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

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PI Name: Deidra Crews

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 incident¹, advanced² and progressive³ chronic kidney disease (CKD); including a 3 to 4-fold greater risk of end-stage renal disease (ESRD) and earlier onset of ESRD⁴ when compared to whites. Racial disparities in CKD are most profound among persons of low socioeconomic status (SES)⁵⁻⁷, 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)⁸ and live in “food deserts”⁹, 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 whites¹⁰, despite AAs being shown to potentially receive the greatest blood pressure benefit from the DASH diet¹¹. Further, AAs are less likely to follow diets rich in fruits and vegetables (base-inducing diets)¹², despite recently emerging evidence that such dietary patterns may lead to favorable kidney outcomes^{13,14} including reductions in markers of kidney damage (i.e. albuminuria).^{15,16}

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.^{17,18} 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/m², 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/1.73m². Based on the results of the Five-Plus pilot study, the ACT study and the CKD prevalence study by Dr. Crews et al¹⁹, 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 or Remington) the Johns Hopkins Outpatient Center (JHOC) and the Johns Hopkins Prohealth Clinical Research Unit. 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) and Johns Hopkins Remington. Once the sorted list has been generated, we will ask

Johns Hopkins 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
Months				0	1	4	12
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 ²⁰			X				X
Short Housing Instability Questionnaire ^{21,22,23}			X				
Eating Habits Questionnaire			X				
Internet Use Survey ⁵ /Technology Use Survey ^{24,25}			X				
Depression Patient Health Questionnaire (PHQ-8) ²⁶		TH	X			X	
Generalized Anxiety Disorder Scale (GAD-7) ²⁷		TH	X			X	
Perceived Stress Scale (PSS-10) ²⁸		TH	X			X	
Discrimination Scale ²⁹		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 ²	X ²

Table 1

Legend:

²: 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 ≥ 30 mg/g with or without estimated GFR 30-59 ml/min/1.73m².
- Must be under regular care with their JHCP or JHOC physician (seen within the past 12 months).
- Must have a systolic blood pressure of ≤ 160 mmHg and a diastolic blood pressure of ≤ 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/1.73m²)
- Unwillingness or inability to adopt a DASH-like diet
- Consumes over 14 alcoholic drinks per week
- Poorly controlled diabetes (Hemoglobin A1c >9%)
- Patients with a serum potassium >4.6 mEq/L⁴⁵
- 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: UAlb/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 (UAlb/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 ≥ 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 ≥ 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)³⁰. 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

We will exclude participants who exemplify uncontrolled diabetes. 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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Ancillary Study: Barriers and Facilitators to Healthy Eating through the Perspectives of Hypertensive African Americans Living in Baltimore: A PhotoVoice Project

13. Abstract

African American neighborhoods are often characterized by fewer supermarkets, more fast food outlets, poorer quality goods, longer travel distances, less fresh produce, and higher prices for nutritious foods. This complex set of barriers may make it difficult for individuals to participate in healthy dietary behaviors, while access concerns may present additional psychological burden. The goal of this ancillary study is to characterize the food environment, including barriers and facilitators to healthy eating, through the lens of African Americans with or at risk for chronic kidney disease (CKD). Findings from this participatory approach may be used to raise awareness among policy-makers and other stakeholders regarding the lived experiences of community members, their food environments, and potential leverage points for facilitating healthy dietary behaviors and, subsequently, improving health outcomes among African Americans.

14. Objectives (include all primary and secondary objectives)

Objective 1: To use Photovoice, to characterize the food environment of the parent study target population through the voice of African Americans with hypertension and with or at high risk for CKD.

Hypothesis: Qualitative exploration of the food environment will provide important context for interpreting quantitative results of the parent study and the proposed ancillary study.

Hypothesis: Visual products of the Photovoice process will provide compelling evidence to facilitate policy discussions among stakeholders regarding Baltimore's food environment and chronic disease outcomes.

