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
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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

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
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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Trabiat Modares

Full name of responsible person
Dr. Fathollahi Yaghoub

Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal al Ahmad

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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 Trabiat 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
Tarbiat Modares University

Full name of responsible person
Shadab Shahali

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Faculty of Medical Sciences, Tarbiat Modares
Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Shadab Shahali
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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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 corresponding author.
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 corresponding author, the request will be forwarded to Tarbiat Modares University Research Unit, and the analyzed data will be sent to researchers if applicable.
Comments