 weeks to 12 months after delivery 3. Having a spouse 5. Primiparous 6. Single 7. Literacy 8 scores less than 26 of the Sexual Function Questionnaire 9. And get a score of 53-20 from the Spielberger questionnaire No entry: 1. History of allergy to Mohammadi flower and its derivatives 2. Specific disease of the breast and uterus 3. Taking certain medications that affect sexual function (such as antidepressants, aspirin, and anticoagulants) 4. Feeding the baby with powdered milk 5. Smoking or alcohol consumption 6. Pregnancy

Intervention groups
Each person will be assigned to a control group or placebo based on a random number table, and their chances of being in each group will be exactly the same.

Main outcome variables
Sexual function (libido; arousal; lubrication; orgasm; satisfaction; pain) overt and covert anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211015052775N1**
Registration date: **2022-02-14, 1400/11/25**
Registration timing: **prospective**

Last update: **2022-02-14, 1400/11/25**
Update count: **0**

Registration date
2022-02-14, 1400/11/25

Registrant information

Name
Gohar Akbarzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3373 8333

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akbarzadeh.g@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Rosa damascena extract on anxiety and sexual function of primi parous breastfeeding women

Public title
The effect of Rosa damascena on anxiety and sexual function in breastfeeding women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Breastfeeding At least 6 weeks up to 12 months after delivery Having a spouse Primiparous Single fetus Basic Literacy Scores less than 26 from the Sexual Function Questionnaire Scores 20-53 from the Spielberger questionnaire

Exclusion criteria:
History of allergy to Rosa damascana and its derivatives Specific disease of the breast and uterus Taking certain medications that affect sexual function (such as antidepressants, aspirin, and anticoagulants) Feeding the baby with formula Smoking or alcohol consumption5 Pregnancy A history of any mental illness or severe trauma in the last 6 months

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher and participant in this study are unaware of the drug or placebo of Rosa Damascena capsules and will be prepared and coded by the pharmacist of the capsules. The drug and placebo will be the same in terms of appearance, such as packaging and color. The nature of the drug and placebo will be revealed after analyzing the results. Each person will be assigned to a control group or placebo based on a random number table and the chances of individuals being in each group will be exactly the same.The nature of the drug and placebo becomes apparent after analyzing the results.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher and participant in this study are unaware of the drug or placebo of Rosa damascen capsules and capsules will be prepared and coded by the pharmacist . The drug and placebo will be the similar in terms of appearance, such as packaging and color. The nature of the drug and placebo will be revealed after analyzing the results. Each person will be assigned to an intervention group or placebo based on a table of random numbers and the chances of individuals attending each group will be exactly the same.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahwaz University of Medical Sciences

Street address
Golestan Ave, Ahvaz Jundishapur University of Medical Science, Nursing and Midwifery School, Midwifery Department

City
Ahwaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2022-01-19, 1400/10/29

Ethics committee reference number
IR.AJUMS.REC.1400.614

Health conditions studied

1

Description of health condition studied
anxiety

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

2

Description of health condition studied
Sexual dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
Score less than 26.5 in the Sexual Function Questionnaire (FSFI) and a score of 53-20 from the overt anxiety questionnaire and a score of 20-53 from the

hidden anxiety section (STAI).

Timepoint

8 weeks

Method of measurement

The Sexual Function Questionnaire (FSFI) and the overt and covert anxiety questionnaire (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At first, Rosa damascena petals will be purchased by a researcher from a reputable shop. Then the plant will be dried, ground and extracted by meceration method (soaking) with 70% ethanol for 48 hours . The hydroalcoholic solution is then separated from the plant particles by filter paper and the remaining ethanol is collected by a rotary apparatus. The concentrated extract is stored in an incubator at 37 ° C and dried. The dried extract is then stored at minus 20 ° C to make capsules containing 400 mg of the extract. At the beginning of the study, participants are given 56 capsules (400 mg) that have the same appearance and their codes are determined by a pharmacist participant should take two tablets every morning and night with a glass of water for 8 weeks.participants will be requested to attend the clinic in (4 and 8 weeks later) are explained to the breastfeeding mother. four weeks later, they are given another 56 capsules to take twice daily. The participants receive a phone call to reminding about accurate usage. Eight weeks after treatment, they will be requeste to complete. FSFI and Spielberger questionnaires again. A sheet will also be reported to the company to record symptoms or complaints and when to use it. They are taught how to fill out the forms and are asked to contact the researcher or refer to the center if they have any problems. Participants will consider as a drop-out if they not taking medication for to continuous they per week. In addition, in order to be sure aout taking the medicine, the clients will be reminded to return the empty drug containers when they come for re-examination.Control group: This group receives placebo in such a way that the capsules will be filled with starch. At the beginning of the study, 56 400 mg capsules are given to the participants which have the same appearance and their codes are specified by the pharmacist for 8 days. Every day of the week, two are consumed in the morning and at night with a glass of water. The duration of use and the date of return (4 weeks and 8 weeks later) are explained to the breastfeeding mother. 4 weeks later, they are given another 56 capsules to take two daily. The client's phone number is dialed to remind him of the visiting times. After treatment, they will be given the FSFI and Spielberger questionnaires again to complete. The participant will also be given a worksheet to record symptoms or complaints and when to use it. They are taught how to fill out the forms and are asked to contact the researcher or refer to the center if they have any problems. Participants will consider medication or placebo as a drop if not used twice a week. In addition, in order to be more sure of taking the medicine, the clients will be reminded to deliver the empty envelope of the medicine when they come for re-examination.

Category

Treatment - Drugs

2

Description

control group: In this group, research units consume one placebo capsule every 12 hours for 8 weeks. Each of these capsules contains 400 mg of starch powder and is made with the appearance and packaging similar to Rosa Damascena capsule in the pharmacology department of medicinal plants by a respected pharmacist.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

East Ahvaz Health Center No. 1

Full name of responsible person

Engineer Amraleh Mardani

Street address

East Ahvaz Health Center, in front of Haft Tir Park, Shahid Rastegari St, Ayatollah Behbahani Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz 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?
No

Title of funding source
Ahvaz Jundishapur 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
Ahvaz University of Medical Sciences

Full name of responsible person
Gohar Akbarzadeh

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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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

All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

To do valid research work

From where data/document is obtainable

To the general respondent: Gohar Akbarzadeh

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

The request will be answered at the earliest opportunity

Comments