

**Community-Based Dietary Approach for Hypertensive African Americans  
with Chronic Kidney Disease**

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## JHM IRB - eForm A – Protocol

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### 1. Abstract

- a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

African Americans (AAs) are disproportionately affected by incident<sup>1</sup>, advanced<sup>2</sup> and progressive<sup>3</sup> chronic kidney disease (CKD); including a 3 to 4-fold greater risk of end-stage renal disease (ESRD) and earlier onset of ESRD<sup>4</sup> when compared to whites. Racial disparities in CKD are most profound among persons of low socioeconomic status (SES)<sup>5-7</sup>, and dietary factors (limited availability of healthy foods and unhealthy dietary patterns) likely underlie much of this disparity. Low SES AAs are more likely to experience food insecurity (the inability to afford nutritionally adequate and safe foods)<sup>8</sup> and live in “food deserts”<sup>9</sup>, which likely contributes to racial differences in dietary patterns. AAs with hypertension, a leading cause of CKD in the U.S., are less likely to follow a Dietary Approaches to Stop Hypertension (DASH) trial accordant diet than are whites<sup>10</sup>, despite AAs being shown to potentially receive the greatest blood pressure benefit from the DASH diet<sup>11</sup>. Further, AAs are less likely to follow diets rich in fruits and vegetables (base-inducing diets)<sup>12</sup>, despite recently emerging evidence that such dietary patterns may lead to favorable kidney outcomes<sup>13,14</sup> including reductions in markers of kidney damage (i.e. albuminuria).<sup>15,16</sup>

There is markedly lower availability of components of the DASH diet recommended foods, such as fresh fruits and vegetables, skim milk and whole grain foods, in predominantly AA and lower-income neighborhoods as compared with white and higher-income neighborhoods.<sup>17,18</sup> Personally-tailored interventions promoting the DASH diet while addressing barriers to accessing healthful foods could substantially lessen the burden of hypertension and CKD among low SES AAs.

We propose to build upon the encouraging results of our pilot study, “The Five-Plus Nuts and Beans Trial” (*Am J Prev Med*, 2015) which was conducted as a partnership between Johns Hopkins investigators, a community supermarket, the Baltimore City Health Department’s “Virtual Supermarket” program, a community-based clinic and a highly engaged Community Advisory Board. This trial tested the effects of a dietary approach to increase consumption of a central feature of the DASH diet--high potassium foods (fruits, vegetables, nuts and beans). A total of 123 AA patients with controlled hypertension recruited from a community-based clinic, were provided personalized dietary advice, assistance with grocery ordering and delivery, and \$30 per week worth of high potassium foods for an 8-week period. With this approach, we demonstrated statistically significant increases in consumption of fruits, vegetables, potassium, magnesium and fiber, and decreases in sodium intake. Also, there was a 14% reduction in urinary albumin excretion overall, and a 30% reduction among patients with significant albuminuria at enrollment. The trial had 100% follow-up on outcomes.

Our current proposal will build on the established partnerships, existing infrastructure and encouraging results of the pilot trial. We propose a longer (1 year) intervention, and the inclusion of AA participants with hypertension (controlled or uncontrolled) plus mild/moderate CKD—a population at very high risk of the adverse effects of diets low in potassium and high in sodium.

**2. Objectives** (include all primary and secondary objectives)

**Primary Objective:**

1. To test the hypothesis that delivery of nutritional advice to adopt the DASH diet and \$30 per week worth of potassium-rich foods, tailored to personal choices and availability in neighborhood stores of patients recruited from community-based clinics, will reduce urinary albumin excretion in low SES AAs with hypertension and CKD.

