Kidney Medicine

The Fruit and Veggies for Kidney Health Study: A Prospective Randomized Trial

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Rationale & Objective: Providing fruits and vegetables (F&Vs) to health care system patients with elevated urine albumin-creatinine ratio (ACR) reduced ACR, slowed chronic kidney disease (CKD) progression and reduced cardiovascular disease (CVD) risk factors in previous studies. This study evaluated a community-based strategy in lower-income populations to identify African Americans with elevated ACR before health care system involvement and sustain them in a 6-month F&V protocol with (F&V + Cook) and without (F&V Only) cooking instructions, with the hypothesis that adjuvant cooking instructions with F&Vs would further reduce ACR.

Study Design: Prospective, randomized, parallel 2-arm design.

Setting & Participants: African American adults with ACR >10 mg/g creatinine randomized to 1 of 2 study arms.

Interventions: Two cups/day of F&Vs with or without cooking instructions in participants followed 6 months.

Outcomes: Participants sustaining the F&V protocol and between-group indicators of CVD risk, kidney injury, and dietary intake at 6 weeks and 6 months.

Results: A total of 142 African American adults (mean age, 57.0 years; ACR, 27.4 mg/g; body mass index, 34.4; 24.9% CKD 1; 24.8% CKD 2; 50.4% CKD 3; 55% female) randomized to F&V Only (n=72) or F&V + Cook (n=70), and 71% were retained at 6 months. Participants received 90% of available F&V pick-ups over 6 weeks and 69% over 6 months. In the adjusted model, 6-month ACR was 31% lower for F&V + Cook than F&V Only ($P = 0.02$). Net 6-week F&V intake significantly increased and biometric variables improved for participants combined into a single group.

Limitations: Small sample size, low-baseline ACR, and potential nonresponse bias for 24-hour dietary recall measure.

Conclusions: These data support the feasibility of identifying community-dwelling African Americans with ACR indicating elevated CVD and CKD risk and sustaining a F&V protocol shown to improve kidney outcomes and CVD risk factors and provides preliminary evidence that cooking instructions adjuvant to F&Vs are needed to lower ACR.

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The prevalence of chronic kidney disease (CKD) progression to advanced stages is increasing[1,2] along with albuminuria,[2] disability-adjusted life-years lost,[3] and its cardiovascular disease (CVD) mortality.[1] Although disability-adjusted life-years for most US chronic diseases have decreased, CKD has increasing disability-adjusted life-years,[3] health burden,[3] and increasing individual[4] and national[5] economic burden. Progression to advanced CKD is associated with higher CVD mortality.[1,6] High-CVD mortality risk in silently progressing CKD[7,8] might conceal unrecognized CKD by causing premature death.[9] African American *individuals* suffer disproportionately high rates of CKD[10] and CVD.[11] Because low-socioeconomic status is associated with increased risk for CKD[12,13] and CVD,[14,15] underresourced African American *communities* warrant particular attention to reduce US CKD and CVD[16] burdens.

Individuals with urine albumin (mg) to creatinine (g) ratio of >10 mg/g have increased CVD[17] and CKD[18] risk. Higher initial urine albumin-creatinine ratio (ACR) is associated with faster subsequent estimated glomerular filtration rate decline[19] and further ACR elevations are associated with increased risk of CVD mortality[19] and CKD progression.[20–23] By identifying increased CVD and CKD risk, albuminuria constitutes an integrated care focus[24] to reduce adverse outcomes from these contributors to premature mortality in the United States.[25]

Epidemiologic studies report that populations eating high proportions of fruits and vegetables (F&Vs) have slower CKD progression.[26-28] Our group's interventional studies support that adding F&Vs to diets of health care system-identified individuals with albuminuria reduced kidney injury in early-stage CKD,[29] slowed estimated glomerular filtration rate decline,[30] reduced CVD risk parameters,[31] and was cost-effective.[32] Many participants in these earlier studies received nonprotocol cooking instructions with provided F&Vs.[29-32] Effective factors of multicomponent interventions must be identified to establish the minimum intervention required to yield maximum beneficial outcomes.[33] The primary objective

PLAIN-LANGUAGE SUMMARY

African Americans, particularly those in low-income communities, have increased rates of chronic kidney disease (CKD) with worsening outcomes over time. Giving fruits and vegetables to individuals with CKD identified in health care systems was previously shown to reduce kidney damage, measured by urine protein albumin, and slow kidney function decline. We recruited African Americans in low-income communities with increased urine albumin levels. They received fruits and vegetables for 6 months, and we tested whether added cooking instructions further reduced urine albumin levels. Most participants continued to receive fruits and vegetables throughout the 6 months. Those given cooking instructions had lower urine albumin levels after 6 months, indicating decreased kidney damage. Providing cooking instructions with fruits and vegetables appears to lessen kidney damage more than just fruits and vegetables alone.

of the *Fruits and Veggies for Kidney Health* study (R21DK113440) was to determine feasibility and preliminary efficacy. Feasibility was defined by the following: (1) identifying African Americans in their communities (versus in health care systems) with early-stage CKD through low-cost, community-based ACR screening; (2) enroll and sustain them for 6 months in a F&V intervention; and (3) test if evidence-based food preparation instructions were associated with further improvements in surrogate measurements of CVD and CKD progression. Our primary hypothesis was that adjunctive food preparation instructions with F&Vs would improve CVD risk and kidney health better at 6 months than F&Vs alone.

