

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

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Sponsor: Texas Christian University

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Statistical Analysis Plan

Composite scores of happiness, digestive health, perceived vulnerability to disease, mood swings, and energy will be computed per scale convention. For our primary analyses, we will test for differences over time in the variables of interest via paired samples t-tests.

Originally, we were going to use ANOVAs to assess whether capsule type (supplement vs placebo) and time (pre vs post) influenced the variables of interest. However, due to recruitment restrictions and changes in the supplement formulation, we were unable to do so. Specifically, there were not enough participants who were willing and eligible to take part in the study to reach the target sample size. Moreover, recruitment cannot continue as the supplement formulation is changing from a capsule to a gummy. Therefore, all participants received the nutritional supplement. Research assistants were unaware that the participants all received the nutritional supplement. They believed some participants were receiving the placebo. Moreover, participants were not told (until the end) that they received the nutritional supplement (they were told they could receive a placebo).