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Research paper

A population health dietary intervention for African American adults with chronic kidney disease: The Fruit and Veggies for Kidney Health randomized study

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ABSTRACT

Background: Chronic kidney disease (CKD) is commonly asymptomatic until its late stages, reduces life quality and length, is costly to manage, and is disproportionately prevalent in low-income, African American (AA) communities. Traditional health system strategies that engage only patients with symptomatic CKD limit opportunities to prevent progression to end stage kidney disease (ESKD) with the need for expensive kidney replacement therapy and to reduce risk for their major mortality cause, cardiovascular disease (CVD). Published studies show that giving fruits and vegetables (F&V) to AA with early-stage CKD along with preparation instructions slowed CKD progression. This effective, evidenced-based, and potentially scalable dietary intervention might be a component of a community-based strategy to prevent CKD progression.

Design: This study supported by NIH grant (R21DK113440) will test the feasibility of an innovative screening strategy conducted at community-based institutions in low-income AA communities and the ability to intervene in individuals identified to have CKD and increased CVD risk with F&V, with or without preparation instructions.

Objectives: The study will prospectively compare changes in urine indices predictive of CKD progression and CVD in participants receiving, compared to those not receiving, preparation instructions along with F&V, six months after the intervention.

Discussion: Addressing the challenge of increasing progression of early to more advanced stages of CKD with its increased CVD risk requires development of effective strategies to screen, identify, and intervene with individuals found to have CKD with effective, comparatively inexpensive, community-based, and scalable strategies to prevent CKD progression, particularly in low-income, AA communities.

1. Background

Chronic kidney disease (CKD) progression from early to advanced stages is increasing [1,2] as is albuminuria [2] and its associated death rate [3]. Individuals with CKD whose albuminuria increases during follow up have augmented risk for end-stage kidney disease (ESKD) and cardiovascular disease (CVD) events, making increased albuminuria a surrogate for these adverse outcomes [4–6]. Progression to advanced CKD augments CVD mortality risk prediction by traditional cardiovascular disease risk factors, including diet [2,7,8]. Indeed, individuals with CKD suffer premature death more commonly than developing ESKD [9]. This enhanced mortality is due predominantly to increased risk for, and earlier onset of, CVD [2] including myocardial infarction [10] and stroke [11]. High CVD mortality might therefore conceal high rates of incubating but asymptomatic CKD.

Chronic kidney disease incubates many years before manifesting symptomatically but awareness among asymptomatic individuals remains low, particularly in early stages [2]. African Americans (AA) are at greater risk for CKD [2,12] and for faster progression to ESKD [13]. This increased risk makes AA communities appropriate for designing

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accessible, community-based strategies to identify early stage CKD and intervene with cost-effective, kidney-protective strategies. Screening for CKD, identifying it, and intervening with proactive kidney-protective strategies in early stage disease might help reduce CKD incidence, its progression to advanced stages, and reduce its associated increased CVD mortality.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) recommends that CKD research foster translation of clinical investigation to community implementation [14]. High CKD risk communities like African American ones can benefit from effective models to 1) facilitate community-level screening, 2) identify early-stage CKD, and 3) intervene with kidney-protecting strategies. Dietary addition of fruits and vegetables (F&V) helps preserve kidney function in individuals with CKD [15–17]. Dietary F&V addition is relatively low-cost, scalable, and implementable by local communities. It presents a novel approach with particular relevance to individuals with CKD whose F&V intake is even lower [18] than the low overall US F&V intake [19]. Diets high in F&V are associated with reduced CVD mortality in the general population [20] and in individuals with CKD [21–23], adding relevance for lower-income AA populations with higher rates of chronic diseases, including CKD, for whom increased F&V intake might be of benefit.

The F&V intervention that slowed CKD progression included preparation instructions [17]. The present study will test if these instructions improve F&V intake, and thereby improve kidney protection, in a randomized trial. The Baylor Scott & White Health and Wellness Center (BSW HWC), a population health and research entity [24], is uniquely positioned to evaluate a community-based CKD intervention. The Center has strong community partnerships and is located in a large, urban, low-income area of Dallas, TX, with high rates of CKD, CVD, and related chronic diseases (e.g., diabetes, hypertension, obesity). This study will determine if individuals with CKD can be identified through low-cost, community-based screening, enrolled in one of two dietary interventions, and sustain the intervention for six months with improvement of urine indices of CKD and CVD.