METHODS

Study Design

The *Fruits and Veggies for Kidney Health* trial (R21DK113440) followed a prospective, randomized parallel 2-arm design. We randomized eligible individuals to one of 2 treatment arms in 1:1 ratio: provision of 2 cups/day of F&Vs with (F&V + Cook) or without (F&V Only) an adjuvant comprehensive cooking/nutrition program. All study activities were conducted at the Baylor Scott & White Health and Wellness Center (BSW HWC)[34,35] with institutional review board approval #017-229.

Study Population

Study participants were recruited from the southern Dallas community surrounding BSW HWC, a historically "redlined",[36] largely African American, underresourced community.

Inclusion/Exclusion Criteria

The inclusion criteria were as follows: (1) men and women aged ≥18 years; (2) able to consent; (3) consent to complete a CKD screening questionnaire and provide a urine sample; (4) willing to participate in a 6-month study; (5) self-declared African American race/ethnicity; (6) internet access; (7) ability to read and write English; and (8) ACR of >10 mg/g.

The exclusion criteria were as follows: (1) ACR of ≤10 mg/g; (2) currently receiving/needing dialysis; (3) receipt/need for a kidney transplant; (4) pregnant or planning to become pregnant in the next 6 months; (5) planning to move outside the Dallas area within 6 months; (6) urine dipstick consistent with nephrotic-range proteinuria; (7) baseline urine potassium >60 mEq/g creatinine (suggesting high-baseline potassium intake, risking potassium toxicity with F&V provision); (8) CKD stage 4 or 5 demonstrated by elevated estimated glomerular filtration rate obtained during baseline measures.

Participant Screening and Recruitment

Participant recruitment began January 24, 2019, and the overall study ended July 13, 2020 after attaining the prespecified sample size (Fig 1). Individuals with positive urine dipstick results (ACR of >10 mg/g) and CKD stages 1-3 were eligible to enroll. Screening results were reported immediately to participants, and those with positive results received educational literature. Those with results indicating advanced kidney disease (stages 4/5), nephrotic-range proteinuria (ACR >3,000 mg/g), or urinary tract infection were ineligible to enroll and were referred for further evaluation.

Intervention

Enrolled participants were randomized to F&V + Cook or F&V Only using a biostatistician-generated randomization scheme assuming a completely randomized design with 1:1 allocation without blocking. The amount and type of base-producing F&Vs provided was designed to reduce dietary acid production by 50%, previously shown to be kidney protective.[29-32]

F&V Only: The preselected amount of F&Vs was provided without charge. F&Vs were retrieved by participants or delivered from the BSW HWC Farm Stand once weekly for the first 6 weeks. Thereafter, participants received BSW HWC farm stand vouchers and reminders to purchase F&Vs at select BSW HWC farm stands for an additional 18 weeks.

F&V + Cook: Participants received the same F&V intervention along with 6 weekly 90-minute group nutrition and cooking education classes. The Happy Kitchen/La Cocina Alegre (THK) curriculum, developed by the Sustainable Food Center for underresourced populations, was delivered by community health workers at the BSW HWC teaching kitchen. F&V + Cook received all ingredients necessary to reproduce the weekly THK recipe. Research staff were trained at the Sustainable Food Center