15. Background

Poor food environment and food insecurity among African Americans represent determinants of chronic disease disparities by race/ethnicity. Social stressors, such as food insecurity, may impact chronic physical and mental health outcomes, including hypertension, hyperlipidemia, diabetes as well as depression and anxiety.^{8,9} Addressing food insecurity—the state of being without reliable access to sufficient quantity of affordable, nutritious food—may have a host of health benefits. An estimated 22.5 percent of AA households are food insecure compared to white, non-Hispanic households (9 percent).¹⁰ This food insecurity occurs within the context of food environments of predominantly AA neighborhoods, which are often characterized by fewer supermarkets, more fast food outlets, poorer quality goods, longer travel distances,^{11,12} less fresh produce,¹³ and higher prices for nutritious foods.¹¹ Although it is known that the presence of a supermarket could lead to a 32 percent increase in fruit and vegetable consumption among AAs,¹⁴ this complex set of barriers may make it difficult for individuals to participate in these healthy behaviors, while access concerns may present additional psychological burden.

We propose this ancillary Photovoice study to examine barriers and facilitators to healthy eating through the perspectives of African Americans with or at risk for CKD and to further contextualize the food environment of study participants. Findings will help build the evidence base for scaling up to a more broadly applicable health equity solution on the population level. Further, the participatory research components of this project will engage business and policy stakeholders towards a sustainable community-based solution.

16. Study Procedures

Photovoice is a community-based participatory research tool that uses photography to engage participants in reflection and dialogue regarding their community's strengths, needs, and capacity for social change. The use of Photovoice in formative research and community development is well documented.¹⁸ It is an effective tool for advancing participant voice¹⁹ and for engaging participants, policy-makers, and other stakeholders in discussions regarding the food environment.²⁰⁻²⁴ We will use qualitative data and photos obtained via Photovoice to engage multiple stakeholders in conversations regarding Baltimore's food environment. The goal will be to identify how to apply effective dietary strategies as sustainable population health solutions.

We will conduct a Photovoice project over the course of the study period. First, we will pilot the Photovoice approach in this population by inviting previous participants of the *Five Plus Nuts and Beans* pilot study who indicated a willingness to be recontacted about future studies. Pilot study participants will be eligible for the Photovoice project if they: 1) live in Baltimore, MD; 2) are able to manage a camera; and 3) agree to participate in 5 group sessions over the course of three months (an opening session, 3 smaller group sessions, and a closing session). Participants will be provided free parking and meals during mandatory group sessions.

After camera training, participants will cover the following over the course of 5 sessions which we will audiorecord for documentation purposes (**Table below**): 1) How would you describe your food environment?; and 2) What barriers or facilitators do people in your community face regarding eating a healthy diet? using the SHOWED²⁵ framework (**See Attachment 1**)—What do you See here? What is really Happening? How does this relate to Our lives? Why does this problem or strength Exist? What can we Do about it?²³

Session 1	<ul style="list-style-type: none"> • Explain project aims and scope • Distribute cameras • Collect demographic information on participants • Provide an overview of group sessions schedule • Provide instructions on subject consent • Provide one-hour photography workshop • Invite subjects to take pictures of their food environment over the next week
Sessions 2-4	<ul style="list-style-type: none"> • Small group breakouts to discuss selected participant-produced photograph using the SHOWED method <p>What do you <u>See</u> here? What is really <u>Happening</u>? How does this relate to <u>Our</u> lives? <u>Why</u> does this problem or strength <u>Exist</u>? What can we <u>Do</u> about it?</p>
Session 5	<ul style="list-style-type: none"> • Introduce small groups to each other • Provide each participant with a parting gift (e.g., a personal portrait) and acknowledgement of their work • Discuss next steps

4.A Recruitment and Consent

For this ancillary study, we will recruit 30 participants identified through the electronic record at participating clinics (e.g. East Baltimore Medical Center, Johns Hopkins Outpatient Center and JHCP-Remmington) who meet initial demographic—age (21 years or older), race (African American), and clinical criteria (hypertension) for the parent *Five Plus Nuts and Beans for Kidneys* study, but on further screening are found to be ineligible (e.g. urinary albumin-to-creatinine ratio <30mg/g). The number of participants typically included in a Photovoice project ranges from 4 to 122 (median 13).¹⁸ Approximately 25 percent of patients identified via the electronic health record and who complete the initial telephone and in person screening are expected to screen as eligible for the parent study, leaving the other 75 percent available for Photovoice recruitment. We will target 30 participants divided into six 5-member Photovoice discussion groups.