2. Methods

2.1. Study aims

The primary aim of the *Fruits and Veggies for Kidney Health* study is to test the hypothesis that providing preparation instructions in addition to F&V yields better improvement of urine indices of CKD and CVD risk than providing F&V without preparation instructions. The outcome of this trial will help inform the conduct of community-based nutritional strategies to reduce CKD and CVD risk in communities at comparatively high risk for both, particularly strategies that include provision of F&V.

2.2. Study design

This study is a prospective, randomized two-group trial to evaluate the feasibility and efficacy of a community-based screening, identification, and F&V intervention strategy to improve CKD outcomes in 140 AA adults (≥18 years). Participants will be voluntarily screened at public, community sponsored health events or on-site at the BSW HWC. Providing free kidney screening services to community members in trusted settings (e.g., churches, community centers, health fairs) fosters effective, functional relationships between BSW HWC and the community it serves while further leveraging previously established trusted and collaborative community relations. Following screening and identification of individuals with CKD and CVD risk as defined by elevated urine albumin excretion, participants will be recruited, enrolled, and randomized to one of two F&V interventions: Provision of F&V only (F&V only), and provision of F&V plus a comprehensive cooking/nutrition program (F&V + Cook). Community health workers (CHWs) will deliver both interventions to improve cultural relevancy.

BSW HWC houses a level 3 primary care medical home clinic that is co-located in one of 43 Dallas Park and Recreation Centers. The BSW HWC is in the Juanita J. Craft Park and Recreation Center, a revered institution in the large, urban, low-income area known as South Dallas. Details of BSW HWC have previously been published [24]. BSW HWC has developed strong collaborations in this community that has disparately high (compared to other Dallas/Fort Worth areas) rates of CKD, ESKD, and related chronic diseases including diabetes, hypertension, and obesity. BSW HWC integrates population health and value-based care approaches such as providing access to affordable F&V through its community center-based, church-based, and clinic-based farm stands.

2.3. Participant recruitment

The research staff will identify individuals at CKD and CVD risk at local health fairs and community events throughout the calendar year (3–5 per month). The BSW HWC research team will be composed of clinical research physicians, nurses, CHWs, and trained & certified volunteers. At screening events, participants consent to participate and complete a CKD screening questionnaire. Participants will provide a small 10–40 mL untimed urine sample in a sterile urine collection cup given by research staff. We will analyze the urine sample in the field by dipstick for elevated albumin excretion by albumin (mg)-to-creatinine (g) ratio (ACR). The Urinalysis Reagent Strips (2CE) simultaneously detect ranges of albumin (mg/L) and creatinine (mg/L) for calculation of ranges of ACR. Positive tests will be albumin ≥30 mg/L in combination with creatinine concentrations between 100 and 3000 mg/L. A combination of albumin 30 mg/L and creatinine 3000 mg/L yields ACR = 10 mg/g, the upper limit of normal, and is an ACR that is associated with increased CKD [25] and CVD [2] risk. The combination of albumin 30 mg/L and creatinine 1000 mg/L yields ACR = 30 mg/g or microalbuminuria, an ACR associated with increased risk for subsequent decline of kidney function [2]. The combination of albumin 30 mg/L and creatinine 100 mg/L yields ACR = 300 mg/g or macroalbuminuria, an ACR associated with an even higher risk for subsequent decline of kidney function [2]. The collected urine sample will also be analyzed with the 10SG dipstick to help exclude individuals with urine infection (leukocytes), kidney inflammation (blood), nephrotic range proteinuria (≥2+), and underlying metabolic abnormalities (ketones, bilirubin). Urine samples collected at screening will be hygienically discarded.

CHWs or clinical research staff members will report urine dipstick results to participants, discuss abnormal values, and provide appropriate educational literature to individuals with positive urine dipstick results. Individuals with elevated urine CKD markers demonstrated by positive urine dipstick will be eligible to enroll in the *"Fruit and Veggies for Kidney Health"* study. Screened individuals with self-reported CKD stage 4–5 or self-reported history of dialysis use will be ineligible to enroll due to advanced CKD stage. These individuals will be referred to BSW HWC clinic with nephrology specialty referral if they do not currently have access to health care. All screened individuals receive a small dollar amount gift card as compensation.