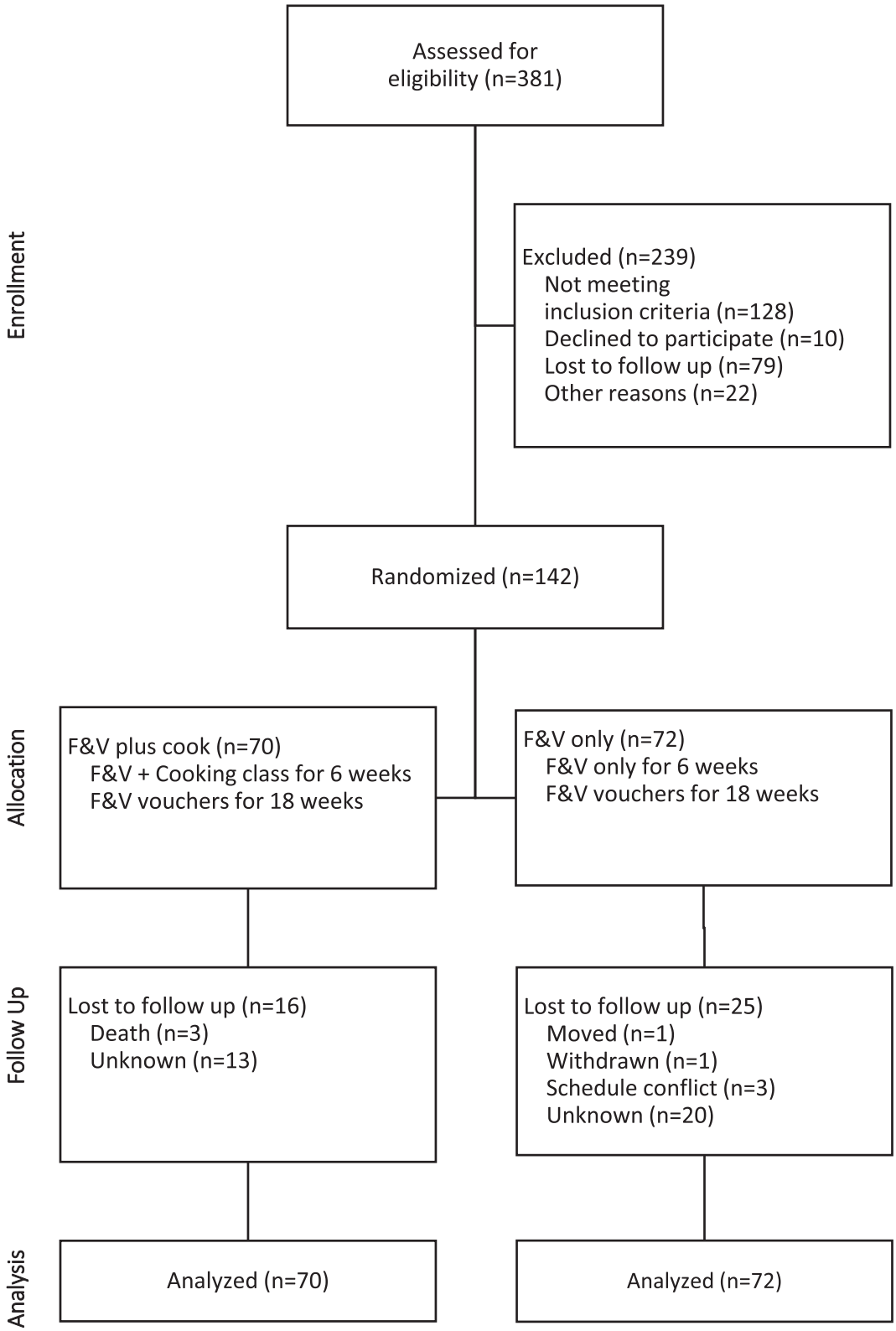

Figure 1. CONSORT diagram.

to deliver THK classes and made culturally relevant adaptations to recipes for African Americans. Behavioral approaches may be necessary to sufficiently increase F&V intake and optimize health benefits, particularly in underresourced communities.[37,38]

There were no harms related to the study interventions.

Measures

We measured urine ACR and angiotensinogen-to-creatinine ratio (AGT/cr, indirect measure of kidney angiotensin II[30]), as indices of kidney injury[30] in duplicates in minimum 20 mL urine collected at baseline, 6 weeks postintervention and at 6 months. Specimens were frozen at −80 °C and analyzed by a contracted laboratory. We chose ACR as the clinically relevant measure of kidney injury[30] because AGT is not clinically available.

Serum creatinine was measured to the nearest 0.1 mg/dL by finger stick using a point of care Abbott i-STAT Blood Analyzer.[39] This measurement was used to estimate glomerular filtration rate (Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI] formula[40]) to identify individuals with stage 4-5 CKD solely for study exclusion and referral for appropriate work-up and treatment. The remaining individuals were treated as per current CKD guidelines.[41]

Study measures were completed at baseline, 6 weeks and 6 months as described.[34] Briefly, anthropometric and biometric measures included blood pressure, fasting blood glucose and cholesterol (total, high-density lipoprotein [HDL], low-density lipoprotein [LDL], triglycerides), hemoglobin A1c (HbA1c), serum creatinine, waist circumference (in), height (in), weight (lb), body mass index (BMI), and laboratory urine analyses of potassium, AGT/cr, and ACR. Participants completed surveys at each study visit to document motivation, self-efficacy, and perceived health status. Dietary data were collected through ASA24 food recall records,[42] validated by the National Cancer Institute.[43] Participants completed 3 ASA24 entries at baseline, 6 weeks, and 6 months. Entries included random reporting of 2 weekdays and 1 weekend day.[44]

Body weight was measured with the Health o meter Professional 500KL digital, medical grade scale and stadiometer to the nearest 0.1 lb. Height was measured to the nearest 0.0125 in. Height and weight measurements were used to calculate BMI (weight [lb]/height [in]^2 × 703). Waist circumference was measured to the nearest 0.1 with a measuring tape per standardized protocols. Anthropometric measures were recorded twice and averaged for accuracy.

