

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Ginkgo biloba pill and inhalation aromatherapy on sexual function in postmenopausal women: A randomized controlled clinical trial

Protocol summary

Summary

The aim of this Triple blind randomized controlled trial is to determine the effect of aromatherapy on sexual function in postmenopausal women. We will recruit 180 women from public health centers in Ardabil, Iran. After getting written informed consent, participants will complete a self-administered questionnaire about demographic and reproductive history and also questions about Female Sexual Function Index (FSFI). Then we will randomly allocate them into 3 groups of 60 subjects: two intervention groups and one control group using permuted block randomization with block sizes of tree and six concealed in sequentially numbered identical containers that are administered serially to participants. Participants are randomized to receive first group: aroma solution and placebo Jynkubyluba. The second group: placebo aromas and tablets Jynkubyluba. Third group: placebo aromas and placebo Jynkubyluba. The drops are placed on skin as follows: 2-3 drops three times a day for 6 weeks and tablets 3 times for 6 weeks. The aroma solution contains essential oils of Lavender, Foeniculum vulgare, Geranium, Rose. tablets containing 40 mg herbal Jynkubyluba. The participants will complete FSFI post -test questionnaires weeks after intervention. The mean of difference in sexual function scores are compared among two groups. In this study we keep blinding for participants and researcher and Data Monitoring Committee .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405108170N7**

Registration date: **2014-06-17, 1393/03/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-17, 1393/03/27

Registrant information

Name

Jamileh Malakouti

Name of organization / entity

Nursing Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1477 2699

Email address

malakoutij@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Nursing and Midwifery
Faculty of Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-09-06, 1393/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ginkgo biloba pill and inhalation aromatherapy on sexual function in postmenopausal women: A randomized controlled clinical trial

Public title

The effect of Ginkgo biloba pill and inhalation aromatherapy on sexual function in postmenopausal women

Purpose

Health service research

Inclusion/Exclusion criteria

ability of writing in Persian language; age range of 45- 55 years; Being married and living with her husband; Lack of chronic disease; No severe emotional stress in past six months; Natural menopause
Exclusion criteria: No willingness to participate; occurrence of drug side effects and allergy to drugs during the study; occurrence of severe emotional stress such as death of close family; occurrence of psychological complications or severe disease during the study; Living away from husband; hysterectomy, ovariectomy, Cystocele, mastectomy, use of tobacco and alcohol, or herbal drugs, impaired sense of smell, according to one's own and other nasal problems (fractures, SD, rhinitis), gastrointestinal disturbances such as nausea, vomiting, stomach - ache, abdominal cramps, absence of any abnormal vaginal bleeding; Not currently taking drugs affecting on sexual response (anti-hypertension, Thiazide diuretics, anti-depression, anti-histamines, Barbiturates, narcotics, diazepam, amphetamines, cocaine) & no HRT

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 180

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

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

Vice chancellor for research, Tabriz University of Medical Sciences, central building, Golgasht street

City

Tabriz

Postal code

00984114796770

Approval date

2014-05-07, 1393/02/17

Ethics committee reference number

9312

Health conditions studied

1

Description of health condition studied

sexual function during postmenopausal

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual function

Timepoint

Before intervention, 6 weeks after intervention

Method of measurement

Female Sexual Function Index (FSFI) that will be self-administered and will be put into a sealed box

Secondary outcomes

1

Description

adverse events

Timepoint

During the intervention

Method of measurement

Checklist

2

Description

the degree of satisfaction

Timepoint

during intervention and after intervention

Method of measurement

Check list

Intervention groups

1

Description

the first intervention group aromas solution (containing plant extracts Lavender, geranium, fennel and rose) and placebo Jynkubyluba 3 times daily for 6 weeks with 3-2 drops of aromas on the skin and 40mg tablets Jynkubyluba 3 times daily

Category

Treatment - Drugs

2

Description

the second intervention group tablets containing herbal Jynkubyluba and placebo aromas . 3 times daily for 6 weeks with 3-2 drops of aromas on the skin and 40mg tablets Jynkubyluba 3 times daily .

Category

Treatment - Drugs

3

Description

third, 2 placebo 3 times daily for 6 weeks with 3-2 drops of aromas on the skin and 40mg tablets Jynkubyluba 3 times .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Number 17 Health Center

Full name of responsible person

Vahid Lotfollahzade

Street address

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Jabbari Freshte

Street address

Faculty of Nursing and Midwifery, South Shariati

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Malakouti Jamileh

Position

MSc in Midwifery

Other areas of specialty/work

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

Postal code

Phone

+98 41 1479 6770

Fax

Email

malakoutij@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Jabbari Freshte

Position

Master of Sciences Student in Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, South Shariati

City

Tabriz

Postal code

51665118

Phone

+98 411479677

Fax

Email

jabbari.freshte@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Jabbari Freshte

Position

Master of sciences student in Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, South Shariati

City

Tabriz

Postal code

51665118

Phone

+98 41 1479 6770

Fax

Email

jabbari.freshte@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty