A Dietary Intervention in Urban African Americans

Results of the "Five Plus Nuts and Beans" Randomized Trial

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Introduction: Unhealthy diets, often low in potassium, likely contribute to racial disparities in blood pressure. We tested the effectiveness of providing weekly dietary advice, assistance with selection of higher potassium grocery items, and a $30 per week food allowance on blood pressure and other outcomes in African American adults with hypertension.

Design: We conducted an 8-week RCT with two parallel arms between May 2012 and November 2013.

Setting/participants: We randomized 123 African Americans with controlled hypertension from an urban primary care clinic in Baltimore, Maryland, and implemented the trial in partnership with a community supermarket and the Baltimore City Health Department. Mean (SD) age was 58.6 (9.5) years; 71% were female; blood pressure was 131.3 (14.7)/77.2 (10.5) mmHg; BMI was 34.5 (8.2); and 28% had diabetes.

Intervention: Participants randomized to the active intervention group (Dietary Approaches to Stop Hypertension [DASH]–Plus) received 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. Participants in the control group received a printed DASH diet brochure along with a debit account of equivalent value to that of the DASH-Plus group.

Main outcome measures: The primary outcome was blood pressure change. Analyses were conducted in January to October 2014.

Results: Compared with the control group, the DASH-Plus group increased self-reported consumption of fruits and vegetables (mean=1.4, 95% CI=0.7, 2.1 servings/day); estimated intake of potassium (mean=0.4, 95% CI=0.1, 0.7 grams/day); and urine potassium excretion (mean=19%, 95% CI=1%, 38%). There was no significant effect on blood pressure.

Conclusions: A program providing dietary advice, assistance with grocery ordering, and $30/week of high-potassium foods in African American patients with controlled hypertension in a community-based clinic did not reduce BP. However, the intervention increased consumption of fruits, vegetables, and urinary excretion of potassium.

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Introduction

Elevated blood pressure (BP) is an extraordinarily common and important risk factor for cardiovascular disease and stroke, particularly among African Americans.[1,2] Recommendations to adopt the Dietary Approaches to Stop Hypertension (DASH) diet are recognized as integral to medical management of hypertension, yet suboptimal diets persist among patients with hypertension and likely contribute to racial disparities in BP control.[3] African American race and low income are strongly associated with unhealthy food intake.[4,5] There is a markedly lower availability of components of DASH diet foods such as fruits, vegetables, low-fat dairy, and nuts in predominantly African American and lower-income neighborhoods compared with Caucasian and higher-income neighborhoods.[5,6]

Unhealthy dietary patterns may contribute to risk of hypertension, in part because deficiencies in potassium, a micronutrient with independent BP-lowering effects, and from excess sodium intake, which elevates BP. Even moderate potassium deficiencies are associated with increased BP and salt sensitivity.[7] Furthermore, use of thiazide-based antihypertensive therapy, which is otherwise highly effective as an antihypertensive agent, worsens potassium deficiencies via increased urinary potassium excretion.[8] Inadequate intake and accelerated loss of potassium not only affect BP control but have also been directly linked to development of glucose intolerance.[9]

Strategies, such as tailored dietary advice, to improve adherence to dietary recommendations and reverse micronutrient deficiencies in African American adults with hypertension are needed.[4,10] We designed the trial to test the hypothesis that in African American adults with controlled hypertension on stable doses of antihypertensive medications, an intervention delivered by a health coach, with weekly provision of $30 worth of high-potassium foods consistent with key elements of the DASH diet, will lower BP; increase consumption of fruits, vegetables, nuts, and beans; increase urine potassium excretion; and improve cardiovascular disease risk factors, such as fasting glucose and low-density lipoprotein (LDL) cholesterol.

Methods

Study Design

We conducted a single-center RCT with two parallel arms as one project in the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities.[11] Our center used the principles of community-based participatory research to build strong ties between the researchers, healthcare provider networks, community members, and policymakers. The Center's Data and Safety Monitoring Board and Community Advisory Board participated in finalizing the design and in oversight throughout implementation.[12] Study visits occurred at an urban community-based clinic within Johns Hopkins Community Physicians in Baltimore, Maryland, serving a predominately low-income and African American patient population. Participants were randomized to one of the two intervention arms: (1) those receiving minimal intervention (control) and (2) those receiving coach-directed, tailored DASH diet advice (DASH-Plus). It was not possible to mask the participant or interventionist to the randomization assignment, but study personnel who performed the outcome follow-up assessments were masked. The total intervention period was 8 weeks, and study visits occurred between May 2012 and November 2013. The study was approved by the Johns Hopkins Medicine IRB. All participants provided written informed consent. The study was registered at clinicaltrials.gov (NCT01689844).

Study Sample

Inclusion criteria were an electronic medical record diagnosis of hypertension (ICD-9 code 401.1); age $\geq$21 years; self-reported African American race; average systolic BP (SBP) of 120–140 mmHg or diastolic BP (DBP) of 80–90 mmHg at the two most recent clinic visits, and stable doses of antihypertensive medications for a minimum of 2 months prior to randomization. Major exclusion criteria were self-report of a cardiovascular event within 6 months; a chronic disease that might interfere with trial participation (e.g., chronic kidney disease defined as an estimated glomerular filtration rate $<$60 mL/minute); unwillingness or inability to adopt a DASH-like diet; consumption of $>$14 alcoholic drinks per week; poorly controlled diabetes (hemoglobin A1c $>$9%); or use of insulin. Those using potassium supplements could enroll if they were willing to stop supplements 1 month prior to randomization and refrain from the supplements during the study.

We mailed brochures inviting potentially eligible participants identified through the clinic electronic medical record database to participate in the study. We recruited exclusively from those who responded with an interest in participating. Each invitation included a letter signed by the person's physician endorsing participation in the trial.

After informed consent and screening visits, eligible participants were randomly assigned in a 1:1 ratio. The study biostatistician generated the assignments using a pseudorandom number generator program with permuted block sizes of two, four, and six. Assignments were placed in consecutively numbered manila envelopes. Two participants lived together and a single randomization allocated both to the same treatment group.

Interventions

Control Group

Those assigned to the control group received printed materials on improving BP control by adoption of the DASH diet at their first visit with the study coordinator. This visit lasted 15 minutes and the coordinator gave no advice during or after this initial visit. Participants in this arm received a total of $240 in a debit account to purchase foods at the same community supermarket.