Nourish: Using digital health to improve diet quality among adults at risk for cardiovascular disease

STUDY PROTOCOL, INFORMED CONSENT & STATISTICAL ANALYSIS PLAN

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STUDY PROTOCOL

Research Abstract

Over 100 million Americans suffer from high blood pressure and thus are at increased risk for cardiovascular disease and premature morality. Evidence supports the DASH (Dietary Approaches to Stop Hypertension) dietary pattern to reduce blood pressure. DASH is rich in fruits and vegetables, legumes, lean protein, and low-fat dairy, and reduced in red meats, sweets and processed foods. In the past 20 years, numerous trials have demonstrated the blood pressure-lowering effects of DASH across a diverse range of populations. As such, DASH is part of national dietary and blood pressure guidelines. Despite this strong evidence, fewer than 1% of U.S. adults with high blood pressure fully meet DASH guidelines. Like most efficacious interventions, the rate-limiting step involves dissemination. Behavioral trials testing DASH have been delivered primarily in-person, an approach that is effective but not accessible to the broader population. Innovative and accessible strategies to disseminate DASH, such as digital health, are critically needed. To address this need, we developed and tested the feasibility of a 3-month digital health intervention called DASH Cloud. The DASH Cloud intervention asked participants to track their diet daily using a commonly-used commercial tracking app with an extensive nutrient database. Our intervention technology platform extracted food and nutrient data from the app using an application programming interface (API). Each day, using this API software, we compared individual participant's nutrient intake to the recommended levels in the DASH diet. We then processed the data against an algorithm and sent automated text messages to each participant with information on DASH diet adherence and diet tips. Results indicated that we successfully recruited and retained individuals with elevated blood pressure, achieved high engagement with daily diet tracking and saw positive changes in diet quality. Based on the results of the feasibility trial, we will improve upon the personalization of the automated text messages and include a scalable and responsive way of delivering coaching, based on diet data received in the app. The efficacy of this approach will be tested via a fully-powered 12-month randomized controlled trial, Nourish. The trial will examine the effects of the intervention on changes in dietary quality and blood pressure among men and women with high blood pressure, using the new blood pressure guidelines for nonpharmacological treatment. The primary outcome is 6-month change in DASH adherence, as measured by 24-hour recalls. We will also measure DASH adherence at 12-months post-randomization. Secondary outcomes include changes in blood pressure and other physiological outcomes (e.g. weight, lipids, glucose). The scientific premise of this proposal represents establishing the efficacy of a previously deemed feasible approach for disseminating the DASH diet. With the millions of Americans in dire need of nonpharmacological treatments for blood pressure, the public health impact of disseminating the Nourish intervention could drastically reduce the incidence of cardiovascular disease. The findings from this study prepare us for a future implementation trial, testing the potential to implement DASH Cloud within clinics and other healthcare institutions, yielding

Research Aims for main RCT:

Aim 1: To determine the efficacy of the 6-month Nourish intervention, compared to an attention control arm, on 6-month changes in DASH adherence.

Aim 2: To determine the efficacy of the 6-month Nourish intervention, compared to an attention control arm, on 6-month changes in blood pressure.

Exploratory aims: To explore the impact of the Nourish intervention, as compared to an attention control arm, on 6-month changes in relevant clinical, behavioral and psychosocial variables (i.e., engagement with intervention components, physical activity, medication use, self-efficacy, and intuitive eating, depression, etc).

Formative Research Phase (for Trial Recruitment)
Aim 1: To determine the barriers and facilitators to improving dietary quality in black adults.
Aim 2: To identify barriers to and facilitators of recruiting black adults into a digital health intervention for dietary improvement

Objectives/Hypothesis:
The overall goal of our research is use digital health to disseminate evidence-based interventions to improve hypertension management. For the over 100 million Americans with high blood pressure, lifestyle changes are indicated, yet evidence-based treatments are not available at scale. Our proposed intervention, Nourish, will establish the evidence for how to disseminate a proven lifestyle approach - the DASH dietary pattern - to millions of Americans using digital health technologies. Our approach will also advance the science of digital health intervention dissemination: The flexibility and scalability of this approach makes it applicable for delivery of other behavioral interventions further broadening the impact of this study. To effectively recruit a diverse sample to participate in Nourish, we will also include a formative research phase as a substudy. The formative work, which will precede the intervention, will include a REDCap survey with sociodemographics and eating habits as well as individual interviews to examine recruitment strategies, and understand barriers and facilitators to engaging in dietary habits aligned with DASH (Dietary approaches to stop hypertension – an eating pattern shown to reduce high blood pressure) among minority participants with high blood pressure.

Background and Significance:
Over 100 million Americans suffer from high blood pressure and thus are at increased risk for cardiovascular disease and premature morality. Evidence supports the DASH (Dietary Approaches to Stop Hypertension) dietary pattern to reduce blood pressure. DASH is rich in fruits and vegetables, legumes, lean protein, and low- fat dairy, and reduced in red meats, sweets and processed foods. In the past 20 years, numerous trials have demonstrated the blood pressure-lowering effects of DASH across a diverse range of populations. As such, DASH is part of national dietary and blood pressure guidelines. Despite this strong evidence, fewer than 1% of U.S. adults with high blood pressure fully meet DASH guidelines. Like most efficacious interventions, the rate- limiting step involves dissemination. Behavioral trials testing DASH have been delivered primarily in-person, an approach that is effective but not accessible to the broader population. Innovative and accessible strategies to disseminate DASH, such as digital health, are critically needed.

