

## **STATISTICAL ANALYSIS PLAN**

**Glycemic effects of substituting pecans for snacks higher in saturated fat and added sugars in individuals with prediabetes**

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## 1. Administrative information

**Clinicaltrials.gov Identifier:** NCT07235358 (Registered November 11, 2025)

### ***Key Personnel***

**Principal Investigator:** Dr. Kristina Petersen PhD, APD, FAHA is an Associate Professor in the Department of Nutritional Sciences at Penn State University. Dr. Petersen is the PI of the clinical trial. Dr. Petersen will be responsible for general study oversight and administration, protocol development and implementation, IRB submission, data analysis and management, and training study personnel required for protocol execution.

**Clinical Research Center:** The Clinical Research Center (CRC) at Penn State is equipped with experienced clinical research staff consisting of physicians, a nurse practitioner, and registered nurses who will work closely with the PI and study personnel throughout the trial to facilitate the research protocol.

**Metabolic Kitchen Manager:** The Metabolic Kitchen manager will be responsible for food preparation, procurement, and provision to study participants and will conduct adherence monitoring during the study.

**Study Coordinators:** Study personnel involving the research laboratory coordinator and research staff will be responsible for recruitment activities, data collection, and study procedures and will facilitate clinical trial operations.

## 2. Introduction

### ***Background and Rationale***

Approximately 38% of US adults have prediabetes.<sup>1</sup> Prediabetes is defined by the American Diabetes Association as a condition that precedes type 2 diabetes and is diagnosed by elevated HbA1C (5.7-6.4%), impaired fasting glucose (100-125 mg/dL), or impaired glucose tolerance assessed with a 75 g oral glucose tolerance test.<sup>2</sup> Individuals with prediabetes are at high risk for type 2 diabetes. For individuals with prediabetes at age 45 years, the lifetime risk of type 2 diabetes is 74%; the risk is higher for those with concomitant obesity.<sup>3</sup> In addition, prediabetes is associated with a heightened risk of cardiovascular disease (CVD).<sup>2</sup> Therefore, the goal of prediabetes management is to improve glycemic control to reduce the risk for progression to type 2 diabetes and the associated complications, including CVD risk.<sup>2</sup>

A key component of prediabetes management is intake of a healthy dietary pattern that emphasizes a variety of nutrient-dense foods to support glycemic control as well as cardiovascular health.<sup>4</sup> In the U.S., adherence to healthy dietary patterns is poor.<sup>5</sup> Therefore, strategies are needed to improve adherence to healthy dietary patterns. In the U.S., snacks comprise ~20% of daily total energy intake.<sup>6</sup> While intake of nutrient-rich snacks is associated with better adherence to healthy dietary patterns, intake of snacks high in added sugars and saturated fat contributes to poorer adherence to healthy dietary patterns.<sup>7,8</sup> Therefore, replacing nutrient-poor snack foods with nutrient-dense alternatives

may be a feasible strategy to improve adherence to healthy dietary patterns, which may assist with improving glycemic control and reducing CVD risk in individuals with prediabetes.

Nuts are a nutrient-dense food that are a recommended part of healthy dietary patterns<sup>4,9,10</sup> and nut intake is associated with better adherence to healthy dietary patterns.<sup>8</sup> Consistent evidence from epidemiological studies shows that higher nut intake is associated with lower risk of CVD.<sup>11</sup> This is supported by clinical trial evidence showing nut intake improves CVD risk factors, including low-density lipoprotein cholesterol (LDL-C), triglycerides<sup>12,13</sup>, and glycemic control.<sup>14,15</sup> Prior clinical trials show pecans improve lipids and lipoproteins compared to non-nut comparators after 4-8 weeks.<sup>16-21</sup>