These individuals will have already consented to participate in the parent study and also agreed to be recontacted for other studies in the future. After the participant has been determined to be ineligible for the parent study based on the criteria above, the ancillary study research assistant will read a script inviting the participant to participate in the ancillary study (**See Attachment 2**).

4.B Obtaining Laboratory Specimens

There are no laboratory specimens collected for this ancillary study.

- g. Study duration and number of study visits required of research participants.

The ancillary study will be comprised of 6 cohorts of 5 participants over the course of 12 months. Each cohort will participate in five sessions over the course of 8 weeks.

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

This ancillary study is not a randomized trial, and will be a non-blinded observational study using qualitative methods.

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

Ancillary study participants will continue to receive their current, routine care.

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

Not applicable, as the Photovoice ancillary project is an observational study.

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

N/A

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

Photovoice ancillary study participants will continue their usual care during and after the study.

17. Inclusion/Exclusion Criteria

Inclusion Criteria: Participants who consented to participate in the *Five Plus Nuts and Beans for Kidneys* study, who: 1) were determined to be ineligible for the parent study; and 2) agreed to be recontacted for invitations to participate in other research studies in the future.

Exclusion Criteria: Individuals with the inability to operate a camera or view photos will be excluded (e.g., visual impairments). Individuals who are unwilling or unable to complete all five sessions will be excluded.

18. Drugs/ Substances/ Devices

N/A

19. Study Statistics

This study is qualitative and does not involve statistics.

Statistical Considerations: Analysis Plan: We will perform a participatory data analysis engaging Photovoice participants throughout the research process.²⁶ In this approach, participants will identify five photos, analyze them using the SHOWED framework (**See Attachment 1**), and Photovoice small groups will work together to sort and categorize emerging themes from their photos. Investigators will further analyze participant categories into themes within and across groups. Using an inductive approach, all project members will collaborate to identify themes and commonalities from the group discussion session transcripts and notes. Thematic patterns in collected data will be investigated using available qualitative data analysis software. These broader themes will be checked for accuracy by Photovoice participants and they will share control over which themes are depicted and which photographs are presented.

Photovoice participants will be included in the dissemination of these findings in 3 ways. First, the Photovoice presentation will serve as an educational tool in the community and among *Five Plus Nuts and Beans for Kidneys* participants at an event at the conclusion of the parent study (to avoid intervention contamination). Secondly, the participatory research experience will include a separate exhibition of photos at the end of the Photovoice project, where participants, community partners, and local policymakers will be invited to participate in open discourse regarding themes that surfaced from the photographs. Finally, participants will be asked to contribute one or more of their photos and captions to share on display during future stakeholder engagement events of the parent study and the Johns Hopkins Center for Health Equity.

d. Early stopping rules. Not applicable.

20. Risks

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

None

g. Steps taken to minimize the risks.

N/A

h. Plan for reporting unanticipated problems or study deviations.

N/A

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

Participant confidentiality will be maintained at all times. By participating in groups, participants will be asked to share personal information to others whom they may or may not know during sessions.

All efforts will be made to minimize risks to the subjects. All study team members will have completed required training in human subjects' research, ethics of conducting research and privacy of health information prior to the start of the study. At the time of informed consent, participants will be informed that all efforts will be taken to maintain their privacy. Prior to groups beginning, the focus group moderator will ask individual participants about their comfortability with sharing information with others present for the group. If participants express concerns, we will offer them the option to cease participation prior to the group starting. The small group meetings will result in notes regarding the discussion of the photographs using the SHOWED framework (Attachment). No unique identifiers will be maintained in notes of group proceedings.

- j. Financial risks to the participants.

None, participants will be compensated for their time.

21. Benefits

- i. Individual participant: A participant in the Photovoice ancillary study may obtain new knowledge about their food environments. In addition, they may benefit from engaging with other participants in the study who represent similar medical and environmental backgrounds.

- ii. Society: Participation in the Photovoice ancillary study may benefit society as a whole if the photographical products engage stakeholders in broader conversations regarding food environments in Baltimore. Additionally, the findings from this ancillary pilot study may lead to new knowledge on the how African Americans in Baltimore view barriers and facilitators to eating a healthy diet in the city.

