



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

27 March 2026

Informed Consent to Participate in Research

Title of Research: Wellness in Women #2

Principal Investigator: Sarah Hill

[Co-investigators:] Melissa Brillhart

Overview: You are invited to participate in a research study. To participate, you must be at least 18 years old, female, a SONA user, taking the hormonal birth control pill, and have no food or medication allergies/interactions that will prevent you from safely taking a nutritional supplement.

Study Details: This study is being conducted via Qualtrics research software at Texas Christian University. The purpose of this study is to understand how a nutritional supplement (vs. a placebo) will affect multiple domains of women's health. The supplement used in this study is a vitamin formulation developed to support women who use hormonal birth control. This study will take approximately 1 hour to complete, in which you will be given a supplement and then respond to several questionnaires assessing your demographics, health, and personality. After receiving the supplement, you will receive daily texts for the study team for 28 days reminding you to take your supplement.

Participants: You are being asked to take part because you are a SONA user at Texas Christian University that is at least 18 years old, female, and on the hormonal birth control pill. If you decide to be in this study, you will be one of 68 participants in this research study at TCU.

Voluntary Participation: Your participation is voluntary. You are not required to participate and may withdraw at any time. You do not have to answer any questions that you are not comfortable answering.

Confidentiality: Even if we publish the findings from this study, we will maintain the confidentiality of your information. Anyone with the authority to look at your records must keep them confidential.

What is the purpose of the research?

The purpose of this research is to examine how a nutritional supplement (vs. a placebo) may affect multiple domains on women's health (e.g., mood, hormonal symptoms).

What are the risks of participating in this study, and how will they be minimized?

The risks of participating in this research are minimal and no different from the risks that you encounter in everyday life. Although you will be asked a small number of personal questions (e.g., about your personality traits, health), you are free to not answer any particular questions if you choose.

Moreover, you will be asked to take a daily supplement for 28 days. This supplement may either be a nutritional supplement or a placebo supplement. The supplement used in this study is a vitamin formulation developed to support women who use hormonal birth control. For example, we are looking to see if usage of this vitamin formulation may improve mood, decrease hormonal symptoms, etc. Depending on which supplement you receive, the supplement may include the following ingredients: vitamin C, vitamin D3, vitamin E, vitamin B1, vitamin B2, vitamin B3, vitamin B6, folate, vitamin B12, pantothenic acid, magnesium, zinc, selenium, tributyrin, coenzyme, hypromellose (vegetable capsule), and capsule binding/caking ingredients (silicon dioxide, microcrystalline cellulose, magnesium stearate, and stearic acid). The only known risks with taking either the nutritional supplement or the placebo supplement are experiencing bright yellow urine and stomach irritation. To avoid stomach irritation, it is recommended that you take the supplement with food. If you are not comfortable taking a supplement, please let a researcher know. You may also stop participating at any time.

during the experiment without penalty. The experimenter will inform you if any new information surfaces that may affect your willingness to participate.

There is the possible loss of confidentiality if your data or information is disclosed outside of this study, but this is not likely. To minimize this risk, once all of the data has been collected, no identifying information will be associated with your data. That is, your responses will only be linked to a random numeric ID number and an identifying information will be destroyed. The numeric ID will be assigned only for data management purposes, and the researchers will not be able to trace this ID or your responses to your identifiable information. Your responses may be accessed by other researchers, but they will have no way to identify you as no identifying information will be associated with your data.

What does my participation involve in this study?

If you decide to participate in this study, you will first respond to several questionnaires assessing your personality, demographics, and health. Then you will receive access to a supplement that you will take daily for 28 days. We expect your participation to take about 1 hour.

Importantly, for the 28 days that you take your supplement, we will send you reminder texts to take your supplement. The day before part 3 of this study, you will receive a reminder text of your study session.

Some of the questions you will be asked to answer may be of a sensitive nature, including questions about your gender/sex (e.g., “What is your gender identity?”). You are free to skip any questions you are not comfortable answering with no penalty.

Are there any alternatives, and how can I withdraw my participation?

You do not have to participate in this research study.

Alternatives to participating in the study include completing the alternative assignment on SONA or completing other studies on SONA.

Your decision to participate or not to participate will not affect your student status, course grade, recommendations, or access to future courses or training opportunities

You should only participate in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. You may withdraw from the study by 1) not providing informed consent at the start of the study and letting a research assistant know that you would like to not complete the study, or 2) exiting out of the study Qualtrics browser prior to completing the study and letting a research assistant know that you would like to not complete the study. If you do not give permission to use your responses, all of your data will be deleted, at the latest, once data collection for this study is complete. Participants who rescind participation will still receive their owed compensation (1 SONA credit), and their information/responses will be deleted and not used in any data analyses.

What are the benefits of participating in this study?

You might benefit from being in this study because you will gain insight into the scientific process and our specific hypothesis when you are debriefed at part 3 of the study. There are no further direct benefits from participating in this study.

Will I be compensated for participating in this study?

You will receive compensation of 1 SONA credit for your participation in this study. Credit will be approved within 48 hours of study completion.

What are my costs to participate in the study?

To participate in this research, you will not need to pay for anything.

How will my confidentiality be protected?

Every effort will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Your records may be reviewed by authorized University personnel or other individuals who will be bound by the same provisions of confidentiality

Your identifiers will be removed from your private records or your samples. Your information or samples could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

What will happen to the information collected about me after the study is over?

We will keep your research data to use for future research or other purpose. Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you.

Who should I contact if I have questions regarding the study or concerns regarding my rights as a study participant?

You can contact Melissa Brillhart at m.brillhart@Tcu.edu, (817) 257-4989 with any questions that you have about the study or Dr. Sarah Hill at s.e.hill@tcu.edu, (817)257-6424.

Dr. Brie Diamond, Chair, TCU Institutional Review Board, (817) 257-6152, b.diamond@tcu.edu; or Dr. Reuben F. Burch V, Vice Provost of Research, research@tcu.edu. For more information, please visit our website <https://research.tcu.edu/research-compliance/irb/for-research-participants/>.

By selecting "Agree to participate" below, you are agreeing to be in this study. Make sure you understand what the study is about before you agree. You will be given a copy of this document for your records upon request. If you have any questions about the study after you agree to participate, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

☐ Agree to participate

☐ I do not agree to participate

Consent to Store/Use Data for Future Research

I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information.

Yes _____ No _____