Effects of DASH Groceries on Blood Pressure in Black Residents of Urban Food Deserts With Treated Hypertension (GoFreshRx)

Short Title: Groceries for Black Residents of Boston to Stop Hypertension

PROTOCOL Version 1.6

August 11, 2025

SUMMARY OF MAJOR PROTOCOL VERSIONS AND CHANGES

Version 1.0

- Original version submitted to the Beth Israel Deaconess Medical Center Institutional Review Board on March 2, 2022**.**

Version 1.1

- Version 1.1 submitted to the Beth Israel Deaconess Medical Center Institutional Review Board on June 24, 2022**.**
- *Change: Reduced laboratory exclusion criteria of potassium from ≥5.2 to ≥5*

Version 1.2

- Version 1.2 submitted to the Beth Israel Deaconess Medical Center Institutional Review Board on August 22, 2022**.**
- *Change: Clarified exclusion related to "Extreme Food Insecurity"*

Version 1.3

- Version 1.3 submitted to the Beth Israel Deaconess Medical Center Institutional Review Board on December 28, 2022**.**
- *Change: Extended eligibility to East Boston, Everett, Jamaica Plain, Malden, and Roslindale, reflecting recent data on neighborhoods with few grocery stores.*

Version 1.4

- Version 1.4 submitted to the Beth Israel Deaconess Medical Center Institutional Review Board on February 3, 2023**.**
- *Change: Increased family size from 3 to 5 adults*

Version 1.5

- Version 1.5 submitted to the Beth Israel Deaconess Medical Center Institutional Review Board on February 17, 2023**.**
- *Change: Revised the safety response for diastolic blood pressure at SVa from ≥100 mm Hg to ≥105 mm Hg to align with systolic blood pressure and screening procedures.*

Version 1.6

- Version 1.6 submitted to the Beth Israel Deaconess Medical Center Institutional Review Board on November 16, 2023**.**
- *Change: Updated family size eligibility from 5 adults to 6 at dinner time*

GoFreshRx Protocol Table of Contents

LIST OF ABBREVIATIONS / GLOSSARY

ABPM	Ambulatory Blood Pressure Monitoring
AOBP	Automated Office Blood Pressure
BIDMC	Beth Israel Deaconess Medical Center
BMI	Body Mass Index
BP	Blood Pressure
CAB	Community Advisory Board
CRC	Clinical Research Center (at BIDMC)
CVD	Cardiovascular disease
DASH	Dietary Approaches to Stop Hypertension
DIGO	Diet Gout Trial
DBP	Diastolic Blood Pressure
DSMB	Data Safety and Monitoring Board
GTE	Getting to Equity
FV (1-3)	Follow-up Visit
GOFRESH	Groceries for Black Residents of Boston to Stop Hypertension Trial
GO	Grocery ordering calls
HIPAA	Health Insurance Portability and Accountability Act
HR	Heart rate
HTN	Hypertension
NIHMD	National Institute of Minority Health and Health Disparity
IRB	Institutional Review Board
OH	Orthostatic Hypotension
PS	Pre-Screening Visit
PRISM	Practical Robust Implementation Sustainability Model
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance [Implementation Framework]
RZ	Randomization Visit
SDOH	Social Determinants of Health
SNAP	Supplemental Nutritional Assistance Program
SBP	Systolic blood pressure
SV (a & b)	Screening Visit
USDA	US Department of Agriculture

1. ABSTRACT

Over **103 million adults** in the US have hypertension (HTN)[1] a major contributor to coronary heart disease and early death.[2] The rising prevalence in HTN is driven by increased consumption of high sodium, processed foods,[3] which is particularly rampant among low-income urban communities that are disproportionately Black.[4] Diet is the most substantial determinant of rising racial disparities in HTN risk,[4,5] highlighting a critical need for innovative solutions to overcome barriers to healthy eating among Black adults in the US. Our proposal tests a dietitian-assisted, technology-based DASH grocery intervention to improve access to and consumption of a DASH eating plan among Black adults in the Boston area urban food deserts. The intervention will provide (1) three months of DASH-patterned groceries, (2) basic and scalable online skills in DASH grocery shopping using a web-based home-delivery platform and training in food storage and preparation, and (3) information on local venues (co-ops, stores, and food pantries) where participants can source healthy foods long-term at lower cost. This study will establish the effectiveness of home-delivered DASH groceries sufficient to meet dietary needs to reduce blood pressure (BP) and improve cardiovascular risk factors. Moreover, we will identify facilitators and barriers to maintenance of DASH adherence and home meal preparation.

2. SPECIFIC AIMS

Aim 1: Determine the effectiveness of dietitian-assisted, virtually ordered, home-delivered DASH groceries on systolic BP (SBP) among Black adults with treated stage 1 or 2 hypertension. *H1.1* DASH groceries will lower SBP (primary outcome) compared to self-directed grocery shopping after 3 months and effects will be maintained at 6 months post-randomization.

Aim 2: Determine the immediate and sustained effects of dietitian-assisted grocery shopping on families' adoption of the DASH eating plan and frequency of home-prepared meals versus out-of-home dining, 3-, 5-6, and 12-months post-randomization. *H2.1* DASH groceries will ↑ DASH adherence (self-report, ↓urine sodium & ↑ potassium) and *H2.2* ↑ home-prepared meals and ↓ out-of-home dining (self-report, quantified using the SHoPPER questionnaire).

Aim 3: Evaluate the reach, maintenance, and cost-effectiveness of the intervention up to 12 months post-randomization using a RE-AIM framework and mixed methods. *H3.1:* Reach, quantified during our recruitment campaign, will be high. *H3.2:* A 3-month, dietitian-assisted program will be cost-effective compared to self-directed grocery shopping at 10 years. *H3.3:* Identifying barriers and facilitators in qualitative interviews will enhance scalability.

3. BACKGROUND

The DASH eating plan is a balanced eating plan rich in fruit, vegetables, low-fat dairy, and lean meats that is reduced in red meat, sweets, and sugary beverages.[6,7] A reduced sodium, DASH eating plan has been demonstrated in randomized trials to lower BP[8] within four weeks[9] and is endorsed by the American Heart Association (AHA).[10] Notably, the recipes in the original DASH trials were modeled after traditional American meals, dietary habits, and foods, using a one-size-fits-all approach,[6,7] but implementation in a diverse range of urban cultural and ethnic groups has been limited.

Over the past 20 years, the average consumption of fruits and vegetables has remained between 1-2 servings/day,[4] much lower than the 7-9 servings/day recommended in the DASH eating plan.[8] While improvements in diet have been observed among higher income groups, the average number of servings of fruit and vegetables among the 42 million recipients of US food stamps (SNAP or Supplemental Nutrition Assistance Program) has stagnated at 1.3 servings/day.[4] Lower diet quality is even more prevalent among Black versus White adults in urban areas.[11] The lower diet quality among Black adults is related to food insecurity, the inability to afford enough food for a healthy lifestyle,[12] and is experienced by 21% of Black (vs 16% of Hispanic and 8% of White) households.[13] Several national studies have found strong associations between food insecurity and higher BP,[14] worsening disparities in the prevalence of cardiometabolic diseases.[15]

Distance, cost, and cultural acceptability perpetuate dietary health disparities.[16] Education is necessary but not sufficient to address disparities in healthy eating because of barriers to accessing healthy foods related to pervasive social determinants of health (SDOH). First, many Black adults live in urban food deserts, defined as communities characterized by lower income and a low concentration of local healthy grocery stores, such that fresh produce cannot be accessed without a car or public transportation.[17,18] Second, DASH-like diets are costly,[19] and price prevents their consumption among adults with low incomes and on food assistance,[20] perpetuating the experience of food insecurity. Finally, urban settings contain rich cultural and ethnic diversity with diverse eating patterns that may not align with the published DASH meals,[21] despite attempts to translate to additional cultural groups.[22]

Virtual grocery delivery is a promising innovation to mitigate the barriers outlined above. Prior studies showed that home delivery of DASH meals improved health.[23,24] However, these studies relied on predetermined and fixed meals, which have limited generalizability to diverse groups and dietary preferences. In contrast, groceries can be prepared, adapted, or tailored to meet each person’s taste, enabling adults to customize healthy eating to their own family traditions, a feature highlighted by some groups as essential for improved acceptability of DASH foods.[25] The sustainability of this strategy is supported by the US Department of Agriculture (USDA), which launched a SNAP virtual purchasing pilot, to add online grocery vendors to their

ecommerce platform, which has seen widespread expansion during the COVID-19 epidemic.[26] The USDA also recently launched a “Food Box” program to provide fresh produce, dairy, and meat groceries to families affected by COVID-19.[27]