Community-based health screening protocols have been successful in low-income, ethnic minority communities in previous studies [26,27]. The authors have shown in published studies that providing appropriate incentives optimizes participant satisfaction and reduces the perceived participant burden to increase successful recruitment, enrollment, and retention of study participants in community-based programs [26]. Community-based screening strategies also provide valuable health information to the medically underserved population at highest risk for CKD and improves trust between academic/clinic and community stakeholders [28].

Screened individuals identified as being at increased risk for CKD and/or CVD by urine dipstick will be contacted by research staff to attend scheduled baseline measures events at BSW HWC. In addition to positive urine dipstick at health screening, other study eligibility criteria include: men and women age ≥18 years and able to give consent, willingness to participate in a 6-month study, self-declared AA race,

access to the internet, and ability to read and write in English. Study exclusion criteria include: negative urine dipstick at health screen, currently receiving or needing dialysis, having received or needing a kidney transplant, being pregnant or planning to become pregnant in the next 6 months, planning to move outside of the Dallas metroplex in the next 6 months, urine dipstick consistent with nephrotic-range proteinuria, or baseline urine potassium >60 mEq/g creatinine (indicates an already increased dietary potassium intake and potential risk for potassium overload when eating the added F&V as per protocol design), or CKD stage 5 determined by serum creatinine. Serum creatinine will be measured at baseline to the nearest 0.1 mg/dL by finger stick using a point of care Abbott i-STAT Blood Analyzer whose creatinine measurement was not significantly different from that for central laboratories [29]. This serum creatinine measurement will be used to estimate GFR by the CKD EPI formula [30] to identify individuals with stage 5 eGFR for exclusion from the study and referral for appropriate work up and treatment. Remaining individuals will be treated as per current guidelines for individuals with CKD [31]. The Institutional Review Board at the Baylor Research Institute approved participant consent and study protocols.

2.4. Intervention

After informed consent and completion of baseline measures, we will randomize participants to one of two dietary interventions: F&V (F&V Only) or F&V plus an evidence-based nutrition/cooking education program (F&V + Cook).

F&V Only: The amount and type of F&V provided is designed to reduce dietary acid intake by 50% and was kidney protective in preliminary studies [15–17]. The prescribed amount of F&V is 2–3 cups of base-producing F&V daily, provided to participants at no charge, and will be distributed by participant pick-up from the BSW HWC farm stand for the first 6 weeks. If participants are unable to pick-up F&V, study staff will contact them to arrange delivery. After six weekly pick-up/deliveries, participants will receive F&V vouchers and reminders to obtain F&V at BSW HWC farm-stands for an additional 18 weeks.

F&V + Cook: Participants will receive the same prescribed F&V intervention described above. In addition to the F&V, participants will receive six-weekly nutrition and cooking education classes using The Happy Kitchen/La Cocina Alegre® (THK) curriculum developed by the Sustainable Food Center, Austin, TX. Research staff received training at the Sustainable Food Center® in Austin, TX to deliver THK classes. The Happy Kitchen classes are educational and instructional nutrition classes delivered in 90-min, small group sessions to 12–25 people. For the intervention, trained research staff in the on-site teaching kitchen located at BSW HWC will deliver all THK sessions. Participants in this group will also receive all the ingredients necessary to reproduce the weekly recipe demonstrated in the THK classes. Previous research indicates that behavioral approaches may be necessary to sufficiently increase F&V intake, particularly in lower-income communities [32,33]. This program is based on social cognitive theory and is designed to promote self-efficacy for cooking healthy meals. Previous research suggests that behavioral approaches that include instructions are necessary to optimize the health benefits of F&V provision, particularly in low-income communities [32,33].

2.5. Measures

Research staff members and trained study volunteers will collect baseline measures from consenting eligible individuals. Anthropometric and biometric measures for the study include blood pressure, fasting blood glucose and cholesterol (total, HDL, LDL, TRG), HbA1C, serum creatinine, waist circumference (in.), height (in.), weight (lbs.), calculated BMI, and urine analyses of potassium (K^+), angiotensinogen (AGT) and ACR (see Table 1). The described assessments of urine albumin and creatinine by on-site urine dipstick will be followed by quantitative laboratory measurement of albumin and creatinine in the same urine sample. Participants will complete a baseline survey to provide demographic information and assess self-motivation, self-efficacy, and perceived health status. Participants also will complete three ASA24® food recall system, one at baseline measures event and two at randomized times prior to beginning the intervention.