Blood glucose and cholesterol (total cholesterol, HDL and LDL cholesterol, triglycerides) measures were collected by finger stick with the Alere Cholestech LDX (Clinical Laboratory Improvement Amendments, CLIA waived) after minimum 8-hour fast. Blood pressure was measured to the nearest 1 mmHg[45] with an automated blood pressure device. HbA1c was measured by finger stick using a point of care Siemens DCA Vantage Analyzer (CLIA waived).

Outcomes

Primary outcomes were feasibility of identifying, enrolling, and sustaining participants in the protocol for 6 months and change from baseline at 6 weeks and 6 months between groups in measures of (1) ACR; (2) AGT/cr; and (3) F&V intake. Secondary outcomes were change from baseline at 6 weeks and 6 months between groups in measures of (1) systolic blood pressure (SBP) and diastolic blood pressure (DBP); (2) serum lipoprotein (LDL, HDL); and (3) HbA1c.

Statistical Analysis

Mean and standard deviation were calculated for continuous variables and frequencies and percentages for categorical variables. To avoid bias because of listwise deletion, missing data were imputed using multiple imputation methods[46] after identifying the pattern of missingness.[47] A total of 20 data sets were imputed using a fully conditional specification method. Analyses were conducted for both complete data and imputed data to ensure quality. Between-group comparisons of baseline demographic variables and biometrics were performed using χ^2 and 2-sample t tests to inform outcome models. Variables with significant differences at baseline were accounted for in multivariable adjusted analyses. Age, sex, BMI, HbA1c, and CKD stages were also included in multivariable adjusted analyses because of known associations with albumin and creatinine excretion.[48-50] A natural log transformation of AGT/cr, ACR, and HbA1c was conducted to achieve normality. The classification and regression tree method dichotomized F&V retrieval based on a differential effect of ACR and AGT/cr, respectively.

An adjusted linear mixed-effects model compared the mean urine AGT/cr at baseline, 6 weeks, and 6 months between the 2 groups. Similarly, adjusted linear mixed models assessed changes in ACR at baseline, 6 weeks, and 6 months between groups in this longitudinal study over time. Models were also fitted for secondary outcome variables, which were dietary intake, LDL, HDL, SBP, DBP, HbA1c, and BMI. Subgroup analyses were performed for the secondary outcome variables for participants in the high category. Clinical guidelines were used to categorize secondary outcome variables as follows: LDL: <100 mg/dL as low and ≥100 mg/dL as high, HDL: <60 mg/dL as low and ≥60 mg/dL as high; SBP: <120 mm Hg as low and ≥ 120 mm Hg as high; DBP: <80 mm Hg as low and ≥80 mm Hg as high; HbA1c: <6.5% as low and ≥6.5% mm Hg as high; BMI: <30 as low and ≥30 as high. Type I error rate was considered 0.05. Statistical significance was P value of <0.05. We used SAS 9.4 (SAS Institute Inc. 2013) and R version 4.0.3 for data analysis.

Power Analysis. Power was calculated from our previous study using a mixed-effects model, assuming a baseline AGT of 35.5 μg/g creatinine and 6 months AGT of 34.1 for F&V Only and 32.7 μg/g creatinine for F&V + Cook.[30] Variance between groups was assumed to be 5.9, and the within-subject variance was 0.76.[30] Accounting for a 20% attrition rate, a total sample size of 140 yielded expected power greater than 80% (PASS software).[51]