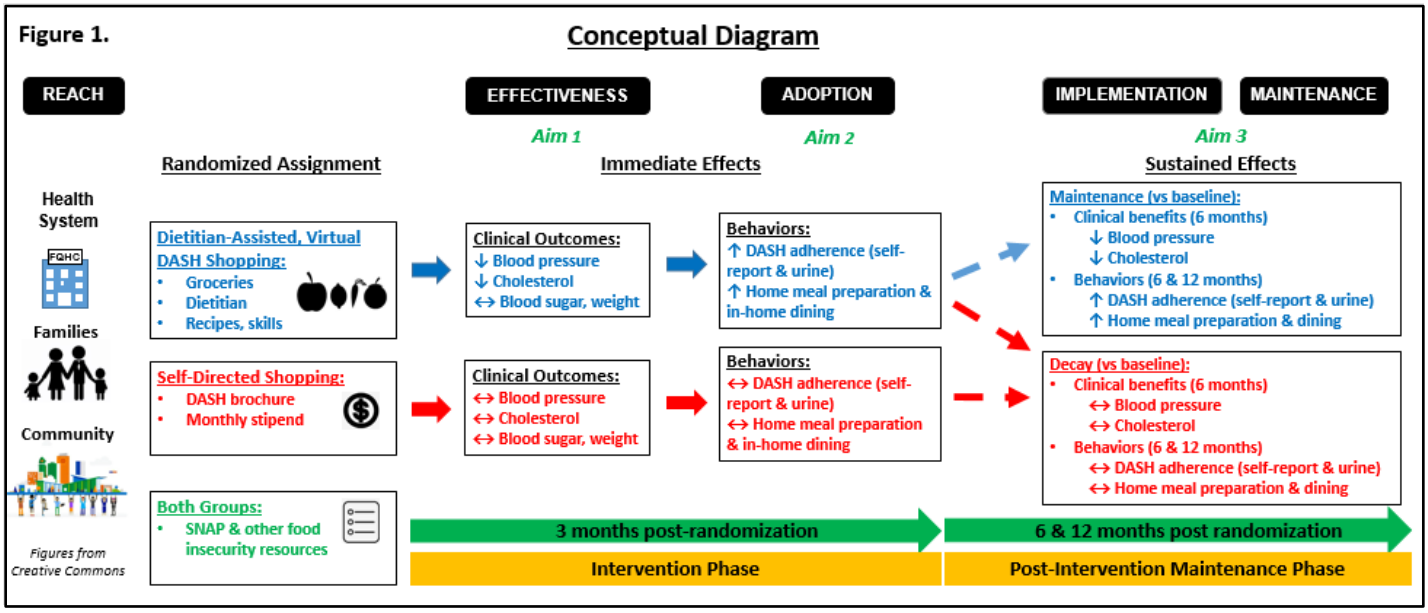
A growing number of food policy experts have advocated for grocery subsidies,[28] with some recommending that SNAP be restricted to fruits and vegetables alone as a means of addressing health disparities.[29,30] However, there is limited evidence that the mere provision of healthy groceries would affect long-term change in dietary intake. In contrast, the 5+ Nuts and Beans trial demonstrated that dietitian-assisted grocery shopping, even when limited to the SNAP allotment of $30/week, increased the number of fruit and vegetable servings consumed by urban-dwelling Black adults.[31] In a subsequent trial, we showed that dietitian-assisted DASH grocery shopping of $105/week with Amazon Fresh (the Diet Gout [DIGO] trial) lowered urine sodium excretion over a 4-week period.[32] These two trials suggest that the provision of groceries coupled with mild skill acquisition does improve consumption of the DASH eating plan.

There is a critical need for a rigorous trial that demonstrates clinical effectiveness. While prior work demonstrated the ability of dietitian-assisted, DASH grocery interventions for changing behavior, neither study significantly affected clinical outcomes like BP or LDL-cholesterol.[31,33] Comparison of our two trials suggests that further replacement of participants’ diets with study foods will achieve greater behavioral and clinical effects.

Translation and sustainability of the proposed intervention require a patient-centered focus that addresses SDoH. Even though the proposed intervention will improve access to healthy foods via grocery delivery, other contextual factors such as family dynamics, SDoH (e.g., food insecurity, lack of transportation), community norms and resources, culture, and even local or state level policies related to nutrition may affect continued consumption of the DASH eating plan. Using qualitative methods, we will evaluate the facilitators and barriers to sustaining the DASH eating plan among Black adults with Stage 1 or 2 HTN living in food deserts and the failure or success of the intervention from the participants’ perspective.

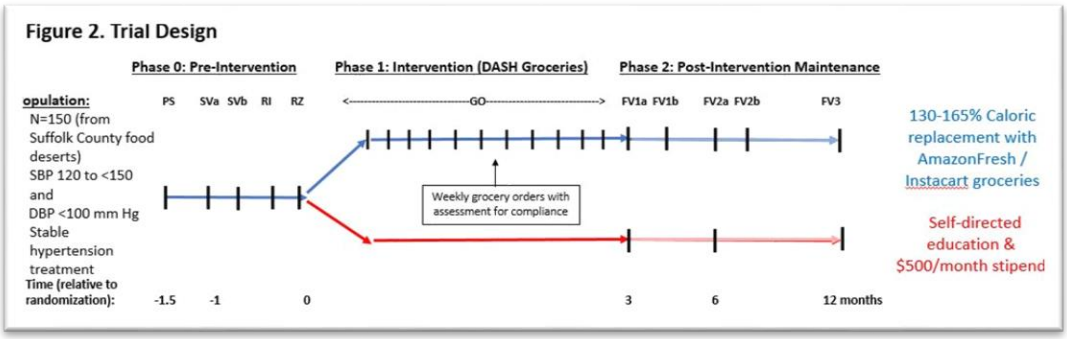
Findings from the proposed study will provide the evidence needed for policy makers to evaluate the long-term impact of addressing the adoption of the DASH eating plan in low-income populations. As more states and the USDA consider using SNAP benefits to purchase online groceries especially in the wake of COVID-19, our proposal has the potential to change national SNAP policies to sponsor a DASH-patterned grocery program if the intervention is effective and can be implemented at an affordable cost.[29]

4. OVERVIEW OF DESIGN



This project is guided by the National Institute of Minority Health and Health Disparities (NIMHD) health equity research framework while its evaluation will be guided by the RE-AIM implementation framework.[34,35] specifically, the NIMHD framework will be used to evaluate the impact of a multilevel intervention (dietitian-assisted, technology-based DASH groceries) to improve access to and consumption of a DASH eating plan by Black adults in Boston area food deserts (**Figure 1**). We will use RE-AIM to evaluate the reach, adoption, maintenance, and cost-effectiveness of the intervention to inform broader scalability (see section 7 for details related to the implementation aims).

Using a Hybrid Type I effectiveness-implementation design, we will randomly assign 150 Black adults with treated stage 1 or 2 HTN to one of two 3-month lifestyle interventions: (1) Dietitian-assisted, virtually-ordered, home-delivered groceries consistent with the DASH eating plan or (2) Self-directed grocery shopping. The study has an intervention phase and a post-intervention maintenance phase. During the intervention phase, we will perform a randomized controlled trial with two parallel arms (**Figure 2**).



Aim 1 focuses on outcomes measured at the beginning and end of the intervention phase (3-months post-randomization) and 6-months post-randomization during the post-intervention maintenance period. The primary outcome is office systolic BP (SBP). Secondary outcomes are office DBP, wake-time 24-hour SBP and diastolic BP (DBP), high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, and hemoglobin A1c. Aim 2 focuses on determining the effect of the intervention on DASH adherence (adoption) based on self-report and 24-hour urine electrolytes at 3- and 6-months post-randomization. We also determine meal preparation and dining practices at 3-, 6-, and 12-months post-randomization. Aim 3 will evaluate the reach, maintenance, and implementation (cost-effectiveness) of the intervention over the entire 12-month study using a RE-AIM framework.

5. STUDY POPULATION AND ELIGIBILITY

Eligibility criteria are summarized below. This trial focuses on hypertension in the setting of active stable blood pressure medication use. We will include families with less than or equal to 6 adults at dinner time to allow for sharing (a child less than 18 is counted as half an adult), while maintaining adequate food for the study participant.

