

Delivering a Digital Health Intervention to Improve Food Access and Dietary Quality Among Adults with Hypertension *(Access Nourish)*

PROTOCOL AND STATISTICAL ANALYSIS PLAN

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Access Nourish Protocol
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1. Abstract

The Dietary Approaches to Stop Hypertension (DASH) eating pattern has demonstrated significant reductions in both systolic and diastolic blood pressure among adults with hypertension, as evidenced by clinical trials showing decreases of 10.7- and 4.7-mm Hg, respectively. Given its efficacy, national guidelines recommend DASH as a primary treatment for the 116 million US adults affected by hypertension. However, adherence to DASH remains low, largely due to limited access to and high costs of healthful foods, particularly in communities lacking supermarkets or large grocery stores. This disparity disproportionately affects lower-income and minority neighborhoods. To address this challenge, members of our team were conducting Nourish (R01HL146768) at Duke University, a digital behavioral health intervention delivered via smartphone application, targeting DASH adherence among adults with hypertension. Nourish included education, skills training, self-monitoring, feedback, goal setting, and health coaching. We aim to scale this intervention to reach millions, but access barriers persist. To address these, we propose Access Nourish, which leverages grocery delivery services to provide tailored lists and home delivery through a smartphone app. We will assess Access Nourish's feasibility among 67 patients with hypertension residing in low-access areas. This intervention, integrated with Nourish, aims to enhance DASH adherence and food access through behavioral mechanisms. Feasibility will be evaluated through participant accrual, retention, acceptability, demand, implementation, practicality, and intervention adaptation, alongside qualitative interviews to identify usage barriers and facilitators. This study promises insights into the effectiveness of online grocery delivery apps in improving access and adherence to hypertension management interventions. Pending efficacy testing, this intervention holds potential for scaling to benefit millions of Americans lacking access to high-quality foods, necessitating dietary modifications for hypertension control and associated comorbidities.

2. Objectives

Aim 1: Develop intervention content and conduct user testing on technology platforms to deliver the Access Nourish intervention to adults with hypertension living in low access census tracts.

Aim 2a: Assess the feasibility of Access Nourish in a 4-month study among adults with hypertension (n=67) living in low access census tracts. Feasibility will be assessed via participant accrual, participant retention, and other indicators of feasibility suggested by Bowen et al, including acceptability, demand, implementation, practicality, and adaptation of the intervention.

Aim 2b: Assess the barriers and facilitators to using a commercial grocery delivery application through in-depth qualitative interviews with approximately 20 Access Nourish participants.

Aim 3: Examine the patterns of differences on 4-month change in DASH adherence and blood pressure between Access Nourish participants and a comparator group from the main Nourish intervention. Following the guidance of Bowen et al., we will not conduct formal efficacy tests; rather, we will seek to determine the presence of a signal indicating support for the Access Nourish intervention. Individuals who were randomized to the parent trial intervention arm and reside in low access census tracts will be the comparator group.

3. Background

Hypertension burdens nearly one in two adults in the United States (U.S.). The DASH (Dietary Approaches to Stop Hypertension) eating pattern is effective at lowering blood pressure; it has been shown to reduce systolic blood pressure by 10.7 mmHg in adults with hypertension. National treatment guidelines recommend DASH as a first-line treatment for patients with hypertension. However, DASH adherence among U.S. adults with hypertension remains exceedingly low. One major barrier to DASH uptake is poor accessibility to healthful foods. Approximately 38% of U.S. census tracts have limited access to high-quality foods; these communities generally lack supermarkets or large grocery stores, which facilitate the availability of healthful food at affordable prices. Healthful food access can be especially constrained in neighborhoods composed of residents with lower-income and/or racial/ethnic minorities. To address the considerable population health challenges of hypertension, we need innovative approaches to expand equitable access to DASH.

Members of our team conducted Nourish (R01HL146768, PI: G. Bennett, Duke University), a digital behavioral intervention that uses a commercially available smartphone application (app), in combination with several behavior change techniques, to improve adherence to the DASH eating pattern among adults with hypertension. The intervention components include DASH education and skills training, goal setting, self-monitoring, personalized feedback, and responsive health coaching. (See Miller et al. manuscripts for trial protocol; trial recruitment; and trial outcomes). We expect that the Nourish intervention can be scaled and disseminated to millions of adults, increasing

adherence to the DASH eating pattern. However, access challenges remain; without additional intervention, a large proportion of U.S. adults will still lack access to high-quality foods--a critical barrier and first step to adopting DASH.

