Impact of Weizmannia (Bacillus) Coagulans JBI-YZ6.3 on Gut Health and Fecal Microbiome Changes

NCT07388264

Status	RECRUITING
Phase	Not Applicable
Sponsor	Lindenwood University
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (1)

• Minimum baseline physical activity level (defined as at least 30 minutes of moderate intensity exercise at least 4 days per week for the past 3 months) Subject is willing and able to comply with the study protocol. Study participant is not currently enrolled in another clinical trial that involves the administration of some investigative agent Subject has given voluntary, written, informed consent to participate in the study.

Exclusion (2)

• Participant has an abnormality or obstruction of the gastrointestinal tract precluding swallowing (e.g., dysphagia) and digestion (e.g., known intestinal malabsorption, celiac disease, inflammatory bowel disease, chronic pancreatitis, steatorrhea) Participant has been treated for a gastrointestinal related disorder, complication, or disorder within the past 30 days Positive medical history for any neurological condition or neurological disease Diagnosed with or being treated for any endocrinological disorder or currently used any form of hormone replacement (prescribed/doctor ordered or not) Women with a history of hormone-related conditions such as endometriosis, fibroids, polycystic ovary syndrome Currently prescribed for the first time statin drugs (i.e., Lipitor, Livalo, Crestor, Zocor, etc.) within the past 6 months or has had their dosage or medication changed within the past 6 months Currently prescribed for the first time hypertension medication (i.e., Beta-blockers, ACE Inhibitors, Alpha blockers, Vasodilators, etc.) within the past 6 months or has had their dosage or medication changed within the past 6 months Current antibiotic use or other prescription or over-the-counter medications that may impact study outcomes Have a known sensitivity or allergy to any of the study products Blood donation in past 60 days Current smoker (average of \> 1 pack per week within the past 3 months) or has quit within the past six months. This includes all forms of nicotine They plan major changes in lifestyle (i.e., diet, dieting, exercise level, travel, etc.) during the study Competitive athletes will be excluded History of alcohol or substance abuse in the 12 months prior to screening Current use of anabolic steroids (medically prescribed or otherwise) Receipt or use of an investigational product in another research study within 30 days of beginning the study protocol Report taking a probiotic or other dietary supplement know to impact digestion or gut function in the past 30 days Recent history (\<3 months) of exercise training or weight loss (\> 5%) Currently following a ketogenic or low carbohydrate diet within the past 30 days.

• Women who are pregnant, planning to become pregnant, or lactating currently or within the past six months Any condition or abnormality that, in the opinion of the investigator, would compromise the safety of the participant or the quality of the study data

Locations (1 total)

Lindenwood University, Saint Charles, Missouri, United States