Inclusion criteria

- Age 18 to 100 years
- Self-reported/self-identified as Black or African American
- Active treatment with medications intended for hypertension treatment within the last 6 months at stable doses
- Resting SBP of 120 to <150 mm Hg and DBP <100 mm Hg based on the cumulative average across three pre-randomization visits
- Residence in communities identified by the Massachusetts Department of Public Health as Suffolk County (Boston area) food deserts: Brighton, Chelsea, Dorchester, East Boston, Everett, Hyde Park, Jamaica Plain, Malden, Mattapan, Revere, Roslindale, Roxbury, or Winthrop
- Able to receive home-delivered groceries or pick them up at a convenient location and willing to eat only the groceries provided over a 12-week period
- Have access to refrigeration, cooking appliances, and Wi-Fi/cellular service
- Have access to mobile device or computer to be able to conduct grocery orders via video conference or by phone
- Willing and able to complete required measurement procedures

Exclusion criteria

Laboratory Exclusions:

- Serum potassium ≥5.0 mmol/L or <3.5 mmol/L
- Estimated glomerular filtration rate (eGFR) <30 mL/min per 1.73 m^2 by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) 2021, race-free, creatinine-based equation
- Hemoglobin A1c ≥6.5%

Medication Exclusions:

- Unstable doses of medications that lower BP or medications intended for hypertension treatment (including antihypertensives taken for non-hypertension purposes) within the last 6 months

- Unstable doses (i.e., a change in the 2 months prior to screening or randomization) of the following:
    - Sodium-glucose co-transporter 2 (SGLT2) inhibitors
    - Stimulants
    - Inhaled or oral medications for asthma or chronic obstructive pulmonary disease (COPD)
    - Hormone replacement therapy or thyroid hormone
    - Weight-increasing psychotropic agents, including antipsychotic agents, lithium, and mirtazapine
- Use of any of the following medications:
    - Potassium supplement, except if part of a multivitamin
    - Warfarin (Coumadin)
    - Chronic oral corticosteroid (intermittent use is okay)
    - Weight loss medications (including GLP-1 receptor agonists)
- Unwillingness to keep same dose of vitamin, mineral, and botanical supplements
- Any medication not compatible with participation as determined by the investigators

Physical Exclusions:

- SBP ≥150 mm Hg or DBP ≥100 mm Hg
- Body weight >420 pounds
- Arm circumference >50cm
- Weight loss or gain of >5.0% of body weight during prior 2 months

Medical History Exclusions:

- Type 1 or Type 2 Diabetes defined as a hemoglobin A1c ≥6.5% or diabetes treatment
- Active cardiovascular disease or any event in the prior 6 months, including coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA), myocardial infarction (MI), cerebrovascular accident (CVA), or congestive heart failure (CHF) exacerbation requiring hospital admission
- Cancer diagnosis or treatment in the last 2 years (non-melanoma skin cancer or localized breast or prostate or bladder cancer not requiring systemic therapy is acceptable)
- Active inflammatory bowel disease, bowel resection, malabsorptive syndrome, pancreatitis (episode within past year), or history of bariatric surgery
- Pregnancy or lactation or planned pregnancy
- Any emergency department (ED) visit for asthma or chronic obstructive pulmonary disease (COPD) in the last 6 months
- Any other serious illness or condition not compatible with participation as determined by the investigators

Lifestyle and Other Exclusions:

- Significant food allergies, preferences, intolerances, or dietary requirements that would interfere with diet adherence
- Consumption of more than 14 alcoholic drinks per week or consumption of more than 6 drinks on one or more occasion per week
- Active substance use disorder that would interfere with participation
- Extreme food insecurity*
- Participation in or planning to start a weight loss program
- Current participation in another clinical trial that could interfere with the study protocol
- Anticipated change in residence prior to the end of the study
- Families with more than 6 adults at dinner time (a child less than 18 is counted as half an adult)
- Investigator discretion

*To determine extreme food insecurity, participants who answer with “often true” responses to both questions on the Hunger Vital Sign questionnaire; i.e., “Within the past 3 months we worried whether our food would run out before we got money to buy more” and “Within the past 3 months the food we bought just didn’t last and we didn’t have money to get more” would be asked the following confirmatory question, “Within the past 3 months, have you involuntarily gone an entire day without eating?”. A “Yes” response to this confirmatory question would be used to define “Extreme Food Insecurity.”

6. RECRUITMENT

BIDMC Clinical Research Center

The trial study assessments will be conducted at the BIDMC Clinical Research Center (CRC), Bowdoin Street Health Center, or at a clinical office where the PI and his team currently practice within the greater BIDMC health network, as approved by our IRB in Boston, Massachusetts.

The Clinical Research Center is a research facility within BIDMC that maintains contiguous space for inpatient, outpatient, and administrative activities. The outpatient area consists of 12 rooms with 2 of these equipped with beds and private bathrooms. The unit staff includes nurses, patient care technicians, dietitians, dietary support staff, a laboratory assistant, and a practice coordinator. The unit is open for patient activity 24 hours per day, 7 days per week. In addition, the Sample Processing Laboratory Service processes samples for analysis at various laboratories, including Quest Diagnostics. Samples are stored at room temperature or in a monitored and alarmed refrigerator, -20 C freezer short-term or -80 C freezer for long-term storage.

Recruitment strategies

We will implement a variety of strategies to achieve our recruitment target, i.e., ~176 participants. Our experience is that multiple strategies work synergistically to promote study name-brand recognition to enhance recruitment. We will employ the following approaches:

(1) Website with information on the trial and GoFreshRx team members, as well as embedded Qualtrics form for sign up. The website is accessibility optimized. Sign up is built into the site and information will be directly sent to the gofresh@bidmc.org email.

(1) Flyers placed in the clinic waiting areas and flyer boards in the zip codes of interest with phone number, website, and QR code options.

(2) Direct mail of study brochures to BIDMC patients and Boston area residents in the ZIP codes of interest who identify as Black/African American. We will purchase community-based lists of Black/African American adults living in the Boston zip codes of interest. In addition, we will identify BIDMC patients through the BIDMC Insight Core based on zip code and race/ethnicity. These individuals will receive a study brochure with business reply mail as well as information on how to contact the study team via phone, web, or email.

(4) Primary care physicians that identify their patients as eligible for the study. We will advertise the study at faculty meetings and provide flyers and brochures to all primary care doctors.

In addition, we will work with our community advisory team to identify supplementary methods to identify patients living in minority communities. These are likely to include:

(5) Community outreach to faith-based organizations in our target communities. We have contacted primarily Black/African American based churches within the zip codes of interest as well as reached out to CAB members who have connections to faith-based Boston area communities. We plan to have church and clinic tabling events.

(6) Traditional media venues we will place advertisements using media with high penetration rates in underrepresented communities, such as the local newspaper, and other sources free to local community members. Although rarely necessary, we have also worked with the Massachusetts Bay Transit Authority (MBTA) to purchase public service advertising on local bus and subway routes. MBTA also offers geofencing, which is an emerging digital strategy to target residents in specific zip codes.

(7) Online advertising primarily using Facebook and Instagram, two social media sites with high numbers of users. Advertising will be done through the overarching Meta for Business platform and will be based out of a Facebook page using the GoFreshRx study information. Advertisements will adhere to language requirements regarding advertising to specific demographics, namely avoiding specifically referencing personal attributes of ad viewers as specified in Facebook's advertising policies.

(8) Clinic Recruitment we will have a recruitment table at the Bowdoin and Dimock Clinic. We will complete the prescreening form with interested participants and perform field-based BP screenings.

(9) MyChart recruitment we will leverage BIDMC's MyChart patient portal to reach potentially eligible participants efficiently. Eligible patients will be identified through the Slicer Dicer function on EPIC based on the study's inclusion/exclusion criteria. These patients will receive a secure MyChart message that includes a brief study overview and an option to express interest directly through the portal. The study team will follow up with interested patients to provide additional information and help answer any questions. MyChart messaging will be sent in waves to monitor engagement and response rates.

Community Advisory Board

The BIDMC Community Advisory Board (CAB) is a community-academic partnership comprised of community leaders, patients, clinicians, and advocates in the Boston area. The members of the CAB are volunteers from the community who will meet virtually on a regular basis, on average quarterly to provide community input on the research process. Volunteers for the CAB are recruited from diverse backgrounds (race, ethnicity, gender, professional, etc.) to afford a range of unique perspectives.

Function of the CAB

The members of the CAB will receive regular updates about the study and advise the research team on a variety of study-related items including the study design, recruitment, consent,

retention, educational material development, and dissemination efforts prior to and throughout implementation. The CAB members will contribute their personal and professional experience to the research project. The CAB will be guided by an agreement that will be generated, agreed upon, and signed by all the CAB members. This agreement includes the membership terms, meeting attendance requirements, roles, and responsibilities. Members of the CAB are expected to participate extensively in the research process so they can adequately address issues such that community dialogue can receive appropriate attention. Members of the CAB are compensated for their time for each meeting attended.

Recruitment for the CAB

Recruitment for the CAB is ongoing and new members will be added as attrition occurs. The CAB members will continue to be recruited through word of mouth, recommendations from community leaders, members, advocates, other CAB members, and BILH/BIDMC staff. The study team will provide CAB members with the background and an orientation for the study, new CAB members will be provided similar orientation prior to their first meeting.

