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Effects of probiotic supplementation on ratings of menopause and markers of health in women

Submission date
03/11/2025

Recruitment status
Recruiting

Registration date
04/11/2025

Overall study status
Ongoing

Last Edited
04/11/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The microbiota plays an important role in influencing gut-brain function and health. Over recent years, there has been growing interest in understanding how gut health influences postmenopausal hormonal changes and symptomatology. The purpose of this study is to investigate the impact of probiotic supplementation on estrogen levels, menopause symptoms, and health markers in postmenopausal women.

Who can participate?
We are recruiting up to 300 postmenopausal female participants (>40 years of age) with a goal of completing 200 participants.

What does the study involve?
Each participant will be asked to visit the lab five times over approximately a 12 week period. Each study visit will last approximately one to two hours depending on how long the participant takes to complete the questionnaires. Each visit after the first screening visit, will include; anthropometric measures, vital sign measures, blood draw, DXA scan, side-effects assessment, food log assessment, physical activity questionnaire, perceived stress scale questionnaire, menopause rating scale questionnaire, menopause specific quality of life questionnaire, sleep questionnaire, and a menopause visual analog scale questionnaire.

What are the possible benefits and risks of participating?
Possible benefits of participation include increased insight into one's health and fitness status (i.e., anthropometric measurements, vital sign measurements, lab values, DXA body composition and bone density values, etc.). Possible risks of participation include complications from the blood draws (i.e., pain, dizziness, nausea, etc.), radiation exposure from the DXA scans (i.e., < 1 mRem per scan), side effects of the supplements (i.e., bloating, cramping, diarrhea, etc.), and possible allergic reactions to the supplements.

Where is the study run from?
The study will be run from the Exercise & Sport Nutrition Laboratory (ESNL) at Texas A&M University (USA).

When is the study starting and how long is it expected to run for?
The study is projected to start on December 1, 2025 and run for approximately one year depending on recruiting, attrition, etc.

Who is funding the study?
This study is being funded by Increnovo LLC (USA).

Who is the main contact?
Dr Richard Kreider, rbkreider@tamu.edu

Contact information

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Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Effects of probiotic supplementation on subjective ratings of menopause and markers of health in postmenopausal women

Study objectives
The objective of this study is to evaluate the effects of probiotic supplementation on estrogen levels, symptoms of menopause, and markers of health in postmenopausal women.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/09/2025, Texas A&M University Institutional Review Board (IRB) (301 Old Main Drive, Suite 3104, College Station, 77843, United States of America; +1 9798458585; irb@tamu.edu), ref: STUDY2025-0794

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled parallel-arm clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Probiotic supplementation on subjective ratings of menopause and markers of health in post-menopausal women.

Interventions
Participants will be randomized into one of the three treatment groups listed below;
1. Placebo (PLA)
2. Treatment 1 - 5 billion CFU Multi-Strain Probiotic (PRO, 2 billion CFU Lacticaseibacillus rhamnosus CA 15, 1 billion CFU Bifidobacterium animalis lactis BLC1, 1 billion CFU, Limosilactobacillus fermentum CS 57, 1 billion CFU Lactiplantibacillus plantarum IMC510) + PLA
3. Treatment 2 - PRO + 1 g Germinated Brown Rice + 25 mcg Colecalcipherol

The supplements will be prepared in powder form in generic, labeled envelopes for double-blind administration by the sponsor. Participants will be asked to consume one dose of their assigned supplement per day for 12 weeks.

This study will utilize Stratified Randomization using sealed envelopes.