In a randomized controlled trial conducted by the PI, it was demonstrated that instructions to eat 2 oz/day of pecans as a replacement for usual snacks improved LDL-cholesterol (-7.2 mg/dL; 95% CI -12.3, -2.1), non-HDL-cholesterol (-9.5 mg/dL; 95% CI -15.3, -3.7) and apolipoprotein B (-4.38 mg/dL; 95% CI -8.02, -0.73) after 12 weeks, compared with continuing usual intake, in adults at risk for cardiometabolic diseases.<sup>20,21</sup> We also observed an improvement in total LDL particles and total triglyceride-rich lipoprotein particles (TRL-P) as well as an improvement in the lipoprotein insulin resistance index, which is indicative of a reduction in early insulin resistance.<sup>20,21</sup> In addition, replacement of typical snacks with pecans increased overall diet quality, assessed by the Healthy Eating Index-2020 (a measure of adherence to the Dietary Guidelines for Americans), by 9.4 points (95% CI 5.0, 13.7) compared to the usual diet group.<sup>20</sup> Collectively, this trial showed that instructions to replace all typical snacks with pecans for 12 weeks improved lipoproteins, early insulin resistance, and diet quality in people at risk for cardiometabolic diseases. Importantly, the lipid/lipoprotein, insulin resistance, and diet quality improvements observed with replacing all snacks with 2 oz/day of pecans were greater<sup>20,21</sup> than we have observed previously in studies examining the replacement of evening snacks only with peanuts (1 oz/day)<sup>22</sup> and pistachios (2 oz/day).<sup>23</sup> In these trials, replacing all snacks<sup>20,21</sup> or evening snacks only<sup>22,23</sup> with nuts did not consistently improve glycemic control, which is generally consistent with evidence on the glycemic effects of nuts.<sup>14</sup> However, previously replacement of snacks higher in saturated fat and added sugars with nuts has not been examined.

It is established that replacement of carbohydrates, including added sugars, and saturated fat with unsaturated fats improves glycemic control assessed by HbA1C. In a meta-analysis of 102 randomized controlled feeding trials, replacement of 5% of energy from carbohydrates with monounsaturated fatty acids (MUFA; -0.09%; 95% CI -0.12, -0.05) or polyunsaturated fatty acids (PUFA; -0.11%; 95% CI -0.17, -0.05) improved HbA1C.<sup>24</sup> Similarly, replacement of SFA with MUFA (-0.12; 95% CI -0.19, -0.05) or PUFA (-0.15; 95% CI -0.23, -0.06) reduced HbA1C.<sup>24</sup> More recently, in a 12-week randomized controlled trial in individuals with overweight or obesity, intake of 1 avocado per day lowered HbA1C by 0.06% after 12 weeks compared to a low-fat, higher carbohydrate food.<sup>25</sup> Thus, it is likely that education to consume pecans, which are low in carbohydrates and rich in unsaturated fats, instead of snacks higher in saturated fat and added sugars, will improve glycemic control, particularly in individuals with prediabetes defined by elevated HbA1C.

Therefore, this trial aims to evaluate the glycemic and cardiovascular effects of education to substitute pecans for snacks higher in saturated fat and added sugars,

compared to continuing usual intake, in individuals with prediabetes. This evidence is expected to contribute to understanding the role of snacking in cardiometabolic health and inform dietary guidelines.

### ***Specific Aims***

The study aims to assess the effect of the intervention compared to the control on the following outcomes:

1. Markers of glycemic control, including hemoglobin A1C (HbA1C), fasting glucose, fasting insulin, homeostatic model of insulin resistance (HOMA-IR), lipoprotein insulin resistance index, mean glucose, time in range, glycemic variability, and insulin resistance.
2. Markers of cardiovascular health, including lipid/lipoprotein concentrations, lipoprotein particle size and concentrations, apolipoprotein B, blood pressure, C-reactive protein (CRP), and vascular health.
3. Dietary intake of saturated fat and added sugars, and overall diet quality.

### ***Hypothesis***

It is hypothesized that instruction to replace usual snacks higher in saturated fat and added sugars with pecans will improve glycemic control, cardiovascular health, intake of saturated fat and added sugars, and overall diet quality compared to continuing usual intake after 16 weeks in adults with prediabetes.