Recruitment of women and Black adults

We will recruit 176 participants, anticipating a potential 15% attrition rate. We will recruit a population that is ~50% women and 100% Black. In order to achieve this goal, we will be tracking our recruitment goals on a weekly basis and making sure we are careful with our enrolment diversity in terms of gender.

7. DATA COLLECTION AND MEASUREMENTS

Measurement Schedule

Visit	PS	SVa & SVb	RI	RZ	GO	FV1a & FV1b	FV2a & FV2b	FV 3
Study Phase (PR = Pre-Intervention; I = Intervention; PO = Post-Intervention)	PR	PR	PR	PR	I	I	PO	PO
Type (C = Clinic; T = Telephone)		C	C/ T	C	T	C	C	T
Months(s)	-1.5	-1	-1	0	0-3	3	6	12
Verbal Consent	X							
Prescreening Questionnaire (PQ)	X							
Informed Consent		X						
Contact Information (CI)		X						
Demographics Form (DEMO)		X						
Medical History Questionnaire (MHQ)		X						
The eHealth Literacy Scale (eHEALS)		X						
Accountable Health Communities Health-Related Social Needs Screening Tool (AHC)		X						
Hunger Vital Sign Questionnaire (HVS)		X				X	X	X
Run-In Visit (Grocery Delivery Practice) (RI)			X					
Randomization Eligibility Form (REF)				X				
Randomization Assignment & Instructions (RA)				X				
Medication Reconciliation (MRX)		X		X		X	X	X
Mifflin St Jeor/Physical Activity Energy Estimator		X		X				
International Physical Activity Questionnaire Short Form (IPAQ-SF)		X		X				
Block Screeners (Fruit/Vegetables, Fat, & Sodium)		X				X	X	X
SHoPPER (meal preparation and behaviors) Questionnaire		X				X	X	X
Dietary Information Questionnaire (DIQ)		X						
Diet Symptoms Form (DS)		X				X	X	X
Height Measurement (BMI)		X						
Weight Measurement (BMI)		X				X	X	
26-Hour Blood Pressure Monitoring (ABPM)		X				X	X	
Omron HEM-907XL BP measurement		X		X		X	X	
Fasting phlebotomy (LAB)		X				X	X	
24-Hour Urine Collection (Na, K, Cr, Albuminuria, Ca, Mg) & Spot Urine (UC)		X				X	X	
24-Hour Recall (NUT)		X				X	X	
Perceived Stress Scale 4 (PSS-4)		X				X	X	X
Krieger Discrimination Questionnaire (KD)		X						
Pre-Post Intervention Knowledge Assessment Form (KNOW)				X		X		
Qualitative Interview (QI)						X		
Short Form Health Survey (SF-12)		X				X	X	X
Close Out Questionnaire (CO)								X
Intervention group only: Grocery Orders, Intervention Understanding (IU)					X			
Intervention group only: Diet Palatability					X	X		

Data collection contact schedule

Eligibility, baseline, and follow-up data will be collected by phone, through mailings, and at in-person visits. In-person data collection visits will primarily be conducted at the Clinical Research Center at BIDMC. Participants will be offered a stipend to help with transportation to and from in-person visits. In general, we will try to be as flexible as possible to meet the needs of our participants. For example, we will schedule in-person visits at times that are most feasible for our participants. See Table below for an overview of proposed data collection items by visit. The data collection points for participant-level data are as follows:

Pre-Screening Visit (PS) – A brief telephone interview for interested adults focused on trial eligibility. Ineligible participants will be provided a thank you note and an explanation of the reason for ineligibility.

Screening Visits (SVa & SVb) – A series of 2 in-person visits performed at the CRC to determine eligibility, describe the trial plan, and obtain written informed consent (SVa). Participants will be screened for health-related social needs including food insecurity modified to reflect the last 3 months. Participants will be asked for demographic information, an expanded medical history, contact information, health communities questionnaire, baseline fruit and vegetable consumption,[9] and estimated resting metabolic rate (Mifflin St Jeor/physical activity questionnaire).[36] We also will administer the SHoPPER questionnaire on shopping habits, food preparation, and dining behaviors.[37,38] Participants also will be asked to rate the baseline presence of symptoms related to the DASH eating plan (e.g. bloating, etc.) adapted from the DASH-Sodium trial.[12] Participants will subsequently undergo physical measures (height, weight, office BP), phlebotomy, and will return home with equipment for 24-hr BP monitoring and urine collection (dropped off at the CRC 1-2 days later; during the SVb visit). SVb will also include questionnaires to assess perceived health, stress, and discrimination. SVb will also include a "practice" food item form to send an item to test receipt for food delivery. To facilitate high through-put and accessible screening, SVa may be split into a "mini" visit focused on the demographic and contact information, the food insecurity screening instrument, and the first set of BP measurements. Eligible participants at the "mini" are invited back to complete the remaining components of SVa.

Run In Visit (RI) – The purpose of this visit will be to determine safe and secure delivery of food items from AmazonFresh or Instacart to participants' homes. At SVb, there will be a form completed by the Research Team that identifies a perishable "practice" food item that the participant would like to receive, as well as their address for delivery. A follow-up telephone call will take place one day after delivery to confirm that the item was received. This visit will be used to identify any barriers to food delivery prior to randomization. In the event groceries cannot reach participants' homes, the dietitian will work with participants to identify a more accessible pick-up location in the participants' community (e.g., a library with a refrigerator).

Randomization Visit (RZ) – Eligible adults will undergo the randomization visit at the CRC within 60 days of screening. This visit includes repeat BP and weight assessments. Once randomized, participants will receive instructions related to their assignment.

Grocery Ordering Calls (GO) – Participants assigned the intervention will order groceries weekly with our study dietitian, who will use examples from the participants' experience the preceding week to reinforce strategies to promote healthy eating. Participants will also be asked about last week's consumption patterns, which will be estimated using a weekly food use worksheet.

Follow-up Visit 1 (FV1a & FV1b) – This includes 2 in-person assessments that will be performed at the CRC, 3 months post-randomization. FV1a includes a food insecurity screener, assessment of current medications, a rapid food frequency questionnaire, the SHoPPER questionnaire (on shopping habits, meal preparation, and dining behaviors), and a dietary symptom questionnaire. The Nutrition Data System for Research,[39] is a dietary analysis program designed for the collection and analysis of 24-hour dietary recalls of macronutrients. In addition, we will measure weight, perform phlebotomy, and perform an office BP measurement. Participants will be provided with a 24-hr ambulatory BP monitor and a 24-hour urine collection kit (to be dropped off at the CRC 1-2 days later at FV1b). FV1b will include a participant self-reported health form (short form health survey), a 24-hr ambulatory BP monitor and 24-urine collection form drop off forms, a perceived stress questionnaire, as well as repeat weight measurement. We will ask participants from both assignments to describe their confidence and preparedness entering the post-intervention maintenance phase. Those who do the DASH grocery intervention will be asked about diet compliance and palatability.

Follow-up Visit 2 (FV2a & FV2b) – This includes 2 in-person assessments that will be performed at the CRC, 5-6-months post-randomization (equivalent to 2-3 months after the intervention). FV2a includes a food insecurity screener, assessment of current medications, a rapid food frequency questionnaire, the SHoPPER questionnaire, perceived stress scale questionnaire,[40] short-form health survey,[41] and a dietary symptom questionnaire. The Nutrition Data System for Research,[39] a dietary analysis program designed for the collection and analysis of 24-hour dietary recalls of macronutrients, will be used to analyze participants' diets. We also will measure weight and BP and perform phlebotomy. Participants will be fitted with a 24-hr ambulatory BP monitor and 24-hour urine collection kit (dropped off at the CRC 1-2 days later at FV2b). In addition, 45 participants (35 from the DASH group and 10 from the self-directed group) will be randomly selected to participate in comprehensive qualitative interviews to characterize facilitators and barriers to DASH adoption ("Post-Intervention Maintenance Phase Qualitative Interviews").

Follow-up Visit 3 (FV3) – Twelve months post-randomization (~6 months after FV2), all participants will undergo via telephone a food insecurity screener, assessment of

medications, a rapid food frequency questionnaire, the SHoPPER questionnaire,[37,38] perceived stress survey, short form health survey, and a dietary symptom questionnaire.

Adherence

General Adherence

To ensure the participants do not miss any of their study visits, we will set reminder calls or text messages based on the participants' preferred method of contact.

BP Adherence

We will be using the OMRON HEM-907XL device. We will ensure the following BP standardized protocols (see section on BP measurement below); we will ensure the participant will sit and rest in the appropriate position for five minutes prior to taking their BP measurements. The study staff will all undergo training and certification prior to BP measurement. Recertification will occur on an annual basis.