All research staff, CHWs, and study volunteers will receive training at the BSW HWC to complete measures using approved study protocols. We will collect study measures at baseline, 6-weeks post completion of the intervention, and at 6-month follow-up. Primary outcome measures for the study are feasibility, dietary changes, and change in urinary markers of kidney health including urine angiotensinogen (AGT) and albumin-to-creatinine ratio (ACR).

We will measure feasibility 6-weeks post intervention and at 6 months follow up based upon amount of F&V procured, retention rates, and participant satisfaction (usefulness, comprehension, enjoyment) measured with a valid self-report survey [43].

Urine markers of kidney health will be measured in duplicates by collection of a minimum 20 mL urine specimen at baseline, 6-weeks post intervention and 6-month follow up. Specimens will be frozen in laboratory −80° freezer and sent to contracted laboratories for measurement of urine AGT and ACR. Urine AGT is an indirect assessment of kidney angiotensin II levels; high such levels are associated with kidney injury [17], and this parameter is the primary outcome measure for kidney injury. Net decreases in urine AGT associated with increased consumption of prescribed base-producing F&V and was directly associated with better eGFR preservation in previous studies by the lead author [17]. We will use ACR as a secondary measure of kidney damage. High urine albumin excretion predicts increased risk for subsequent eGFR decline [6,44] and ACR change during follow up is directly associated with ESKD risk [4,6,45].

We will measure dietary intake using the ASA24® food recall system that is validated by the National Cancer Institute and United States Department of Agriculture [40]. Participants will complete three ASA24 entries at baseline, as well as three entries at 6-weeks post intervention and three entries at 6-month follow-up. Entries include random reporting of 2 weekdays and 1 weekend day per randomized protocols used in previous studies [46].

We will measure body weight with a digital, medical grade scale to the nearest 0.1 lbs. Height will be measured with a medical grade stadiometer to the nearest 0.0125in. We will use height and weight measurements to calculate body mass index (weight [lbs.]/height [in.]^2 x 703). We will measure waist circumference to the nearest 0.1 in. with a standard measuring tape per standardized protocols (see Table 1). Each anthropometric measure will be recorded twice and averaged for accuracy.

Blood glucose and cholesterol (total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL), triglycerides) measures will be collected by finger stick after a minimum 8-h fast with the Alere Cholestech LDX (Clinical Laboratory Improvement Amendments, CLIA waived). Blood pressure will be measured to the nearest 1 mmHg according to the Eighth Report of the Joint National Committee of Prevention, Detection, Evaluation and Treatment of high blood pressure (JNC VIII) using an automated blood pressure device. Research staff will select the appropriate blood pressure cuff size per measurement protocols from previous studies. Two separate readings will be recorded to define blood pressure. If readings vary by 10 mmHg or more an additional measure will be taken. We will measure glycosylated hemoglobin (Hemoglobin A1C) by finger stick using a point of care Siemens DCA Vantage Analyzer (CLIA waived).

2.6. Data analysis

Descriptive statistics will be provided for variables and the primary and secondary analyses will be conducted as intent-to-treat. To avoid

Table 1
Study measures.

