# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The effect of rose oil essence on the sexual dysfunction of menopaused women

### Protocol summary

**Study aim**
Determining the effect of rose essential oil on sexual dysfunction and quality of life in postmenopausal women

**Design**
This study is a double-blind randomized clinical trial on 90 postmenopausal women. in this study, the placebo was made in the same shape, size, and color as the main drug, so the triple-blind method will be used. The intervention is in the form of medication or placebo for 8 weeks and daily consumption of two capsules.

**Settings and conduct**
This study will be performed on women referring to the health centers of Tabriz University of Medical Sciences. Made in the same shape and synchronously with the drug for placebo blinding. The random allocation method will be used for groups and opaque envelopes will be used to hide random allocation in numbered consecutive packets.

**Participants/Inclusion and exclusion criteria**
Women with normal menopause, Being between 45 and 65 years old, married, at least one year old and up to 5 since menopause Do not use any medication that affects a person's sexual response, including hormonal, herbal, or complementary medications to relieve menopausal symptoms. Reluctance to continue participating in research Do not take medication or placebo for more than 6 days during the study Use of other treatment and intervention methods to reduce menopausal symptoms during research other than the instructions provided by the researcher The occurrence of unfortunate events such as loss of spouse or close relatives during the research period

**Intervention groups**
Intervention group: Rose essential oil in the form of soft capsules containing 15 mg Control group: placebo with a similar appearance and containing only sesame oil or soybean oil

**Main outcome variables**
Overall sexual function score; Overall quality of life score

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190818044553N1**
Registration date: **2020-07-22, 1399/05/01**
Registration timing: **prospective**

Last update: **2020-07-22, 1399/05/01**
Update count: **0**

**Registration date**
2020-07-22, 1399/05/01

**Registrant information**

**Name**
Rana Dousti

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-08-22, 1399/06/01

**Expected recruitment end date**
2021-05-20, 1400/02/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

The effect of rose oil essence on the sexual dysfunction of menopaused women

**Public title**

The effect of rose oil essence on the sexual dysfunction of menopaused women

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women with normal menopause, Being between 45 and 65 years old, married, at least one year old and up to 5 since menopause Do not use any medication that affects a person's sexual response, including hormonal, herbal or complementary medications to relieve menopausal symptoms. No known mental health problems or systemic illness affecting sexual function Do not take any sedatives or antidepressants, aspirin or anticoagulants Lack of sensitivity to herbal medicines Absence of digestive disorders such as nausea, vomiting, nausea and vomiting No addiction or smoking having a minimum literacy in order to complete the questionnaire No accidents at least in the last 6 months

**Exclusion criteria:**

Creating any sensitivity to the essential oils used in this research Occurrence of any disease during this study that interferes with the results of this study. Reluctance to continue participating in research Do not take medication or placebo for more than 6 days during the study Use of other treatment and intervention methods to reduce menopausal symptoms during research other than the instructions provided by the researcher Occurrence of traumatic events such as loss of spouse or close relatives during the research period

**Age**

From **45 years** old to **65 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The selected samples will be randomly assigned using a computer random number table through blocks of 4 and 6 to receive the desired treatment in both groups of soft capsules, red and placebo, and will be assigned according to the assigned group. On closed opaque envelopes, which will be written by a person not involved in the selection of research subjects and data collection, consecutive numbers will be written by the same person in accordance with the assigned group of glasses containing the group of soft red capsules and placebo It will be placed inside the envelopes.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Rose essential oil is available in soft capsules containing 15 mg of essential oil (standardized based on the presence of at least 7.5 mg of citronellol in each soft capsule) based on sesame oil or soybean oil. The placebo will have a similar appearance and only contain sesame or soybean oil, so that the samples and the service provider, the researcher is unaware of the contents of the capsules, and the researcher analyzing the results of the analysis will be unaware of the allocation of individuals in groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

Tabriz, Azadi St., Golgasht St., Tabriz University of Medical Sciences, Central Building No. 2, Third Floor, Research Deputy

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tabriz

**Province**

East Azarbaijan

**Postal code**

00984113357311

**Approval date**

2020-07-05, 1399/04/15

**Ethics committee reference number**

IR.TBZMED.REC.1399.342

## Health conditions studied

### 1

**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**
sexual function
**Timepoint**
before and 4 weeks after intervention, 8 weeks after intervention
**Method of measurement**
Female Sexual Function Index Questionnaire

### 2

**Description**
Quality of Life
**Timepoint**
Before and 4 weeks after intervention, 8 weeks after intervention
**Method of measurement**
Menopause Quality Of Life Questionnaire ( MENQOL)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group: Soft capsules containing 15 mg of essential oil (standardized based on the presence of at least 7.5 mg of citronellol in each soft capsule) based on sesame oil or soybean oil twice daily oral for 8 weeks. Made in the laboratory of the Faculty of Medicine, Tabriz University of Medical Sciences.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Placebo with similar appearance and containing only sesame oil or soybean oil
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Community Health Centers of Tabriz
**Full name of responsible person**
Rana Dousti
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Dr. Mahammad Samiei
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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue
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**Email**
Samiei.moh@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Tabriz 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**
Persons

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Tabriz University of Medical Sciences
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Rana Dousti
**Position**
PHD Student Midwifery
**Latest degree**
Master
**Other areas of specialty/work**

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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**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Yes - There is 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
**Title and more details about the data/document**
The results of the clinical study will be published in the form of an article
**When the data will become available and for how long**
Immediately after printing the results
**To whom data/document is available**
All researchers
**Under which criteria data/document could be used**
Scientific use with reference to the article
**From where data/document is obtainable**
Rana dousti Email
**What processes are involved for a request to access data/document**
Up to one week after correspondence by email
**Comments**