**Secondary Objectives:**

1. To determine if our intervention lowers blood pressure
2. To conduct exploratory analyses related to the effects of the intervention on:
  - a) subgroups defined by gender, age, diabetes status, and level of albuminuria
  - b) potential mediating variables (e.g. antihypertensive medication type, weight changes, etc.)
3. To pursue mobile platforms for food selections (i.e. smartphone applications)
4. To estimate direct costs of broadly implementing the intervention and conduct a cost analysis
5. To develop a dissemination plan with community partners to ensure sustainability

**3. Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Dr. Edgar (Pete) Miller and our study team led the pilot trial, the “Five-Plus Nuts and Beans” Trial which previously tested the impact of a community-based dietary intervention (*Am J Prev Med*, 2015). In this trial we tested the effectiveness of coach-directed dietary advice and assistance with weekly online ordering and purchasing of high potassium foods (\$30/week) delivered by a community supermarket to a neighborhood library, and tested other outcomes in urban African-American adults with controlled hypertension. We recruited patients from an urban primary care clinic in Baltimore MD and implemented the trial in partnership with a community supermarket and the Baltimore City Health Department. Advised to do so by our CAB/community partners, participants in the control group received a printed DASH diet brochure along with a debit account of equivalent value to that of the intervention (DASH-Plus) group at the same community supermarket. We randomized 123 participants and achieved 100% follow-up. At baseline, mean (SD) age was 58.6 (9.5) years, 71% were female, screening BP was 131.3 (14.7)/ 77.2 (10.5) mmHg, BMI was 34.5 (8.2) kg/m<sup>2</sup>, and 28% had diabetes. Self-reported fruit and vegetable intake of 3.5 (1.8) servings/day and estimated potassium intake of 2.7 (0.9) grams/day were well below recommended intakes. Compared to the control group, the DASH-Plus group increased self-reported consumption of fruits and vegetables by a mean (95% CI) of 1.4 (0.7, 2.1) servings/day and an estimated intake of potassium by 0.4 (0.1, 0.7) grams/day. DASH-Plus compared to control resulted in a significant increase in urine potassium excretion of 19% (1, 38)% and lower urine sodium excretion -20% (-38, -3)% (Figure 4). Also, there was a 14% reduction in albuminuria overall, and a 30% reduction among the subset of patients with significant albuminuria at enrollment. While we were underpowered to detect a BP effect at 8 weeks, we concluded that the Five-Plus intervention increased consumption of fruits and vegetables and excretion of urine potassium (an objective marker of potassium intake), and decreased excretion of urine sodium (an objective marker of sodium intake). Recognizing the needs of AAs with or at risk for CKD in Baltimore, and the lack of existing clinical trials of lifestyle modifications for AAs with CKD, we proceeded to develop an approach for AAs with both hypertension and mild/moderate CKD. Here, we describe plans for this intervention.

#### 4. Study Procedures

- a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

This study will be a single center, randomized controlled trial with 2 parallel arms to test the hypothesis that delivery of nutritional advice to adopt the DASH diet and \$30 per week worth of potassium-rich foods, tailored to personal choices and availability in neighborhood stores of patients recruited from community-based clinics, will reduce urinary albumin excretion in low SES AAs with hypertension and CKD. The primary outcomes are change in ACR as a marker of kidney damage and change in systolic SP. Secondary outcomes are other dimensions of blood pressure (DBP, lipid levels (total cholesterol, LDL-C, HDL-C, and triglycerides); glucose, and Framingham Risk Score.

We anticipate enrolling 150 self-identified African American adults who are above the age of 21 diagnosed with hypertension and mild/moderate CKD based on the presence of albuminuria [urinary albumin-to-creatinine ratio (ACR) >30 mg/g] with or without eGFR 30-59 ml/min/1.73m<sup>2</sup>. Based on the results of the Five-Plus pilot study, the ACT study and the CKD prevalence study by Dr. Crews et al<sup>19</sup>, we anticipate ~25-30% of those with hypertension will have albuminuria and would be eligible for participation. All 150 participants will be randomly assigned to one of two groups: 1) Self-Shopping DASH diet advice group (S-DASH) or 2) Coaching DASH diet advice group (C-DASH) with \$30/week allowance for the purchase of high potassium foods from a local grocer.

##### 1. Self-Shopping DASH diet advice Group (S-DASH):

###### Phase 1 (Months 0-4)

The S-DASH group will receive printed patient-centered materials on the DASH diet and chronic kidney disease. Participants will also receive \$30/week allowance for the purchase of the foods of their choosing from a local grocer (Klein's ShopRite stores of Maryland).