Measure	Time Point	Instrument	Description	Validity	Reliability
Weight	0, 6-week, 6-month	Health o meter® Professional 500 KL	Measured twice to the nearest 0.1 kg, averaged	–	–
Height	Baseline	Health o meter® Professional 500 KL	Measured twice to the nearest 0.1 cm, averaged	–	–
Waist Circumference (WC)	0, 6-week, 6-month	Tape Measure	Measured twice with inelastic tape to the nearest 0.1 cm using NIH Guidelines [34]	r = 0.62 for correlation between WC and visceral abdominal tissue among women [35]	r = 0.998 for intraclass correlation in females [36]
Body Mass Index (BMI)	0, 6-week, 6-month	Health o meter® Professional 500 KL	The formula for BMI is weight in kilograms divided by height in meters squared	–	–
Blood Pressure	0, 6-week, 6-month	Omron Digital Blood Pressure Monitor (HEM-907XL)	Measured twice to the nearest 1 mmHg, averaged	–	–
Blood Lipids	0, 6-week, 6-month	Alere Cholestech LDX System	Measures fasting blood lipids and glucose profiles from blood samples collected via finger stick	TC, r = 0.92; TRG, r = 0.93; HDL, r = 0.92; LDL, r = 0.86; with lab results [37]	p > 0.75 ICC for all 4 lipid categories [38]
HbA1c	0, 6-week, 6-month	Siemens DCA Vantage Analyzer	HbA1c measure collected via finger stick	r = 0.987 with Laboratory Results [39]	Coefficient variation of <3% and error criteria of ±0.85% as specified by the NGSP [39]
Diet	0, 6-week, 6-month	Automated Self-Administered 24-Hour (ASA) Dietary Assessment tool	Questionnaire designed to assess dietary intake	mean r = 0.62 compared to mean r = 0.63 of dietician recall with a 95% CI [40]	
Urine Proteinuria	Baseline	McKesson Consult® diagnostics 10SG Urine Reagent Strips *Detects albumin as low as 7.5–15 mg/dL (0.075–0.15 g/L)	The test strip will be dipped into a urine specimen and read after at least 1 min has passed	–	Sensitivity 0.80, Specificity 0.95, positive predictive value 0.22, negative predictive value 0.99 [41]
Urine microalbumin & creatinine	0, 6-week, 6-month	McKesson Consult® diagnostics Microalbumin/ Creatinine Urine Reagent Strips	The test strip will be dipped into a urine specimen and read after at least 1 min has passed		Sensitivity 0.51, Specificity 0.91, positive predictive value 0.89, negative predictive value 0.58 [42]
Urine potassium	Baseline	Quest Diagnostics	Assayed urine sample, >60mEq/g creatinine (crt)	–	–
Urine angiotensin (AGT)	0, 6-week, 6-month	Baylor Scott & White laboratory	Assayed urine sample	–	–
Urine alb/crt ration (ACR)	0, 6-week, 6-month	Baylor Scott & White laboratory	Assayed urine sample	–	–
Serum creatinine	Baseline	Abbott I-STAT ® Point of Care blood analyzer	Blood samples collected via finger stick.	p = 0.323 0.9%,CI:0.0,1.9% [55]	–

bias due to list-wise deletion, missing data will be imputed using multiple imputation methods (Rubin, 2004) after testing the pattern of missingness (Little, 1988). Analyses will be conducted for both complete data and imputed data to assess if there are any drastic differences. A comparison of baseline factors will be conducted between completers and lost to follow up subjects to understand the differential characteristics of attrition and to facilitate missing data imputation. A comparison of the primary analysis will be performed with a per-protocol analysis. Between group comparisons of baseline demographic, anthropometric, and CVD/Diabetes risk will be performed, and adjusted for (if statistically significant) in analysis. Feasibility (F&V procured, mean participant satisfaction, retention) will be evaluated with parametric or non-parametric statistics.

Primary analysis. A mixed-effects model will compare mean urine AGT at baseline and 6-months between the two intervention groups. Let Y_{ij} be the AGT for subject j ($j = 1, \ldots, m$) at time i ($i = 0$ *or* 1), X_j is an indicator variable of group assignment (coded as 0 for F&V and 1 for F&V + C), t_{ij} is an indicator variable for measurement time (coded as 0 for baseline and 1 for 6-month). Then the formal linear mixed effects model is: $Y_{ij} = \beta_0 + \beta_1 X_j + \beta_2\, t_{ij} + \beta_3 X_j t_{ij} + \varepsilon_{ij}; j = 1, \ldots, m$, with m is the sample size per group. It is assumed that the random errors ε_{ij} are bivariate normally distributed with zero mean and heterogeneous compound symmetric covariance matrix. See O'Connell et al. (2017) for further reading. The model will include confounding variables reported in the literature such as age, gender, educational level, baseline blood pressure, body-weight, serum glucose level, CKD stages, and variables that are differentially distributed by treatment conditions at baseline. A parsimonious model will be used determined by log-likelihood test between two competing nested models.

