

DASH-Patterned Groceries and Effects on Blood Pressure The GoFresh Randomized Clinical Trial

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IMPORTANCE The Dietary Approaches to Stop Hypertension (DASH) eating plan lowered blood pressure (BP) among Black adults in a controlled environment, but to date, there are no grocery shopping strategies that replicated its health effects in a community setting.

OBJECTIVE The Groceries for Black Residents of Boston to Stop Hypertension (GoFresh) trial was conducted to determine the effects of low sodium-DASH groceries on systolic BP.

DESIGN, SETTING, AND PARTICIPANTS This parallel-group randomized clinical trial was conducted in Boston from August 2022 to September 2025 among Black residents of urban communities with few grocery stores, a systolic BP of 120 to less than 150 mm Hg, a diastolic BP less than 100 mm Hg, and no hypertension treatment. Data were analyzed from June through October 2025.

INTERVENTIONS Participants were randomly assigned to 12 weeks of home-delivered, DASH-patterned groceries ordered weekly with dietitian counseling without emphasizing cost or three \$500 stipends every 4 weeks intended for self-directed grocery shopping.

MAIN OUTCOMES AND MEASURES The primary comparison was the difference in the 3-month change in model-estimated office systolic BP (based on 3 measurements over at least 2 visits) between interventions. Adherence was assessed via 24-hour urine collection. Secondary outcomes included diastolic BP, body mass index (BMI), hemoglobin A_{1c} levels, and low-density lipoprotein (LDL) cholesterol. Maintenance of effects was assessed 3 months after intervention cessation.

RESULTS Among 180 participants, (mean [SD] age, 46.1 [13.3] years; 102 female [56.7%]; 180 self-reported Black [100%]; 12 Hispanic [6.7%]), 175 individuals (97.2%) completed the primary outcome assessment. Mean (SD) baseline systolic BP and diastolic BP were 130.0 (6.7) mm Hg and 79.8 (8.1) mm Hg. At 3 months, the mean systolic BP changed −5.7 mm Hg (95% CI, −7.4, to −3.9 mm Hg) in the DASH-patterned group and −2.3 mm Hg (95% CI, −4.1 to −0.4 mm Hg) in the self-directed group (difference in changes, −3.4 mm Hg; 95% CI, −5.9 to −0.8 mm Hg; *P* = .009). Compared with the self-directed group, after 3 months the DASH-patterned group changed mean diastolic BP by −2.4 mm Hg (95% CI, −4.2 to −0.5 mm Hg), urine sodium level by −545 mg/24 h (95% CI, −1041 to −50 mg/24 h), and LDL cholesterol by −8.0 mg/dL (95% CI, −13.7 to −2.3 mg/dL) (to convert LDL cholesterol to millimoles per liter, multiply by 0.0259). Effects were not maintained 6 months after the intervention was initiated. No effects occurred in BMI or hemoglobin A_{1c} level.

CONCLUSIONS AND RELEVANCE In this study, a program of home-delivered, DASH-style groceries plus dietitian counseling decreased BP and LDL cholesterol levels beyond comparable monetary compensation. However, effects were not maintained after the intervention ended.

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Elevated blood pressure (BP) and hypertension are prevalent in the US and disproportionately affect Black adults.¹ Interventions that lower BP reduce the risk of cardiovascular disease and premature death.² Previous studies suggested that diet was primarily responsible for disparities in hypertension between Black and White adults.³ The Dietary Approaches to Stop Hypertension (DASH) diet,^{4,5} a balanced eating plan emphasizing fruits, vegetables, low-fat dairy, and lean meats, lowered BP among Black adults with high BP⁵ by optimizing potassium relative to sodium in meals.⁴ However, food items used in DASH are less accessible⁶ for many adults living in communities with fewer grocery stores (ie, “food deserts”).⁷

Advances in home delivery from online grocery stores present a solution to improve access to healthy groceries⁸ by offering a wide selection of foods that may be customized to family preferences⁹ while overcoming geographic barriers related to store location. Indeed, the US Department of Agriculture continues to expand its Supplemental Nutrition Assistance Program (SNAP) ecommerce platform with an increasing number of vendors.^{10,11} Whether food supplementation programs like SNAP could be used to improve health through access to healthy food items is the focus of ongoing policy debate.¹² However, no strategies for selecting groceries from contemporary vendors have achieved the health benefits of DASH in general population settings. Such knowledge is essential for grocery prescription programs aimed at directing patients toward foods that will improve their health. In this setting, we conducted the Groceries for Black Residents of Boston to Stop Hypertension (GoFresh) trial to test whether home-delivered groceries, ordered online according to a flexible distillate of DASH principles with dietitian counseling, lowered systolic BP (SBP) compared with the provision of similar monetary compensation.

Methods

This randomized clinical trial was approved by the Beth Israel Deaconess Medical Center (BIDMC) institutional review board. All participants provided written, informed consent. This study is reported following the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Overview

GoFresh was an investigator-initiated, individually randomized, parallel-assignment trial conducted in Boston, Massachusetts (NCT05121337) (see eFigure 1 in Supplement 1 and the trial protocol and statistical analysis plan in Supplement 2).¹³ Participants were recruited from August 31, 2022, to March 20, 2025. The first participant was enrolled (randomized) on September 30, 2022. In this study, data collection through the 6-month maintenance visit (3 months after the intervention ended) concluded September 17, 2025, but follow-up through the 12-month visit will end in March 2026.

Population

Study visits occurred at the BIDMC Clinical Research Center or the Bowdoin Street Health Center, a BIDMC community clinic

Key Points

Question Can home-delivered, DASH-style groceries with dietitian counseling lower blood pressure among Black adults living in communities with few grocery stores?

Findings In this randomized clinical trial of 180 Black adults with elevated blood pressure or hypertension, low sodium-DASH groceries ordered online with dietitian counseling decreased blood pressure at 3 months vs a monetary stipend. Blood pressure increased back to baseline levels after the grocery intervention ended.

Meaning In this study, home-delivered, DASH-patterned groceries and dietitian counseling meaningfully decreased blood pressure among Black adults, but effects were not maintained after the intervention ended.

(Dorchester, Massachusetts). Recruitment focused on BIDMC patients and community-dwelling adults, using a broad range of strategies and advised by a community advisory board.¹³ Major inclusion criterion were being aged 18 years or older, self-identifying as African American or Black, having a measured SBP of 120 to less than 150 mm Hg and a diastolic BP (DBP) less than 100 mm Hg, and living in Boston-area communities with few grocery stores.^{14–16} Medical exclusions were active pharmacologic treatment for hypertension, diabetes (hemoglobin A_{1c} level $\geq 6.5\%$ [to convert to proportion of total hemoglobin, multiply by 0.01] or active pharmacologic treatment), a serum potassium level of 5.0 mEq/L or greater or less than 3.5 mEq/L (to convert to millimoles per liter, multiply by 1.0), an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73 m², or significant health conditions that could interfere with participation in the trial. Participants were also required to have access to refrigeration, cooking appliances, and Wi-Fi or cellular service and could not have significant food intolerances, nutritional requirements, or allergies that would interfere with diet adherence. No more than 1 member per household was permitted to enroll.

