Randomize placebo-controlled trial of a dietary prebiotic influences body composition, stress, and the distal gut microbiome

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**Abstract**

**Introduction**

**Materials and Methods**

This study utilized a single blind, placebo controlled, parallel design to assess the effect of dietary fiber on the gut microbiome, perceived stress, and anthropometric variables.

*Participants*

All participants in this study were resident physicians at the Family Health Center in Waco, TX. This population was selected based on pilot data indicating they are at a greater risk for weight gain and have higher levels of stress than the average population. Exclusion criteria for this study included: 1) Pregnancy 2) Currently on prescribed metformin or NSAIDS 3) A diagnosed gastro-intestinal disease (Ie: irritable bowel syndrome or Crohn’s disease) 4) Known allergy to the supplement, placebo, or provided meals 5) Antibiotic use within the last 3 months. Interested individuals were verbally screened using the indicated inclusion/exclusion criteria, those passing the screening were enrolled in the study. Informed consent was obtained prior to partaking in any study procedures.

*Dietary Fiber Intervention*

After obtaining informed consent, participants were randomly assigned to two groups – fiber or placebo. This study lasted for thirteen weeks, with baseline assessments being conducted during the first week and the intervention occurring during the subsequent twelve weeks. The fiber group received a p-inulin supplement (Prebiotin; Camp Hill, PA) while the placebo group received an isocaloric amount of maltodextrin placebo. Supplement/placebo was consumed every day for twelve weeks, with the dosage ramped such that 2g/day were consumed during week 1, 4g/day during week 2, 8g/day during week 3, 12g/day during week 4, and 16g/day during weeks 5 through 12. In addition to the supplement, participants in the fiber group consumed a high fiber meal replacement three days per week (BuffBake; Santa Ana, CA) while participants in the placebo group consumed a low fiber meal replacement three days per week (MyCookie; Frisco, TX). To enhance compliance, supplements and meal replacements were provided to participants one week at a time. Participants reported their degree of compliance at the end of each week.

*Microbiome Analysis*

To assess for changes in the gut microbiome, stool samples were obtained from participants at baseline and at the end of weeks 4, 8, and 12 of the intervention. Prior to each sampling timepoint, each participant was provided with a stool sample kit (OMNIgene gut, DNA genotek Inc, Canada) and instructions to take home with them. The stool sample was turned into the researchers the following week. Sequencing analysis...

*Diet Analysis*

Baseline dietary habits were measured using the Diet History Questionnaire version 3 (DHQIII). The DHQIII is a web-based tool that was completed during the baseline week of the study. To control for acute dietary changes to the gut microbiome, a 24-hour dietary recall was obtained for the day prior to the collection of each stool sample (at baseline, and the end of weeks 4, 8, and 12) using the Automated Self-Administered 24-hour Dietary Assessment Tool (ASA24).

*Stress Response and Analysis*

To assess for the relationship between the gut microbiome and stress, participants completed the Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1993) during baseline and at the end of the twelve-week intervention period. The PSS is a 10 item self-report measure of stress within the last month, in terms of unpredictability, overload and uncontrollability. Each question is answered with a range of 0-4 with 0 equating to “never” and 4, “very often.” Possible scores range from 0 to 40 with higher scores indicating greater perceived stress

*Body Composition Analysis*

Anthropometric measures were obtained during the baseline week and at the end of the twelve-week intervention. Height was measured to the nearest 0.10 centimeter using a stadiometer. Weight was measured to the nearest 0.10 kilogram using a calibrated digital scale. Waist circumference was measured three times to the nearest 0.10 centimeter using a Gulik tape measure at an area just above the iliac crest per National Heart, Lung, and Blood guidelines. Percent body fat was measured using the InBody...

*Blood Analysis*

Blood draws were conducted with participants in the fasted state before and after 12 weeks of supplementation. Blood samples were collected via venipuncture at the most prominent vein in the antecubital space. Samples were allowed to clot on ice for 60min before centrifuging at 3500g for 15 min. After centrifugation, serum samples were aliquoted into microcentrifuge tubes and stored at -80°C for later analysis.

Serum levels of Peptide YY (PYY) were measured using a commercially available enzyme-linked immunosorbent assay (ELISA) following the manufacturer’s instructions (Raybiotech Inc., Peachtree Corners, GA). High-sensitivity C-Reactive Protein (hsCRP) levels were measured via particle enhanced immunoturbidimetry (Roche, Basel, Switzerland). Insulin levels were assessed utilizing electrochemiluminescence immunoassay (ECLIA) (Roche, Basel, Switzerland). A basic metabolic panel and lipid panel were conducted using Roche COBAS automated methodology (Roche, Basel, Switzerland).

**Results**

**Discussion**

**Figure Legends**

**References**

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