Secondary analysis. As in the primary analysis, we will utilize mixed models to complete the secondary objectives. We will evaluate changes over the three measurement times for clinical variables of interest and explore the possibility of differential rates of change across the treatment groups. We will build models for K^+, AGT, ACR, lipoproteins, blood pressure, hemoglobin A1c, BMI, and dietary assessments. We will additionally consider the intake/dose of F&V as a factor of change for CKD/CVD risk and DM markers. Using the mixed model approach offers the ability to extend to multivariable models in which we can adjust for additional confounders, as necessary. To account for the effect of multiple testing on Type I error rate, we will use Bonferroni's correction for level of significance in drawing inference on statistical significance.

Power Analysis. Using this model, we simulated 1000 power calculations for various sample sizes assuming a baseline AGT of 35.5 μg/g Cr and 6 months AGT levels of 34.1 for F&V and 32.7 μg/g Cr for the F&V + C. The variance between groups was assumed to be 5.9 and the subject variance was 0.76 [17]. We fixed significance level at 0.05. We used different types of covariance structures and all simulations were robust to the change of structure. The means in these assumptions are the same as in the referenced article. The differences are based on observed differences at 1 year from the data in the study, as well as the standard deviation for the difference. Based on 20% attrition, a total sample size of 140, will yield expected power between 80 and 90% (PASS software) [47].

3. Results

3.1. Screening results

To date we have screened 381 individuals for CKD and CVD risk (Fig. 1). Of those, 64.0% (N = 244) had urine albumin ≥30 mg/L by urine dipstick which combined with the associated urine creatinine levels on the dipstick yielded a minimum ACR of 10 mg albumin-to-g creatinine. Participants were an average age of 55.2 years (SD = 13.9), 72.7% were female, and 92.4% were self-declared African American.

Results from the screening urine dipstick were used to calculate an estimated baseline albumin-to-creatinine ratio (ACR) (Table 2). Albuminuria rates for the US general population by the United State Renal Data System (USRDS) [2] show 8.5% with ACR 30–300 mg/g and 1.6% with ACR >300 mg/g. Screening ACRs for our targeted population ranged from 5 to 2000 mg/g with an average of 53.6 mg/g (SD = 120.5). We categorized participants' albuminuria level as per USRDS [2]: 51.4% (N = 188) had normal-to-mild albuminuria (A1), 45.1% (N = 165) had moderate (A2), and 3.6% (N = 13) had severe albuminuria (A3), showing much higher proportions of participants with higher categories of albuminuria compared to the general US population.

3.2. Preliminary findings

At the time of analysis, 142 individuals were enrolled into the trial and randomized. Enrolled participants were 56.5 years (SD = 11.5), 76.6% were female, and 100% were self-declared African Americans (Table 3). Of enrolled participants, serum creatinine measures were available for 138 (97.2%). Average serum creatinine among measured participants was 1.26 mg/dL (SD = 0.45) that yielded a calculated (CKD-EPI creatinine formula [30]) baseline estimated GFR (eGFR) of 69.96 ml/min/1.73 m^2 (SD = 30.64). Sixty-nine (50.0%) participants were categorized as CKD stage 3a or worse (Table 3), a proportion that is much higher than the reported 6.9% of the US general population with CKD stage 3 or worse [2].

4. Discussion

Chronic kidney disease is a major health burden that is increasingly prevalent, reduces employability, life quality and length, and thereby is devastating to communities with high CKD rates. It greatly increases CVD risk and is largely unrecognized until late stages when it becomes symptomatic and less amendable to corrective intervention. Chronic kidney disease disproportionately affects AA communities that constitute an appropriate context to design focused strategies to reduce disease burden in this population. This study will incorporate an innovative screening approach in a community at high CKD risk to identify individuals with CKD and increased CVD risk as determined by elevated urine albumin excretion, intervene with effective, community-based strategies to prevent CKD progression, and institute feasible strategies to sustain the intervention. Initial screening results in the target community show high rates of elevated urine albumin excretion, higher rates than reported for the general population [2], strongly supporting the importance of this study. In addition, these initial screening results show a comparatively low urine K^+ excretion, consistent with low dietary K^+ intake likely due to low F&V intake that supports the potential efficacy of the F&V intervention.

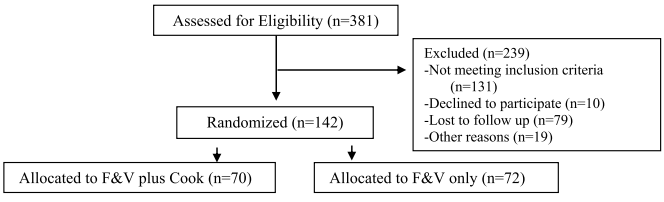

Fig. 1. CONSORT diagram.