## **3. Study Methods**

### ***Trial design***

This is a two-arm randomized parallel study. Participants will be randomized to one of the following attention and resource matched interventions for 16 weeks  $\pm$  7 days: 1) instruction to consume 1.5 oz./day of pecans in place of the snacks they usually eat that are higher in saturated fat and/or added sugars; 2) continue consuming their current diet with provision gift cards worth \$15 monthly (equivalent value to the pecans) and matched contact with study personnel.

### ***Randomization method, allocation concealment, blinding***

Intervention assignment will be randomized at the individual level. The randomization sequence will have block sizes of 2, 4, and 8 and be computer-generated by a person not involved in recruitment or data collection. The person will upload it to REDCap. REDCap will be used to ensure allocation concealment. Prior to baseline testing, the metabolic kitchen manager will use the randomization module in REDCap to reveal the participant's randomization. The person generating the randomization sequence and the metabolic kitchen manager will be the only study team members with user access to the randomization module in REDCap. The PI, nurses drawing blood and laboratory staff conducting the assays will be blinded to the randomization schedule. The randomization

code will be unsealed only once all participants have completed the study and the dataset has been reviewed and cleaned. Due to the nature of the study interventions, participants will not be blinded.

### ***Sample size estimate***

The primary outcome is HbA1c measured at baseline and at the end of the 4-month intervention period. The primary endpoint is change in HbA1c from baseline. Sample size calculations show 128 participants (64 per group) will provide 80% power to detect a 0.08 (SD 0.16)<sup>20</sup> percentage point between-group difference in HbA1C change from baseline ( $\alpha=0.05$ ). In total, 147 participants will be randomized to allow for an attrition rate of ~15%.

### ***Hypothesis testing framework***

The superiority framework will be used for hypothesis testing.

#### ***Null hypotheses:***

1. Instruction to replace snacks higher in saturated fats and/or added sugars will not improve HbA1c to a greater extent than continuing usual diet.
2. Instruction to replace snacks higher in saturated fats and/or added sugars will not improve glycemic control, blood pressure, vascular function, blood lipid profile, inflammatory markers, saturated fat and added sugar intake, or diet quality to a greater extent than continuing usual diet.

### ***Interim analyses***

No interim analyses will be performed.

### ***Timing of outcome assessment***

At the beginning and the end of the 16-week study period, testing will be conducted on 2 consecutive days. Blood will be collected on both days, and vascular testing will be conducted on 1 day. Participants will wear a CGM for 7 days (week 0) prior to the first study visit and for 7 days (week 16) during the last week of the study. Participants will also complete three 24-hour dietary recalls prior to baseline (week 0) and during the last week of the study for assessment of dietary intake and diet quality. Table 1 provides an overview of the schedule of measurements for the study.

**Table 1: Schedule of Measurements**

<b>Outcomes</b>	<b>Week 0</b>	<b>Week 1</b>	<b>Week 16</b>	<b>Week 17</b>
<i>Outcomes assessed with venous blood</i>				
HbA1c		✓✓		✓✓
Fasting glucose		✓✓		✓✓
Fasting insulin		✓✓		✓✓
HOMA-IR		✓✓		✓✓
Lipid/lipoprotein concentrations (triglycerides, total cholesterol, LDL-C, HDL-C, non-HDL-C)		✓✓		✓✓
Apolipoprotein B, lipoprotein particle size and concentration (LDL, HDL, triglyceride- rich lipoproteins)		✓		✓
Lipoprotein insulin resistance index		✓		✓
C-reactive protein		✓✓		✓✓
<i>Vascular Outcomes</i>				
Central and peripheral blood pressure		✓		✓
Pulse wave velocity		✓		✓
<i>Continuous Glucose Monitor Assessed Outcomes</i>				
Mean glucose	✓		✓	
Time in tight range	✓		✓	
Glycemic variability	✓		✓	
<i>Dietary Outcomes</i>				
Saturated fat and added sugar intake	✓✓✓		✓✓✓	
Overall diet quality	✓✓✓		✓✓✓	

#### **4. Trial Population**

##### ***Recruitment***

Participants will be recruited from University Park and State College, PA and surrounding areas using public advertisements and recruitment flyers posted on campus and in the local community (State College/University Park area).