ABPM Adherence

The participant will be given an activity log with the ABPM monitor to ensure accurate documentation of the sleep and wake hours while wearing the ABPM. To ensure adherence using the ABPM monitor we will complete the log with the participant in-person during the SVb, FV1b, FV2b visits if they were not able to bring it with them when returning the monitor for the SVb, FV1b, and FV2b visits. We will also give participants an ABPM Survey to complete after their 26-hour monitoring period. This instrument will be reviewed by staff for completeness at SVb, FV1b, and FV2b.

Lab tests/phlebotomy Adherence

We will send out reminder calls, or messages based on the participants' preferred method of contact as a reminder for phlebotomy visits (SVa, FV1a, FV2a) and to bring in their urine jug (SVb, FV1b, FV2b).

Primary outcome variable.

The primary outcome (Aim 1) is mean SBP via automated office BP (AOBP). Secondary outcomes (Aim 1) include DBP (AOBP), wake-time 26-hour SBP and DBP, BMI, lipids, and hemoglobin A1c. Other outcomes (Aim 2), include the self-reported fruits and vegetables intake (servings/day), 24-hour urine sodium and potassium (our intervention is low in sodium and high in potassium), and family shopping, preparation, and dining habits (SHoPPER questionnaire).[37,38]

A. *Primary Effectiveness Endpoint (Aim 1):* Office-based automated SBP will be measured during all in-person visits using an OMRON HEM907-XL, a validated oscillometric device.[42] BP will be measured by trained and certified staff, using an appropriately sized cuff. Three measurements (separated by 60 seconds) will be obtained at each visit, using participants' non-dominant arm after 5 minutes of quiet, seated rest with a supported back.[43] The same cuff size and arm will be used all visits. Baseline BP will be averaged across SVa, SVb, and RZ visits. Follow-up BP will

be measured at FV1a & FV1b and FV2a & FV2b (3- and 6-months post-randomization, respectively).[44]

Secondary outcome variables.

1. Office-based automated DBP will be measured concurrent with SBP described above.

2. Awake-time 26-hour SBP and DBP: A Spacelabs 90227 device will be used to perform ambulatory BP monitoring (ABPM). This Spacelabs device has been validated in multiple adult populations.**[45]** Awake-time will be defined by a participant log. The ABPM device will measure BP every 20 minutes over a 26-hour period. We will also examine sleep-time and 26-hour BP as well as nocturnal BP and dipping status (wake to sleep ratio, relevant for CVD risk).**[46]**

3. BMI is based on height and weight. Height will be measured with a stadiometer at SVa and weight will be measured via a calibrated scale at SVa, SVb, RZ, FV1a, FV1b, FV2a, and FV2b.

4. Fasted biomarkers will be measured by Quest diagnostics (Secaucus, New Jersey) at SVa, FV1a, and FV2a. These include lipids (total cholesterol, high density lipoprotein cholesterol, derived low density lipoprotein cholesterol, and triglycerides), hemoglobin A1c, and serum creatinine and potassium. Additional specimens for ancillaries will be stored in a biorepository.

Secondary Adoption Endpoints: Behaviors (Specific Aim 2)

1. Fruit and vegetable servings: Assessed via 5-minute, validated food screener (SV, FV1-3).[47]
2. 24-hour urine potassium and sodium will be collected at home after a clinic void (SVa, FV1a, FV2a) and returned 1-2 days later at the (SVb, FV1b, FV2b) as objective measures of compliance.
3. Food shopping, meal preparation, and dining behaviors and habits will be assessed via the interviewer-administered SHoPPER questionnaire[37,38] at the (SVa, RZ, FV1a, FV2a), which has been adapted for this study. A 24-hour recall will also be conducted by a blinded study dietitian at visits SVb, FV1b, and FV2b, using the Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool.
4. ***Other Measures (Questionnaires):*** The Accountable Health Communities Health Related Social Needs Screening Tool[48] will be interviewer-administered at SVa to examine the prevalence of health-related social needs among participants at baseline. The Perceived Stress Scale[40] will be administered at SVb, FV1b, FV2b, FV3 to assess the participant's feelings of stress. In addition, all participants will complete the 2-item Hunger Vital Sign,[49,50] a food insecurity screener, at SVa, FV1, FV2, and FV3. The IPAQ[51] will be used at SVa and

RZ with the Mifflin-St. Jeor estimator (along with age, sex, and BMI) to estimate resting metabolic rate (average across visits) to determine the amount of groceries. A Diet Symptoms Questionnaire adapted from the DASH-Sodium trial will be administered at SVa, FV1a, FV2a, and FV3 to document any dietary reactions, including light-headedness, bloating, headaches, or fatigue. Medication lists will be assessed via pill bottle evaluation at SVa and updated throughout the study (RZ, FV1a, FV2a, and FV3). We will especially monitor the addition of anti-HTN medications between visits. Grocery order sheets from the intervention phase will be used to compare the micronutrient profile of the intervention, using ESHA software (Salem, OR) and for exploratory stratified analyses based on the distribution of specific food items or micronutrients (e.g., potassium).

RE-AIM Secondary Endpoints: Reach & Implementation (Specific Aim 3)

1. Reach: We will track referrals, participation rates, and recruitment yields as in prior work.[52,53]
2. Implementation: The SF-12 will assess global health related quality of life at SVb, FV1b, FV2b, and FV3. A standard intervention costing instrument will gather costs of groceries and dietitian salary and effort gathered over study phases through structured interviews of staff, financial records, and direct observation. Beyond these instruments we will also track process information (e.g., Run-in Visit results), that can be used to access scalability.

8. QUALITY ASSURANCE AND QUALITY CONTROL

The investigative team understands the critical importance of collecting complete, high-quality data and developing procedures to accomplish this important objective. Core activities include:

- Standardization – maintaining common study documents (protocol, MOP, case report forms) with special efforts to minimize version control issues.
- Training – developing training procedures led by experienced investigators and senior staff, developing and implementing certification procedures and performance metrics, and conducting annual training.
- Robust data systems – implementing a web-based data entry system with duplicate data entry; using off-site data storage with automated back-up systems; programming data queries to check logic and consistency of data between forms over time; implementing replicate programing for major papers.
- Study visits – conducting study visits has an important role in promoting best practices, identifying operational problems not evident in trial reports, and maintaining a culture that promotes high quality.
- Performance monitoring with feedback – tracking enrollment and follow-up (observed/expected, overall); monitoring missed visits and rescheduling another visit within 1 week; data completeness; protocol deviations; and data entry errors (by staff review); distributing feedback through routine trial monitoring reports. These reports, together with constructive feedback, have an important role in identifying and resolving issues expeditiously.

9. QUALITATIVE INTERVIEWS

A random subset of participants from the intervention arm (N = 35; including participants who discontinued the intervention early) and the self-directed arm (N = 10) will be invited to participate in semi-structured qualitative telephone interviews to understand the acceptability of the intervention as well as facilitators and barriers to maintaining the DASH eating plan. This number of interviews is aligned with qualitative data collection standards for reaching saturation of information;[54] however, we will conduct additional interviews if new themes continue to emerge or fewer is saturation is reached earlier. Random selection of participants to complete the interview may be stratified based on relevant variables (e.g., sex, age group, and hypertension level).

Participant interviews will last 45-60 minutes, and a $25 incentive will be offered for participation. Participants will be reminded of the possibility of being selected for an interview at FV2a and will be informed if they were randomly selected at FV2b. Participants can choose to conduct the interview at the time of FV2b or can schedule the interview for a more convenient time. All interviews will be audio recorded and the audio recordings will be transcribed via an outside transcription service (transcripts will exclude any identifying information).

Interview guides were developed for both participants and dietitian coaches with Getting to Equity (GTE)[55] and the Practical, Robust Implementation Sustainability Model (PRISM)[56] frameworks. Both emphasize the “people perspective” and the interplay of person, environment, and other contexts. We will apply a health equity lens to understand: (a) the ways adhering to the DASH eating plan are relevant and important to the population, (b) if home-delivered groceries are an effective and appropriate mechanism to address access and consumption barriers, and (c) what are the other multi-level contextual factors that may facilitate or impede adherence. These qualitative data will be combined with the Health-Related Social Needs Screening Tool, 2-item Hunger Vital Sign,[57,58] and SHoPPER questionnaire[37,38] to identify contextual facilitators and barriers.

10. RANDOMIZATION AND MASKING

After screening, consenting participants will be 1:1 randomized to the DASH grocery or self-directed arm using web-based, password-protected, randomization software following a permuted block scheme (sizes of 2, 4, or 6). Participants and staff directly administering the intervention will be informed of randomization assignments, but they will be masked to study results until after the study is complete. Meanwhile, staff who perform clinic assessments and the study investigators will be masked to randomization assignments.

