

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Investigating the effect of Melissa officinalis capsule on the sexual function of Menopause women

#### Protocol summary

##### Study aim

Determining the effect of Melissa capsules on sexual function of postmenopausal women

##### Design

A clinical trial with a control group. with parallel groups, triple blind, randomized, phase 3 on 100 patients. Excel software is used for randomization.

##### Settings and conduct

The researcher selects four centers from the comprehensive health service centers affiliated to SBMU located in the north and east of Tehran by simple random sampling, then eligible postmenopausal women are attended. The informed consent form and relevant questionnaires are completed. Women are randomly assigned to groups 1 or 2 using Excel software in the same order as they enter the study and each group is given a medicine. The researcher, the samples, and the statistical consultant are unaware of what medicine each envelope contains except for pharmaceutical consultant. After the completion of the two-month period, the FSFI questionnaire is completed again because it measures sexual function in the previous month, it is completed again one month after the end of the course. Finally, the data is analyzed by a statistical consultant.

##### Participants/Inclusion and exclusion criteria

In Iranian cases, at least one year had passed since their menses, do not has hormone replacement therapy, has sexual activity, menopausal women and their husband known for no mental illness, no addiction to smoking or drugs, not acquire depression and anxiety, unknown for any chronic diseases, is not allergenic to medicinal plants and gluten, If cases show sensitivity to Melissa capsules, has not used capsules for two days or more, hasn't taken regularly and the person is reluctant to continue the treatment are removed.

##### Intervention groups

In intervention group, the samples consumed one Melissa capsule daily, and in the control group, the capsule containing dry bread was consumed for two

months.

##### Main outcome variables

Sexual function score.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230831059313N1**

Registration date: **2023-11-02, 1402/08/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-11-02, 1402/08/11**

Update count: **0**

##### Registration date

2023-11-02, 1402/08/11

##### Registrant information

##### Name

Hamide Ahmadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3669 2645

##### Email address

hamideahmadi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-22, 1402/07/30

##### Expected recruitment end date

2024-03-18, 1402/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of Melissa officinalis capsule on the sexual function of Menopause women

**Public title**  
Investigating the effect of Melissa officinalis capsule on the sexual function of Menopause women

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Be Iranian. At least be literate in reading and writing. At least one year has passed since their menopause. Have a married life with her husband. Not willing or required to use hormone replacement therapy. According to Miss Menopause don't use any chemical or herbal medicine to treat your problem. have sexual activity. Do not use herbal teas while taking medicines.  
**Exclusion criteria:**  
 Have speech, hearing or mental disorders that prevent communication with the researcher. Have undergone hysterectomy and ovariectomy, cystocele and rectocele, and mastectomy. Have a history of known chronic diseases such as high blood pressure, diabetes, asthma, weakening the immune system, etc. Her husband of a menopausal woman have sexual problems. Menopausal women and their husbands are known to have mental illness. Addicted to smoking or drugs. A special event or incident that constitutes a crisis in their life, such as the death of a loved one, incurable illness in family members, change of residence, loss of job has occurred since 6 months ago. Have a history of allergy to medicinal plants. Have a history of endometrial cancer and other estrogen-related cancers in first-degree relatives. Have a history of gluten sensitivity.

**Age**  
No age limit

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First, in order to select health service centers, the researcher needs to select four centers by simple random sampling. Random numbers function of Excel software is used to randomize the samples into intervention and control groups. to this extent, the numbers represented the samples are sorted from 1 to 100 then written in order in the first column and in the

next column, the numbers 1 and 2 are randomly placed in front of each sample. Finally, the samples are divided into two groups in the same order as they enter the study.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
This study is a triple-blind randomized clinical study. Therefore, the researcher, the research units, and the statistics consultant professor are not aware of the coding and what sort of medicine each package contains and only the pharmaceutical consultant of the research is aware of the coding of the envelopes and the type of drugs.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
 Ethics Committee of Schools of Pharmacy, Midwifery Nursing - Shahid Beheshti University of Medical S  
**Street address**  
 13th floor, Block A, Headquarters of Ministry of Health, Treatment and Medical Education, Simai Iran St, between South Flamak and Zarafshan, Quds town (west), Tehran  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 ethics@receaeach.ac.i

**Approval date**  
2023-08-01, 1402/05/10

**Ethics committee reference number**  
IR.SBMU.PHARMACY.REC.1402.074

**Health conditions studied**

**1**

**Description of health condition studied**  
Sexual function of Menopause women

**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Sexual function score in female sexual function index questionnaire

#### **Timepoint**

At the beginning of the study (before the start of the intervention) and immediately after the end of the intervention and one month after the end of the intervention

#### **Method of measurement**

Female Sexual Function Index Questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Sexual satisfaction score

#### **Timepoint**

Before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention.

#### **Method of measurement**

Female sexual Function Index Questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: In this research, the intervention group consumes Melissa capsules. These capsules contain 500 mg of Melissa plant extract powder. These capsules are prepared in the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences. In this way, the purchased plant is extracted by the pharmaceutical consultant. It is made into a powder and poured into capsules similar to a placebo and one capsule per day is consumed by a menopausal woman for two months.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: In this study, the control group uses a placebo. Placebo means edible capsules containing dry bread powder And these capsules are adapted to Melissa capsules in terms of shape and size. They are prepared in the laboratory of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences, by the pharmaceutical consultant professor. also, the capsules are placed along side to each other so that they smell similar and then they are provided to the samples in similar envelopes. One capsule is taken daily for two months by a menopausal women.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Nader Health Comprehensive Service Center

##### **Full name of responsible person**

Panthea Mahdavi

##### **Street address**

Esfandani Street, Jashnvare Street, Tehran Pars

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

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##### **Phone**

+98 21 7732 2277

##### **Email**

mbsh@sbmu.ac.ir

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Kadus Comprehensive Health Service Center

##### **Full name of responsible person**

Ahmad Ali Dad Khodei

##### **Street address**

Sojdeh Street, Jashnvare Street, Tehran Pars

##### **City**

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##### **Province**

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### **3**

#### **Recruitment center**

##### **Name of recruitment center**

Comprehensive health service center of Ba'ath al-Nabi

##### **Full name of responsible person**

Arin Mansouri

##### **Street address**

7th street, 15 meters third, Afsarieh

##### **City**

Tehran

##### **Province**

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##### **Postal code**

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## 4

### Recruitment center

**Name of recruitment center**

Taqavi Comprehensive Health Service Center

**Full name of responsible person**

Seyed Mehdi Seyed Darabi

**Street address**

Porzargar Alley, Aghajanlu St., Mujahideen St.,

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Zarghi

**Street address**

Building No. 2, Next to Taleghani Hospital, Erabi St.,  
Student Blvd., Shahid Chamran Highway

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**Province**

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+98 21 2243 9780

**Email**

info@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hamide Ahmadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Elham Zare

**Position**

Associate professor

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Ph.D.

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## Person responsible for updating data

**Contact****Name of organization / entity**

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Hamide Ahmadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

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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