###### Phase 2 (Months 5-12)

S-DASH participants will be asked to continue to follow the dietary advice provided. They will not be provided a food allowance during this phase.

##### 2. Coaching DASH diet advice group (C-DASH):

###### Phase 1 (Months 0-4):

The C-DASH intervention will be a patient-tailored program, delivered by a study coach that is trained by a dietitian, which emphasizes key self-management behaviors – diet and self-monitoring. The C-DASH intervention will consist of a 1-hour one-on-one session with the study coach at randomization.

Thereafter, the study coach will meet with the participant at 1 month followed by phone calls only. Fifteen minute calls with participants will be weekly. During these interactions the study coach will build upon the participants' strengths and provide positive reinforcement of the progress being made.

The C-DASH group will purchase \$30 worth of fruits, vegetables, nuts and beans through the study coach to reach a certain goal of potassium intake daily. The target for purchases will be a goal of 17,000 mg/week of potassium in order to increase dietary intake of potassium to 4.7 grams per day (DASH diet target) based on an estimated daily baseline intake of 2.4 g/d in this population. ShopRite will provide free packaging of food orders and foods will be delivered for pick up to Sisters Together And Reaching (S.T.A.R.) community center on Milton Avenue or by arrangement.

**Phase 2 (Months 5-12):**

Participants will be maintained in their assigned group. The C-DASH group will be advised by the study coach on how to maintain the high potassium diet in their home food environment. Between months 5-12, there will be calls as needed, not to exceed six phone calls during Phase Two with the study coach. In addition to assessing diet and providing educational materials, the study coach will assist each participant in setting goals, provide advice and arrange follow-up to monitor progress. Customizable, literacy sensitive modules about nutrition, including the DASH diet, developed by our study dietitian, will be used by the study coach to guide the discussion.

**Participant Recruitment:**

For this trial, recruitment will be conducted at the Johns Hopkins Community Physicians Sites (e.g. East Baltimore Medical Center) and/or the Johns Hopkins Outpatient Center (JHOC). We plan to implement the following recruitment methods in order to meet our recruitment goals:

1. We will rely primarily on clinical databases (e.g. EPIC), sorted on age and diagnosis of hypertension; and on African American patients with hypertension who have previously participated in studies that included the investigators (Five Plus Nuts and Beans Trial (NA\_00051935) or Achieving Blood Pressure Control Together (ACT) trial (NA\_00078591), and who indicated willingness to be contacted for future studies. Additionally, patients under the direct care of the PI or co-investigators may be directly referred to the study if they have given their permission to be contacted by the study team.

a. For the patients described in #1 above, the study team will mail invitational letters, along with a stamped, self-addressed reply card. The addresses are typically available, either as part of the query of the clinical database or from the chart screening. There will be a check-box for participants to let us know if they are not interested in participating.

2. We plan to contact participants who do not have a direct clinical relationship with the physicians on the research team by pulling a list of potentially eligible participants from EPIC based on the inclusion criteria. We will then sort the list of eligible participants by provider at East Baltimore Medical Campus (EBMC). Once the sorted list has been generated, we will ask the EBMC providers to review the lists and indicate if any of their patients on the list should not be contacted for the study (e.g. patient had a recent severe illness). Once the providers have agreed on the list, we will then contact the potentially eligible participants.

3. We plan to contact individuals who respond 'yes' on the reply and those individuals who do not return the reply card. We will contact persons by phone in order to ascertain their level of interest. Our study coordinator, Jasmine Mensah, will be the primary contact. For those persons who express interest, we will then schedule the eligibility visit.
4. During the eligibility visit, participants will be approached by a study team member (Jasmine Mensah) in the privacy of an exam room at the patients' clinic, regarding their interest in participation in the study.

