Protocol and Statistical Analysis Plan

Dietary Guidelines: 3 Diets (DG3D) – Aim 1 Study

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Institution	University of South Carolina

Protocol Title
Ensuring the Cultural Relevance of Dietary Guidelines Diet Patterns Among African American Adults: The Dietary Guidelines: 3 Diets (DG3D) Aim 1 Study

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1.0 Objectives

1.1 Primary Objectives

The primary objective of this study is to compare changes in dietary quality and cardiometabolic risk factors among African American adults randomized to follow one of three dietary patterns recommended by the 2020–2025 US Dietary Guidelines for Americans: Healthy U.S.-Style (H-US), Healthy Mediterranean-Style (Med), or Healthy Vegetarian (Veg).

1.2 Specific Aims and Hypotheses

Conduct a 3-month randomized trial among AAs comparing adoption of the 3 dietary patterns [1) US, 2) Med, or 3) Veg] using existing materials from the USDG and examine differences in diet quality (HEI) and T2DM risk factors (weight, HgbA1c).
Hypothesis: Participants assigned to the Mediterranean and Vegetarian dietary patterns will demonstrate greater improvements in outcomes compared to those assigned to the Healthy U.S.-Style pattern.

2.0 Background

The US Dietary Guidelines for Americans (USDG) provide the foundation for federal nutrition policy and outline three healthy dietary patterns: Healthy U.S.-Style, Mediterranean-Style, and Vegetarian. However, the evidence supporting these patterns is largely derived from observational studies conducted among predominantly White populations. African American adults experience disproportionate rates of obesity and type 2 diabetes, yet there is limited randomized trial evidence evaluating how these dietary patterns impact dietary quality and cardiometabolic risk in this population.

The Dietary Guidelines: 3 Diets (DG3D) study was designed to address this gap by testing the three USDG dietary patterns in a randomized, behavioral nutrition intervention among African American adults at risk for type 2 diabetes. The DG3D intervention also served as a formative study to inform a longer-term trial by identifying challenges and solutions for culturally relevant delivery of USDG-based dietary guidance.

3.0 Study Intervention

This is a 12-week, three-arm randomized dietary intervention. Participants are assigned to one of the following dietary patterns:
1) Healthy U.S.-Style Eating Pattern (H-US)

2) Healthy Mediterranean-Style Eating Pattern (Med)
3) Healthy Vegetarian Eating Pattern (Veg)

3.1 Common Elements Across Groups

All intervention content is derived from the 2020–2025 USDG and MyPlate resources and incorporates behavioral strategies adapted from the Diabetes Prevention Program and Social Cognitive Theory. Participants attend weekly 90-minute group-based nutrition and cooking classes delivered via Zoom. Classes include nutrition education, behavioral skills training, cooking demonstrations, and goal setting.

- Weekly 90-minute classes (12 total)
- Delivered via Zoom
- Structure:
    1. Welcome
    2. Weekly check-in
    3. USDG-based nutrition topic
    4. DPP behavior change topic
    5. Cooking demonstration
    6. SMART goal setting
- Personalized calorie prescriptions via MyPlate calculator
- Use of Start Simple with MyPlate app

3.1 Outcome Measures

Primary Outcomes

1. Change in body weight (kg)
2. Change in HbA1c (%)
3. Change in HEI score

Secondary Outcomes

- Systolic BP
- Diastolic BP
- Energy intake (kcal)
- Macronutrients (carbohydrates, fat, protein)

4.0 Procedures Involved

4.1 Study Design

Randomized, parallel-group, three-arm behavioral dietary intervention.

4.2 Methods Employed

☒ Behavioral Interventions

☒ Surveys/Questionnaires

☒ Focus Groups/Interviews

☒ Clinical Assessments

☒ Specimen Collection or Analysis

☐ Investigational Drug/Device (N/A)

☐ Deception/Manipulation (N/A)

4.3 Research Procedures

Potential participants complete an online screening questionnaire followed by telephone verification. Eligible participants attend an orientation session and provide informed consent.

Baseline assessments include demographic questionnaires, three 24-hour dietary recalls (ASA24), and an in-person clinical lab visit to assess height, weight, waist and hip circumference, blood pressure, and HbA1c via finger stick.