Randomization and Masking

The randomization schedule was generated by a computer algorithm by the study statistician (R.B.D.) and securely loaded into REDCap (REDCap Consortium).^{17,18} Allocation followed a permuted block scheme (sizes of 2, 4, or 6) in strata of baseline BP (SBP 120 to <140 mm Hg or 140 to <150 mm Hg). The allocation sequence was concealed. Participants and dietitians were aware of assignment after allocation but masked to outcome assessments. Staff performing outcome assessments, analysts, and other investigators were masked to assignment until after the last primary outcome assessment was completed.

Interventions

GoFresh interventions are described elsewhere.¹⁹ Participants were assigned 1 of two 12-week interventions: home-delivered DASH groceries or self-directed shopping with a monetary stipend. Participants assigned the DASH groceries condition completed weekly calls with a study dietitian (including K.F., J.M., and S.A.) to order groceries each week for

12 weeks via online grocery stores (Amazon Fresh, Instacart, or Whole Foods). The self-directed group received an unrestricted stipend every 4 weeks.

The grocery intervention was intended to be weight neutral. Calorie needs were estimated via the Mifflin-St Jeor energy estimator²⁰ and increased based on family size to allow for sharing at dinner. Groceries were ordered in fixed proportions of food groups to mirror DASH at different kilocalorie levels following the sliding scale and most serving sizes published by the National Heart, Lung, and Blood Institute at a median weekly cost of \$240 per family (eTables 1-3 in Supplement 1).²¹

During weekly calls, dietitians recorded meals consumed using nonstudy groceries to calculate weekly adherence,¹⁹ delivered a brief (target <15 minutes) nutrition lesson,¹⁹ and reviewed grocery orders, aiming to ensure a potassium to sodium ratio greater than 2.0 and a saturated fat level of less than 7% of total energy.⁴ After the grocery intervention, participants were asked via a 5-point Likert scale if they enjoyed the groceries and if the diet was easy to understand (1 [none of the time] to 5 [all the time]). A response of 4 or 5 was considered agreement.

Participants who were assigned self-directed shopping received a handout about DASH²² and a stipend of \$500 disbursed at weeks 4, 8, and 12 during the intervention phase. There were no restrictions placed on the stipend, and participants were informed that they would not be asked about how it was spent.

Study Visits

Interested participants underwent a prescreening call, at least 2 on-site screening visits, a virtual run-in visit used to test food delivery, and a randomization visit. After randomization, participants entered the 12-week intervention phase. Within the last week of the intervention phase, participants returned for 2 follow-up visits typically scheduled within 24 hours of each other to assess primary and secondary outcomes. After the second follow-up visit, participants entered the maintenance phase, with no groceries or stipend and minimal study contact. At 6 months after randomization, participants underwent another pair of in-person visits. At 12 months after randomization, participants underwent a final, closeout telephone call focused on longer-term behavior change (to be reported later).

Primary Outcomes and Comparison

The primary outcome was change in mean office-based SBP after 3 months comparing the DASH groceries condition with the self-directed shopping condition. The mean of the prerandomization SBP was determined over 3 visits (the 2 screening visits and 1 randomization visit). After randomization, SBP was based on the mean of the 2 visits after the intervention phase at 3 months and the mean of 2 visits at 6 months during the maintenance phase.

Prior to BP measurement, participants were instructed to rest for 5 minutes with a supported back and with their arm at heart level and then undergo 3 measurements separated by a 60-second pause between measurements using an Omron

HEM907XL. Team members were present during measurements and used the nondominant arm with a cuff matching the measured midarm circumference. The same cuff size and arm were used throughout the study. Staff were recertified for BP measurement annually, and all devices were calibrated quarterly using a SimCube SC-4Kit BP simulator.²³ BP was required to be measured within a 2-week window for 3-month visits and a 3-month window for 6-month visits.

Adherence Outcomes

Adherence was assessed via 24-hour urine, 24-hour dietary recall, and validated food frequency questionnaires. For urine, participants could miss only 1 measurement and no more than 2 hours of recording over the 24-hour period. Participants could not be menstruating during the assessment. Urine sodium, potassium, and creatinine levels were measured by Quest Diagnostics. The 24-hour dietary recall was administered by staff using the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool^{24,25} and used to determine a DASH Diet Index score.²⁶ Food frequency questionnaires focused on fruits, vegetables, fiber, and fat.^{27,28}

Secondary Outcomes

Body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) was derived from height measured during screening and weight measured using the mean of 4 measurements (2 measurements over 2 visits) at the prerandomization visit, 3 months after randomization, and 6 months after randomization. Awake ambulatory BP monitoring was performed before randomization and at 3 months and 6 months after randomization. A Spacelabs OnTrak 90227 device was worn over 24 to 26 hours on the nondominant arm and programmed to record every 20 minutes during the day and every 30 minutes between 1:00 AM and 5:00 AM. Phlebotomy was performed before randomization and at 3 months and 6 months. Hemoglobin A_{1c} and serum lipid, potassium, and creatinine levels were measured by Quest Diagnostics; eGFR was reported using the 2021 race-free, creatinine-only equation.²⁹

Other Covariates

Participants self-reported age, sex assigned at birth, race and ethnicity (in addition to Black, if relevant; ethnicity options were Hispanic or Latino and not Hispanic or Latino), education level, marital status, annual income, weekly cost of groceries, employment status, and family size. Social Vulnerability Index percentile was used to estimate participant neighborhood socioeconomic status based on zip code.^{30,31} Primary meal preparer status was determined by whether a participant ate meals alone or reported cooking more hours than anyone else in their household.

Safety Monitoring and Dietary Symptoms

Participants were monitored for adverse events through scheduled visits and ad hoc reporting. Prespecified adverse events were extreme BP values (SBP ≥ 180 mm Hg or DBP ≥ 110 mm Hg), hyperkalemia (potassium levels ≥ 5.5 mEq/L), severe allergies (eg, anaphylaxis), or bowel problems resulting in hospitalization.

At prerandomization, 3-month, and 6-month visits, participants were administered a 4-point symptom scale used in DASH-Sodium,⁴ ranging from 1 (symptom did not occur) to 2 (symptom did occur and was mild), 3 (symptom did occur and was moderate), and 4 (symptom did occur and was severe). In addition, participants were asked about how they felt overall in the past 3 months, with responses using a Likert scale in which 1 corresponded to “Much worse than usual” and 5 corresponded to “Much better than usual.”

Statistical Analysis

The primary outcome comparison was difference in change in SBP between the 2 assignments. The sample size of 150 participants was powered to detect a between-group difference in SBP of -5.8 mm Hg (type I error of .05 and a power of 0.85) based on an SD of 11.85 and 11.40 observed elsewhere.⁴ We aimed to recruit at least 176 participants to account for a 15% attrition rate.

Analyses were performed using a modified intention-to-treat analysis. Given low attrition and minimal missing data, we performed a complete case analysis. Our primary comparison was the net effect of randomized assignment (DASH vs self-directed shopping) on office SBP from baseline to 3 months (primary) and 6 months after randomization. We estimated these effects from a generalized estimating equations model of SBP with 3 independent variables: assignment (DASH groceries vs self-directed shopping), visit (baseline, 3 months, and 6 months), and the assignment-visit interaction, using an exchangeable correlation structure and a robust variance estimator. We performed prespecified sensitivity analyses to address BPs measured outside time windows, off protocol, and in the setting of medication changes.³²⁻³⁵ Other sensitivity analyses examined non-adherence or adjusted for baseline BP and zip code. The 20 eligible zip codes were grouped into 13 neighborhoods and treated as a categorical variable. Effect modification was assessed in prespecified strata of baseline age, sex, meal preparer status, BMI, hemoglobin A_{1c} level, family size, and SBP via generalized estimating equations using 3-way interaction terms.