Intervention Type
Supplement

Primary outcome(s)

1. Menopause Rating Scale (MRS) Questionnaire at 0,4,8,12 weeks
2. Menopause-Specific Quality of Life Questionnaire (MENQOL) at 0,4,8,12 weeks

Key secondary outcome(s)
1. Estrogen (blood test) at 0,4,8,12 weeks
2. Pittsburgh Sleep Quality Index (PSQI) at 0,4,8,12 weeks
3. Menopause Visual Analog Scale (VAS) Questionnaire at 0,4,8,12 weeks
4. Perceived Stress Scale (PSS) at 0,4,8,12 weeks
5. Patient-Reported Outcomes Measurement Information System (PROMIS) at 0,4,8,12 weeks
6. International Physical Activity Questionnaire (IPAQ) at 0,4,8,12 weeks
7. Complete Blood Count (CBC) at 0 and 12 weeks
8. Blood Chemistry Panel (Chem Panel) at 0 and 12 weeks
9. Blood Lipids (Lipid Panel) at 0 and 12 weeks
10. Blood Hemoglobin A1c (HBA1c) at 0 and 12 weeks
11. DXA body composition and bone density at 0 and 12 weeks
12. Side-Effects Assessment at 0,4,8,12 weeks

Completion date
21/05/2027

Eligibility

Key inclusion criteria
1. Women (>40 years of age) with a BMI on average < 30 kg/m² and a max individual BMI = 32 kg /m².
2. Women who are postmenopausal as defined by the Stages of Reproductive Aging Workshop (STRAW) criteria (i.e., at least 12 months amenorrheic) and experiencing menopause-related symptoms (e.g., vaginal dryness, hot flashed, night sweats, sleep problems, mood changes, memory issues, etc.)
3. Participant agrees to maintain their normal dietary, activity patterns throughout the study period.
4. Participant agrees to refrain from alcohol, caffeine, and strenuous exercise for 24 hours prior to each testing day.
5. Participant agrees to refrain from consuming probiotic, prebiotic (e.g., fiber, omega-3 fatty acids), and phytoestrogen-based supplements outside of the study for the duration of the study period.
6. Participant is willing and able to comply with the study protocol.
7. Participant has given voluntary, written, informed consent to participate in the study.
8. Participant will be allowed to take current medications as long as it is not believed to affect study outcomes.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
41 Years

Upper age limit
99 Years

Sex
Female

Key exclusion criteria
1. Women (>40 years of age) who are not postmenopausal as defined by Stages of Reproductive Aging Workshops (STRAW) criteria (i.e., at least 12 months amenorrheic).
2. Women who are postmenopausal but not experiencing symptoms.
3. Women on Hormone Replacement Therapy (HRT).
4. Women who are determined to have lever, renal, cardiovascular, or other metabolic disease.
5. Women who have a known allergy or sensitivity to probiotic supplements.
6. Women who are pregnant, breast feeding, or planning to become pregnant during the trial.
7. Women who have used antibiotics or antifungals within three months prior to enrollment, including topical antibiotics or antifungals.
8. Women who have a clinically significant abnormal laboratory results at the screening visit.
9. Women who have used tobacco or nicotine products in the past 12 months prior to starting the study.
10. Women who have Type I or Type II diabetes mellitus or on treatment with anti-diabetic medication.
11. Women who have unstable metabolic diseases or chronic diseases.
12. Women who have documented or self-reported current or pre-existing thyroid conditions.
13. Women who have unstable hypertension.
14. Women with current or a history of any significant diseases of the gastrointestinal tract (including but not limited to inflammatory bowel disease and diverticulosis).
15. Women with a current use of any probiotic, prebiotic, and synbiotic product unless they are willing to undergo a 4-week washout period to run-in period and abstain from consuming such products during the study.
16. Women who use cannabinoid products (including synthetics) within one month of study entry or during the study.
17. Women who use alcohol or have abused drugs within the last 12 months.
18. Women who report a high alcohol intake (average of > 2 standard drinks per day or > 10 standard drinks per week).
19. Women who report the use of other dietary supplements to address menopausal symptoms.
20. Women who have donated blood 30 days prior to screening, during the study, or have a planned donation within 30-days of the last study visit.
21. Women who have participated in other clinical research trials 30 days prior to the screening visit.
22. Any other conditions which, in the PI's opinion, may adversely affect the participant's ability to complete the study, its measurements, or pose a significant risk to the participant.

Date of first enrolment
01/12/2025

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
United States of America

Study participating centre
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Sponsor information

Organisation
Increnovo

Funder(s)

Funder type
Industry

Funder Name
INCRENOVO LLC

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr Richard Kreider at rbkreider@tamu.edu

IPD sharing plan summary
Available on request