The randomization schemes will be generated by the Beth Israel Deaconess Medical Center biostatistician using permuted block methods. Randomly-varying block sizes of 2, 4 and 6 will be used. Randomization will be stratified by baseline SBP: 120-139 mm Hg or 140-<150 mm Hg (stage II hypertension) in order to ensure balanced treatment assignments in each BP group.[59] Details of the block sizes will be concealed from study staff and investigators and generated prior to the study and added to the data management system/REDCap for digital randomization. Randomization tables will be uploaded to REDCap corresponding to the two BP strata. A designated staff member that is unblinded (mostly commonly our dietitian interventionist) will randomize participants by clicking on a digital randomization button in REDCap after informed consent, confirmation of eligibility, reviewing details of the intervention, and signing an intervention understanding form. This will be performed in a private location in the clinical research center away from other study staff. Once assigned order is revealed in REDCap, this information will be shared with the study dietitian, who will provide instructions pertinent for each intervention phase. Order of intervention will not be shared with research coordinator or assistants performing data assessments or with study investigators. Other members of the study team will not be able to access this assignment information in REDCap. Study personnel and investigators will not be unmasked until follow-up and all data collection are completed.

11. INTERVENTIONS

Distribution and adherence

Overview: Participants will be assigned to one of two 3-month interventions: (1) dietitian-assisted, DASH-patterned, home-delivered groceries ordered weekly through AmazonFresh, Whole Foods, or Instacart over 12 weeks or (2) self-directed grocery shopping (monthly stipend and DASH eating plan brochure) over 3 months (referent). All participants will receive materials for addressing food insecurity, a set of measuring cups and spoons, a digital food thermometer, and page one of NHLBI's "Your Guide to Lowering Your Blood Pressure with DASH."[18,60]

Self-Directed Shopping: These participants receive an unrestricted stipend of $500/month (at 4, 8, and 12 weeks). There will be a call with the dietitian at week 8 to establish contact, check on the payments, and schedule FV1.

Dietitian-Assisted DASH Grocery Intervention: Participants randomized to the DASH grocery intervention will participate in weekly calls with the study dietitian. These calls will serve three purposes: (1) order groceries for the week, (2) assess compliance from the prior week's order, and (3) allow for education on fundamentals of healthy grocery shopping, meal storage, preparation, and in-home eating (**Table 3**).

Table 3: Curriculum
Module 1: Principles of DASH
Module 2: Food storage to reduce waste
Module 3: Sodium and potassium: What do they mean for your health?
Module 4: Quick food safety tips
Module 5: Enhance your favorite meal and explore something new
Module 6: Understanding nutrition labels
Module 7: Strategies to increase fruits and vegetables servings
Module 8: Quick and healthy meal prep
Module 9: DASH at Home
Module 10: DASH at restaurants and special events/holidays
Module 11: Smart Shopping
Module 12: Recap and DASH principles

Participants will also be provided instructions on how to receive food deliveries, food storage strategies to avoid spoiling, meal preparation tips, and example recipes that incorporate cultural foods and dishes. We will also prepare 24 instructional cooking videos (10-15-minute duration) based on recipes derived from various heritage diets. The dietitian will specifically address documented concerns about distrust of online grocery shopping among minoritized groups.[13-16] The first grocery ordering session will last 60-90 minutes to review principles, place initial orders, and review instructions. Based on prior experience, subsequent sessions, conducted over the phone, last about 30 minutes as participants standardize their orders and become familiar with the intervention. Follow-up calls will increasingly focus on each participant's experience with

groceries the prior week, how to optimize food storage and preparation, and exploration of new healthy food items.

The allocation of groceries, like DASH, is designed to be isocaloric (i.e., weight neutral). Calorie needs will be estimated using the Mifflin-St. Jeor estimator based on age, sex, body mass index (BMI), and self-reported physical activity (based on the IPAQ instrument),[51] a validated predictor of resting metabolic rate.[10] The intervention will target a quantity of foods that meet a participant's Calorie needs in addition to up to five additional adults at dinner. The calorie replacements will be categorized based on number of food servings. Groceries will be ordered weekly with the assistance of our study dietitian through AmazonFresh or Instacart in fixed proportions of grains, vegetables, fruits, low-fat/fat-free dairy, lean meat (fish/poultry), and nuts/beans/legumes to achieve a low sodium (<2,300 mg/d) and high potassium diet modeled after DASH. For example, servings for an adult consuming 14,000 Calories/week (i.e., 2,000 Calories/day) will be sent: 49 servings of grains, 35 servings of vegetables, 35 servings of fruits, 21 servings of fat-free/low-fat dairy, <42 servings of lean meats, and 4-5 servings of nuts, seeds, and legumes,[60] 14 servings of healthy fats and oil. See Table 4.1 number of food servings by Calorie level. Table 4.2 outlines number of food servings by Calorie level for additional adults at dinner time.

Table 4.1: DASH Eating Plan—Number of Food Servings by Weekly Calorie Level

Food Group	8400 kcal	9800 kcal	11200 kcal	12600 kcal	14000 kcal	16000 kcal	18200 kcal	21700 kcal
Grains	28-35	35-42	42	42	42-56	56-70	70-77	84-91
Vegetables	21-28	21-28	21-28	28-35	28-35	30-37	35-42	42
Fruits	21-28	21-28	21-28	28-35	28-35	30-37	35-42	42
Fat-free or low-fat dairy products	14-21	14-21	14-21	14-21	14-21	21	21	21-28
Lean meats, poultry, and fish	21 or less	21-28 or less	21-28 or less	42 or less	42 or less	42 or less	42 or less	42-63 or less
Nuts, seeds, legumes	3 per week	3 per week	3-4 per week	4 per week	4-5 per week	6 per week	7 per week	7 per week
Fats and oils	7	7	14	14-21	14-21	21	21	28

Adapted from NHLBI's DASH Eating Plan. https://www.nhlbi.nih.gov/education/dash/following-dash

Table 4.2. Number of Food Servings by Calorie Level to be Increased by the Addition of Adults at Dinner Time

Food Group	800 kcal (+1 adult)	1600 kcal (+2 adults)	2400 kcal (+3 adults)	3,200 kcal (+4 adults)	4,000 kcal (+5 adults)
Grains	3 servings/day	6 servings/day	9-10 servings/day	12-13 servings/day	15-16 servings/day
Fruit	2 servings/day	4 servings/day	4-5 servings/day	6-7 servings/day	8-9 servings/day
Vegetable	2 servings/day	4 servings/day	4-5 servings/day	6-7 servings/day	8-9 servings/day
Fat-free or low-fat dairy	1-2 servings/day	2-3 servings/day	3 servings/day	4 servings/day	5 servings/day

Lean meats, poultry, and fish	1-2 oz/day, or less	3-4 oz/day, or less	6 oz/day, or less	8 oz/day or less	9-10 oz/day or less
Nuts, seeds, legumes	1-2 servings per order	3-4 per week order	1 serving/order	1-2 servings/order	1.5-2 servings/order
Fats or oils	1 serving per day	2 servings per day	3 servings per day		

Adapted from NHLBI DASH Eating Plan—Number of Food Servings by Calorie Level. Note that children under age 18 years count as 0.5 adults.

Sodium, potassium, and saturated fat are the primary nutrient focuses for GoFreshRx, (**Table 5**) modelled after the DASH eating plan.[6,7,61] Orders will be placed to comply with both absolute milligrams of sodium and potassium per day. Grocery orders will also be required to achieve sodium and potassium density targets adjusted to match participants' caloric intake.

Table 5. Daily Nutrient Targets

Daily Nutrient Targets	GoFreshRx Plan
Sodium (mg/day)	≤2300
Potassium (mg/day)	≥4700
Saturated fat	7% of total energy (~15 g/day)
Ratios	
Na/kcal	<1.1
K/kcal	>2.2

Intervention Adherence Strategy: Grocery lists will include an extensive range of spices and food items that conform to a DASH dietary pattern (i.e., low sodium, high potassium, reduced added sugars, and reduced saturated fat). Participants will also be given recipes that incorporate a sampling of the groceries on our DASH menu to provide ways to prepare and incorporate foods into their daily life and that are culturally relevant to diverse Black cultural groups. At randomization and during GO calls, participants will be reminded not to eat fast food or at restaurants, which will be monitored. It is possible that participants need to supplement our groceries with their own (e.g., if cooking for others). However, we will ask participants to adhere to our groceries for their own consumption. Participants will be strongly encouraged not to eat out more than once a month, especially not within 2 weeks of the follow-up visit. In addition to grocery orders, the study dietitian will ask participants about food consumption the preceding week, assessing for hoarding, sharing, spoilage, and delivery concerns, as well as providing tips to improve adherence.