Online grocery delivery services offer a timely and novel approach to improve access to the DASH eating pattern. Grocery delivery services provide high-quality food items at affordable prices and remove transportation barriers. Online grocery delivery services are accessible through web and smartphone apps, and thus, are available to most U.S. adults. In fact, 85% of the U.S. population own a smartphone, with high ownership rates among racial/ethnic minorities and individuals with lower incomes. Despite their promise, we are unaware of a study that has evaluated the feasibility of utilizing grocery delivery services, alongside a robust behavioral intervention, to promote access and adherence to DASH among adults with hypertension. This is a promising approach to reach underserved populations with hypertension who are disproportionately affected by barriers to accessing high-quality foods.

Therefore, we propose to test the feasibility of Access Nourish, an intervention that will provide tailored grocery lists and grocery delivery options through a commercially available smartphone app, among 67 adults with hypertension and constrained access to healthful foods. We will deliver Access Nourish in addition to the existing intervention components of Nourish, as described above, to provide a comprehensive intervention package that targets behavioral mechanisms to increase DASH adherence while improving food access, a key social determinant of dietary change. We will leverage pre-established protocols (publications previously attached) and technology infrastructures developed to implement *Access Nourish.*

4. Study Procedures

Study design
The proposed intervention, *Access Nourish*, is a single-arm 4-month feasibility study. All participants will be prospectively assigned to receive a behavioral intervention and grocery delivery intervention. All intervention components will be delivered remotely using smartphone technology. The intervention is delivered in addition to participants' regular medical care. Timing of study procedures for data collection and study visits are as follows:

Pre-Screening Survey: Potential participants will complete initial survey (in REDCap) to determine basic eligibility for the study. This will include questions regarding major eligibility criteria. If eligible, participants will receive an email to complete informed consent and the baseline survey. Aggregate, de-identified data collected through this screening survey will be analyzed to evaluate recruitment effectiveness and characterize individuals responding to study recruitment efforts.

Informed Consent and Baseline Survey: Similar to the pre-screening survey, participants will complete informed consent and a longer survey, with baseline study measures, in REDCap.

ASA24: Following completion of the baseline survey, participants will be prompted to complete one 24-hour dietary recall, at baseline, two months and four months post enrollment which will be administered by the National Cancer Institute's Automated Self-Administered 24-hour recall tool.

Pre-Enrollment Visit: A pre-enrollment phone call will be scheduled to provide a study overview. Research staff will also orient participants to the study procedures and apps including how to access daily dietary tracking, how to obtain DASH educational materials, and how to view, modify and order their groceries from the pre-loaded cart. After completion, a BP monitor and batteries will be shipped to the participant.
Enrollment Visit: Participants will be trained by research staff to take their BP on-camera to confirm final eligibility. Eligible participants will be enrolled and provided an overview of study activities and next steps.

Health Coach Visit: Participants will meet with the intervention health coach for 30-45 minutes within one week of enrollment for study onboarding, a DASH overview, and goal setting. Participants will be provided access to their grocery delivery membership.
Follow-Up Visits: One follow-up survey will occur at 2-months post enrollment and a follow-up visit with study staff will occur at 4-months post-enrollment. Data collection for study visits will be documented within a REDCap project.

All study visits will be conducted via Zoom. This protocol was implemented in the parent trial. As such, our investigators are well-equipped to implement the current intervention. Participants will be compensated for participating in visits. The intervention will be 4-months in duration and include the following components:

a) *DASH education and skills training:* Participants will be provided videos and information sheets that include education about BP and DASH. Examples include nutrient-specific videos (i.e., how to increase calcium intake) and general training videos, such as tips on intuitive eating; managing stress; and how to follow DASH on a budget or dining out.
b) *Nutrient goal setting:* Participants will receive daily and weekly nutrient goals via text message. The goals focus on individual nutrients (i.e., potassium, fiber, calcium, magnesium, sodium, saturated fat, and protein) and improving overall DASH adherence.
c) *Daily dietary tracking:* Participants are asked to track their daily dietary intake, including drinks, snacks, and meals in the dietary tracking app.
d) *Text message feedback:* Participants will receive automated, personalized feedback via text message based on their daily dietary tracking and progress toward their nutrient goals. Our intervention technology platform will extract nutrient data from the dietary tracking app using an API. After, a computer algorithm will calculate each participant's adherence to the DASH nutrients; these data are used to inform simplified, automated feedback. The text messages will be tailored to lifestyle and eating habits, such as work schedules and dietary restrictions, that are identified during baseline data collection. The text messages will be sent by a software partner.