**Study Design** (Refer to Table 1 and Table 2 as references):

**Screening Visits:** The study visits will begin with two initial screening visits after recruitment to determine the eligibility and commitment to the research study. During the first two screening visits, the study research team will determine if the interested participant is eligible to participate in the study (see Inclusion/Exclusion criteria). The research team will proceed with discussing the protocol, and obtain consent for access to contact information, blood pressure measurements, medication and medical history review, obtaining weight measurements, review eating habits, collection of spot urine samples, and blood samples.

Once the informed consent has been obtained, the following tests and procedures will be done:

- review the informed consent form
- ask to provide medication and medical history
- dietary assessment (review eating and other habits)
- ask to provide contact information
- ask to provide demographic information
- collect weight measurements
- measure blood pressure
  - collect spot (random) urine samples:
    - the study team will carefully review instructions with the participant
    - measure the albumin, urine potassium, urine sodium and urine creatinine

**Randomization Visit:** Upon confirmation of eligibility and completion of an up to two month run-in and the informed consent process, participants will be randomized in a 1:1 ratio to the self-shopping DASH diet advice group (S-DASH) or the coaching DASH (C-DASH) diet advice group with \$30 per week in high potassium foods from a local grocer. Randomization will be performed using a web-based, password-protected, software set up to ensure authorized access to group assignment, restricted to designated study personnel. The randomization protocol will be in variable blocks (3 and 6) after stratification by gender, using the Moses-Oakford algorithm, adapted for SAS statistical software. The research team will convey randomization assignment to participants. At this study visit, the following will be obtained/performed:

- medication history review
- measure weight measurements
- measure blood pressure

**Follow-up Visit #1 (Month “1”):** The participant will be asked to come to a Johns Hopkins Community Physician Site (e.g. East Baltimore Medical Center) or the Johns Hopkins Outpatient Center for three in-person follow-up visits at 1, 4, and 12 month(s) after the randomization visit. At this study visit, the following will be obtained/performed:

- medication history review
- dietary assessment (review eating and other habits)
- measure blood pressure
- collect spot (random) urine samples:
  - The study team will review instructions with the participant
  - measure the albumin, urine potassium, urine sodium and urine creatinine
- collect blood samples:
  - collect 8.5 cc (less than 2 teaspoons) of blood. The study team will ask the participant not eat or drink anything except water before the blood sample is collected if he/she has not done so during the first screening visit.
  - measure the creatinine, potassium, glucose, and cholesterol.

**Follow-up Visit #2 (Month “4”):** This study visit will be identical to the Month “1” study visit. An additional urine sample will be collected within one month of the follow-up visit.

**Follow-up Visit #3 (Month “12”):** This study visit will be identical to Month “4” study visit.

**Telephone Calls:** If research participants are randomized to the C-DASH group, telephone calls will be included throughout the intervention of the study. To monitor and improve the study programs, we may record some interviews and may ask experts from the study to listen to some of the counseling sessions. In the first 4 months (Phase 1), the C-DASH group will have fifteen minute telephone calls with a study team member which will occur every week for the first two months, then bi-weekly for two months. In months 5-12 (Phase 2), the calls will occur every other week for the first 2 months, and then on a monthly basis for a total of no more than 6 calls.

**Questionnaires:** The study team will collect questionnaire data including a demographic/medical history questionnaire that provides a self-report of sociodemographic factors (e.g. age, gender, health insurance status, income, employment, education level, food insecurity), current health status (e.g. post-menopausal status, presence of diabetes, cardiovascular disease), and health habits (e.g. tobacco use). Medication use will be collected at baseline and during follow-up visits. The primary interest are medications used to treat hypertension, diabetes and hypercholesterolemia.

**Dietary Assessment:** Fruit, vegetables, fiber, sodium and potassium intake will be assessed at each visit using the Block Brief screener. The screeners are self-administered, it is used to assess intake over the preceding month, and estimates micronutrient intake including dietary potassium and sodium.

**Fasting glucose, lipids and uric acid:** Fasting blood collections will occur in the morning after a minimum 10 hour fast. Serum will be collected during screening visits, month 4, and month 12. From the fasting blood specimen, estimated GFR, glucose, total cholesterol (TC), HDL cholesterol (HDL), triglycerides, and potassium will be measured. LDL cholesterol (LDL-C) will be estimated by the equation  $(LDL=TC-HDL-triglyceride/5)$  54.