Table 2
Estimated CKD and CVD risks from calculated albuminuria by urine dipstick results.

Albuminuria category	Calculated ACR (mg/g) [2]	N (%) participants (N = 366**)
Estimated CKD risk		
A1 (low to mild)	<30	188 (51.4)
A2 (moderate)	30–299	165 (45.1)
A3 (severe)	≥300	13 (3.6)
Estimated CVD risk		
Normal	<10	31 (8.5)
Abnormal/Elevated	≥10	335 (91.5)

**ACR 30–300 mg/g for >3months indicates CKD. A few (n = 15) participants had missing information.

ACR ≥10 mg/g is associated with a linear increase in CVD mortality [48]. To estimate CVD and CKD risk, screening albuminuria results were further analyzed. The analysis showed that 8.5% (N = 31) of participants had a normal risk (ACR<10 mg/g) but 91.5% (N = 335) had elevated CVD and CKD risk (ACR ≥10 mg/g). The sample population demonstrates a greater combined CVD and CKD risk than reported in the general population [2].

Epidemiologic studies show an association of increased F&V intake with lower CKD risk [49–51] and this is supported by the comparably low F&V intake in low-income AA communities [50]. Published studies show that providing F&V along with instructions as to their preparation slowed CKD progression [15–17]. These findings suggest the need to test the described intervention in high-risk, low-income AA communities. A key component of these previous studies was the use of established collaborations with local churches to deliver F&V preparation instructions. The current study will test whether providing F&V preparation instructions is necessary to yield the described kidney-protective benefits of a scalable F&V intervention. Testing the benefits of individual components of a "value" chain intervention [52] helps determine the structure of the necessary intervention and develop a template for designing effective, community-based interventions for chronic disease. It is important to determine the effective factors of multi-component interventions to establish the minimum intervention required to yield the maximum beneficial outcome being investigated [53].

This study will use its innovative screening strategy to identify individuals with ACR >10 mg/g who have increased CVD and CKD risk, those with ACR >30 mg/g to identify those additionally with increased risk for eGFR decline toward ESKD, and those with ACR >300 mg/g to identify those with even greater risk for subsequent eGFR decline [2]. There is nevertheless controversy as to whether the general population should be routinely screened [54–57]. This study's initial screening data in the target community demonstrates higher rates than the general population of individuals with elevated urine albumin excretion, identifying them to be at increased CVD risk and/or to have CKD with increased risk for subsequent eGFR decline. These initial results are consistent with previous literature that supports screening in particularly high-risk groups, including AAs living in low socio-economic status (SES) communities [58]. When applied to a low SES, urban minority population, ACR ≥200 mg/g identified individuals at the highest risk for progression to ESKD with 80% specificity and >50% sensitivity [58].

Demonstrating feasibility and efficacy of inexpensive point of care techniques, like the urine dipstick, to detect elevated urine albumin excretion (ACR >10 g/g), microalbuminuria (ACR >30 mg/g), and macroalbuminuria (ACR >300 mg/g) facilitates design of effective community-based screening strategies. Elevated urine ACR is associated with increased CVD risk and micro- and macroalbuminuria are additionally associated with increased risk for subsequent worsening of kidney function [2]. NHANES data show that ~30% of the US general population has elevated ACR and ~10% has micro- or macroalbuminuria [2]. Preliminary findings of the present study show that 91.5% of those screened in the target population had elevated ACR

Table 3
Baseline demographic characteristics and estimated CKD stages of the participants enrolled in the study.

