Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Feb 2026

Evaluation the effect of combination use of synbiotics and vitamin D compared to their separate use on sexual function and sexual self-expression in lactating women: A randomized double blind clinical trial

Protocol summary

Study aim

Determination the effect of combination use of synbiotics and vitamin D compared to their separate use on sexual function and sexual self-expression in lactating women

Design

112 eligible individuals are randomly assigned to three groups A (Vitamin D), B (Synbiotic), and C (combination of Vitamin D and Synbiotic) using block randomization. The randomized list of blocks of varying sizes (3, 6, and 9) is generated through a reliable website, and participants are allocated accordingly to ensure balanced numbers in each group and to reduce the predictability of group assignment.

Settings and conduct

This study will be conducted in Yasuj health centers after obtaining the necessary approvals and registration in the relevant systems. The intervention duration is 8 weeks. The study is double-blind, with the packaging and coding of supplements carried out by an independent person, ensuring that both participants and researchers are unaware of the type of intervention received.

Participants/Inclusion and exclusion criteria

Participants are lactating women aged 18 to 40, 1 to 4 months postpartum, and have sex at least once a month. They should not have a history of chronic diseases or have taken hormonal medications, antidepressants, or similar supplements in recent months. Also, women who are allergic to supplements or taking medications that affect sexual function will not be included in the study.

Intervention groups

Group A: Received one vitamin D 1000 and one placebo supplement of synbiotic daily Group B: Received one synbiotic and one placebo supplement of Vitamin D 1000 daily Group C: Received vitamin D and synbiotic simultaneously daily

Main outcome variables

- Sexual function of breastfeeding women, assessed using the Female Sexual Function Index questionnaire - Level of sexual self-disclosure, assessed using the Halbert Sexual Self-Disclosure questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250207064679N1**
Registration date: **2025-09-19, 1404/06/28**
Registration timing: **prospective**

Last update: **2025-09-19, 1404/06/28**
Update count: **0**

Registration date

2025-09-19, 1404/06/28

Registrant information

Name

Maryam Naeemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-21, 1404/08/30

Expected recruitment end date

2026-06-20, 1405/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of combination use of synbiotics and vitamin D compared to their separate use on sexual function and sexual self-expression in lactating women: A randomized double blind clinical trial

Public title
The effect of vitamin D and synbiotics consumption on sexual function and sexual self-expression in lactating women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
- Age between 18 and 40 years - At least 1 month has passed since the start of sexual intercourse and a maximum of 4 months after childbirth (before the start of complementary feeding) - Active and exclusive breastfeeding - Having sex at least once a month - No history of chronic diseases (diabetes, thyroid, epilepsy, etc.) - No use of hormonal or antidepressant medications in the past 3 months - Consent to participate in the study and completion of the informed consent form

Exclusion criteria:
- Allergy to prescribed supplements - Taking medications that affect sexual function and self-expression, such as blood pressure reducers, antihistamines, H2 blockers, barbiturates - Taking birth control pills - Taking supplements containing synbiotics, probiotics, or vitamin D (except for the usual doses of pregnancy supplements if taken continuously during pregnancy and no more) for at least 4-6 weeks prior - Taking any new medications that affect mood or sexual function

Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals who meet the eligibility criteria for participation in the study will be assigned to the intervention groups. A block randomization method will be used to assign individuals to the study groups. The advantages of blocked randomization are that the balance of the number of patients in each group is guaranteed. The groups are defined as codes A, B, C. Group (A) receiving vitamin D 2. Group (B) receiving synbiotics 3. Group (C) receiving simultaneous consumption of vitamin D and synbiotics Before assigning individuals to one of the groups, a list of letters (A, B, C) in the form of blocks is formed. This random assignment list will be formed by the reliable website https://www.sealedenvelope.com. Each of the referring and eligible individuals will be assigned to one of the groups according to the created list. To prevent the predictable risk of assigning individuals to different groups, blocks of different sizes (3, 6, and 9) will be created. Triple blocks like ACB – Six-blocks like ABBCAD – Nine-blocks like DBCADACBA
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be double-blinded, meaning that neither the participants nor the researcher will know which intervention each person is receiving. The purpose of this method is to control bias. Double-blinding means that neither the participants nor the principal investigators and data collectors will be aware of the assigned group (synbiotic and vitamin D group simultaneously, separate group + placebo). To ensure complete and effective blinding, the following measures will be taken: * Supplement/placebo packaging and coding: - Synbiotic, vitamin D, and placebo supplements will be prepared and packaged by an independent individual outside the research team. To maintain the blinding structure in the study, the placebos used in this study will be prepared and formulated by the Drug Manufacturing Center of the Faculty of Pharmacy, Yasuj University of Medical Sciences. These placebos are made in the form of capsules without active ingredient but of the same shape, color and weight as the original supplements so that there is no possibility of differentiation by the participant or the researcher. In groups where only one of the supplements (vitamin D or synbiotic) is received, the second supplement will be replaced with placebo; so that all participants in all three groups will receive two capsules daily (one real supplement and one placebo or two real supplements). In this way, the double-blind structure and balance in the way of consumption are maintained. - All packages (both supplement and placebo) will have the same shape, color, taste, smell and appearance so that they are not physically distinguishable. - Each package will be labeled with a unique numeric or alphanumeric code, the meaning of which (which group it belongs to) is known only by the independent coder. - The coding list will remain confidential until the completion of data collection and initial statistical analysis and will only be opened in case of emergency (e.g. serious complications in the participant) or after the end of the study. * Distribution and monitoring: - Distribution of supplements/placebo to participants will be carried out by a person who is not part of the main research team and is unaware of the group allocation. - Follow-up procedures will be carried out to ensure correct and regular intake of supplements/placebo (e.g. counting remaining pills at subsequent visits), without providing information about the type of supplement to the participant or the data

collector. * Data collection and analysis: - Data collectors who interact with participants will have no knowledge of the group allocation of participants. - The statistical analyst will also receive data based on blinded codes and will be unaware of the nature of groups A, B, and C until the end of the initial analysis.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences

Street address
Somayeh Girls' Dormitory, Sahely Street, towards Emam Sajjad Hospital.

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591994834

Approval date
2025-09-04, 1404/06/13

Ethics committee reference number
IR.YUMS.REC.1404.098

Health conditions studied

1

Description of health condition studied
sexual function

ICD-10 code

ICD-10 code description

2

Description of health condition studied
sexual self-expression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sexual function of lactating women

Timepoint
At the beginning of the study and 8 weeks after starting the supplements

Method of measurement
The Female Sexual Function Index (FSFI) questionnaire

2

Description
sexual self-expression of lactating women

Timepoint
At the beginning of the study and 8 weeks after starting the supplements

Method of measurement
Hulbert Index of Sexual Assertiveness questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: receiving vitamin D supplement (one capsule of 1000 international units, made in Iran or imported, depending on availability and approval by the Food and Drug Administration/daily for 8 weeks) and placebo, daily Lactofem supplement

Category
Prevention

2

Description
Second intervention group: Recipient of Lactofem supplement manufactured by Zist Takhimr Company. One tablet daily for 8 weeks) and placebo vitamin D supplement 1000

Category
Prevention

3

Description
Third intervention group: Simultaneously receiving vitamin D and lactofem supplement (one of each drug daily according to the same schedule)

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Yasuj Comprehensive Health Service Centers

Full name of responsible person
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Sponsors / Funding sources

1

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

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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
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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