

A 12-Week Virtual, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Effects of Daily Nouri Hormone Balance Probiotic on Metabolic, Inflammatory, and Symptom Outcomes in Women with Hormonal Imbalance Symptoms

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BACKGROUND & RATIONALE

The Research Gap

Probiotic research in women's hormonal health has focused on clinically diagnosed PCOS populations, excluding the majority of symptomatic women who fall outside formal diagnostic criteria. This represents a substantial gap as up to 70% of women estimated to have PCOS remain undiagnosed (WHO, 2024), with many more experiencing significant hormonal symptom burden without ever meeting diagnostic criteria. The PCOSQ-26, designed and validated for use in confirmed PCOS populations, has similarly not been applied beyond that diagnostic boundary (Cronin et al., 1998).

The role of the gut microbiome in estrogen regulation is one of the more significant developments in women's health science over the past decade and is a mechanistic foundation still being actively mapped. Central to this is the estrobolome, the set of gut microbial genes involved in estrogen metabolism, which operates via bacterial β -glucuronidase activity that reactivates conjugated estrogens for re-entry into systemic circulation (Baker et al., 2017; Ervin et al., 2019). Probiotic strains with documented β -glucuronidase activity have demonstrated capacity to modulate serum estrogen levels in women (Honda et al., 2024), and population-level data associate probiotic consumption with higher circulating estradiol in premenopausal women (NHANES, 2013–2016).

Concurrent with this trial, a 2026 global consensus now formally recognizes hormonal conditions in women as multisystem and symptom-diverse, extending beyond those meeting formal diagnostic criteria (Teede et al., Lancet, 2026). The present study advances that evidence base further by applying a well-established outcome measure and gut-hormone targeted intervention to a symptom-defined population that has not previously been studied.