**Urinary sodium and potassium:** From the spot urine collections for urine albumin-to-creatinine samples, urine sodium and potassium excretion will be collected to estimate group compliance with dietary aspects of the intervention.

Table 1:

Questionnaires Table	Pre Screen	Phase 1 (0-4)					Phase 2 (5-12)
		SV1	SV2	RV	FV01	FV04	FV12
<b>Months</b>				<b>0</b>	<b>1</b>	<b>4</b>	<b>12</b>
Telephone Prescreening Script	X						
Informed Consent Form		X					
Contact Information	X	X	X	X	X	X	X
Demographic Questionnaire			X				
Medical History		X			X	X	X
Medication Questionnaire		X	X	X	X	X	X
Block Fruit, Veg, Fiber Screener			X			X	X
Block Na Screener			X			X	X
Food Security Questionnaire <sup>20</sup>			X				X
Short Housing Instability Questionnaire <sup>21,22,23</sup>			X				
Eating Habits Questionnaire			X				
Internet Use Survey <sup>5</sup> /Technology Use Survey <sup>24,25</sup>			X				
Depression Patient Health Questionnaire (PHQ-8) <sup>26</sup>		TH	X			X	
Generalized Anxiety Disorder Scale (GAD-7) <sup>27</sup>		TH	X			X	
Perceived Stress Scale (PSS-10) <sup>28</sup>		TH	X			X	
Discrimination Scale <sup>29</sup>		TH	X				
Height Measurement		X					
Weight Measurement		X		X		X	X
Blood Pressure Measurement		X	X	X	X	X	X
Comprehensive Metabolic Panel (fasting)			X		X	X	X
Hemoglobin A1c			X			X	X
Urine (Potassium, Sodium, Creatinine, and Albumin)		X	X		X	X <sup>2</sup>	X <sup>2</sup>

Table 1

Legend:

<sup>2</sup>: Participants will provide two urine samples at two different point of times

TH: Participants will take home documents to complete

## Study duration and number of study visits required of research participants

The study will require 6 in person visits and up to 25 telephone (15 minutes only) calls over the course of 12 months.

- b. Blinding, including justification for blinding or not blinding the trial, if applicable.

Participants will know their intervention assignments, as will study staff involved in delivering the interventions. However, study staff involved in follow-up data collection will be kept masked to participants' randomization assignments, and all intervention staff will be kept masked to participants' study measurements.

- c. Justification of why participants will not receive routine care or will have current therapy stopped.

Participants will continue with their routine clinical care without interruption.

- d. Justification for inclusion of a placebo or non-treatment group.

N/A. Our intervention group will be compared to a usual care group that receives \$30/week food allowance for 4 months.

- e. Definition of treatment failure or participant removal criteria.

Participants who develop an exclusion criteria (e.g. stages 4 or 5 of CKD) will be removed from the study prematurely and documented correctly.

- f. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

If a participant chooses to withdraw from the research study, study personnel will inform the participant that compensation from the study will be held, due to prematurely ending participation.

## 5. Inclusion/Exclusion Criteria

### Inclusion Criteria:

- Self-identified African American race
- Age 21 years or older
- Clinical diagnosis of hypertension and have a urine ACR of  $\geq 30$  mg/g with or without estimated GFR 30-59 ml/min/1.73m<sup>2</sup>.
- Must be under regular care with their JHCP or JHOC physician (seen within the past 12 months).
- Must have a systolic blood pressure of  $\leq 160$  mmHg and a diastolic blood pressure of  $\leq 100$  mmHg (average of two visits)
- Be on stable doses of antihypertensive medications for a minimum of two months prior to randomization.

