

Using a Targeted Supplement to Replenish Depleted Nutrients for Young Adults on Hormonal Birth Control

Protocol Number: IRB #2025-383

National Clinical Trial (NCT) Identified Number: NCT07271316

Principal Investigator: Sarah E. Hill

Sponsor: Texas Christian University

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Study Protocol.

Objectives

The objectives of this study are to better understand whether the use of a supplement created to target nutritional depletion associated with hormonal birth control use can: (a) increase happiness levels, (b) increase energy levels, (c), decrease mood swings, (d) increase perceived immune function, and (e) better digestion.

Relevant Scientific Background

Prior research has demonstrated that women on hormonal birth control may experience nutrient depletion (Palmer et al., 2013). Specifically, use of hormonal birth control has been associated with deficits in B vitamins, magnesium, and zinc (Muscaritoli, 2021). These deficiencies are hypothesized to directly interfere with the underlying systems that regulate emotional stability, energy, and physical resilience (Kennedy, 2016). To counteract the negative side effects associated with nutritional depletion for women on the hormonal birth control pill, the current study aimed to examine the efficacy of a targeted nutritional supplement for hormonal birth control pill users.

Design and Method

Participants first took an online prescreen survey. Before beginning this survey, participants were presented with a consent form informing them about the purpose of the research and potential risks for participating in the study. Participants who consented to participate in the study then responded to questions asking if they were willing to participate in two more surveys and if they were willing to take a daily supplement. Participants were then asked questions about their demographics and health experiences (e.g., usage of hormonal birth control, time on hormonal birth control, current medication usage, current supplement usage, etc.). Participants finished the study by indicating if they paid attention to the survey and if they recommended analyzing their data. Participants were invited to participate in the main study if they were willing to take the supplement daily, willing to take part in two more surveys, did not take any medications that would interact with the supplement, were not taking any supplements or were willing to stop using their current supplements to take part in the study, were on the hormonal birth control pill for at least six months, were between the ages of 18 to 25, were female, and did not have any allergies that would prevent them from safely taking the supplement.

Participants who were eligible to take part in the study were invited to come in on day 2 of their hormonal birth control pill pack. Participants began the study by reading through a consent form informing them about the purpose of the research and potential risks for participating in the study. After consenting to participate in the study, participants answered measures regarding happiness levels, perceived vulnerability to disease, digestive health,

frequency of mood swings, energy levels, demographic information, and menstrual health information. Participants finished the survey by reporting if they paid attention to the survey items and if they believed their data was good to use for data analysis. Participants then received a blank pill bottle and were told to take three pills per day for 28 days. Neither the participants nor the research assistants running the study knew if they were giving the participants a placebo or the targeted supplement.

After receiving the capsule bottle, participants received daily reminders for 28 days to take their capsules. After 28 days of taking the capsules, participants filled out another survey either in the lab or online. Participants began the study by reading through a consent form informing them about the purpose of the research and potential risks for participating in the study. After consenting to participate in the study, participants answered measures regarding happiness levels, perceived vulnerability to disease, digestive health, frequency of mood swings, energy levels, demographic information, and menstrual health information. Participants also reported any side effects they experienced while taking the capsules. Additionally, they reported how many times they forgot to take the supplement as well as any medications or supplements they took during the study period. Subsequently, participants gave the research assistants their capsule bottle with any remaining capsules they forgot to take. Finally, participants were debriefed on the study and dismissed.

Relevant Amendments approved by Texas Christian University

- **January 20, 2026**
 - Created an amendment to allow to study team to use an excel file to help keep track of eligible study participants.
- **January 23, 2026**
 - Created an amendment to give participants more information about the supplement. Specifically, on the prescreen, participants were asked if they “would be willing to participate in a study where you take a daily supplement intended to help women feel better while using hormonal birth control? (For example, we are looking to see if usage of this vitamin formulation may improve mood, decrease hormonal symptoms, etc.).”
 - On the consent form for the first in-person session, participants were now told that the purpose of this research is to examine how a nutritional supplement (vs. a placebo) may affect multiple domains on women’s health. Please note, this edit to the consent form was created before any participants completed the first in-person session.
 - Finally, an email template was created for participants who reported they were unsure if they were willing to take a daily supplement. This email template included further information about the supplement to help participants decide whether they are interested in participating further in the study.
- **March 6, 2026**
 - Created an amendment to allow participants to take the final survey virtually.
- **March 27, 2026**
 - Created an amendment to aid on the first in-person consent form that stomach irritation is a potential side effect of taking the supplement.