

Gut Health and the effect on substance and alcohol cravings

8/10/23

Study Protocol and Statistical Analysis Plan

This protocol is designed to evaluate substance, including alcohol, cravings before and after gut health intervention. Consent and a pre survey on cravings will be collected. Then participants will take a probiotic/prebiotic and a pickle for 30 days. After 30 days the same survey will be taken by the participants and a paired t test will be used to analyze if there is a statistical change in cravings.

Sample size: The total number of individual subjects is expected to reach approximately 30-40 participants. The sample size is based on a compromise of time, cost and feasibility for a pilot study.

Study population : The study population will be representative of adults at least 18 years of age to 75 years of age, male and females who have alcohol or substance cravings. Inclusion and exclusion criteria have been listed elsewhere.

This is a pilot study with quantitative research and experimental design. The same survey will be used at the start of the study and at the end. The results of the data will be compared using a paired t-test.