22. Payment and Remuneration

Participants of this ancillary study will receive meals at the Photovoice small group sessions and will be provided parking passes and cab vouchers. There will be no penalties for not completing the protocol.

23. Costs

There is no cost associated with participating in the study.

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Ancillary Study: Experiences of Participants Who Completed the 5 Plus Nuts and Beans for Kidneys Study

24. Abstract

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

The main trial for this ancillary study tests a novel, multi-component intervention consisting of coach-directed dietary advice and assistance with weekly ordering and purchasing of high potassium foods (worth \$30/week) during Phase 1. This intervention (C-DASH) is believed to modify eating behaviors that will lead to improved biomarkers of CKD. Then, during Phase 2 of the study, intervention supports are reduced or removed. The ability of participants to sustain the behavioral changes acquired in Phase 1 may be challenging. These challenges are compounded when access to healthy foods is poor, a common reality among many of the study participants. While the C-DASH and S-DASH (control) groups may experience similar barriers and facilitators in adhering to the dietary recommendations, we hypothesize that C-DASH participants will have had experiences and challenges unique to the transition from Phase 1 to Phase 2. This ancillary study aims to elucidate the perceived barriers and facilitators of healthy eating for the study population as a whole, as well as the perceived effective components of the intervention, using qualitative research methods. Understanding these factors could identify crucial components that can enhance and sustain improvements in dietary behavior and disease markers in future studies.

25. Objectives (include all primary and secondary objectives)

The primary objective of this ancillary study is to identify key themes surrounding factors that facilitated or impeded participants' ability to adhere to the dietary guidance presented in the 5 Plus Nuts and Beans for Kidneys study.

The secondary objectives are:

- a. to inform and enhance the dissemination of the main study findings by highlighting the participants' perceived facilitators and impediments encountered during the study;
- b. to identify barriers to modifying dietary behaviors that can be addressed in the design of future effectiveness studies; and
- c. to identify facilitators to modifying dietary behaviors that can be incorporated into the development of future interventions

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

Adherence to the Dietary Approaches to Stop Hypertension (DASH) and other similar dietary patterns have demonstrated kidney-related benefits. However, many African Americans with low socioeconomic status (SES) face barriers to healthful eating, including food insecurity (the inability to afford nutritionally adequate foods) and lack of healthy food options in neighborhood stores. These factors likely contribute to low SES African Americans' greater risk of advanced and progressive CKD.

Our research group has conducted a series of quantitative and qualitative studies regarding health disparities among low SES African Americans who have hypertension and, or were at risk for,

CKD. Specifically, we published a qualitative study of low SES African Americans with multiple clinical risk factors for CKD. The themes that emerged included multiple perceived barriers to healthful dietary changes that might reduce risk of developing CKD. Moreover, none of the study participants had prior knowledge of the DASH diet, despite 53% reporting a diagnosis of hypertension.¹ Concordant with our other findings, mention of the DASH diet was uncommon (12%) during primary care visits by hypertensive African Americans in Baltimore.² Furthermore, only 14.5% of participants in a behavioral intervention trial of African Americans with uncontrolled hypertension had 5 of the DASH food categories in their homes (fruits, vegetables, low fat dairy, whole grains, and plant proteins).³ Approximately 30% of this sample also had CKD (unpublished data).

Building upon this body of work, the main study of this protocol (5 Plus Nuts and Beans for Kidneys) tests an intervention that specifically addresses aspects concerning knowledge of DASH and food insecurity among low SES African Americans with hypertension and CKD. The first ancillary study of the 5 Plus Nuts and Beans for Kidneys study (A PhotoVoice Project) is a qualitative study that characterizes the food environment of the study target population and the results are currently being analyzed. This second proposed ancillary study will help to develop more effective supports in future interventions, as well as provide important information for the dissemination and sustainability of these efforts into the broader community.

27. Study Procedures

This ancillary study is designed to elucidate the experiences of participants who completed a clinical trial on the effect of the C-DASH intervention on CKD progression. The study consists of a one-time, 30 to 45 minute, semi-structured qualitative phone interview.

1. Sample Size and Participant Recruitment

As of April 2020, 47 participants have completed the 12-month 5 Plus Nuts and Beans for Kidneys study. We expect that a total sample size of at least 25 participants (~12 from each study arm) will lead to thematic saturation (the point at which interview participants collectively begin to provide repeated responses to interview questions)⁴ of important topics related to the main study. We anticipate that almost all of the individuals who completed the study to-date and who agreed to be contacted for future studies will enroll in this ancillary study.