Using similar models, we determined the effect of DASH groceries vs self-directed shopping on 24-hour urine sodium and potassium levels, 24-hour dietary recall (nutrients, food groups, and DASH Diet Index²⁶), and validated food frequency screeners,^{27,28} as well as secondary outcomes: office DBP, awake SBP and DBP, eGFR, and lipid, hemoglobin A_{1c}, serum potassium, and serum creatinine levels.

Adverse events were tabulated by assignment. In addition, we described participant-reported symptoms (median and proportion with no symptoms), comparing them at each period with Wilcoxon signed-rank tests.

Data were adjudicated prior to unblinding (June 26, 2025) using a randomly generated assignment variable. Analyses were conducted with SAS statistical software version 9.4 (SAS Institute). A 2-tailed $P < .05$ was considered statistically significant. A hybrid parallel line plot³⁶ was created in Stata statistical software version 15.1 (StataCorp). Data were analyzed from June through October 2025.

Results

Study Participants

Of 5548 adults assessed for eligibility, we randomized 180 participants (mean [SD] age, 46.1 [13.3] years; 102 female [56.7%]; 180 self-reported Black [100%]; 12 Hispanic [6.7%]) (Figure 1; Table 1). Among these, 175 individuals (97.2%) completed the primary outcome assessment at 3 months and 167 individuals (92.8%) completed the 6-month visit within the window (eTables 4-5 in Supplement 1). Mean (SD) baseline systolic BP and diastolic BP were 130.0 (6.7) mm Hg and 79.8 (8.1) mm Hg.

Blood Pressure

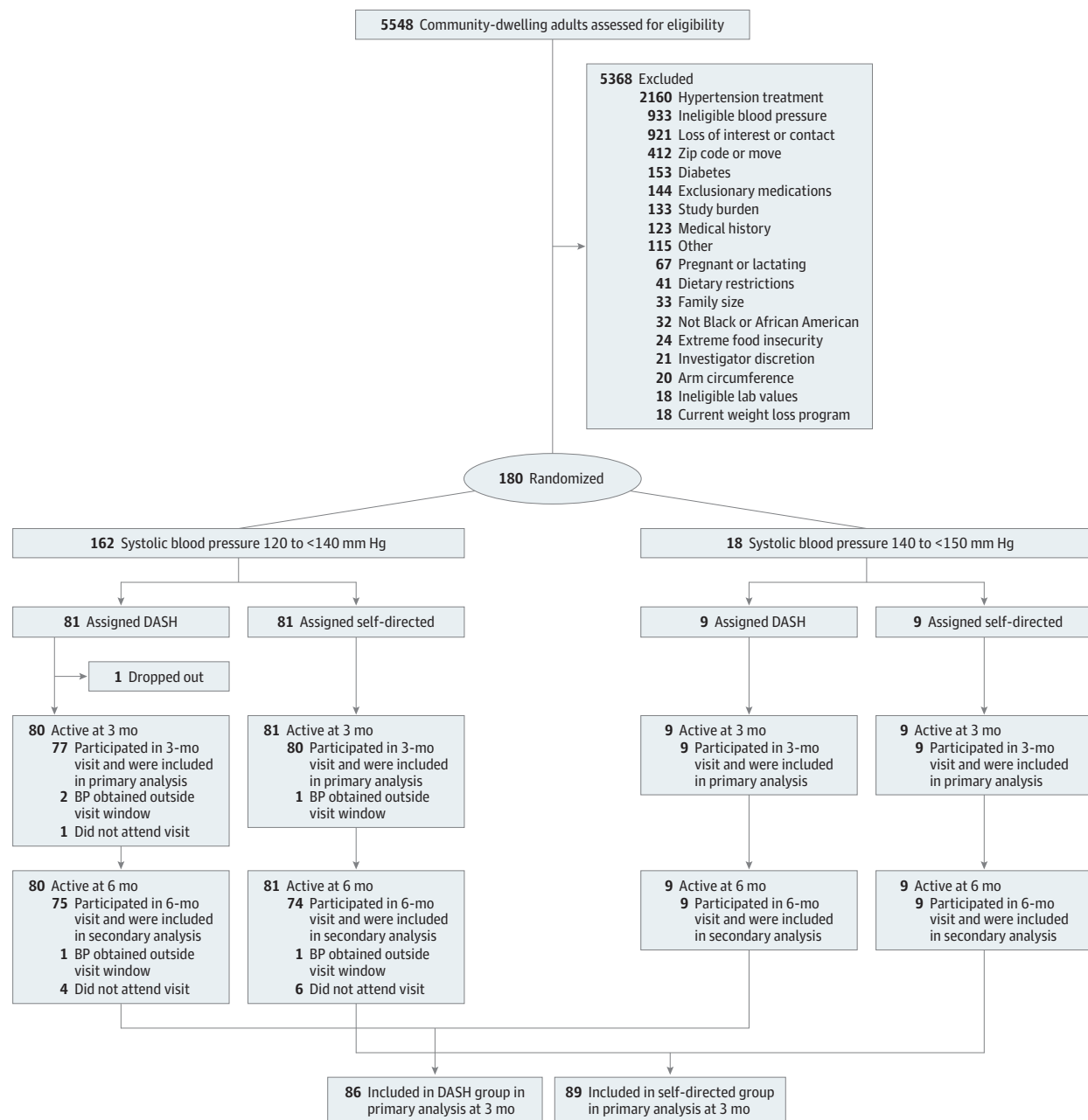
At 3 months, the mean SBP (primary outcome) changed by -5.7 mm Hg (95% CI, -7.4 to -3.9 mm Hg) in the DASH group and -2.3 mm Hg (95% CI, -4.1 to -0.4 mm Hg) in the self-directed group (difference in changes, -3.4 mm Hg; 95% CI, -5.9 to -0.8 mm Hg; $P = .009$) (Figure 2A; eFigure 2 in Supplement 1; Table 2). After 3 months of the maintenance phase, the mean SBP increased significantly among participants assigned to DASH (2.4 mm Hg; 95% CI, 0.8 to 4.0 mm Hg) but not the self-directed group (-1.1 mm Hg; 95% CI, -3.1 to 0.9 mm Hg), with a difference in changes of 3.5 mm Hg (95% CI, 0.7 to 6.0 mm Hg) (Figure 2B; Table 3). Mean DBP (a secondary outcome) followed a similar pattern (eFigure 2 in Supplement 1); after 3 months the DASH-patterned group changed mean diastolic BP by -2.4 mm Hg (95% CI, -4.2 to -0.5 mm Hg) compared with the self-directed group. There was no significant difference in hypertension medication changes between groups (eTables 6-7 in Supplement 1), and sensitivity analyses resulted in comparable inferences (eTables 8-9 in Supplement 1). Mean effects were similar across subgroups, although, maintenance between 3 and 6 months was better among primary meal preparers (eTable 10 in Supplement 1).

