STATISTICAL ANALYSIS PLAN

SPICE UP MyPlate - Strategy for Promoting Intake of Delicious Healthful Dietary Patterns Based on MyPlate: A Pilot Study

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1. Administrative information

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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.

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

Cardiovascular disease (CVD) is the number one cause of death and disability worldwide and accounted for 33% of all deaths and 16% of disability adjusted life-years in 2019.[1] Notably, poor diet quality accounts for a substantial proportion of CVD-related death and disability. Worldwide and in the U.S., poor diet quality is the leading risk factor for all-cause death.[1,2] Globally, 22% of all deaths are diet-related, although 53% of CVD deaths are attributed to dietary risks.[3] In the U.S., 18% of deaths are attributed to dietary risks, with 48% of CVD deaths associated with poor diet quality.[3] Consistently, epidemiological evidence shows higher diet quality is associated with lower risk of CVD.[4–6] Thus, strategies to improve diet quality are needed to reduce the burden of CVD.

Diet quality as assessed by the Healthy Eating Index (HEI) is suboptimal in the U.S.[7] The HEI assesses adherence to the Dietary Guidelines for Americans. The maximum attainable score for the HEI is 100; a higher score represents greater adherence to the Dietary Guidelines for Americans and higher diet quality. Based on the most recent data for the U.S. (NHANES 2015–2016), the mean Healthy Eating Index-2015 (HEI-2015) score for Americans ≥2 years of age is 59 out of 100.[7] In adulthood, the mean HEI-2015 score for the 19–30 years group was 56 with slightly higher scores observed for the 31–59 age group (59 points) and the 60+ age group (63 points). In the U.S., at the population level, diet quality is poor across all adult life stages. Higher diet quality is associated with lower risk of cardiometabolic diseases, thus approaches to incrementally increase diet quality are needed.

These approaches need to be based on health behavior theory and take into consideration the key drivers of food choice and intake. Nutrition education is typically underpinned by the Health Belief Model whereby the focus is on providing a cue to promote awareness of disease risk to increase readiness to make change. However, a limitation to this approach is that potential health risks/future health status are not motivators of behavior change for everyone and diet is a complex behavior with many potential enablers and barriers to change. It is established that key determinants of food choice are taste and food enjoyment. Unfortunately, the perceived poor taste of healthier foods is a known barrier to intake and is described as the unhealthy = tasty intuition, which posits that the less healthy an item is portrayed to be, the better the inferred taste, and the more it is enjoyed.[8] Thus, culinary focused nutrition education may be an effective approach to move individuals through the stages of change (Transtheoretical Model) to adopt and maintain a healthy dietary pattern.

Studies conducted in dining settings show taste-focused labeling of healthy foods increases selection of healthy foods compared health focused labeling. Four field studies (total n=4273) conducted in several dining settings in northern California demonstrated that changing healthy food labels to emphasize taste and satisfaction rather than nutritional properties increased healthy food selection by 38% compared to health focused labeling.[9] Interestingly this study also showed that labeling healthy foods as tasty, compared to as healthy, enhances the taste experience when consuming healthy foods. Another study conducted in a university cafeteria showed labeling vegetables with indulgent descriptors (culinary focused eating experience related) significantly increased the number of people choosing vegetables and the total mass of vegetables consumed compared with basic (what the dish is) or healthy descriptions (highlights health attributes), despite no changes in vegetable preparation.[10] Finally, in a randomized controlled study conducted at 5 U.S. university dining halls it was demonstrated that taste focused labels increased vegetable selection by 29% compared with health-focused labels and by 14% compared with basic labels. Interestingly, increased expectations of a positive taste experience mediated the effect of taste-focused labels on vegetable selection.[11] Collectively, the results of these studies suggest that messaging based on the taste profile and experience of eating healthy foods may promote selection and intake to a greater extent than health focused messaging.

MyPlate is the current nutrition guide, published by the United States Department of Agriculture's Center for Nutrition Policy and Promotion (CNPP), that translates the Dietary Guidelines for Americans for the U.S. public. CNPP publishes numerous resources on their website to promote greater adherence to the Dietary Guidelines (www.myplate.gov). These resources are commonly used in nutrition education programs. These resources are health focused and include messages such as "A healthy eating routine is important at every stage of life. It can have positive effects that add up over time". In addition, most of the recipes included on the website use basic descriptors for the recipe name including "Apple & Chicken Salad" or "Apple Carrot Soup". Therefore, in the study we aim to assess the feasibility, acceptability, and potential effectiveness of nutrition education that emphasizes taste and enjoyment of healthy foods, rather than the health benefits of healthy eating. This

will be achieved by modifying MyPlate documents/resources to focus on choosing, preparing, and enjoying tasty foods. It is hypothesized that modifying nutrition education materials to put taste and enjoyment of food first will be acceptable to participants, participant engagement in the program will be high and trends towards improvements in adherence to the Dietary Guidelines for Americans will be observed compared to standard healthy eating education materials (i.e., MyPlate handout).