**Exclusion Criteria:**

- Cardiovascular (CV) event within 6 months
- Chronic disease that might interfere with trial participation (e.g. stage 4 or 5 CKD, eGFR <30 ml/min/1.73m<sup>2</sup>)
- Unwillingness or inability to adopt a DASH-like diet
- Consumes over 14 alcoholic drinks per week
- Poorly controlled diabetes (Hemoglobin A1c >9%), or use of insulin.
- Patients with a serum potassium >4.6 mEq/L<sup>45</sup>
- Urine ACR ≥ 1,000 mg/g
- Unable to participate in the study protocol based on the discretion of the Principal Investigator
- Pregnant or trying to become pregnant

**6. Drugs/ Substances/ Devices**

- a. The rationale for choosing the drug and dose or for choosing the device to be used.  
N/A
- b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.  
N/A
- c. Justification and safety information if non-FDA approved drugs without an IND will be administered.  
N/A

**7. Study Statistics**

- a. Primary outcome variable

**Primary Outcome Variable:** The primary outcome variable for this study is change in albuminuria.

- b. Secondary outcome variables.

**Secondary Outcome Variable:** The secondary outcome variable for this study will be change in blood pressure, glucose, and weight.

- c. Statistical plan including sample size justification and interim data analysis.

The trial has sufficient resources and adequate power to enroll 150 participants, who will be randomly allocated in equal proportions to the 2 groups: **Group A:** Self-Shopping DASH (S-DASH) diet advice group. **Group B:** Coaching DASH (C-DASH) diet advice group. The primary contrast is the difference in the percent change in (B vs. A) in urine albumin excretion (Urine Albumin to creatinine ratio, mg/g: UA1b/Cr mg/g). We used the standard deviation of the percent difference in the Urine Alb/Cr (post-pre/pre) of 63% and 53% in the intervention arm and the control arm, respectively. These variance estimates are from our pilot study (Five, Plus Nuts and Beans) published in 2016. The pilot trial enrolled African American patients with hypertension (similar to our eligibility criteria). Although albuminuria was not an eligibility criterion, 17 of 123 randomized had albuminuria (UA1b/CR ≥30 mg/g).

Power calculations for our trial are based on a basic model that compares (4 month - baseline) differences among treatment groups (**Table**). The trial has 80% power to detect a treatment effect of 20% difference between arms at  $\alpha = 0.05$  if we enroll 150 participants. For this estimate, we set the correlation between baseline and follow-up at 80%. This is a conservative estimate as the correlations of the log Alb/Cr between pre and post measurements in the pilot trial was 0.92 and 0.82 in the intervention and the control group, respectively. The weaker correlation in the intervention group would be expected, as variability in response to treatment in this arm would be greater. These treatment effects are achievable. In the pilot trial, the effect size noted was a ~39% difference (N=17) between the 2 arms in the subgroup with UAlb/Cr  $\geq 30$  mg/g at baseline. In the ACT Trial (a second trial of blood pressure management strategies in African Americans with uncontrolled hypertension) we observed a 31% difference between arms in the subgroup of participants with UAlb/Cr  $\geq 30$  mg/g (N=34). Hence, our goal of achieving a 20% contrast is likely. As a secondary source of variance data we used SD of change data and sample size estimates published in 2016 (Sontrop JM et al., 2016) derived from a population of adults with CKD and based on a SD of change of 49% (less than what we observed)<sup>30</sup>. In that study they report that the sample size needed to detect a 20% difference in UAlb/Cr would be N=152 (correlation was not reported). Secondary analyses of effects on blood pressure and weight will be evaluated at the nominal  $\alpha = 0.05$  level. This trial is not powered to see an effect on these secondary outcomes, yet analyses of effect of the intervention on protocol driven BP and weight measurements will be assessed.

Net treatment effect, % difference in UAlb/Cr	Power for single test at $\alpha=0.05$	Sample size needed
20%*	0.8	148
25%*	0.8	96
20% **	0.8	152
*SD of %change is 63% and 53% in intervention and control arm, respectively (from 5+plus study). **SD of change of 49% (Sontrop JM et al., 2016)		

### Analysis Plan

This trial is a randomized trial that tests the effects of an innovative intervention against a minimal intervention on a selected set of outcomes. The primary contrast is (A vs. B) in Urine albumin excretion (**Primary Specific Aims**). For secondary analyses, we will test the contrast for reducing blood pressure, glucose, and weight (**Secondary Aim**). The analysis will be conducted under the intent-to-treat principle for both the Primary and the Secondary Aims before any supplemental analyses are conducted.