Adherence

Participant median (IQR) adherence to meals was 94.8% (91.7%-97.2%) based on weekly reports to dietitians. Among 82 responders, 80 individuals (97.6%) agreed that they enjoyed the groceries, and among 83 responders, 80 individuals (96.4%) reported that DASH was easy to understand. At 3 months, there was a significant change in mean 24-hour urine sodium excretion of DASH vs the self-directed group (-545 mg/24 h; 95% CI, -1041 to -50 mg/24 h) (Table 2 and Table 3; eTables 11-12 in Supplement 1). In contrast, there was no significant change in mean 24-hour urine potassium excretion of DASH vs the self-directed group (158 mg/24 h; 95% CI, -86 to 402 mg/24 h).

At 3 months, there was a significant difference in the change in mean 24-hour recall for sodium intake (-1118 mg/d; 95% CI, -1727 to -508 mg/d), total kilocalories (-490 kcal/d; 95% CI, -845 to -134 kcal/d), saturated fat intake (-10.6 g/d; 95% CI, -16.4 to -4.7 g/d), and the DASH index score (0.69 points; 95% CI, 0.16 to 1.22 points) (Table 2 and Table 3; eTables 11-14 in Supplement 1). Similarly, the rapid food frequency screener generally showed higher consumption of fruit and vegetables and lower consumption of fat and

Figure 1. Study Flowchart



There were 380 participants who screened more than 1 time, among whom, results of the last screening visit are presented. After randomization, some people may have skipped a visit for miscellaneous reasons. In some cases, participants provided information (eg, family death), but the reason was not determined in many cases. However, many of these participants returned for later visits. The figure indicates individuals contributing to blood pressure analyses and those who remained active in the study. Exclusionary medications included (1) unstable doses over the past 2 months in sodium-glucose cotransporter 2 inhibitors, stimulants, inhaled or oral medications for asthma or chronic obstructive pulmonary disease, hormone therapy or thyroid hormone, and weight-increasing psychotropic agents (including antipsychotic agents, lithium, and mirtazapine);

(2) any use of potassium supplementation (except if part of a multivitamin), warfarin, chronic oral corticosteroid use, weight loss medications (including glucagon-like peptide-1 receptor agonists); (3) unstable doses of vitamin, mineral, and botanical supplements; or (4) any medication not compatible with participation as determined by investigators. Ineligible laboratory values were serum potassium levels of 5.0 mEq/L greater or less than 3.5 mEq/L, an estimated glomerular filtration rate less than 30 mL/min/1.73 m² by the Chronic Kidney Disease Epidemiology Collaboration equation, or hemoglobin A_{1c} levels of 6.5% or greater. (To convert hemoglobin A_{1c} to proportion of total hemoglobin, multiply by 0.01; potassium to millimoles per liter, multiply by 1.0.) DASH indicates Dietary Approaches to Stop Hypertension.

saturated fat at 3 months in the DASH vs self-directed group (Table 2 and Table 3; eTable 12 in Supplement 1). These

between-assignment differences were not as pronounced and were nonsignificant in the maintenance phase.

Table 1. Baseline Participant Characteristics

Characteristic	Participants, No. (%) (N = 180)	
	DASH groceries (n = 90)	Self-directed grocery shopping (n = 90)
Demographic characteristics		
Age, mean (SD), y	46.5 (12.7)	45.8 (14.0)
<65	83 (92.2)	82 (91.1)
≥65	7 (7.8)	8 (8.9)
Sex		
Female	47 (52.2)	55 (61.1)
Male	43 (47.8)	35 (38.9)
Black or African American ^a	90 (100)	90 (100)
Ethnicity		
Hispanic or Latino	5 (5.6)	7 (7.8)
Not Hispanic or Latino	85 (94.4)	83 (92.2)
Birth region		
Africa	5 (5.6)	9 (10.0)
Caribbean	13 (14.4)	14 (15.6)
US	72 (80.0)	67 (74.4)
Education		
≤High school	14 (15.6)	9 (10.0)
Some college	34 (37.8)	30 (33.3)
≥College graduate	42 (46.7)	51 (56.7)
Marital status		
Single	57 (63.3)	50 (55.6)
Married or living with partner	22 (24.4)	20 (22.2)
Divorced or separated	9 (10.0)	17 (18.9)
Widowed	1 (1.1)	2 (2.2)
Unknown or prefer not to answer	1 (1.1)	1 (1.1)
Annual household income, \$		
<30 000	23 (25.6)	16 (17.8)
30 000 to 59 999	23 (25.6)	20 (22.2)
≥60 000	35 (38.9)	43 (47.8)
Unsure or prefer not to answer	9 (10.0)	11 (12.2)
Social Vulnerability Index percentile, median (IQR) ^b	99.0 (96.0-99.0)	96.0 (94.0-99.0)
Employment status		
Full time	47 (52.2)	51 (56.7)
Part time	17 (18.9)	11 (12.2)
Unemployed	26 (28.9)	28 (31.1)
Past weekly spending on groceries, mean (SD), \$	163.6 (110.8)	194.5 (128.1)
Meal preparer status of index participant		
Primary meal preparer	74 (82.2)	71 (78.9)
Not primary meal preparer	16 (17.8)	19 (21.1)
Family size		
No. members, median (IQR) ^c	2.5 (1.5-3.5)	2.0 (1.0-3.0)
Single person	19 (21.1)	24 (26.7)
>1 Person	71 (78.9)	66 (73.3)
Previous experience with online grocery shopping ^d		
No. with data	89	90
No. (%)	46 (51.1)	47 (52.2)

(continued)

Table 1. Baseline Participant Characteristics (continued)

Characteristic	Participants, No. (%) (N = 180)	
	DASH groceries (n = 90)	Self-directed grocery shopping (n = 90)
Physical findings		
Systolic BP, mean (SD), mm Hg ^e	129.8 (6.7)	130.3 (6.7)
120 to <130	52 (57.8)	47 (52.2)
130 to <140	29 (32.2)	34 (37.8)
140 to <150	9 (10.0)	9 (10.0)
Diastolic BP, mean (SD), mm Hg ^e	79.1 (7.4)	80.5 (8.7)
<80	48 (53.3)	40 (44.4)
80 to <90	40 (44.4)	40 (44.4)
90 to <100	2 (2.2)	10 (11.1)
BMI, mean (SD)	30.8 (6.0)	31.3 (6.7)
Underweight (<18.5)	0	0
Normal (18.5 to <25)	16 (17.8)	14 (15.6)
Overweight (25 to <30)	29 (32.2)	28 (31.1)
Obesity (≥30)	45 (50.0)	48 (53.3)
Laboratory findings^f		
Hemoglobin A _{1c} , mean (SD), %	5.5 (0.4)	5.5 (0.4)
<5.7	58 (64.4)	61 (67.8)
5.7 to <6.5	32 (35.6)	29 (32.2)
eGFR, mean (SD), mL/min/1.73 m ²	94.5 (16.4)	95.4 (18.4)
30 to <60	2 (2.2)	6 (6.7)
60 to <90	34 (37.8)	22 (24.4)
≥90	54 (60.0)	62 (68.9)
LDL cholesterol, mean (SD), mg/dL	121.0 (34.6)	112.9 (29.5)

Abbreviations: BP, blood pressure; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); DASH, Dietary Approaches to Stop Hypertension; eGFR, estimated glomerular filtration rate; LDL, low-density lipoprotein.