Participants are randomized after completion of baseline assessments and attend weekly intervention classes for 12 weeks. Post-intervention assessments replicate baseline measures and include participation in a focus group.

4.4 Assessment Procedures

- Height (baseline only; wall-mounted stadiometer)
- Weight (calibrated digital scale; light clothing)
- HbA1c
    - Measured via DCA Vantage Analyzer
    - Finger-stick sample
    - CV <3%
- Blood Pressure
    - Omron Hem 705 CP
    - 5-minute seated rest
    - Minimum 2 readings
    - Mean used
- Dietary Intake
    - Three unannounced 24-hour recalls using ASA24: 2 weekdays and 1 weekend day
    - Averaged per timepoint
    - HEI calculated using NCI SAS macros

5.0 Data and Specimen Storage for Future Research

De-identified study data will be stored on secure, password-protected university servers. Biological specimens will not be stored for future research.

6.0 Sharing Results with Subjects

Participants will receive a summary report comparing baseline and post-intervention results for weight, HbA1c, and dietary intake. Individual clinical results will be shared in writing.

7.0 Study Duration

Participation will last approximately 4 months and includes an orientation session, baseline and 3-month assessments, 12 weekly classes, and a focus group.

8.0 Recruitment Methods

8.1 Recruitment Strategies

Participants will be recruited using multiple methods including:

☒ Email

☒ Flyers

☒ News and media advertisements
☒ Community outreach events
☒ Online/Social Media Advertisement

Recruitment materials will provide a brief study description and direct interested individuals to complete an online eligibility screener.

8.2 Minimization of Undue Influence
Participation is voluntary. Recruitment materials will emphasize that individuals may decline or withdraw at any time without penalty.

9.0 Inclusion and Exclusion Criteria
9.1 Inclusion Criteria
- Self-identify as African American
- Age 18–65 years
- BMI 25–49.9 kg/m^2
- ≥3 risk factors for type 2 diabetes
- Internet access and ability to attend virtual sessions

9.2 Exclusion Criteria
- Diagnosed diabetes
- Pregnancy or breastfeeding
- Current participation in a weight loss program
- Recent significant weight loss (>10 lbs)
- Major medical or psychiatric conditions that would interfere with participation

10.0 Withdrawal of Subjects
Participants may withdraw at any time. Investigators may withdraw participants for safety concerns, pregnancy, or failure to complete study procedures.

11.0 Risks to Subjects
Risks include minimal discomfort from finger-stick blood sampling, potential emotional discomfort during group discussions, and risk of breach of confidentiality.

12.0 Potential Benefits to Subjects or Others
Participants may experience improvements in dietary quality and cardiometabolic health. The study may benefit society by informing culturally relevant nutrition interventions.

13.0 Data Management and Confidentiality
Data will be identified by unique study ID numbers and stored on encrypted servers. Access will be restricted to authorized study personnel.

14.0 Provisions to Monitor Subject Safety
This study involves minimal risk. Adverse events will be monitored and reported to the IRB as required.

15.0 Subject Costs and Compensation

Participants will receive up to $50 for completing study assessments and the focus group. No additional costs beyond transportation are anticipated.

16.0 Statistical Analysis Plan

16.1 General Analytic Principles

All statistical analyses will be conducted according to the intention-to-treat principle, whereby all randomized participants will be analyzed in the groups to which they were assigned regardless of adherence to the intervention. Statistical tests will be two-sided with a significance level set at $\alpha = 0.05$. Analyses will be performed using SAS statistical software (version 9.4 or later). The study statistician will remain blinded to group assignment during primary analyses.

Baseline characteristics will be summarized using descriptive statistics. Continuous variables will be reported as means and standard deviations, and categorical variables will be summarized using frequencies and percentages. Baseline comparability among intervention groups will be evaluated using one-way analysis of variance for continuous variables and chi-square tests for categorical variables. These baseline comparisons are descriptive in nature and will not be used to determine eligibility for covariate adjustment unless clinically meaningful imbalances are observed.