e) *Responsive health coaching:* Participants will receive tailored coaching from the health coach. The frequency and modality (i.e. text message, phone call, and/or video conferencing) of coaching is informed by the same computer algorithm, as described above. The following platforms will be used for coaching delivery:
   - *Texting*: Software partner platform
   - *Phone call:* Microsoft Teams
   - *Videoconferencing:* Zoom

f) *Grocery delivery membership*: We will purchase a 4-month subscription to the grocery delivery service for each participant. This subscription will cover delivery costs of groceries.

g) *Pre-made DASH-friendly grocery lists:* Each week the study health coach curate a tailored grocery list, using the grocery delivery app, that will include high-quality foods that align with DASH. Carts will be curated based on personalization criteria used to tailor text messages, described above (e.g., household size, work status).

Intervention components (a-e) above were previously implemented in the parent trial. Our team will leverage the parent trial's protocols and computer algorithms to develop the current intervention.

Following study completion, a subset of participants will be invited to participate in qualitative interviews, which will also occur via Zoom. Participants will be asked if they are willing to be contacted to participate in a qualitative interview at their 4-month study visit. Research staff will use a purposive sampling strategy to select and invite a subset of interested participants (n=20) based on participant self-reported online grocery delivery use to ensure users and non-users are equally represented. Two staff members will conduct interviews as facilitator and notetaker, respectively, and interviews will be audio-recorded and transcribed via Zoom. Interview transcripts will be reviewed and edited against audio recordings for accuracy.

A rapid qualitative analysis approach will be used to analyze interviews. A standardized template of thematic domains will be created and used to summarize each interview; thematic domains will be determined based on the interview guide questions. Interview questions will be designed to elucidate barriers and facilitators to online grocery delivery and DASH-friendly grocery list use; overall intervention feasibility and satisfaction; and improvement areas. After all interviews are summarized, templates will be combined into a matrix to identify and synthesize themes across participants.

Study duration: The study duration is 4-months. There will be a total of 4 study visits:
1. Pre-enrollment Phone Call Visit
2. Enrollment Visit
3. Health Coach Visit
4. 4-month follow-up visit

Randomization and blinding: This is a single arm feasibility trial. Therefore, all participants will receive the full intervention and there will be no blinding.

Withdrawal: Participants will be withdrawn from the study if it is determined that the intervention poses a risk to their health or wellbeing.

Participants will be able to continue to use DASH educational materials provided to them during the intervention. They will also be able to continue using the smartphone applications used for study purposes. As this intervention does not affect their medical care, no other actions will occur if the participant's participation ends prematurely.

5. Eligibility Criteria

Inclusion Criteria:

- Adult: 18 years of age or older
- Has hypertension, defined as a systolic BP of 130-159 mmHg and/or diastolic BP of 80-99 mmHg, whether or not taking hypertension medications.
- Resides in a census tract defined as low access by the USDA
- Resides in a zip code serviced by the grocery delivery app
- BMI 18.5 kg/m^2+
- Has a smartphone with a data plan
- Willing to receive daily text messages
- Can participate in online videoconference visits
- Can read and write in English
- Has a working debit or credit card
- Has an address that is deliverable through the online grocery delivery service

Exclusion Criteria:

- Participating in another related research study
- Cardiovascular disease event in the last 6 months
- Active cancer
- Recent hospitalization due to psychiatric condition or event
- Pregnancy or planned during the study period
- BMI 37 kg/m^2 or higher
- Documented dementia
- On kidney dialysis
- Instructed to eat a low potassium diet
- Planned or recent bariatric surgery
- Severe food allergy

6. Study Statistical Plan

Primary outcome variable:
The primary outcome variable is feasibility, which will be assessed via participant accrual, participant retention and other indicators of feasibility suggested by Bowen et

al, including acceptability, demand, implementation, practicality, and adaptation of the intervention.
Secondary outcome variables:
Secondary outcomes include 4-month changes in DASH adherence and blood pressure.

Primary Outcome Statistical Plan:

To assess participant accrual, the number of screener completions, eligible individuals, and consented participants will be tracked and reported for overall sample and by different socio-demographic characteristics. In addition, aggregate, de-identified data collected through the pre-consent screening survey will be analyzed to characterize individuals responding to study recruitment efforts and evaluate recruitment effectiveness. Analyses will use demographic information collected through the screening survey, along with eligibility outcomes, recruitment source, and enrollment outcomes. Descriptive statistics will be used to summarize participant characteristics and recruitment outcomes. Regression analyses will also be conducted to examine associations between participant characteristics and recruitment outcomes, including study eligibility and enrollment. Results will be reported only in aggregate form.