SSI conversion factors: To convert hemoglobin A_{1c} to proportion of total hemoglobin, multiply by 0.01; LDL cholesterol to millimoles per liter, multiply by 0.0259.

^a Self-reported Black or African American race was an inclusion criterion.

^b Social Vulnerability Index was based on zip code using crosswalk files from the Department of Housing and Urban Development. The range is 0 to 100. Most vulnerable is indicated by 100.

^c Number of people eating at least 1 meal together; children aged younger than 18 years were designated by 0.5, while persons aged 18 years and older were designated by 1. These numbers were totaled to provide the total family size per enrollee.

^d One participant assigned DASH groceries was missing this information.

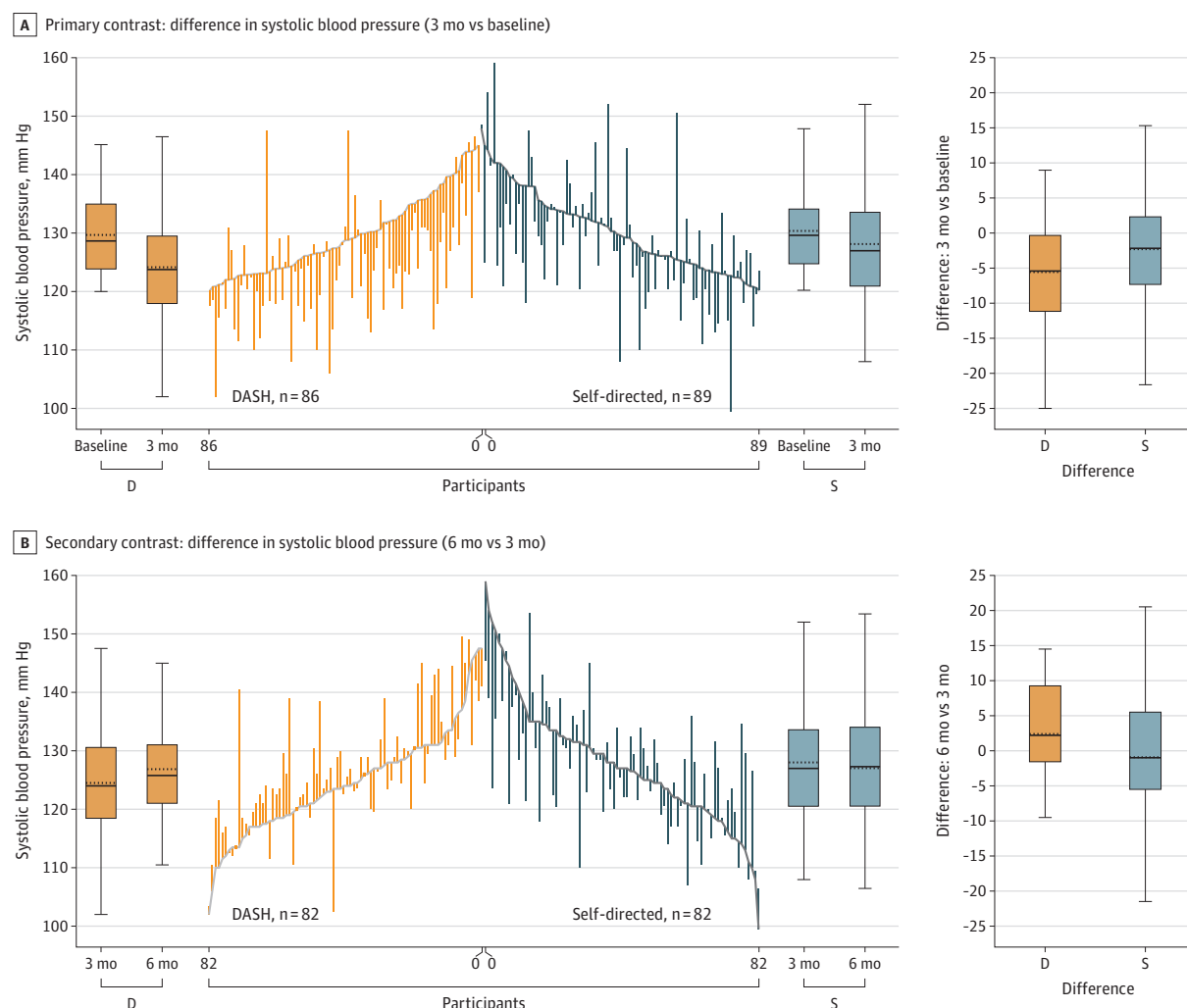
^e Blood pressure is based on the mean of 3 measurements per visit over 3 visits prior to randomization.

^f Reference ranges were defined by Quest Diagnostics (hemoglobin A_{1c} <5.7%; eGFR ≥60 mL/min/1.73 m²; LDL cholesterol <100 mg/dL).

Secondary Outcomes

Compared with the baseline, 3-month changes in mean BMI, hemoglobin A_{1c} levels, and eGFR did not differ significantly between DASH and self-directed groups (Table 2 and Table 3; eTables 15-16 in Supplement 1). In contrast, at 3 months DASH resulted in significantly decreased awake SBP (difference in changes of −2.8 mm Hg; 95% CI, −5.3 to −0.2 mm Hg), mean awake DBP (difference in changes of −1.8 mm Hg; 95% CI, −3.4 to −0.1 mm Hg), total cholesterol level (difference in changes

Figure 2. Parallel Line Plot of Difference in Systolic Blood Pressure



The primary contrast of 3 months vs baseline (A) and secondary contrast of 6 months vs 3 months (B) are shown. Central are participant prerandomization and postrandomization systolic blood pressure values ordered by the prerandomization value. Orange (left) indicates the Dietary Approaches to Stop Hypertension (DASH) assignment, and blue (right) indicates the self-directed group. Light and dark gray lines represent prerandomization systolic blood pressure values for the DASH and self-directed groups, respectively. Box-and-whisker plots on the left (orange; labeled *D*) show the distribution of DASH group systolic blood pressure values at baseline (90 participants) and 3 months (86 participants). The first set of box-and-whisker plots on the right

(blue; labeled *S*) show the distribution of DASH group systolic blood pressure values at baseline (90 participants) and 3 months (89 participants). The most rightward pair of box-and-whisker plots (orange and blue; labeled *Difference*) show the distribution of the difference (postrandomization – prerandomization systolic blood pressure values). The number of participants in panel A (86 + 89 participants) totals to the 175 individuals who contributed to the primary analysis (Figure 1). In Panel B, the number of participants (82 + 82 participants) is less than the total 167 participants contributing to the primary analysis because of 3 participants who did not participate in the 3-month visit. See eTable 5 in [Supplement 1](#) for additional details of participant participation.

of -9.3 mg/dL; 95% CI, -15.9 to -2.7 mg/dL), and LDL cholesterol level (difference in changes of -8.0 mg/dL; 95% CI, -13.7 to -2.3 mg/dL) compared with the self-directed group (to convert LDL and total cholesterol to millimoles per liter, multiply by 0.0259).