Table 1. Baseline demographic, socioeconomic, and biometric variables

Variable	Level	F&V + Cook	F&V Only	*P*
N		70 (49.3%)	72 (50.7%)	
Sex	Female	54 (77.1%)	56 (77.8%)	0.93
	Male	16 (22.9%)	16 (22.2%)	
Age		56.5 (11.8)	57.4 (11.8)	0.64
Educational status	Less than high school/GED/diploma	10 (14.5%)	24 (33.3%)	0.03
	Technical degree/some college	29 (42.0%)	23 (31.9%)	
	College or graduate degree	30 (43.5%)	25 (34.7%)	
Annual household income	25K or less	29 (42.0%)	37 (52.1%)	0.42
	25K – 50K	21 (30.4)	20 (28.2%)	
	50K to 75K	19 (27.54)	14 (19.72%)	
Marital status	Single	23 (33.3%)	25 (35.2%)	0.95
	Married or with partner	24 (34.8%)	23 (32.4%)	
	Divorced/separated/widowed	22 (31.9%)	23 (32.4%)	
Biometrics	Body mass index	34.5 (8.9)	34.2 (7.6)	0.83
	Total cholesterol (mg/dL)	181.9 (41.4)	180.7 (41.7)	0.85
	HbA1c (%)	6.8 (2.1)	6.5 (1.7)	0.41
	SBP (mm Hg)	136.3 (18.6)	130.1 (19.0)	0.05
	DBP (mm Hg)	81.1 (13.0)	76. 8 (12.3)	0.05
	ACR (mg/g creatinine)	31.3 (38.1)	23.5 (32.2)	0.19
	ACR: median (25^{th}, 75^{th})	9.02 (2.80, 25.80)	17.62 (4.71, 42.30)	0.11
	AGT/cr (μg/g creatinine)	11.1 (8.6)	10.1 (8.8)	0.50
CKD stage at baseline	I	17 (24.7%)	17 (25.0%)	0.92
	II	18 (26.1%)	16 (23.5%)	
	IIIa	18 (26.1%)	16 (23.5%)	
	IIIb	16 (23.2%)	19 (27.9%)	

Note: Data are presented as mean (standard deviation) or n (%), unless otherwise specified.
Abbreviations: ACR, urine albumin (mg)-to-creatinine (g) ratio; AGT/cr = angiotensinogen (μg)-to-creatinine (g) ratio; CKD, chronic kidney disease; DBP, diastolic blood pressure; F&V, fruit and vegetable; HbA1c, hemoglobin A1c; SBP, systolic blood pressure.

RESULTS

We screened 381 individuals for CKD and CVD risk, of whom 91.5% (N=335) had ACR of >10 mg/g. Of those, 142 (42.4%) met inclusion/exclusion criteria and were randomized (Fig 1). Table 1 summarizes demographic, socioeconomic, and biometric variables of participants by treatment group. All were self-declared African Americans, and 66 (47.1%) were low-income (≤$25K annually) by regional measures. Educational achievement was higher in F&V + Cook than F&V Only ($P = 0.03$). Baseline diastolic (DBP) ($P = 0.05$) but not SBP ($P = 0.054$) was higher in F&V + Cook than F&V Only.

Seventy-one percent (101 of 142) remained in the protocol at 6 months. An intervention effect for between-groups was assessed for dietary intake at baseline and 6 weeks, including total calorie, fat, protein, F&V, and sodium intake; however, no statistically significant effects were identified between groups. Table 2 shows mean dietary intake by group at baseline and 6 weeks. There was an insufficient number of participant responses at 6 months to accurately assess dietary intake at that time point. Net F&V intake increased in both groups at 6 weeks but was significant for F&V Only ($P = 0.01$) but not F&V + Cook ($P = 0.51$). Table 2 also shows no statistically significant difference in dietary sodium, potassium, protein, fat, or calories between baseline and 6 weeks. F&V Only retrieved an average ± standard deviation of 5.36 ± 1.09 F&V bags and F&V + Cook retrieved 5.46 ± 1.36 for the first 6 weeks. During the follow-up phase (ie, 6 weeks to 6 months), F&V Only retrieved 10.76 ± 6.29 F&V and F&V + Cook retrieved 11.51 ± 6.40 bags. F&V + Cook attended 5.23 ± 1.47 of 6 weekly cooking classes.

From the adjusted mixed model in Table 3, average ACR was lower for F&V + Cook at 6 months compared with F&V Only ($P = 0.02$). The adjusted ACR was 0.69 mg/g lower for F&V + Cook compared with FV Only at 6 months, which represented 31% lower ACR. In addition, those with less education had higher ACR across all time points. Furthermore, the adjusted model showed that average ACR was lower for participants who retrieved 20 or more F&V bags than those who retrieved less than 20 ($P < 0.01$). Across all groups, lower HbA1c and lower DBP were associated with lower ACR. For each 1 unit increase in HbA1c, ACR increased by 17.4% ($P < 0.01$). For each 1 unit increase in DBP, ACR increased by 2.0% ($P = 0.03$). There was not a statistically significant difference in AGT/cr between groups over time.