We will also track the number of participants who are lost-to follow-up for the overall sample and by different socio-demographic characteristics. Participant socio-demographics will be summarized by mean and standard deviation for continuous variables and frequency and percentage for categorical variables. Descriptive statistics will be used to summarize each of the feasibility indicators (acceptability, demand, implementation, practicality, and adaptation) based on its level of measurement. Additionally, we will explore the association between socio-demographic variables and each feasibility indicator by using appropriate bivariate analysis, such as chi-square, and t-tests and calculating corresponding effect sizes. Given our sample size, we will rely on effect sizes (odds ratio for 2 x 2 table; Cramer's V for larger contingency tables, cohen's D for two group on a continuous outcome; eta^2 for 3 or more groups on a continuous outcome variable) rather than p-value to evaluate the meaningfulness of socio-demographic differences in feasibility.

Sample size justification:
Informed by best practice, the proposed (n=67) sample size is not based on formal power analysis, but a reasonable sample size to assess the feasibility and acceptability of the intervention, the primary goal of the study. This proposed sample size accounts for an expected attrition of 20% and a small number of screening failures at the enrollment visit.

Secondary Outcomes Statistical Plan:
We will assess if baseline DASH adherence or any of the baseline socio-demographic variables, such as income level, education, race, or education, are different between the *Access Nourish* group and a comparator group. The comparator group will be participants from the parent trial. If there are multiple confounding variables, we will use propensity score matching to select the comparator group to avoid selection bias. We expect that we can find 50 participants out of 82 available participants to be in the comparator group because both samples are recruited from the same platforms, but if

not, we will use inverse probability-weighting method to adjust for confounding. We will calculate Cohen's d in 4-month change in DASH adherence between the *Access Nourish* group and the selected comparator group. The effect sizes will also be calculated within subgroups for different sex and race ethnicity groups to explore differences. We will also estimate the variability in 4-month change in DASH adherence and blood pressure in each group, which can be used for power analysis for future efficacy testing in a randomized clinical trial. Additional exploratory analyses will use similar methods to look for patterns between the additional measurement scores and change in DASH adherence to inform future trials and hypothesis generation.

Early stopping rules
Given that these are such minimal risk interventions, we do not expect that serious adverse events (SAE) will occur and require stopping the study. However, the study PIs and an independent safety monitor will closely monitor any injury rates and notify the Johns Hopkins Medicine IRB if a larger than expected SAE rate is observed.

7. Risks

There are no anticipated medical risks as a result of the proposed intervention. Should an adverse event be encountered, such as very high or low blood pressure readings (see Miller et al. 2022 for published protocol), an adverse event will be reported, and the independent safety monitor (ISM) will be notified. The ISM will identify if it is necessary to report any specific out-of-range data to the participant and/or his/her primary care provider.

The primary risk of participating in this study is loss of confidentiality. Several steps will be taken to minimize this risk, described below:

The intervention and evaluation protocols pose minimal risk to participants. However, we will implement several measures to minimize research-associated risk. First, we will exclude participants to whom the low-risk intervention may pose a safety threat. This includes individuals who are participating in another related research study; had cardiovascular disease event in the last 6 months; have active cancer; were recently hospitalized due to psychiatric condition or event; are currently pregnant or planning to be during the study period; have documented dementia; are on kidney dialysis; are instructed to eat a low potassium diet; and/or planned or recent bariatric surgery.

Second, we will not collect more information than is necessary for the research objectives. Third, the PIs and ISM will conduct regular monitoring on any adverse or serious adverse events. Reporting of adverse and serious adverse events will be de-identified. Fourth, we will implement procedures to protect against risks including breach of confidentiality. In brief, after informed consent is obtained, participants will be assigned a unique identification number to ensure the confidentiality of data collected. All identifiable data collected by the study team will be entered into a password-protected database, Research Electronic Data Capture (REDCap), by study identification number only. Qualitative interviews with be completed via Johns Hopkins Zoom and data will be stored securely on a Johns Hopkins networks server. Data cleaning and analyses will be conducted on the Johns Hopkins Secure Analytic

Framework Environment (SAFE) virtual desktop, a virtual machine cloud-based platform that is fully HIPAA compliant and allows for secured analyses and sharing of sensitive data. Reporting of results will not involve the identification of participant's data, and data will be reported in collective or aggregate form.