Adverse Events and Symptoms

Adverse events were rare (eTable 17 in [Supplement 1](#)). There was 1 unrelated gastrointestinal event among participants in the grocery intervention group and no hyperkalemia events among individuals with chronic kidney disease. Compared with the self-directed group at 3 months, the DASH group re-

ported more flatulence and more frequent urination but also fewer changes in fluid intake, with more participants reporting that they felt better overall (eTable 18 in [Supplement 1](#)).

Discussion

In this randomized clinical trial of Black adults living in urban communities with a lower number of grocery stores, a home-delivered program consisting of low sodium-DASH groceries ordered in conjunction with dietitian counseling resulted in greater reductions in SBP, DBP, and LDL cholesterol

Table 2. Effect of Intervention at 3 mo vs Baseline on Primary, Adherence, and Secondary Outcomes

Outcome	Participants, No. ^a		DASH groceries group		Self-directed group			DID, β (95% CI) ^b	
	Baseline	3 mo	Mean (SE)		Mean (SE)				
			Baseline	3 mo	Baseline	3 mo			
Primary									
SBP, mm Hg ^c	180	175	129.8 (0.7)	124.1 (1.0)	-5.7 (-7.4 to -3.9)	130.3 (0.7)	128.1 (1.1)	-2.3 (-4.1 to -0.4)	-3.4 (-5.9 to -0.8)
Adherence									
24-h urine									
Potassium, mg/24 h	179	172	1940 (83)	2053 (88)	113 (-61 to 287)	1900 (72)	1855 (83)	-45 (-216 to 126)	158 (-86 to 402)
Sodium, mg/24 h	179	172	3123 (164)	2493 (121)	-630 (-992 to -268)	2994 (135)	2910 (148)	-85 (-424 to 254)	-545 (-1041 to -50)
Creatinine, mg/24 h	179	172	1578 (59)	1529 (57)	-49 (-141 to 43)	1518 (56)	1473 (56)	-44 (-134 to 45)	-5 (-133 to 124)
Potassium-sodium ratio	179	172	0.43 (0.03)	0.60 (0.04)	0.17 (0.10 to 0.25)	0.42 (0.02)	0.43 (0.02)	0.01 (-0.04 to 0.07)	0.16 (0.07 to 0.25)
Potassium-creatinine ratio	179	172	0.33 (0.02)	0.36 (0.02)	0.03 (0.00 to 0.05)	0.34 (0.01)	0.34 (0.01)	-0.00 (-0.02 to 0.02)	0.03 (-0.00 to 0.06)
Sodium-creatinine ratio	179	172	0.91 (0.04)	0.75 (0.04)	-0.16 (-0.24 to -0.07)	0.89 (0.03)	0.89 (0.04)	-0.00 (-0.09 to 0.08)	-0.15 (-0.28 to -0.03)
24-H diet recall									
Calories, kcal/24 h	179	171	2106 (132)	1808 (91)	-298 (-587 to -10)	1756 (88)	1948 (102)	192 (-16 to 399)	-490 (-845 to -134)
Saturated fat, g/24 h	179	171	27.2 (2.1)	18.7 (1.1)	-8.5 (-12.7 to -4.4)	22.1 (1.6)	24.1 (1.8)	2.0 (-2.1 to 6.1)	-10.6 (-16.4 to -4.7)
Sodium, mg/24 h	179	171	3474 (216)	2630 (125)	-845 (-1288 to -401)	2891 (151)	3164 (210)	273 (-145 to 691)	-1118 (-1727 to -508)
Potassium, mg/24 h	179	171	2688 (172)	2701 (132)	12 (-406 to 431)	2213 (98)	2588 (128)	375 (92 to 658)	-363 (-868 to 142)
DASH Diet Index, points ^d	179	171	3.71 (0.14)	4.32 (0.16)	0.61 (0.23 to 0.98)	3.80 (0.15)	3.72 (0.16)	-0.08 (-0.46 to 0.29)	0.69 (0.16 to 1.22)
Food screener									
Fruit and vegetable, servings/24 h	180	177	3.81 (0.20)	4.97 (0.19)	1.16 (0.73 to 1.58)	3.48 (0.19)	3.79 (0.15)	0.30 (-0.04 to 0.65)	0.85 (0.31 to 1.40)
Saturated fat, g/24 h	180	178	27.4 (0.8)	20.1 (0.8)	-7.2 (-9.0 to -5.5)	25.9 (0.8)	23.9 (0.7)	-2.0 (-3.5 to -0.6)	-5.2 (-7.5 to -2.9)
Total fat, g/24 h	180	178	92.5 (2.2)	72.7 (2.2)	-19.8 (-24.7 to -14.9)	90.5 (2.3)	85.0 (1.9)	-5.5 (-9.4 to -1.5)	-14.3 (-20.6 to -8.1)
Calories from fat, %/24 h	180	178	34.5 (0.5)	29.5 (0.5)	-5.0 (-6.2 to -3.7)	33.9 (0.6)	32.6 (0.5)	-1.4 (-2.4 to -0.4)	-3.6 (-5.1 to -2.0)
Secondary									
DBP, mm Hg	180	175	79.1 (0.8)	75.1 (0.8)	-3.9 (-5.2 to -2.7)	80.5 (0.9)	79.0 (1.1)	-1.6 (-2.9 to -0.2)	-2.4 (-4.2 to -0.5)
BMI	180	175	30.81 (0.63)	30.79 (0.62)	-0.02 (-0.27 to 0.23)	31.33 (0.70)	31.35 (0.67)	0.02 (-0.18 to 0.23)	-0.04 (-0.37 to 0.28)
Awake SBP, mm Hg	180	175	133.0 (0.9)	128.8 (1.1)	-4.2 (-6.0 to -2.4)	132.9 (1.0)	131.4 (1.1)	-1.4 (-3.2 to 0.4)	-2.8 (-5.3 to -0.2)
Awake DBP, mm Hg	180	175	82.7 (0.8)	80.0 (0.8)	-2.7 (-3.9 to -1.5)	82.4 (0.8)	81.5 (1.0)	-0.9 (-2.0 to 0.2)	-1.8 (-3.4 to -0.1)
Total cholesterol, mg/dL	180	176	202.6 (4.0)	188.5 (4.1)	-14.0 (-18.8 to -9.3)	192.5 (3.6)	187.7 (3.8)	-4.7 (-9.3 to -0.1)	-9.3 (-15.9 to -2.7)
Log (HDL cholesterol, mg/dL) ^e	180	176	4.09 (0.03)	4.04 (0.03)	-0.05 (-0.08 to -0.02)	4.09 (0.03)	4.06 (0.03)	-0.02 (-0.06 to 0.01)	-0.02 (-0.07 to 0.02)
LDL cholesterol, mg/dL	179	175	121.2 (3.6)	109.8 (3.5)	-11.4 (-15.5 to -7.3)	112.9 (3.1)	109.5 (3.0)	-3.4 (-7.4 to 0.6)	-8.0 (-13.7 to -2.3)

(continued)

Table 2. Effect of Intervention at 3 mo vs Baseline on Primary, Adherence, and Secondary Outcomes (continued)

Outcome	DASH groceries group			Self-directed group		
	Participants, No. ^a	Mean (SE)		Mean (SE)		
	Baseline	3 mo		Baseline	3 mo	
Log (triglycerides, mg/dL) ^e	180	176	4.41 (0.05)	4.43 (0.05)	4.34 (0.04)	4.34 (0.05)
HbA _{1c} , %	180	175	5.50 (0.04)	5.52 (0.04)	5.47 (0.04)	5.51 (0.04)
Serum potassium, mEq/L	180	176	4.22 (0.03)	4.27 (0.03)	4.23 (0.03)	4.19 (0.03)
Serum creatinine, mg/dL	180	176	0.89 (0.02)	0.90 (0.02)	0.88 (0.02)	0.87 (0.02)
eGFR, mL/min/1.73 m ²	180	176	94.5 (1.7)	93.7 (1.8)	95.4 (1.9)	95.5 (1.9)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); DASH, Dietary Approaches to Stop Hypertension grocery intervention group; DBP, diastolic blood pressure; DiD, difference in difference; eGFR, estimated glomerular filtration rate; HbA_{1c}, hemoglobin A_{1c}; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure; SDG, self-directed group.

