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

Submission date	Recruitment status	[X] Prospectively registered
03/11/2025	Not yet recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
04/11/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
04/11/2025	Nutritional, Metabolic, Endocrine	[X] 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

#### Type(s)

Scientific, Principal investigator

#### Contact name

Dr Richard Kreider

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#### Type(s)

Public

#### Contact name

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# 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

#### Study design

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

#### Primary study design

Interventional

#### 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**

#### Kev inclusion criteria

- 1. Women (>40 years of age) with a BMI on average < 30 kg/m<sup>2</sup> and a max individual BMI = 32 kg/m<sup>2</sup>.
- 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
Exercise & Sport Nutrition Laboratory
675 John Kimbrough Blvd.
Suite #206
College Station
United States of America
77843-4253

# 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

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 11/11/2025 No Yes