16.2 Primary Outcome Analyses

The primary outcomes of this study are change in body weight (kg), hemoglobin A1c (HbA1c; %), and Healthy Eating Index (HEI) score from baseline to 12 weeks. These outcomes will be analyzed using repeated-measures mixed-effects models with maximum likelihood estimation. Fixed effects in each model will include time (baseline and 12 weeks), intervention group (Healthy U.S.-Style, Mediterranean, and Vegetarian), and the group-by-time interaction. The group-by-time interaction will serve as the primary test of intervention efficacy.

Robust computation of standard errors will be employed to account for potential violations of distributional assumptions. The mixed modeling framework incorporates all available data under the assumption that missing data are missing at random (MAR) and allows for unbiased parameter estimation in the presence of incomplete follow-up data. No single imputation methods, such as last observation carried forward, will be used.

If the omnibus group-by-time interaction is statistically significant, planned contrasts will be conducted to compare mean changes at 12 weeks between specific diet groups. These comparisons will include Mediterranean versus Healthy U.S.-Style, Vegetarian versus Healthy U.S.-Style, and Mediterranean versus Vegetarian. Estimated mean differences and 95% confidence intervals will be reported.

16.3 Secondary Outcome Analyses

Secondary outcomes include systolic blood pressure, diastolic blood pressure, total energy intake, and macronutrient intake (carbohydrates, fat, and protein). These outcomes will be analyzed using the same repeated-measures mixed-effects modeling approach described for the primary outcomes. Fixed effects will include time, group, and the group-by-time interaction.

Within-group changes over time will also be estimated to describe the magnitude and direction of changes within each dietary pattern. When appropriate, post-hoc pairwise comparisons will be conducted with adjustment for multiple comparisons using Tukey procedures to control the family-wise error rate.

16.4 Sample Size and Power Considerations

The study was powered based on change in Healthy Eating Index (HEI) score. Based on prior research examining dietary pattern interventions, a pooled standard deviation of approximately 9 HEI points was assumed. With a target enrollment of 21 participants per group, allowing for anticipated attrition, the study provides 95% power to detect a between-group difference of 10 HEI points and 80% power to detect a difference of 7.5 HEI points at a two-sided alpha level of 0.05. Although changes in body weight and HbA1c are clinically meaningful outcomes, the primary statistical powering was based on dietary quality improvement given the short-term duration of the intervention and the study's role in informing the refinement of a longer-term trial.

17. Safety Monitoring and Adverse Events

This study is considered minimal risk, as it consists of behavioral dietary counseling and non-invasive clinical assessments. Participant safety will be monitored throughout the study period. Any adverse events reported by participants or observed by study staff will be documented and reviewed by the Principal Investigator.

Serious adverse events will be reported to the Institutional Review Board (IRB) in accordance with institutional and federal regulatory requirements. The study is overseen by an independent Data Safety and Monitoring Board (DSMB) that periodically reviews study progress, retention, protocol adherence, and safety data. The DSMB will make recommendations regarding continuation or modification of the study if safety concerns arise.

18. Data Management and Confidentiality

Each participant will be assigned a unique study identification number. Identifiable information will be stored separately from research data and will be accessible only to authorized study personnel. Electronic data will be maintained on secure, password-protected university servers with restricted access. Any physical records will be stored in locked cabinets within secured research facilities.

Quality control procedures will include verification of anthropometric measurements, laboratory values, and dietary recall completeness. The analytic dataset provided to the study statistician will be de-identified and coded using study ID numbers only. All data management procedures will comply with institutional policies and applicable federal privacy regulations.

19. Dissemination of Results

Study findings will be disseminated through publication in peer-reviewed scientific journals and presentation at national and international conferences. Authorship will follow accepted academic

guidelines. Participants will receive a summary of overall study results upon completion of data analysis.

Data sharing will be conducted in accordance with NIH data sharing policies and institutional requirements. De-identified datasets may be made available to qualified investigators upon reasonable request and completion of appropriate data use agreements.

20. Registration and Regulatory Compliance

The study is registered at ClinicalTrials.gov under identifier NCT04981847. All study procedures were reviewed and approved by the Institutional Review Board at the University of South Carolina prior to initiation. Written informed consent was obtained from all participants before participation in any study-related procedures.

The trial is conducted in accordance with the ethical principles of the Declaration of Helsinki and in compliance with Good Clinical Practice guidelines. All research personnel completed required human subjects protection and Good Clinical Practice training prior to engaging in study activities.