##### ***Screening and eligibility criteria***

Individuals responding to advertising will be emailed information about the study and complete a pre-screening survey via REDCap. Potentially eligible individuals will be telephone screened. Based on the answers to the questions, participants will be deemed eligible or ineligible by the staff member assessing eligibility in consultation with the PI. Eligible individuals will be scheduled for a clinic screening visit. At the clinic screening appointment, anthropometrics and blood pressure will be measured. Fasting blood samples

will be assessed for glucose, a complete blood count, including liver and kidney function, and a blood lipid panel. Inclusion/exclusion criteria will be assessed.

At the screening visit, participants must meet all the following inclusion criteria and none of the exclusion criteria to participate in this study.

#### **Inclusion criteria**

- Age 25-65 years
- Prediabetes assessed by an HbA1c of 5.7-6.4% at screening
- BMI 25-40 kg/m<sup>2</sup> at screening
- Low habitual nut consumption (<3.5 oz-eq/week) assessed at the telephone screening
- Regularly eats snacks higher in saturated fat and/or added sugars assessed at the telephone screening

#### **Exclusion criteria**

- Unwilling/unable to eat 1.5 oz of pecans every day as a snack during the duration of the study
- LDL-C  $\geq$ 190 mg/dL at screening
- Hemoglobin
  - Men: <13.2 g/dL at screening
  - Women: <11.7 g/dL at screening
- Fasting triglycerides >350 mg/dL at screening
- $\geq$ 10% change in body weight within the 6 months prior to enrollment
- Blood pressure >140/90 mmHg at screening
- Type 1 or type 2 diabetes
- Prescription of anti-hypertensive, lipid-lowering, or glucose-lowering drugs
- Intake of supplements or over the counter medications that affect the outcomes of interest (i.e., lipid, blood pressure, or glucose lowering; vitamin C or multi-vitamins containing vitamin C) and are unwilling to cease during the study period. Eligible if willing to discontinue. If willing to discontinue, the following washout period should be adhered to:

Washout prior to screening visit:

- 2-weeks for vitamins, probiotics, fermented drinks (e.g. kefir, kombucha)
- 2-weeks for omega 3 supplements  $\leq$ 2 g/day
- 4-weeks for omega 3 supplements >2g/day

Washout prior to baseline visit:

- 4-weeks for probiotics, fermented drinks, vitamins, and omega-3 supplements  $\leq$ 2g/day
- 6 weeks for omega-3 supplements >2g/day
- History of liver, kidney, or autoimmune disease
- Prior cardiovascular event (e.g., stroke, heart attack)

- Current pregnancy or intention of pregnancy within the next 12 months
- Lactation within the prior 6 months
- Pecan allergy/intolerance/sensitivity/dislike
- Antibiotic use within the prior 4 weeks
- Oral steroid use within the prior 4 weeks
- Use of tobacco or nicotine-containing products within the past 6 months
- History of cancer at any site within the past 10 years (eligible if  $\geq 10$  years without recurrence) or non-melanoma skin cancer within the past 5 years (eligible if  $\geq 5$  years without recurrence)
- Participation in another clinical trial within 60 days of baseline
- Unwilling to contact study staff before enrolling in other health-related research and avoid participating in any research that may interfere with this study.
- Currently following a restricted or weight-loss diet
- Prior bariatric surgery
- Intake of  $>14$  alcoholic drinks/week and/or not willing to avoid alcohol consumption for 48 hours prior to test visits
- Principal Investigator discretion related to the potential participant's ability to adhere to the study requirements, including being able to come to attend visits
- Does not speak and/or understand English
- Unwilling to refrain from donating blood and/or plasma during the study
- Weight  $<110$  lb
- If a potential participant takes thyroid medicine, abnormal thyroid stimulated hormone (TSH) concentration (TSH outside of normal range), or change in dose of thyroid medication within the last 6 months

#### ***Early withdrawal of participants***

Participants will be withdrawn from the study for the following reasons:

- Risks to the other participants/research team members, disruptive behavior during the study visit or food pick-ups
- Diagnosis of a disease listed as an exclusion criterion or a serious medical condition requiring active intervention.
- Prescription of anti-hypertensive, lipid-lowering or glucose-lowering drugs
- Prescription of steroids or antibiotics for longer than 7 days
- Pregnancy

#### ***Presentation of baseline characteristics***

Baseline demographic and clinical characteristics will be reported for the total analysis population and by randomization according to CONSORT guidelines.<sup>26</sup>

### **5. Analysis Population**

Analyses will be conducted consistent with intent-to-treat principles. All available data from randomly assigned participants will be included in data analyses.