SI conversion factors: To convert creatinine to micromoles per liter, multiply by 88.4; HbA_{1c} to proportion of total Hb, multiply by 0.01; HDL, LDL, and total cholesterol to millimoles per liter, multiply by 0.0259; potassium to millimoles per liter, multiply by 1.0; triglycerides to millimoles per liter, multiply by 0.0113.

^a No. of participants contributing measurements at baseline and 3 months.

^b Difference-in-difference and change values were generated via generalized estimating equations (exchangeable correlation structure, normal family, identity link, and robust variance estimator). Diets were compared with the visit-by-assignment interaction. Changes within assignment, 6 month vs baseline comparisons, and *P* values may be found in eTable 12 and eTable 16 in Supplement 1.

^c Mean SBP and DBP are based on the mean of 3 measurements per visit over 3 visits prior to randomization and 2 visits at 3 months.

^d In the DASH index, 1 is lowest DASH adherence, while 11 is highest DASH adherence.

^e Natural log transformed to address data skew.

levels compared with a condition of comparable monetary compensation. The DASH grocery intervention had a stronger effect on sodium than potassium. Effects were not maintained after grocery intervention withdrawal.

In various research settings, low-sodium-DASH dietary patterns have been inversely associated with hypertension and cardiovascular disease.³⁷⁻⁴¹ Mechanisms by which a low-sodium DASH diet lowers BP among Black adults include ancestry (increased sodium retention and salt sensitivity)^{42,43} and potassium (potentially due to lower intake).⁴⁴ Prior provisions of DASH foods in community settings have not been effective for BP reduction,⁴⁵ possibly due to incomplete dietary replacement or not emphasizing the right nutrients.^{46,47} GoFresh represents one of the first general population demonstrations that low-sodium DASH groceries tailored for family preferences following simplified DASH nutrient principles (fixed ratios of food items, a potassium to sodium ratio >2.0, and a saturated fat target of <7%) may be effectively implemented with contemporary grocery providers as an approach to lower BP. This knowledge may be applied by practitioners to advise patients on how to purchase groceries to improve their cardiometabolic health or by those administering nutrition plans and programs to inform grocery purchases for larger populations of people.

Potassium was a major focus of the grocery intervention due to its direct effects on BP, ability to facilitate sodium excretion,⁴⁸ and proven effectiveness among Black adults.⁴⁹ Nevertheless, grocery orders fell below the per-kilocalorie density level achieved in the DASH-Sodium trial,⁴ and the grocery intervention did not result in a significant increase in urine potassium levels (158 mg/24 hours in GoFresh vs approximately 1500-1600 mg/24 hours in DASH-Sodium). This may explain why GoFresh did not decrease SBP as much as the original DASH-Sodium population of Black participants who were not hypertensive).⁴ Notably, unlike early DASH trials, GoFresh did not allow fruit juice, which can be high in potassium, to avoid added sugar that seemed to worsen glycemia in 1 grocery intervention.⁴⁶ Sodium, in contrast, was easier to reduce through replacement with less-processed grocery items naturally lower in sodium. Smaller changes in potassium may also indicate a higher baseline intake of vegetables observed via the 24-hour recall, as well as suboptimal adherence to fruit and vegetable recommendations during the study.

Groceries were higher in kilocalories from monounsaturated and polyunsaturated fat compared with the original DASH diet. In the OmniHeart trial,⁵⁰ replacing carbohydrates with healthy fats further decreased BP and LDL cholesterol levels. Like the original DASH trial, our grocery intervention resulted in lower LDL cholesterol levels, presumably related to the reduction in saturated fat. Notably, fiber intake, an alternative determinant of LDL cholesterol, did not differ significantly between randomized groups. Our findings are aligned with the current understanding of saturated fat intake as a major determinant of LDL cholesterol levels.⁵¹ Like with BP, the magnitude of reduction was not as large as in the original DASH trial (−8.0 mg/dL in GoFresh vs −10.7 mg/dL in DASH⁴); however, this was greater than prior grocery interventions.^{46,47}

Table 3. Effect of Intervention at 6 mo vs 3 mo on Primary, Adherence, and Secondary Outcomes