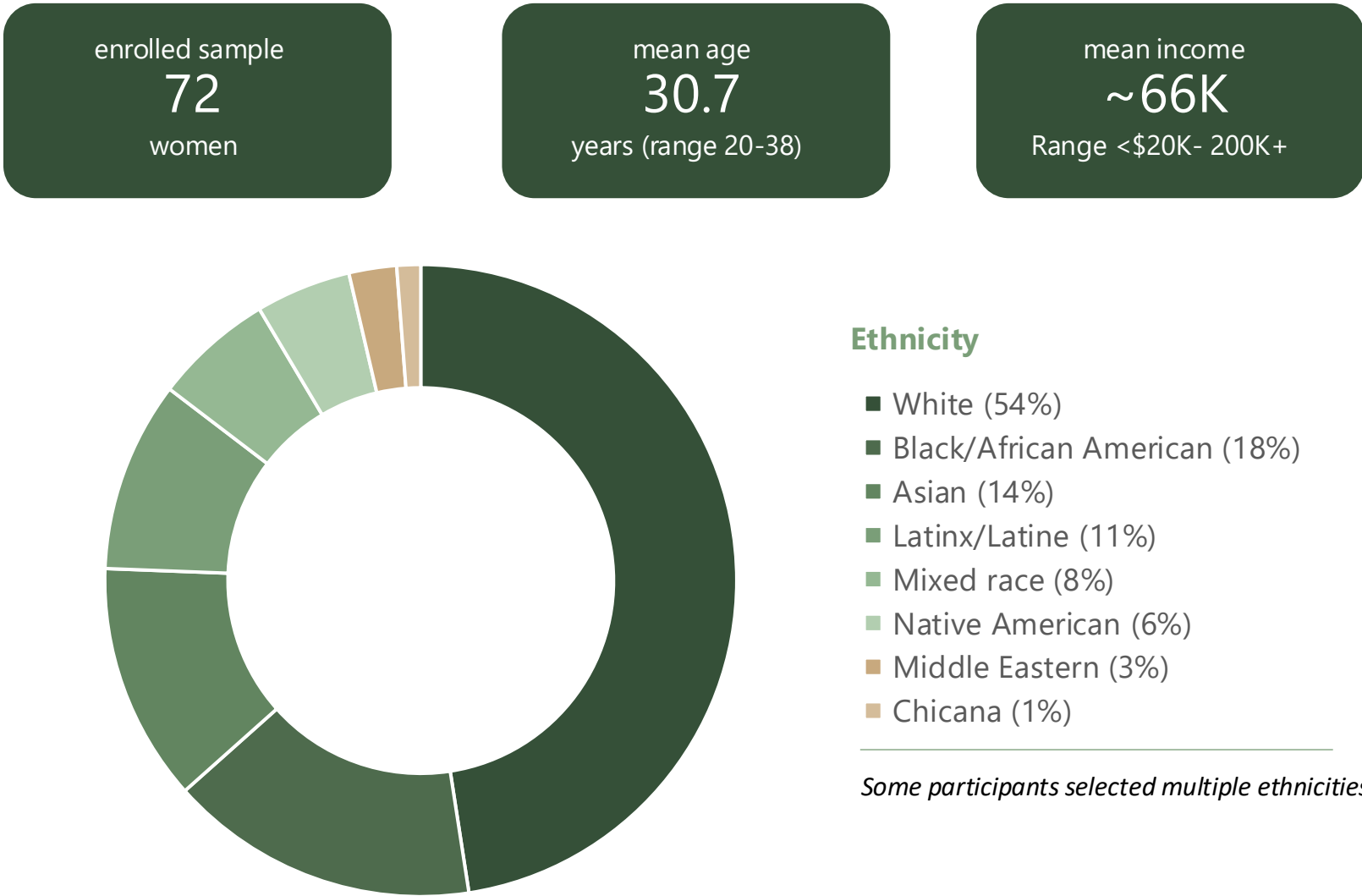
STUDY OBJECTIVES

Primary Objective

To evaluate the effect of a gut-hormone targeted probiotic on PCOSQ-26 total score (across five domains: Emotions, Hirsutism, Weight, Infertility, Menstrual) from baseline to Week 12.

Secondary Objectives

- PROMIS-29 (Cella et al., 2019) domain T-scores: physical function, fatigue, pain, sleep, social function, anxiety, depression (baseline → Week 12)
- Metabolic & inflammatory biomarkers via dried blood spot: HbA1c | fasting glucose | hsCRP



METHODS

Study Design

A 12-week, randomized, double-blind, placebo-controlled, fully virtual (decentralized) trial. Registered at [ClinicalTrials.gov](https://clinicaltrials.gov): NCT07268404

Population

Women aged 18–35 years (BMI 18.5–35 kg/m²) with self-reported hormonal imbalance symptoms, with or without menstrual irregularities, were enrolled without requirement of a formal PCOS diagnosis. This yielded a symptomatically diverse sample spanning varied hormonal health backgrounds.

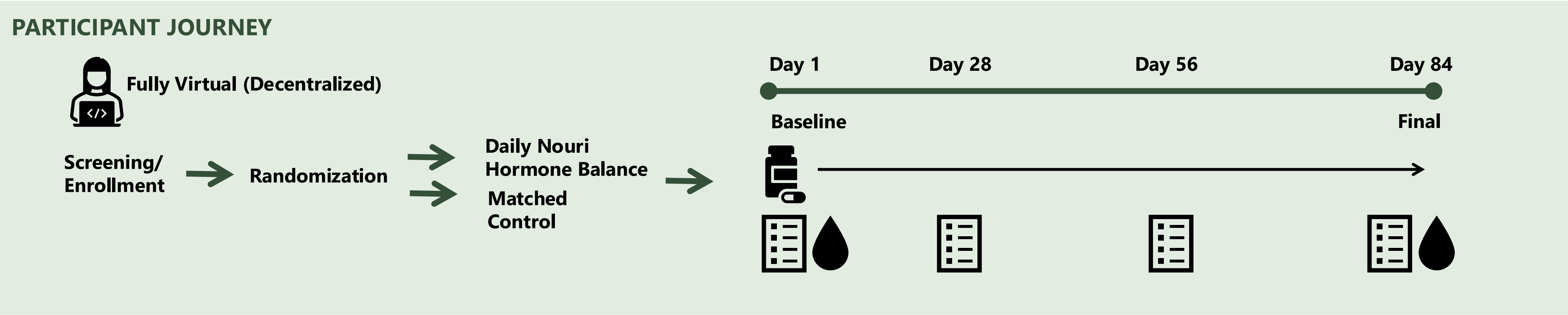
Intervention

Active: Daily Nouri Hormone Balance Probiotic (1 capsule daily) - 370mg Ahiflower oil containing 265mg Omega 3s, 12 billion CFU/75mg Hormone Balance Probiotic Blend

Control: Matched placebo capsule (1 capsule daily)

Statistical Power

Powered to detect a clinically meaningful PCOSQ-26 effect (80% power, $\alpha=0.05$). Target: ≥ 60 protocol completers.



IMPLICATIONS

The Symptom-First Paradigm

This trial challenges the diagnosis-gated model that has historically defined enrollment in women's hormonal health research. By recruiting based on symptom burden alone, without requiring a formal PCOS diagnosis, the study reaches a population that is underserved, and largely invisible in the clinical literature. The fully decentralized design removes geographic barriers to participation, enabling recruitment of a cohort that reflects the true demographic diversity of women with hormonal imbalance symptoms. As the field moves toward recognizing hormonal conditions as multisystem and symptom-diverse (Teede et al., Lancet, 2026), this enrollment model offers a replicable framework for future research.

Clinical & Commercial Significance

Results from this study will offer preliminary efficacy data in a consumer population that is vast, highly motivated, and actively seeking evidence-based solutions for hormonal wellness — one of the largest underserved markets in women's health. Together these contributions position this work as a building block for a broader program of research in women's hormonal health.

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