## 6. Hypothesis Testing

Analyses will include assessment of between-group differences in the change from baseline for all outcome variables using linear regression.

### ***Primary outcome:***

The primary endpoint is change in HbA1c from baseline. HbA1c will be measured by a lab on the Penn State campus or a commercial lab.

### ***Secondary outcomes:***

The secondary outcomes will be change from baseline:

- Fasting glucose and insulin<sup>1</sup>
- Homeostatic model of insulin resistance (HOMA-IR)<sup>1</sup>
- Continuous glucose monitor (CGM) assessed mean glucose, time in tight range (70 to 140 mg/dL) and glycemic variability assessed by the coefficient of variability<sup>2</sup>
- Lipid/lipoprotein concentrations (triglycerides, total cholesterol, LDL-C, HDL-C, non-HDL-C)<sup>1</sup>
- Apolipoprotein B, lipoprotein particle size and concentration (LDL, HDL, triglyceride-rich lipoproteins)<sup>3</sup>
- Lipoprotein insulin resistance index<sup>3</sup>
- C-reactive protein<sup>1</sup>
- Central and peripheral blood pressure<sup>3</sup>
- Pulse wave velocity (PWV)<sup>3</sup>
- Saturated fat and added sugar intake<sup>4</sup>
- Overall diet quality, assessed by the Healthy Eating Index 2020<sup>4</sup>

<sup>1</sup>Change from baseline will be calculated by subtracting the mean of the values taken at baseline day 1 and day 2 testing from the mean of the values taken at endpoint day 1 and day 2 testing.

<sup>2</sup>Change from baseline will be calculated by subtracting the baseline value from 7 days of wear from the endpoint value from 7 days of wear.

<sup>3</sup>Change from baseline will be calculated by subtracting the baseline value from the endpoint value.

<sup>4</sup>Change from baseline will be calculated by subtracting the mean of values collected over three days at baseline from the mean of values collected over three days at endpoint.

### ***Exploratory outcomes:***

Fecal samples will be collected at baseline and at the end of the intervention period to enable assessment of gut microbiota composition. Dimensions of psychological well-being will be collected through surveys at baseline and at the end of the intervention period to enable assessment of psychological well-being. Salivary and hair cortisol will be collected at baseline and at the end of the intervention period to enable assessment of physiological stress.

## 7. Statistical Analyses

All data collected from randomly assigned participants will be included in data analyses consistent with intent-to-treat principles. Assumptions for all statistical tests will be checked and confirmed prior to conducting analyses for hypothesis testing. The primary analyses for all outcomes will assess the between-group (pecan or usual diet) differences in the change from baseline using linear regression. The change from baseline will be calculated by subtracting the baseline value from the endpoint value. Secondary analyses will be conducted to assess the between-group differences in endpoint means for all outcomes using linear mixed models. This will be done to confirm the primary analyses. Group will be included as a fixed effect, and visit will be included as a repeated effect. Intervention effects will be determined by examining the group-by visit interaction. When significant group-by-visit interaction is detected, post hoc testing will be conducted, and the Tukey-Kramer method will be used to adjust for multiple comparisons. For secondary outcomes assessed through CGMs (i.e. mean glucose, time in tight range (70 to 140 mg/dL) and glycemic variability), all CGM data will be included in the primary and secondary analyses in accordance with international consensus guidelines for the use of CGMs in clinical trials.<sup>27</sup> Sensitivity analyses will be conducted to assess the robustness of findings after excluding CGM data identified as artifacts (e.g., implausible low-frequency readings).

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