

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effects of oral ginger capsules on sexual function and sexual quality of life of married women in the reproductive age

Protocol summary

Study aim

Exploring and determining the effects of oral ginger capsules on sexual function and sexual quality of life of woman in the reproductive age

Design

A clinical trial, with control group, double blind, and randomized

Settings and conduct

It will be a double-blind phase 3 of clinical trial. Research units will be 190 women referring to Alborz Health Centers which are in reproductive age and eligible for inclusion in this study. The subjects will be randomly assigned into two groups of 95 participants (homogeneity of the sample according to formula of sample size and drop of 10% to 190 persons). which will be allocated randomly in to two groups by 4 blocks randomization. The control group will receive placebo capsules and the intervention group will receive ginger capsules orally for 4 weeks. The tutorial will provide to participants. In the control group, placebo capsules containing 250 mg of chickpea powder which will be administered orally daily for 4 weeks. Participants' contact numbers and addresses will be recorded for access to the samples and follow-up assessments, and the researcher's contact number will also be available to answer samples of potential questions.

Participants/Inclusion and exclusion criteria

Iranian reproductive aged women (18-49 years old) who have no allergy to ginger capsules.

Intervention groups

Intervention group: 95 women who will receive 4 tablets of ginger 250 mg daily for 4 weeks orally. Control group: 95 women who will receive 4 tablets of ginger 250 mg daily for 4 weeks orally.

Main outcome variables

Sexual function; sexual quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191013045086N1**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Zahra Afshar

Name of organization / entity

Tatbiat modares

Country

Iran (Islamic Republic of)

Phone

+98 26 4426 1347

Email address

za.afshar53@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-21, 1398/04/30

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral ginger capsules on sexual function and sexual quality of life of married women in the reproductive age

Public title

Effects of oral ginger capsules on sexual function women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Reproductive aged women (age: 18-49 years old) Having sex at least twice a month Lack of known underlying disease Lack of mental illness Being a single spouse and living with the spouse now and during the study Can read and write the Persian language Being Iranian Couples not being addicted to drugs or alcohol No-use of drugs that affect the function of the genus No stressful accident during the past month No urinary tract infection Absence of active or lesion in genital area that interferes with sexual intercourse No history of infertility No record of pelvic surgeries No allergy to ginger Absence of pregnancy or lactation

Exclusion criteria:

Unwilling to stay in study Not taking ginger capsules Ginger allergy or complications during the intervention Creating active or lesion in the genital area that interferes with intercourse during intercourse Use of drugs that affect sexual function during the intervention Experiencing a stressful accident during the intervention Urinary tract Infection during Intervention

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be use for randomizing participants within blocks such that an equal number will assigned to treatment. we will give a block size of 4, which there are 6 possible ways to equally assign participants to a block. Allocation proceeds by randomly selecting one of the orderings and assigning the next block of participants to study groups according to the specified sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the researcher and the study participants will not aware of the drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Faculty of Medicine, Tarbiat Modares University, Jalal al Ahmad high way

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2019-10-25, 1398/08/03

Ethics committee reference number

IR.MODARES.REC.1398.144

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Scores obtained from the Female Sexual Function scale

Timepoint

Assessment of sexual function before and 4 weeks after intervention

Method of measurement

Female sexual function scale

2

Description

Scores obtained from the Sexual Quality of Life-Female (SQOL-F) questionnaire

Timepoint

Assessment of sexual quality of life before and 4 weeks after intervention

Method of measurement

Sexual Quality of Life-Female (SQOL-F) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 95 women who were included in the study according to inclusion criteria. They will consume 4 tablets of 250 mg oral ginger daily prepared by Isfahan Flower Drug Company for 4 weeks. Following the intervention, the researcher will contact the research units in the intervention group each week to ensure proper use of the ginger capsule. Evaluation of the research units will be done one month after the intervention using the questionnaires completed by the research units in person.

Category

Treatment - Drugs

2

Description

Control group: 95 women who were included in the study according to inclusion criteria. Placebo capsule containing 250 mg of chickpea powder prepared by Isfahan Flower Drug Company will consume 4 tablets per day orally for 4 weeks. Weekly contact the research units in the intervention group to ensure proper placebo capsule use. Evaluation of the research units will be done one month after the intervention using the questionnaires completed by the research units in person.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz province health centers

Full name of responsible person

Shadab Shahali

Street address

Nazar Abad Health Center, Farhangian Town

City

Nazar Abad

Province

Alborz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Trabiati Modares

Full name of responsible person

Dr. Fathollahi Yaghoub

Street address

Faculty of Medical Sciences, Tarbiati Modares University, Jalal al Ahmad

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Email

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Web page address

<http://www.modares.ac.ir/en>

Grant name

0

Grant code / Reference number

0

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

Yes

Title of funding source

The University of Trabiati Modares

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

Tarbiati Modares University

Full name of responsible person

Shadab Shahali

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Faculty of Medical Sciences, Tarbiati Modares

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat modares university

Full name of responsible person

Shadab Shahali

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

The University of Tarbiat Modares

Full name of responsible person

Shadab Shahali

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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<http://www.modares.ac.ir/en>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only the main outcome will be published.

When the data will become available and for how long

The main outcome will be available after 2021

To whom data/document is available

The data will be available for college researchers

Under which criteria data/document could be used

For more research, researchers could send their request letter to the co respond anther.

From where data/document is obtainable

Correspondence Author. Department of Reproductive Health and Midwifery, Faculty of Medical Sciences, Tarbiat Modares University.

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

Upon receiving the request letter by the coresponding author, the request will be forwarded to Tarbiat Modarres University Research Unit, and the analyzed data will be send to researchers if applicable.

Comments