Outcome	Participants, No. ^a		DASH groceries group		Self-directed group		DIDs, β (95% CI) ^b
	3 mo	6 mo	Mean (SE)	6 mo – 3 mo, β (95% CI)	Mean (SE)	6 mo – 3 mo, β (95% CI)	
			3 mo	6 mo	3 mo	6 mo	
Primary							
SBP, mm Hg ^c	175	167	124.1 (1.0)	126.5 (1.1)	128.1 (1.1)	127.0 (1.1)	3.5 (0.9 to 6.0)
Adherence							
24-h urine							
Potassium, mg/24 h	172	164	2053 (88)	1764 (95)	1855 (83)	1889 (103)	–323 (–596 to –50)
Sodium, mg/24 h	172	164	2493 (121)	2609 (157)	2910 (148)	3075 (183)	–49 (–534 to 436)
Creatinine, mg/24 h	172	164	1529 (57)	1418 (56)	1473 (56)	1548 (69)	–185 (–340 to –31)
Potassium-sodium ratio	172	165	0.60 (0.04)	0.49 (0.04)	0.43 (0.02)	0.40 (0.02)	–0.08 (–0.18 to 0.03)
Potassium-creatinine ratio	172	165	0.36 (0.02)	0.33 (0.02)	0.34 (0.01)	0.32 (0.01)	–0.02 (–0.06 to 0.02)
Sodium-creatinine ratio	172	165	0.75 (0.04)	0.81 (0.04)	0.89 (0.04)	0.88 (0.04)	0.07 (–0.05 to 0.19)
24-H diet recall							
Calories, kcal/24 h	171	168	1808 (91)	1775 (89)	1948 (102)	1793 (97)	122 (–144 to 388)
Saturated fat, g/24 h	171	168	18.7 (1.1)	21.4 (1.5)	24.1 (1.8)	20.8 (1.3)	5.9 (1.7 to 10.2)
Sodium, mg/24 h	171	168	2630 (125)	2809 (153)	3164 (210)	2962 (208)	382 (–154 to 918)
Potassium, mg/24 h	171	168	2701 (132)	2390 (130)	2588 (128)	2382 (150)	–104 (–544 to 336)
DASH Diet Index, points ^d	171	168	4.32 (0.16)	3.99 (0.16)	3.72 (0.16)	3.74 (0.15)	–0.35 (–0.92 to 0.23)
Food screener							
Fruit and vegetable, servings/24 h	177	170	4.97 (0.19)	3.91 (0.19)	3.79 (0.15)	3.71 (0.19)	–0.98 (–1.49 to –0.48)
Saturated fat, g/24 h	178	170	20.1 (0.8)	20.8 (0.8)	23.9 (0.7)	22.2 (0.7)	2.4 (0.7 to 4.2)
Total fat, g/24 h	178	170	72.7 (2.2)	74.6 (2.1)	85.0 (1.9)	80.3 (1.9)	6.6 (1.7 to 11.5)
Calories from fat, %/24 h	178	170	29.5 (0.5)	30.0 (0.5)	32.6 (0.5)	31.4 (0.5)	1.7 (0.4 to 2.9)
Secondary							
DBP, mm Hg	175	167	75.1 (0.8)	76.3 (0.9)	79.0 (1.1)	77.7 (1.0)	2.4 (0.7 to 4.1)
BMI	175	167	30.79 (0.62)	30.75 (0.63)	31.35 (0.67)	31.35 (0.65)	–0.05 (–0.35 to 0.25)
Awake SBP, mm Hg	175	166	128.8 (1.1)	131.8 (1.2)	131.4 (1.1)	132.1 (1.1)	2.3 (–0.2 to 4.8)
Awake DBP, mm Hg	175	166	80.0 (0.8)	81.7 (0.9)	81.5 (1.0)	81.9 (0.9)	1.2 (–0.4 to 2.9)
Total cholesterol, mg/dL	176	168	188.5 (4.1)	194.9 (4.1)	187.7 (3.8)	188.8 (4.1)	5.3 (–0.9 to 11.5)
Log (HDL cholesterol, mg/dL) ^e	176	168	4.04 (0.03)	4.08 (0.03)	4.06 (0.03)	4.06 (0.03)	0.04 (0.01 to 0.08)
LDL cholesterol, mg/dL	175	165	109.8 (3.5)	114.0 (3.6)	109.5 (3.0)	110.4 (3.2)	3.3 (–1.9 to 8.5)

(continued)

Table 3. Effect of Intervention at 6 mo vs 3 mo on Primary, Adherence, and Secondary Outcomes (continued)

Outcome	Participants, No. ^a			DASH groceries group		Self-directed group				
	3 mo	6 mo		Mean (SE)		Mean (SE)		3 mo	6 mo	6 mo – 3 mo, β (95% CI)
Log (triglycerides, mg/dL) ^b	176	168		4.43 (0.05)	4.42 (0.05)	4.34 (0.05)		4.34 (0.05)	4.39 (0.05)	0.04 (–0.02 to 0.11)
HbA _{1c} , %	175	169		5.52 (0.04)	5.56 (0.04)	5.51 (0.04)		5.51 (0.04)	5.53 (0.04)	0.02 (–0.01 to 0.05)
Serum potassium, mEq/L	176	168		4.27 (0.03)	4.24 (0.03)	4.19 (0.03)		4.19 (0.03)	4.18 (0.03)	–0.01 (–0.08 to 0.06)
Serum creatinine, mg/dL	176	168		0.90 (0.02)	0.90 (0.02)	0.87 (0.02)		0.87 (0.02)	0.89 (0.02)	0.01 (–0.01 to 0.03)
eGFR, mL/min/1.73 m ²	176	168		93.7 (1.8)	93.5 (1.8)	95.5 (1.9)		95.5 (1.9)	93.5 (2.0)	–2.0 (–4.2 to 0.2)

^b Difference-in-difference and change values were generated via generalized estimating equations (exchangeable correlation structure, normal family, identity link, and robust variance estimator). Diets were compared with the visit-by-assignment interaction. Changes within assignment, 6 month vs baseline comparisons, and *P* values may be found in eTable 12 and eTable 16 in Supplement 1.

^c Mean SBP and DBP are based on the mean of 3 measurements per visit over 2 visits at 3 months and 2 visits at 6 months.

^d In the DASH index, 1 is lowest DASH adherence, while 11 is highest DASH adherence.

^e Natural log transformed to address data skew.

Future work should examine the impact of the grocery intervention on subclinical cardiac damage.^{40,41}

Our study did not show greater effects from the intervention with increased age, for women vs men, or by baseline hypertension, which were observed in the original DASH trials.^{4,5} Beyond differences in the intervention, DASH enrolled participants with higher BP, and interventions were not randomized within strata of these characteristics. GoFresh randomized the intervention in strata of hypertension. Further research is needed to replicate these findings.

GoFresh resulted in lower SBP and LDL cholesterol at levels comparable to those in large trials performed outside the US that reduced cardiovascular disease; the Salt Substitute and Stroke Study (SSaSS) trial lowered SBP by 3.3 mm Hg,⁵² while Prevención con Dieta Mediterránea (PREDIMED) lowered LDL cholesterol levels by 5.8 mg/dL at 3 months.^{53,54} These findings provide evidence for how groceries may be ordered to improve cardiometabolic health. However, GoFresh health benefits were not maintained after the grocery intervention withdrawal, suggesting that either or both groceries and active dietitian counseling were essential for long-term maintenance. Currently, neither of these items is accessible to many US communities. DASH groceries can be expensive⁹ and inaccessible.⁵⁵ Moreover, there is a national shortage of registered dietitians,⁵⁶ as well as variable insurance coverage. While future research should examine strategies that make grocery provision and dietitian services more cost-effective, policy discussions around making these groceries and services accessible are critical to prevent disease. Strengths of the study include inclusion of adults with distinct cultural traditions (ie, US, African, and Caribbean traditions), rigorous measures, high retention, and an intervention that can be scaled nationally.

Limitations

This study has several limitations. First, the grocery intervention was multifactorial (groceries, education, home delivery, and support for DASH food selection), and thus effects of DASH groceries cannot be isolated from those of other components, which represents an important focus for subsequent research. Second, the median grocery cost was \$240 a week per household, which may or may not be cost-effective relative to their existing groceries expenditures. However, the intervention has potential impacts on family members beyond the index participant and beyond hypertension alone. Moreover, it is unclear whether the unrestricted \$500 stipend every 4 weeks was more or less valuable in economic terms than the groceries. GoFresh did not focus on optimizing the intervention for cost. This could be accomplished in multiple ways (eg, choice of vendor, delivery arrangements, subsets of groceries, or digital technologies), which represents an important area for future research. Third, GoFresh was implemented in an urban setting with multiple grocery delivery options; this strategy would need to be replicated across other regions. Fourth, interventions were tested among Black adults without treated hypertension and without diabetes and would need to be evaluated among more demographic groups and health conditions.

Conclusions

In this randomized clinical trial, the provision of home-delivered, DASH-patterned groceries ordered with dietitian counseling to Black residents of Boston communities with

fewer grocery stores resulted in decreased SBP, DBP, and LDL cholesterol levels after 3 months, informing grocery-ordering strategies to improve cardiometabolic health. Longer-term maintenance of these benefits will likely require sustained access to healthy groceries and nutrition counseling.

ARTICLE INFORMATION

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Author Contributions: Dr Juraschek had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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