		Whole sample	F&V plus Cook	F&V only	p-value[a]
N		142	70 (49.30)	72 (50.70)	–
Age, mean (SD)		56.47 (11.51)	56.13 (11.88)	56.81 (11.21)	0.7274
Gender, N (%)	Male	33 (23.40)	16 (22.86)	17 (23.94)	0.8789
	Female	108 (76.60)	54 (77.14)	54 (76.06)	
Marital status, N (%)	Married or living with a partner	46 (33.33)	23 (33.82)	23 (32.86)	0.9695
	Divorced/separated/widowed	44 (31.88)	21 (30.88)	23 (32.86)	
	Single	48 (34.78)	24 (35.29)	24 (34.29)	
Education, N (%)	Some high school or less	17 (12.23)	2 (2.94)	15 (21.13)	0.0170
	GED/Technical degree	23 (16.55)	11 (16.18)	12 (16.90)	
	Some college	44 (31.65)	25 (36.76)	19 (26.76)	
	College degree or more	55 (39.57)	30 (44.12)	25 (35.21)	
Household annual income, N (%)	$25,000 or less	64 (46.04)	28 (41.18)	36 (50.70)	0.4610
	$25,000 to $50,000	42 (30.22)	21 (30.88)	21 (29.58)	
	$50,000 to $75,000	23 (16.55)	12 (17.65)	11 (15.49)	
	$75,000 or more	10 (7.19)	7 (10.29)	3 (4.23)	
Baseline CKD stage based on calculated eGFR[b], N (%)	1	37 (26.81)	16 (23.19)	21 (30.43)	0.4438
	2	32 (23.19)	19 (27.54)	13 (18.84)	
	3a	34 (24.64)	19 (27.54)	15 (21.74)	
	3b	32 (23.19)	13 (18.84)	19 (27.54)	
	4	3 (2.17)	2 (2.90)	1 (1.45)	
	5	0 (0.00)	0 (0.00)	0 (0.00)	

[a] P-values are presenting the null hypothesis significance test between 'F&V plus Cook' and 'F&V only'.
[b] Four participants had missing serum creatinine values.

(>10 mg/g) and 45.1% had micro- (ACR 30–300 mg/g) and 3.6% had macroalbuminuria (ACR >300 mg/g). Although this extraordinarily high proportion of individuals with increased albuminuria who elected screening does not represent a random sample of the community, it strongly suggests that the rate of incubating, unrecognized CKD and those with increased CVD risk in low-income AA communities is much higher than that for the US general population.

Because individuals with CKD have a high rate of premature mortality, mostly from CVD, before developing ESKD [9], this apparent higher than expected prevalence of elevated urine albumin excretion and CKD was recognized with the described proactive strategy that leverages trusted institutions to screen individuals in settings that are routine in their communities that are at high CKD risk. Specifically, this strategy reaches directly into these low-income African American communities to test asymptomatic residents in their routine living environments who have not interfaced with health systems, at least in ways that would prompt CKD screening. Without the described proactive screening, this apparent high rate of incubating CKD would go unrecognized because it more commonly manifests as symptomatic CVD. This might be so because CKD becomes symptomatic only at very low levels of kidney function reached after a long time of progressive decline whereas the accompanying increased CVD associates with albuminuria that typically precedes progressive kidney function decline [6]. The high CVD mortality that precedes very low kidney function might mask incubating CKD in communities at high CKD risk.

Effective population health models must include implementation of community-based strategies outside of traditional health system (hospital/clinic) ones that target low-income, minority communities to identify individuals at high CKD risk who may not interface with healthcare systems due to disparities. The NIDDK developed six cross-cutting recommendations to improve CKD research, one of which was *"to foster translation from clinical investigation to community implementation"* [14]. The present study tests an innovative strategy to identify individuals with early CKD and will intervene with the evidenced-based strategy of F&V that can be implemented in the high CKD risk AA communities in which they live [15–17]. The F&V strategy holds the additional promise of reducing rates of, and complications therefrom, other related chronic diseases for which these low-income communities suffer, including diabetes, hypertension, and obesity. Treating *communities* at high CKD risk rather than just *individuals* identified with CKD and/or at high risk for it holds promise to reduce CVD, reduce CKD incidence, reduce progression of underlying but unrecognized CKD, and reduce CKD-related increased CVD mortality.

In summary, these ongoing studies test the effectiveness of a community-based screening strategy to identify increased urine albumin excretion that indicates high CVD and high CKD/CVD risk in individuals living in a community at high CKD risk, to thereafter intervene in those with elevated albuminuria in a program of added dietary F&V with and without food preparation education, and if the intervention(s) reduce urine indices of kidney injury and CVD risk. The studies hold promise for identifying effective, easily accessible, and scalable strategies to reduce CKD incidence and CVD outcomes in communities at high CKD risk.

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Declaration of competing interest

Dr. Wesson has a portion of his salary paid through his employer to serve as a consultant for Tricida, Inc. (San Francisco). None of the remaining authors has disclosures.

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