Delivery Action Plan:
After the grocery order is placed and delivered, participants will be asked to inform the dietitian if anything is missing from their order through a text, call, or email. Participants will also be asked to inventory any damaged or spoiled items. In addition, the dietitian will receive alerts about items that were not delivered or out of stock. A supplemental order will be placed using an alternative vendor if greater than 25% of the servings targeted within a food group are not available for consumption or if the dietitian feels the participant cannot reach the DASH goals without the missing item(s).

Interventionist Training: The intervention will primarily be delivered by our research dietitians. All staff will participate in three 60-minute sessions that will consist of training in clear communication skills, person-centered care, impact of literacy, oral literacy load, barriers to diet adherence, and the teach-back method. Training will also focus on cultural competence, the role of social determinants of health in health disparities, and the importance of food in Black culture. These sessions will include didactics and role-playing exercises.

Monitoring Adherence

We will ask participants assigned the DASH grocery intervention to list what foods they have left over from the previous week's order. This will allow the dietitian to quantify how much they consumed versus threw away from the previous week. They will also be asked to list consumption of non-protocol foods (e.g., dining out or grocery purchases beyond the study foods). Finally, participants will be asked about the timeliness, accuracy, and quality (damage/spoilage) of food delivery throughout the intervention phase.

Two forms are designed to monitor adherence in the DASH grocery intervention group, the Knowledge Assessment Form (KNOW) and Diet Palatability (PAL) form. The KNOW form will test the participants' knowledge on basic principles of the DASH Eating Plan before and after the study. The purpose is to assess the effectiveness of the education modules delivered by the dietitian. Topics assessed are purposes of the DASH, role of sodium and potassium, compliant DASH foods, and high sources of sodium. PAL is meant to assess diet acceptability, implementation, and behavioral effects. Key information collected is how much non-study food they consumed during the intervention period (including reasons why), reasons why they did not finish all the study groceries, confidence entering the observation phase, likeliness to continue DASH when the study is over, and a general rating of the at-home grocery delivery service. This form also goes into significant detail about online grocery shopping. It assesses the likelihood of using an at-home grocery delivery service after the study is over, participant's confidence in ordering groceries online, and if they would recommend this program to family and friends. Lastly, this form gives the participants an opportunity to express their feelings about the intervention as a whole and provide suggestions they have for improvement.

All GO calls will be scheduled at the randomization visit for the same time each week to encourage consistent adherence. If a participant does not pick up the first time, the study dietitian will leave a voicemail and call back in 5 minutes. If the participant still does not pick up, the dietitian will call back at the end of the business day and then attempt to reach the participant's emergency contact. At this point, a text message and email will be sent to the participant to give them the opportunity to ask for last week's order again if they are unable to talk on the phone that week. For those individuals without text or email access, groceries will not be sent to the house until the dietitian is able to get into contact with them. If over three weeks pass by with no contact, a letter will be sent to the participant's home to encourage reconnecting to the GoFreshRx team, as well as coming to the follow up visit.

Extension Period

An extension period is possible if a participant misses two weeks during the active 3-month intervention. The ultimate goal is for each participant to be active in the intervention for the two

consecutive weeks preceding the follow-up visit. Because of this, there will be a greater emphasis on those who miss weeks 10-12. If a participant misses one visit between weeks 2-10; the dietitian will assess the best course of action. Options include doubling up on modules that are shorter in time, asking the participant if they can meet for a longer period of time during one of the visits, or combining similar modules. If a participant misses more than one visit between weeks 2-10, the GoFreshRx team will discuss and decide if an extension period is necessary. In general, a participant will only be extended for two weeks (weeks 13 or 14). Any other exceptions based on extenuating circumstances (e.g., COVID19, institutional requirements, etc.) will be discussed with the investigative team

If a participant states they do not want to receive groceries anymore, staff will still encourage them to come in for their follow up visit for a BP measurement. If the participant states they wish to leave the study, the staff member will document this discussion and the staff will no longer reach out to this individual as delineated in their consent agreement.

12. Safety

Safety Monitoring

This trial has minimal risks. Nevertheless, participant safety is a priority. We will monitor safety as described in this section. Prior to enrollment in this study, we will screen potential participants to ensure it is safe for them to participate. Substantial effort has been made to identify and minimize potential risks where possible and to exclude participants for whom participation in this study might incur undue risk (see eligibility criteria for full details on exclusions). Once enrolled, if a participant develops an adverse event or other medical problem, the safety of continuing in the study will be determined by study clinicians during a weekly trial meeting.

At the beginning of the study, we will ask participants to provide the information to their usual healthcare provider. If they do not have a usual healthcare provider, we will provide them with resources to identify one. We will provide a printed provider letter participants can give to their healthcare provider outlining their involvement in the study. With the participant's permission, we may also contact their healthcare providers for urgent medical issues that may arise during the study as described in more detail below.

Potential Risks

Risks related to breaches of confidentiality

As with any medical information, there is the risk of psychological distress if personal health information is not kept confidential. To minimize the risk of a breach of confidentiality, all researchers involved are trained in HIPAA compliance. Data will be de-identified and stored on a secure, password-protected server hosted by computers in locked offices that only the research study team can access. All paper records associated with this study will be stored in a locked file cabinet in a locked room. Biospecimens will be stored using de-identified labels and kept in a secure location within BIDMC. Data are only used in aggregate and no identifying characteristics of individual participants will be published.

Identifying participants with food insecurity

At screening visits, we will assess food insecurity. Although potential participants who are deemed food insecure will not be eligible for participation, all participants will receive locally adapted information about available resources in the event they develop food insecurity during the study.

Risks related to phlebotomy

Blood work will be done at designated study visits. Common but less serious risks of phlebotomy include minor bleeding, bruising, swelling and pain at the phlebotomy site. Rare but more serious risks from phlebotomy include vasovagal syncope or infection. There is no alternative to phlebotomy for measuring serum biomarkers and all of these risks exist in the course of routine

medical care. To minimize any additional risk, the frequency of phlebotomy is kept to a minimum and will be drawn by trained staff using aseptic techniques.

Risks related to dietary changes

The diet intervention is patterned after standard recommendations for a healthy diet and should pose minimal risk for participants. Nevertheless, any dietary changes can cause some symptoms, and there may be a risk of a reaction to new food types. Common reactions include rash or hives, itching or watery eyes, wheezing or difficulty breathing, and itching and/or swelling of the mouth and throat. Participants might experience mild gastrointestinal discomfort related to a diet that has higher amounts of fiber, dairy, fresh fruits and vegetables than they usually consume. These symptoms are generally mild and resolve quickly.

Participants will be monitored for these reactions and their grocery orders can be modified as needed. Severe allergies or reactions to new foods should be rare and care will be taken to avoid any known food allergens. Should a reaction occur, we will recommend that the participant avoid the food item and seek medical care.

Risks related to family members

Participants assigned the dietitian-directed intervention will be provided a food safety handout for family members that might eat some of the groceries. This handout has information about allergies, food intolerance, and food recalls.

Risks related to food recalls or food storage issues

We will regularly monitor Amazon Fresh and Instacart for food recalls that might impact participants. We will notify participants of any recalled products within 3 business days of discovery.

Identifying patients with high BP (hypertension)

We anticipate that the intervention will decrease participant's BP. However, if we discover unusually high BP at our study visits, we will implement the following safety procedures.

- For an average SBP 160-179 mm Hg or DBP 105-109 mm Hg, we will recommend that the participant seek care with their usual provider within 1 month, and email the study clinical team
- For an average SBP ≥ 180 mm Hg or DBP ≥ 110 mm Hg, we will recommend that the participant seek same day care with their usual provider, urgent care or a local emergency room, and page/call the study clinical team

Identifying patients with low BP (hypotension)

We anticipate that the intervention will decrease participants' BP. If we discover an unusually low BP at our study visits, we will implement safety procedures as follows:

- For an average SBP < 90 mm Hg or DBP < 50 mm Hg with symptoms (described below), we will recommend participants seek same day care with their usual provider, urgent care or a local emergency room, and page/call the study clinical team.

If participants have NEW or SEVERE symptoms such as nausea, vomiting, shortness of breath, chest pain, headache, vision changes, lightheaded or dizziness, fainting, or loss of consciousness during BP assessment, they will be referred for same day care with their usual care provider, urgent care or a local emergency room, regardless of BP level.

Identifying patients with lab abnormalities

As part of this study, we may discover lab values that are outside of the normal range. All lab results will be reviewed by the study clinical team within 72 hours of release from Quest. Participants will be notified of lab results and given recommendations for follow-up care with their usual care provider.