For the **Primary Aim**, groups will be compared using within-person differences in outcome levels obtained on those diets. Because we anticipate some dropouts (although there were none in the pilot), we will conduct our primary analysis using mixed effects modeling (likelihood) and multiple imputation approach under the missing at random (MAR) assumption. We will adjust for baseline UAlb/Cr which should increase our power and account for any power lost by drop-outs. We will then carefully examine all available data and build sensitivity analyses using clinically sensible missing scenarios to evaluate the potential impact by non-ignorable missing data. A parallel approach will be used for **Secondary Outcomes**. Distribution of data will be checked and transformed where appropriate. Other outcome variables will be analyzed with a similar approach. Adjustments for baseline variables will be made, where appropriate, in multivariable analyses. Ninety-five percent confidence intervals of the estimated mean differences will be constructed for each outcome.

## 8. Risks

- a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

**Blood Draw:** Taking blood may commonly cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is also a small risk of infection at the draw site.

**Increase in Levels:** Participants with diabetes may increase their blood glucose levels from the various fruit, grains and vegetables consumed throughout the study. We will take measures to reduce the risk of this by not including food items particularly high in sugar (i.e. fruit juices) in the options for the intervention (C-DASH) group.

- b. Steps taken to minimize the risks.

In order to minimize the risks during the study, study personnel will provide instructions for the participants and answer any questions that may arise.

**Severe Chronic Kidney Disease:**

We will exclude participants with stage four or five CKD. During screening visits, we will measure urine ACR prior to enrolling interested participants.

**Uncontrolled Diabetes and/or Use of Insulin:**

We will exclude participants who exemplify uncontrolled diabetes or use of insulin. Study personnel will obtain medical and medication history.

**Increase Potassium Levels:**

The study team will check the chemistry panel (serum potassium) to ensure potassium levels are in range. We will measure potassium levels throughout the study from blood samples.

- c. Plan for reporting unanticipated problems or study deviations.

Risk events, problems, and deviations will be reported by the PI directly to the IRB.

- d. Legal risks such as the risks that would be associated with breach of confidentiality.

There is a small potential risk to confidentiality. Most participant related data will be stored on an electronic database (encrypted and secured). If members of other Federal Agencies and IRB need to inspect potential trial records and documents, they will be release. Complete confidentiality cannot be guaranteed.

- e. Financial risks to the participants.

There will be no financial risks to the participants. The study will pay for groceries, tests (urine and blood) and allowance from Klein's Shoprite stores of Maryland.

## 9. Benefits

- a. Description of the probable benefits for the participant and for society.

We hope that the adoption of the DASH diet along with nutritional advice will help reduce hypertension and prevent kidney damage in individuals who are diagnosed with hypertension and CKD by the end of this trial. There might be improvement in lowering systolic blood pressure.

There is a larger benefit to the African American population as a whole, such that if there is a way to have more access to healthier food choices, many individuals can prevent and/or reduce these diseases that affect low SES African American communities.

**10. Payment and Remuneration**

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

**S-DASH Group:**

During Phase one (months 0-4) the S-DASH group will receive a \$30/week allowance for the purchase of foods of their choosing from the local grocer (Klein's ShopRite stores of Maryland). During Phase one (months 0-4), the allowance will be for a total of up to \$480.00. The S-DASH group will not receive \$30/week allowance during Phase two (months 5-12).

**C-DASH Group:**

The C-DASH group will also receive \$30/worth of fruits, vegetables, nuts, and beans through the study coach and Klein's Shoprite stores of Maryland. During Phase one (months 0-4), the allowance will be for a total of up to \$480.00. Similar to the S-DASH group, the C-DASH group will not receive \$30 worth of fruits, vegetables, nuts, and beans during Phase two (months 5-12).

**11. Costs**

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

Study participants will not be responsible for any study related costs.

## 12. References

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