NCT04990973

Brief Title: Evaluation of Diet and Sleep in Vascular Health: A Pilot Study

Official Title: Influence of Diet on Sleep and Cardiovascular Risk

Unique Protocol ID: AAAT7042

Date: 03/26/2024

Protocol

The goal of this study is to test the impact of diet on sleep and cardiovascular disease risk factors.

Poor sleep quality is highly prevalent in adults in the U.S. and worldwide. Recent work suggests that dietary intakes may influence sleep. This pilot mechanistic study will tests whether consuming a diet aligning with recommendations for a Mediterranean dietary pattern, relative to a typical American diet, improves sleep quality in U.S. adults. Furthermore, we gather preliminary data on whether this diet pattern improves cardiovascular disease risk profile. Given the established relationship between sleep and cardiovascular health.

This pilot study is a randomized, crossover, dietary intervention study with 2 phases: Mediterranean Diet or Average American Diet. Each diet is provided to participants in amounts necessary to maintain baseline body weight given stable activity levels, a requirement of the study; estimated energy needs are computed using the Mifflin St. Jeor equation. During the study, participants are provided 3 isocaloric meals and one snack daily for 4 weeks in each condition. Condition order is randomized by the Biostatistician, and phases are separated by at least 4 week washout. The experimental "Mediterranean Diet" is composed of approximately 40% energy from fat, 20% from protein, and 40% from carbohydrates. The control/comparison diet "Average American Diet" provides 35-37% of energy from fat, 15% from protein, and 48-50% from carbohydrates. Diets differ in fiber content: 40 g/2000 kcal/d for the Mediterranean Diet vs 10 g/2000 kcal/d for the Average American Diet. Participants are not blinded to the intervention.

Prior to enrollment in the study, participants are screened for assessment of health history and current sleep behaviors. Individuals meeting initial eligibility criteria: aged 18-65 y, BMI of 20-34.9 kg/m^2, sleep complaints, will complete the informed consent process. Those providing consent will continue with screening. Prospective participants are not included if they currently smoke (or quit less than 3 years prior), are diagnosed with a cardiometabolic disease or neurologic disorder, have a psychological or sleep disorder, have gained or lost significant weight in the past 3 months, have allergies to foods included in the study, or are deemed unable to comply with study procedures (either self-expressed or determined by the investigator). Participants also complete a sleep screening; those reporting sleep complaints on the Pittsburgh Sleep Quality Index who also have average total sleep time ≥6 h/night based on 2 weeks of daily wrist actigraphy and willing to undergo the interventions post-screening are accrued into the study.

Participants are randomized to the diet for phase 1 at their first baseline visit. At the baseline visit of each phase, measures are collected prior to beginning the corresponding study diet. Following the baseline visit, food is provided by the Bionutrition Unit of the Irving Institute for Clinical and Translational Science at CUIMC according to diet allocation. The participants return to the study site every 3-4 days to

collect their study foods over the course of the 4 weeks during each phase. Throughout each phase, sleep is measured daily using wrist actigraphy along with a sleep diary. Fasting blood, overnight urine and fecal samples, and venous endothelial cells are collected at baseline and endpoint of each phase. Participants are instructed to collect all urine from voids occurring after bedtime until the first, next-morning void on the night prior to the first and last study visit of each phase. Tryptophan metabolites and 6-sulfatoxymelatonin are measured from blood and urine samples, respectively. Anthropometric measurements, blood pressure, and heart rate are obtained weekly during each phase. One night of in-home polysomnography is performed in the last week of each phase using a 9-channel portable device (Z-Machine Synergy System, General Sleep Corporation, Cleveland, OH).

Statistical Analysis Plan

Outcome data collected from the study will be assessed for normality using the Shapiro-Wilk test and histograms. Descriptive characteristics for the full sample, and stratified by sex, will be assessed for baseline demographic and sleep data. For continuous variables, means, standard deviations, and ranges will be assessed. For categorical variables, number of participants and corresponding percent of total participants, will be determined. Given the pilot nature of the study and within-person design, analyses of condition effects will be conducted only among those with complete data from both conditions. To assess condition effects, we will use linear mixed models with repeated measures or paired t-tests (for outcomes measured at one time point). Outcomes will be post-baseline values, and each outcome will be tested separately. Participant will be a random effect in the model. Study phase and participant sex will be fixed effects. Models will be adjusted for baseline values of the corresponding outcome measure.