The intervention will provide groceries that are higher in potassium than a typical American diet. In general, in healthy individuals, a DASH-style diet should not increase potassium levels outside the normal range. Nevertheless, we may incidentally discover abnormal potassium levels during this study.

Hyperkalemia is defined as a serum potassium ≥ 5.5 mEq/L. If hyperkalemia is detected in the absence of hemolysis, investigators will do the following:

- For mild hyperkalemia with hemolysis (K = 5.5-6.4), we will recommend repeating the lab within 48-72 hours and contact the study clinician team
- For mild hyperkalemia without hemolysis (K = 5.5-6.4), we will recommend repeating the lab same day and page/call the study clinician team
- For severe hyperkalemia (K > 6.4), we will recommend repeating the lab same day and page/call the study clinician team.

Adverse event surveillance and reporting procedures

The office of human research protection (OHRP) defines an adverse event as “Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.” The National Institute on Aging defines serious adverse events as any adverse event that:

- Results in death
- Is life-threatening or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity

- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

Surveillance for Severe Adverse Events (SAE) and other relevant clinical events that may be associated with study participation will occur at in-person and telephone visits. In addition to the fixed time points, participants may report events in other settings, e.g., phone contacts. A study clinician will review completed adverse events forms, will classify the event according to several dimensions (expectedness, relatedness to participation in GoFreshRx, and type), and will take appropriate action.

In view of the study population and the 1-year duration of follow-up, medical events unrelated to participation in GoFreshRx are expected to occur, including the development of cancer, heart disease, stroke, cognitive decline, and the development or worsening of other chronic conditions; increased symptoms from a chronic condition; surgeries and procedures; musculoskeletal problems; and accidents.

All serious adverse events and all unanticipated problems will be reported individually to the IRB (GoFreshRx has a specific ad-hoc form for such reports), and these reports will be forwarded to the DSMB, the Study Chair, and the Steering Committee within 3-5 working days of when the study team learned of the event.

Other adverse events will be reported to GoFreshRx on a study specific ad-hoc form and we will complete the appropriate IRB form and report to the DSMB at the time of regular data reports. However, clinics will have the option of bringing any event to the immediate attention of the IRB (via emailing a local or non-local report form to the IRB) for review and discussion by the Steering Committee and for consideration of immediate reporting to the DSMB.

13. ANALYSIS

The trial has sufficient resources to enroll 150-176 participants who will be randomly allocated to 1 of 2 sequences for each of the two groups: (1) the Self-Directed group or (2) the DASH intervention group.

Power and sample size

A. Aim 1 Immediate Effects: Clinical Outcomes (Effectiveness)

1. *Primary endpoint:* The proposed study is powered for office SBP. Based on the 12-week SBP means and variances from the DASH-Sodium trial,[6] with 75 people in each arm, we will be able to detect a difference in SBP of -5.8 mm Hg (type 1 error of 0.05, power of 0.85). The 12-week between-group difference in SBP in DASH-Sodium was -8.9 mm Hg.

2. *Secondary endpoints:* We will have adequate power to detect small differences (i.e., <15%) in awake-time SBP, BMI, cholesterol, triglycerides, and hemoglobin A1c.

B. Aim 2 Immediate Effects: Behaviors (Adoption)

We will be able to detect changes of 13.0% to 29.5% in self-reported fruit and vegetable intake, urine sodium and potassium, and home-prepared dinners per week. These differences are smaller in magnitude than actual differences observed in prior trials.[29,30]

Analysis Plan (RE-AIM Framework)

Reach. As in prior work, we will quantify recruitment yields and engagement.[52,53]

Effectiveness & Adoption. The analysis will be conducted by the Statistical Core under the intent-to-treat principle for both effectiveness and adoption endpoints. The residual distribution of all outcomes will be checked for normality and log-transformed where appropriate. For the Primary Aim, we will use generalized estimating equation (GEE) models with a treatment-by-visit interaction term. The visit term will be used to compare changes on office SBP between 3 months versus baseline, 6 months versus 3 months, and 6 months versus baseline with a product (interaction) term to compare changes across intervention assignment (DASH vs self-directed shopping). Models will be adjusted for ZIP code or baseline BP in sensitivity analyses. Continuous variables will be analyzed with a Gaussian distribution, identity link, while dichotomous variables will be analyzed with a binomial distribution, logit link.

Implementation. Quality-of-life and cost data will be used to analyze health economic data and budget impact, based on cost per HTN case prevented and 10-year cost per quality-adjusted life-year gained.

Maintenance. In qualitative analyses, a coding dictionary will be developed and implemented based on review of the transcripts' content and interview questions. Codes will denote content of questions, GTE and PRISM domains/principles, and concepts naturally emerging from discussion. During the coding process, inter-rater reliability will be established by comparing the agreement in coded text with 20% of the transcripts between coders. Coding differences will be

resolved through consensus via regular and iterative discussions. A qualitative database will be compiled, coded, and analyzed using qualitative software (NVivo). We will use text retrieval and grouping functions on specific codes and combinations of codes for a particular topic and summarize the issues, agreements, and disagreements in content for each item. This process will result in a list of themes related to intervention acceptability[31] and determinants (barriers and facilitators) of DASH eating plan sustainability. As we summarize and interpret, we will identify findings or patterns among themes and will review data for statements that directly confirm or discredit our interpretations.[62] This theme-focused analysis will provide qualitative data to be integrated with our quantitative findings and guide refinement of the intervention.

Missing data

Based on the existing literature, we will employ recommended strategies to address missing data.[63,64,65,66] However, every effort will be made to collect outcome data on all participants.

14. DATA MANAGEMENT

Data will be collected from the following main sources: 1) Data collected by trial staff on trial forms for later entry or directly inputted into the data management system (DMS)/REDCap; 2) Data from Quest laboratories electronically available for upload; 3) Data from Spacelabs ambulatory BP monitoring devices available for direct upload; 4) Data from the Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool, estimating the nutrient content of consumed foods, and 5) Data derived from ESHA software, estimating the nutrient content of the intervention; 6) Data collected from self-administered forms; and 7) Data collected via our online Qualtrics (Seattle, Wa) screening survey or a recruitment tracking Excel database. The DMS will be accessible only via the secure website and only to authorized personnel. Data entered into the DMS will be subject to intra- and inter-item checks, such as range checks, logic checks, and consistency checks. Missing data items will be noted in the database, although certain key values (e.g., BP measurement) will not be allowed to be marked 'missing.' Data entry staff will perform data entry as soon as possible after data has been collected (within one week).

Recruitment data for tracking enrollment sources and goals will be managed separately in a secured team folder. All laptops are password protected and encrypted.

Data confidentiality and integrity

The investigative team, including staff at all levels of the study, will be trained in the importance of data integrity and maintaining participant confidentiality, including HIPAA (Health Insurance Portability and Accountability Act). All data will be stored on secure servers. All study-related computers will be located behind appropriate firewalls and will maintain automated virus update mechanisms. Printed materials will be maintained in locked rooms and file cabinets accessible only to the study team. All staff will sign statements attesting to their understanding of and willingness to abide by policies regarding confidentiality and data integrity.

Trial-wide data release

De-identified trial data will be shared with external investigators on an individual basis through contact with the trials' principal investigator.

15. COLLABORATIONS

GoFresh and GoFreshRx

As a sister study to GoFresh, GoFreshRx has adopted standardized data elements that correspond with the GoFresh project to enable cross-study comparisons of the various

implementation strategies. GoFreshRx study team will compare de-identified, common data elements with GoFresh to facilitate pooled analyses and ancillary studies.

GoFreshRx focuses on adults with treated hypertension funded by the National Institute of Minority Health and Health Disparities, using a similar intervention and design, focused on Black adults with treated hypertension. Instruments for both trials will be shared to facilitate pooled analysis of data elements.

16. TIMELINE

The trial consists of four main phases: (1) Protocol development with IRB review (year 1, quarters 1-3); (2) Intervention development (year 1, quarters 2-4); (3) Recruitment, randomization, and follow-up (year 1, quarter 4 to year 5, quarter 2); and (4) Data analyses and dissemination (year 3, quarter 3 to year 5, quarter 4). Qualititative interviews occur in years 1-4 with analysis in year 5.

Table. Timeline	**Year 1**				**Year 2**				**Year 3**				**Year 4**				**Year 5**			
Calendar Year	1/1/22-12/31/22				1/1/23-12/31/23				1/1/24-12/31/24				1/1/25-12/31/25				1/1/26-12/31/26			
Quarters	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Protocol Development																				
Intervention Development																				
Recruitment, Randomization, Follow-up																				
Qualitative Interviews																				
Data Analysis, Publication, and Dissemination																				

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