Mean ± standard deviation for ACR at baseline was 31.3 ± 38.1 and 23.5 ± 32.2 for F&V + Cook and F&V Only, respectively; at 6 weeks was 24.2 ± 34.1 and

Table 2. Descriptive statistics for dietary intake at baseline and 6 weeks for F&V + Cook and F&V Only group

Variable	N	Baseline Mean (SD)	6 wks Mean (SD)	*P*
F&V+Cook group				
Total calorie intake (kcal)	43	1,676.93 (625.42)	1,607.74 (538.17)	0.52
Total fat intake (g)	43	72.48 (29.96)	66.46 (26.48)	0.24
Total protein intake (g)	42	70.09 (27.57)	71.03 (25.7)	0.86
Total sodium intake (mg)	44	3,074.11 (1,241.5)	2,854.55 (1,119.59)	0.29
Total potassium intake (mg)	44	2,345.53 (740.86)	2,286.95 (845.28)	0.12
Total fruit intake (cups)	44	1.05 (0.85)	1.31 (1.03)	0.11
Total vegetable intake (cup)	44	1.86 (1.15)	1.81 (1.21)	0.78
Total F&V intake (cups)	44	2.91 (1.47)	3.11 (1.76)	0.51
F&V only group				
Total calorie intake (kcal)	47	1,671.42 (594.69)	1,670.3 (594.6)	<0.99
Total fat intake (g)	47	73.71 (33.45)	71.32 (29.95)	0.68
Total protein intake (g)	45	71.44 (25.6)	71.72 (35.11)	0.96
Total sodium intake (mg)	45	2,922.46 (1,020.84)	3,056.72 (1,179.9)	0.49
Total potassium intake (mg)	47	2,167.14 (796.10)	2,390.31 (1,045.60)	0.68
Total fruit intake (cups)	47	1.01 (0.88)	1.23 (1.14)	0.20
Total vegetable intake (cups)	47	1.45 (0.95)	2.13 (1.38)	0.004
Total F&V intake (cups)	47	2.46 (1.49)	3.35 (2.15)	0.01

Note: Only participants with 2 or more ASA24s were included.
Abbreviation: F&V, fruit and vegetable.

22.7 ± 30.1 for F&V + Cook and F&V Only, respectively; and at 6 months was 21.2 ± 33.0 and 23.4 ± 37.0 for F&V + Cook and F&V Only, respectively, as shown in Fig 2.

Secondary outcomes were evaluated because more compared with less F&V showed favorable effects on blood pressure,[52] LDL cholesterol,[53] and HbAlc.[44,54] There were no statistically significant changes from baseline at 6 months between groups for these secondary outcomes. This was confirmed through analyses considering these outcomes dichotomized as high or low risk. Additionally, in models analyzing the subgroup with elevated baseline values, no statistically significant changes were observed over time between groups.

A subanalysis evaluated the effect of increased F&V consumption on secondary health outcomes in the entire study population by analyzing F&V + Cook and F&V Only as a combined group. The net increase in F&V intake was significant for the combined group ($P < 0.02$). Models fitted for participants in the combined group with elevated values at baseline showed significant changes over time in adjusted models. Among participants with elevated baseline values (Methods), SBP decreased by 5.4 mm Hg ($P < 0.01$) and DBP by 5.0 mm Hg ($P < 0.01$) at 6 weeks compared with baseline after adjusting for other variables ($P < 0.01$). Participants with baseline elevated LDL had a 12.1 mg/dL decrease ($P < 0.01$) and a 10.3 mg/dL decrease ($P < 0.02$) compared with baseline at 6 weeks and 6 months, respectively. HDL increased by 3.9 mg/dL at 6 months ($P < 0.01$) compared with baseline. Compared with baseline, HbA1c decreased at 6 weeks ($P < 0.01$) and 6 months ($P < 0.01$), including only those with elevated baseline values.

DISCUSSION

This randomized parallel 2-arm trial supported the feasibility of a screening strategy to identify community-dwelling African Americans with elevated ACR indicative of elevated CVD and CKD risk and enroll and sustain them in a 6-month protocol that increased F&V intake. This feasibility trial importantly showed that participants receiving adjuvant cooking instructions with F&Vs had 31% lower ACR at 6 months than those receiving F&Vs alone. These data support the potential importance of adjuvant cooking instructions to achieve the cardiovascular and kidney health benefits of F&Vs assessed by ACR reduction. This suggests that scaling this F&V intervention to achieve its community-wide cardiovascular and kidney health benefits associated with reduced ACR requires adjunctive cooking instructions with its added logistics and costs. This finding helps identify effective factors of multicomponent interventions to establish minimum interventions needed to yield maximum beneficial health outcomes.[33]

The ACR reduction associated with F&V provision reiterates findings in participants receiving nonprotocol cooking instructions with higher baseline ACR (macroalbuminuria).[29] The present study supports that the F&V intervention with cooking instructions can effectively reduce ACR in individuals with lower ACR elevations, which are nevertheless associated with increased CVD[17] and CKD[18] risk. Further larger studies will examine if the F&V intervention yields lower CVD and better kidney health outcomes in individuals with milder ACR elevations and if adjunctive cooking instructions are required to achieve this benefit.