Research staff will recruit potential participants by telephone. After several unsuccessful attempts by phone, research staff may send a recruitment letter using the last known address on file (uploaded to Section 13 (7)). Research staff will briefly describe the study using the recruitment telephone script (uploaded to Section 13 (7)). If the participant is interested, research staff will proceed to the oral consent process.

2. Consent process

Research staff will read the verbal consent script over the telephone, paraphrasing as needed, and provide opportunities for the individual to ask and have questions answered. The oral consent script has been uploaded to Section 16 (2.0).

3. Semi-structured interviews

After obtaining verbal consent, interviews will be scheduled and conducted over the

telephone or computer (see below). The interview will take approximately 30 to 45 minutes to complete. Trained research assistants will conduct interviews using an interview guide to ensure consistency in data collection. The interviewers will follow interview guides specific to the participants' study arm during the 5 Plus Nuts and Beans for Kidneys main trial.

The interview consists of primarily open-ended questions that require participants to elaborate beyond 'yes/no' responses, and allows us to explore actual participant perspectives in their own terms.^{5,6} The majority of interview questions pertain to all study participants, however, some of the questions are specific to and asked only of the S-DASH or the C-DASH participants. The Interviewer's Guides have been uploaded to Section 20 (2).

4. Audio-recording procedures

Research staff will audio-record interviews remotely through the Zoom conferencing platform within the Hopkins-supported SAFE desktop. Only the audio component of the Zoom platform will be used for the interview. The research assistant will initiate the invitation to the participant who will then be able to connect at the scheduled time by dialing in through a phone or via Zoom link on a personal computer. The research assistant will begin the recording as described in the Interviewer's Guide(s). After completing the interview, Zoom will encode the recording to mp4 format and the research assistant will store the recording on a Hopkins-supported, secured shared drive. The filename will contain no PHI.

28. Inclusion/Exclusion Criteria

Inclusion Criteria: Individuals who:

1. completed the *Five Plus Nuts and Beans for Kidneys* study 12-month follow-up assessment; and
2. agreed to be contacted for future research

Exclusion Criteria: Individuals who:

1. are unable to consent or participate over a telephone or computer; or
2. do not agree to audio taping of the interview

29. Drugs/ Substances/ Devices: N/A

30. Study Statistics

This study is qualitative and does not involve statistics.

Transcription and data analysis: Each interview will be digitally audio-recorded and then professionally transcribed verbatim for analysis. Transcripts will be redacted to remove identifying information and analyzed using qualitative thematic methods. Our thematic analysis will involve an iterative process of reading through the transcripts and coding for substantive themes that are raised.⁷ The analysis will begin by review of an initial set of 2-3 transcripts by the Study PI and a research assistant. Two research assistants will then code the transcripts to achieve

consensus in the concepts and definitions of the codes. These data will be further arranged into meaningful categories, which will be expanded, merged, split, and adjusted until the thematic categories are mutually exclusive and no new categories can be generated.

31. Risks

There are no medical risks associated with participating in the research interview.

The PI will report directly to the IRB any unanticipated problems or study deviations.

There is a small risk of breach of confidentiality associated with conducting the research interview. All efforts will be made to maintain confidentiality. All study team members will have completed required training in human subjects' research, ethics of conducting research and privacy of health information prior to the start of the study. All interview data (audio recordings and transcriptions) will be de-identified prior to storage in an encrypted and secure electronic database. However, complete confidentiality cannot be guaranteed.

There is a small risk that participants may be uncomfortable answering interview questions. Participants may choose not to answer interview questions.

There are no financial risks to the participants, they will be compensated for their time.

32. Benefits

There is no direct benefit to the individual participant, and the individual may or may not benefit by expressing their perspectives about participating in the study and/or making dietary changes. Society may benefit from research that identifies barriers and facilitators toward eating healthy among African Americans living in low resource environments.

33. Payment and Remuneration

Participants will be compensated with a \$25 Visa gift card for completing the interview.

34. Costs

There is no cost associated with participating in the study.

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