Dietary guidelines in many countries including the U.S., United Kingdom and Australia have recommended flavoring foods with spices and herbs as a strategy to reduce salt intake.[7,12,13] In the 2020-2025 Dietary Guidelines for Americans, it is stated that spices and herbs can help flavor foods when reducing added sugars, saturated fat, and sodium, and they also can add to the enjoyment of nutrient-dense foods, dishes, and meals.[7] Therefore, use of spices and herbs is a recognized strategy to improve taste, flavor and enjoyment of healthy nutrient-dense foods. In addition, Anderson et al.[14] showed that a behavioral intervention emphasizing herbs and spices lowered urinary sodium excretion (-957 mg/d; 95% CI -1539, -375) after 20 weeks compared to the control group that received no education. To date, no trials have assessed whether use of spices and herbs improves diet quality. Evidence on the effect of nutrition education + culinary education will inform the development of programs and guidelines to improve population diet quality. In addition, evidence on the effect of culinary education focused on taste enhancement using herbs and spices may result in specific guidance for use of spices and herbs as part of a healthy dietary pattern.

Specific Aims

To conduct a pilot study to assess the feasibility, acceptability, and potential effectiveness of culinary focused nutrition education to promote increased adherence to the Dietary Guidelines for Americans compared to standard low-intensity care.

Hypothesis

It is hypothesized that a 12-week nutrition education program based on the 2020-2025 Dietary Guidelines for Americans plus culinary education to use herbs and spices to flavor foods will be acceptable to participants, participant engagement in the program will be high and trends towards improvements in adherence to the Dietary Guidelines for Americans will be observed compared to standard healthy eating education materials (i.e., MyPlate handout).

3. Study Methods

Trial design

This is a 2-arm randomized controlled trial of free-living, generally healthy men and women and living in the State College, PA area. In a 1:1 ratio, participants will be randomized to the intervention arm or the control arm. The intervention group will receive a 12-week culinary focused nutrition education program, The control group will receive standard low-intensity

care. Outcome measures will be assessed at baseline and 15 weeks ±7 days in both groups. Participants in the intervention group will receive culinary focused nutrition education based on MyPlate with an emphasis on taste and enjoyment of healthy foods. Using herbs and spices to flavor foods will be the emphasis. The intervention will be delivered in an online format with online content delivery by email via REDCap. The intervention will consist of eight modules. Modules one to four will be provided during the first month. Modules four to eight will be provided during months 2 and 3. The control group will represent standard low intensity care.

Randomization method, allocation concealment, blinding

Group assignment will be randomized at the individual level. The allocation sequence will have block sizes of 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. At baseline testing, the study coordinator will use the randomization module in REDCap to reveal the participant's randomization. Participants and study staff involved in recruitment and data collection will not be blinded due to the nature of the intervention. Statistical analyses will be performed using a masked dataset (e.g., group labels A/B), with unblinding occurring after completion of the primary analyses.

Sample size estimate

Limited comparable data exist to inform a power calculation; therefore, 50 participants (25 per group) will be recruited based on convenience.

Hypothesis testing framework

The superiority framework will be used for hypothesis testing.

Null hypotheses:

1. Trends towards improvements in adherence to the Dietary Guidelines for Americans will not be observed compared to standard healthy eating education materials in a 12-week nutrition education program based on the 2020-2025 Dietary Guidelines for Americans plus culinary education to use herbs and spices to flavor foods.
2. A 12-week nutrition education program based on the 2020-2025 Dietary Guidelines for Americans plus culinary education to use herbs and spices to flavor foods will not be acceptable to participants compared to standard healthy eating materials.
3. Participant engagement in a 12-week nutrition education program based on the 2020-2025 dietary guidelines plus culinary education to use herbs and spices to flavor foods will not be high compared to standard healthy eating materials.

Interim analyses

No interim analyses will be performed.

Timing of outcome assessment

Outcomes will be assessed during the single-day baseline and endpoint visits. The endpoint visit will occur 15 weeks ± 7 days following the baseline visit.