Table 3. Adjusted estimate of the effect of intervention on ACR

Variable	Levels	Estimate	Standard Error	95% Confidence Interval	*P*
Time	6 wk	0.21	0.20	(-0.19, 0.61)	0.30
	6 mo	0.40	0.22	(-0.03, 0.83)	0.07
	Baseline (reference)	.	.	.	.
Group	F&V+ Cook	0.33	0.26	(-0.19, 0.85)	0.21
	F&V Only (reference)	.	.		.
Total F&V pickup	>=20 bags	-0.61	0.22	(-1.04, -0.17)	<0.01
	<20 bags (reference)	.	.	.	.
GROUP EFFECT Time × Group	6 wk F&V+ Cook	-0.41	0.29	(-0.98, 0.16)	0.16
	6 mo F&V+ Cook	-0.70	0.30	(-1.29, -0.11)	0.02
	[a]Reference (F&V Only)				
Covariates					
Age		-0.001	0.01	(-0.02, 0.02)	0.90
Sex	Female	-0.19	0.26	(-0.69, 0.31)	0.45
	Male (reference)	.	.	.	.
Education	Less than high school/ GED/diploma	-0.56	0.27	(-1.10, -0.02)	0.04
	Tech/some college	-0.09	0.24	(-0.57, 0.39)	0.71
	College or Grad (reference)	.	.	.	.
Baseline CKD Stage	II	0.38	0.28	(-0.18, 0.94)	0.18
	IIIa	0.45	0.29	(-0.11, 1.02)	0.11
	IIIb	0.32	0.29	(-0.25, 0.90)	0.27
	I (reference)	.	.	.	.
BMI at baseline		0.004	0.01	(-0.02, 0.03)	0.75
HbA1c at baseline		0.16	0.05	(0.05, 0.26)	<0.01
DBP at baseline		0.02	0.01	(0.002, 0.04)	0.03

Notes: ACR is log adjusted, inverse-logarithm was used when interpreting the estimates. Parameters were estimated using mixed-effect model to account for the within-subject correlation due to repeated measures.
Abbreviations: ACR, albumin (mg)-to-creatinine (g) ratio; CKD, chronic kidney disease; DBP, diastolic blood pressure; F&V, fruit and vegetable.
[a]Reference = control group (F&V Only).

Earlier studies showed that the F&V intervention was associated with significant ACR reductions at 1 month,[29] yet the present study showed no significant ACR reduction at 6 weeks. These earlier studies[29-32] provided F&Vs to the entire participant household, increasing measured F&V intake by 2.0 cups/d[32] compared with 0.55 cups/day in the present trial that provided F&Vs to only study participants. These earlier studies, however, assessed dietary intake using 3-day diaries,[29-32] not the "gold standard" ASA24[42] used in the present trial; dietary intake was therefore not the same between studies. As described, the present trial supports greater ACR reduction with greater F&V access, as participants in both groups who more frequently retrieved provided F&Vs had greater reductions in ACR, supporting a dosage effect of F&V retrieval. The greater net increase in F&V intake in the earlier studies might have been sufficient to reduce ACR at 1 month whereas the lower net F&V increase in the present trial did not reduce ACR at 6 weeks. Nevertheless, ACR reduction was detected at 6 months in the present trial. Further studies will better define the F&V "dose" with cooking instructions needed for ACR reduction, logistics required to achieve this dose (F&Vs for the entire household or to just the individual with elevated ACR), if effective dose differs according to ACR, and inform scaling strategies.

Earlier studies showed that the described average 2.0 cups/day net F&V increase in participants with CKD was associated with reduced urine AGT/cr at 1 year,[30] but the current trial showed that higher F&V intake was associated with no change in AGT/cr at 6 months. Further studies will determine if a greater net increase in F&V intake and/or longer exposure to increased F&Vs is necessary to decrease urine AGT/cr.

Across both groups, lower baseline HbA1c and DBP were associated with lower ACR and hence, lower risks of CVD[55] and CKD progression.[56,57] Like earlier studies showing that interventions providing F&Vs[52] or the Dietary Approaches to Stop Hypertension diet[58] with high proportions of F&Vs were associated with reduced BP, the current study supports that F&V addition was associated with lower BP over time in participants with baseline elevated BP. Lower BP in those with CKD has been associated with lower risk for CVD,[59,60] lower overall mortality,[61,62] and lower CKD progression risk in those with proteinuria.[63] Further, F&V provision across both groups was associated with improved cholesterol and HbA1c for those with elevated baseline values. Together, this illustrates that provision of F&Vs alone using a farm stand