Plan for reporting unanticipated problems or study deviations:
The study PIs and ISM will use the following questions, as outlined in the OHRP guidance, to determine if an AE represents an unanticipated problem:

1. Is the adverse event unexpected?
2. Is the adverse event related or possibly related to participation in the research?
3. Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?

If the answer is yes to all three questions, the AE will be considered an unanticipated problem and will be reported to the IRB and NINR within 2 weeks of the investigators becoming aware of the problem. Legal risks such as the risks that would be associated with breach of confidentiality.

There are risks of breach of confidentiality. However, we will take precautions to limit this risk. Participant data will be collected and stored in several places:

1) a secure REDCap database at Johns Hopkins University;
2) the National Cancer Institute ASA24;
3) with an outside digital company via their text-messaging platform;
4) in the dietary tracking and online grocery delivery service apps on participants' mobile devices.

The Johns Hopkins REDCap database will be used to store identifiable participant information, such as contact/demographic information, survey information, study visits, and adverse events. REDCap is a password-protected database and will only be accessible to approved study staff. Further, REDCap settings will limit the access permissions of end-users to protect against data exporting with identifiable participant information. AE reports and other summaries will not include subject PHI/PII. All data will be de-identified before results reporting or public data sharing.

The ASA24 system, which is used to collect 24-hour dietary recalls, is encrypted by the internet browser and does not capture any personally identifiable data from participants (our study team will provide each participant with a specific user ID to access the application).

We will share certain information from REDCap with the software partner's platform to personalize our text message feedback. This information will be shared using an application programming interface (API). The software partner's platform will also receive food logging data from the dietary tracking mobile app. After, the software partner's platform will store food logging data and analyze it daily according to pre-determined computer algorithms. We will use a software partner to send text messages

from the platform to participants.

This study will ask participants to track their food and beverages on a commercially available dietary tracking smartphone application (app) and receive grocery lists through a commercial grocery delivery app. Our informed consent processes will describe the potential risks of loss of confidentiality associated with these apps. We will inform participants that information collected via these apps is subject to their terms of use, which should be read carefully. We will encourage participants to limit personal identifiers on these apps to those that they wish to voluntarily share. We will state that Johns Hopkins cannot guarantee that these apps are free of risk. We will review these risks a second time during the pre-enrollment visit.

Financial risks to the participants:
Participants will require a smartphone with a data and texting plan to participate in the study; however standard data and text messaging rates will apply. The study will provide participants with a grocery delivery subscription. Should participants choose to order their groceries using the grocery delivery service app, they will be responsible for paying for their groceries. Participants will be informed that participation does not require them to order their groceries using the application; suggestions will only be provided for them to consider.

8. Benefits

Participation in this study offers potential direct medical benefits to participants. Utilizing smartphone applications for grocery delivery and monitoring dietary intake has the potential to enhance participants' dietary habits and manage their blood pressure effectively. Additionally, access to educational resources and health coaching may provide valuable support and feedback to participants. It is anticipated that insights gained from this study may contribute to improving interventions for individuals with high blood pressure in the future.

9. Payment and Remuneration

Participation in Access Nourish involves compensation for participants to acknowledge their time and contribution to the study. Upon enrollment, participants will receive an Omron® digital blood pressure monitor and a subscription to an online grocery delivery service. Furthermore, participants will be reimbursed up to a total of $180 in electronic gift cards for their participation in various study activities. Specifically, they will receive $75 for the enrollment visit, $30 for the 2-month follow-up visit, and $75 for the 4-month visit. Participants will also receive a $10 credit for an online grocery delivery service each month to assist with service fees. Additionally, participants may have the opportunity to engage in qualitative interviews about their study experiences, with an extra compensation of $30 in the form of an electronic gift card provided for their time if they opt to participate.

10. Costs

As a remotely delivered study, participation in this research does not entail direct costs, except for potential expenses associated with data usage on participants' phones for activities such as dietary tracking, completing online surveys, texting/calls, and/or Zoom

videoconferencing visits. These costs will vary based on individual data/wireless and mobile phone plans, and the study is unable to reimburse participants for such expenses. Additionally, participants will be encouraged to utilize the online grocery delivery subscription provided to them via smartphone application and website, featuring DASH-friendly food suggestions. However, the study will not cover the actual cost of purchasing groceries.