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 given 30 days to complete three dietary recalls and several surveys. If all recalls and surveys are completed within the allotted timeframe, participants will be scheduled for their baseline visit and randomized. Participants must meet all the following inclusion criteria and none of the exclusion criteria to participate in the study.

Inclusion criteria

- Age 31-59 years
- Involved in meal cooking at home and consumes a home cooked meal ≥ 1 time per week
- Individuals taking medications for blood pressure, lipid or glucose lowering will be eligible if they have been on a stable dose for the 1 month prior to baseline

Exclusion criteria

- A member of the household is already enrolled (only one person per household will be eligible for inclusion in the study).
- Unstable medical conditions requiring active intervention (surgeries, medication/drug therapy for < 3 months) as assessed during the telephone screening (e.g. cancer, kidney disease requiring dialysis, heart or gastrointestinal diseases requiring surgery).
- Received nutrition education for a medical condition within the past 6 months
- Currently following a weight loss diet
- Lost ≥ 10% body weight in the past 6 months
- Currently (within 6 months) smoke or use any tobacco or nicotine containing products
- Currently pregnant or planning to become pregnant during the next 5 months
- Gave birth within the prior 6 months
- Participating in another clinical trial within 30 days of baseline
- Principal investigator discretion (e.g., disrespectful or inappropriate interactions with study staff)
- Does not speak or understand English
- Relocating out of State College, PA area within the next 5 months
- Unwilling to refrain from plasma/blood donation during the study

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 data collection visit
- Diagnosis of a serious medical condition requiring active intervention (e.g., cancer, cardiovascular disease).
- Pregnancy
- Unwilling and/or unable to adhere to the study requirements.

Presentation of baseline characteristics

Baseline demographic and clinical characteristics will be reported for the total analysis population and by randomization according to CONSORT guidelines.[14]

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

For all primary analyses, the between-group difference in the change from baseline for all outcome variables except program acceptability and satisfaction will be assessed. A sensitivity analysis will be conducted to examine between-group differences in endpoint means for continuous outcomes. Between-group differences in program acceptability and satisfaction will be assessed with chi-square test for proportions.

Primary outcome:

The primary outcome is change in diet quality assessed by the Healthy Eating Index-2015 (HEI-2015) between baseline and post intervention (assessed at 14-16 weeks). HEI-2015 scores will be calculated at each timepoint from three 24h dietary recalls using the per-person scoring algorithm, which derives a single HEI-2015 score for multiple 24h recalls.[15]

Secondary outcomes:

The secondary outcome variables will be

- Change in the HEI-2015 component scores between baseline and post intervention
- Changes in food group intake (fruits; vegetables; refined grains; wholegrains; dairy; meat, poultry, eggs; seafood; nuts, seeds and soy products; oils) between baseline and post intervention
- Changes in intake of added sugars, sodium and saturated fat between baseline and post intervention
- Change in weight between baseline and post intervention
- Change in waist circumference between baseline and post intervention
- Change in central and peripheral systolic and diastolic blood pressure between baseline and post intervention
- Change in PWV between baseline and post intervention
- Change in lipids and lipoproteins between baseline and post intervention
- Change in fasting glucose between baseline and post intervention
- Change in HbA1c between baseline and post intervention

- Program acceptability and satisfaction.

7. Statistical Analyses

Statistical model assumptions will be evaluated and confirmed prior to analyses for hypothesis testing being conducted, and where necessary transformations will be made to meet assumptions for normality. All primary analyses will follow intent-to-treat principles. The primary analyses will assess between-group change from baseline for all continuous repeated-measure outcome variables using linear regression (PROC GLM). Sex effects will be examined by including sex × group as a fixed effect. If the main effect of sex × group is non-significant, sex × group will be removed from the model. As a sensitivity analysis, between-group differences in endpoint means will be assessed using linear mixed models (PROC MIXED). Group assignment will be modeled as a fixed effect and study visit will be modeled as a repeated effect. When a 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. Selection of model covariance structures will be based on optimizing fit statistics (evaluated as the lowest Bayesian information criterion). Between-group differences in variables assessed only at endpoint (i.e., program acceptability and satisfaction) will be assessed with chi-square test for proportions. Data from continuous repeated-measure variables will be presented as least squared means ± SEM. Data from categorical endpoint variables will be presented as frequency and percentage of sample. Non-normally distributed data will be presented as geometric mean (95% confidence interval). Data from post-hoc testing will be presented as the pairwise mean difference and 95% confidence interval with the Tukey–Kramer adjusted P value. Statistical significance will be set at $p<0.05$. All analyses will be conducted with SAS 9.4 (SAS Institute, Cary, NC).

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