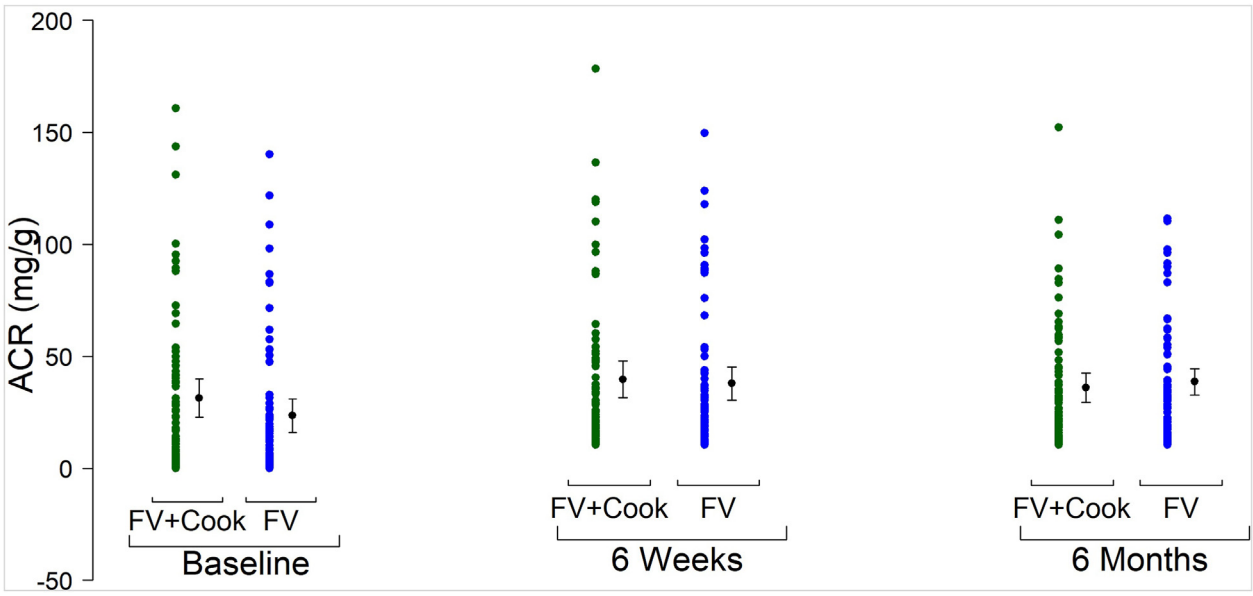

Figure 2. Individual participant values for albumin (mg)-to- creatinine (g) ratio (ACR) for F&V (fruit and vegetable) + Cook group and F&V Only group by time points. Green circles represent F&V + Cook participants and blue circles represent participant values for those who received F&V Only. Black circles to the right of the dot plots indicate mean and 95% confidence interval for the respective group.

model improves chronic disease risk factors. Targeted cooking instructions for specific chronic diseases, or use of culinary medicine practices, could further amplify the health benefits of added F&Vs. Because lower education is associated with worse outcomes in CKD,[64] cooking instructions should be relevant for underresourced populations.

Outcomes of exclusively health care system-based execution of current CKD guideline management are suboptimal.[65] Suboptimal outcomes likely relate to low implementation of evidence-based dietary adjuncts for diabetes and hypertension, the 2 most common causes of CKD in the United States.[1] High-dietary proportions of F&Vs are recommended as first-line diabetes treatment but are not adequately implemented in most people with diabetes.[66] Similarly, the Dietary Approaches to Stop Hypertension diet is recommended first-line hypertension therapy but is also underused.[67] The present F&V intervention including brief cooking instructions provides a simple adjunct that potentially increases use and scalability, particularly for underresourced communities.

Individuals with CKD generally have lower F&V intake[68,69] than already low US F&V intake,[70] and average F&V intake is lower still in African Americans.[71-73] The effectiveness of the F&V intervention to reduce indicators of CVD risk and CKD progression in individuals recruited from this high-risk community, not from health care systems, could inform strategies to reduce CVD and CKD incidence/prevalence in similar communities. Because many African Americans are concentrated in underresourced communities due to historic social policy,[74] these data support more focused CKD screening in underresourced African American communities at high-CKD risk[75] to identify asymptomatic individuals before advanced and symptomatic disease requires health care system engagement. Targeted screening of communities at high-CKD/CVD risk permits execution of "precision public health."[76] Hence, whether to screen *individuals* for CKD[77-79] should instead be whether to screen high-risk *communities* for CKD.[78,80]

Study limitations include small sample size, low-baseline ACR levels, and potential nonresponse bias for the ASA24 analysis at 6 months. Other limitations include 41 (29%) of 142 of participants were lost to follow-up and variable compliance in participant F&V retrieval during follow-up.

In conclusion, this trial showed the effectiveness of a community-based screening strategy to identify African Americans with elevated ACR and enroll them in a community-based intervention that increased F&V intake that was highly utilized. Participants receiving food preparation instructions adjunctive to F&Vs experienced reduced ACR, associated with reduced risks for CVD and CKD progression. Further, study participants improved chronic disease risk factors by study end regardless of cooking instruction. This trial and previous studies hold promise for identifying effective, easily accessible, and scalable strategies to reduce CVD outcomes and CKD incidence in communities at high risk for both.

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