For the past decade, our team has developed and tested numerous digital health behavior change interventions that are highly engaging and effective for obesity management. However, few have studied how to harness digital health tools to extend the reach of evidence-based dietary interventions like DASH. Smartphone applications (apps) for improving diet offer a ubiquitous method to reach millions of Americans interested in changing their eating habits. Yet, these apps are often merely “food trackers,” thereby lacking effective theory- and evidence-based behavior change components. Combining the effectiveness of evidence- based behavior change components with the reach of diet tracking apps offers a promising strategy to disseminate DASH.

In addition, the impact of clinical research trials is limited by suboptimal recruitment of black populations. Mistrust of medical, research, and government institutions is common among black adults. Barriers to recruitment can span structural, linguistic and cultural domains influencing if and

how blacks participate in research. Relatedly, gender becomes important as black men and women have differing barriers and reasons for research participation. Gender differences in recruitment are important as black women have outnumbered black men in previous dietary trials promoting DASH which limits findings specific to black men. To ensure applicability of clinical research outcomes to diverse populations, adequate recruitment of blacks is essential.

Ensuring adequate representation of blacks is helped by the use of digital tools for delivering DASH interventions. Most adults in the United States own a smartphone (81%), including 80% of blacks, indicating a space where inclusivity may be reached across racial/ethnic groups. Broad smartphone ownership in blacks highlights the potential to engage populations experiencing disparities in hypertension and to improve diet quality. Investigators of the parent study for this supplement conducted a pilot digital health intervention (DASH Cloud) using smartphones to improve DASH diet adherence. Results demonstrated high retention (90%), participant engagement (92%), and improvement in DASH diet score. However, 20% of the DASH Cloud pilot study sample was non-white. More inclusive and representative recruitment is a critical starting point to producing broadly-relevant clinical research trial results for this formative research phase.

Design & Procedures

mTurk: Prior to the start of our 2-arm randomized controlled trial, we will conduct feasibility testing using Amazon mTurk. Consenting project participants will first complete a two-question eligibility screener to determine if he/she has ever been diagnosed with high blood pressure or takes medication to manage blood pressure. If the participant answers 'yes' to either question, he/she is eligible and will continue on. If a participant answers 'no' to both questions, the survey will discontinue due to ineligibility. Project participants will be shown a series of questions and simulated text messages (see mTurk document) we propose to use in the study. Following a sequence of simulated "days" in the Nourish study, participants will answer a number of questions about message frequency, message preference, and 'coaching' frequency; as well as their impressions of motivational language.

Recruitment Formative Research: To effectively recruit a diverse sample to participate in Nourish, we will include a formative research phase. The formative work, which will precede the intervention, will recruit African American adults with high blood pressure. It will include an online survey with sociodemographics and eating habits followed by recorded semi-structured individual interviews (n=20-30) to examine recruitment strategies, and understand barriers and facilitators to engaging in dietary habits aligned with DASH (Dietary approaches to stop hypertension – an eating pattern shown to reduce high blood pressure) among minority participants with high blood pressure.

To support diverse sample recruitment in the randomized controlled trial, a formative phase will be conducted. Individual interviews (n=20-30) will be held to examine barriers and facilitators of DASH adherence and refine the Nourish intervention recruitment methods. The interview will be directed by a moderator using a semi-structured interview guide.

Initial questions will focus on participants conceptualization of healthy food and its role in high blood pressure management. Subsequent questions will examine barriers and facilitators of eating recommended DASH foods for high blood pressure management. Questions about the context of

consuming DASH recommended foods will also be presented. Questions about intervention and recruitment for the intervention will be asked about Nourish, to inform components of the parent grant.

At the end of the interview, participants will be asked if they are interested in being contacted to participate in the main trial, Nourish, as another recruitment channel for the parent trial (and to help reach minority recruitment goals).

Nourish RCT: We will conduct a 2-arm randomized controlled trial (N=300) testing the efficacy of the 6-month DASH Cloud intervention, as compared to attention control, on 6- and 12- month changes in DASH adherence, blood pressure and other relevant outcomes. We will recruit participants using a multi-pronged strategy: 1) direct marketing; 2) local media; 3) social media; 4) community organizations; 5) primary care clinics and 6) Duke MyChart recruitment. Those that respond to initial study advertisements will be screened using an online screener to determine initial eligibility and complete an online informed consent process and complete some self-report measures (all in REDCap).

As we near the end of recruitment for our sample of 300 randomized participants, we plan to remove REDCap links on our study website that links to the REDCap project to ask participants to email the study email addressed to be sent the REDCap link, if enrollment is still open. This will ensure that we do not overenroll participants, as there is potentially a long period of time from screening to randomization and that participants are not unnecessarily screening, consenting and/or filling out surveys when the study already has enough people in the pipeline. Once recruitment is complete, the website and REDCap screener will be updated with a notice that recruitment for Nourish is complete.

Those eligible according to the screening questionnaire and who complete the baseline survey, will be invited to track their dietary intake on the NCI's ASA-24 tool for 2 unscheduled days. Once that is complete, they will be invited to participate in an online Duke Zoom Visit (Visit 1) and will be oriented to 1. 2. 3. 4. 5. the study, the Pattern Health dietary tracking app and taking blood pressure for the study via Zoom. They will be shipped a box of materials including an Omron digital blood pressure monitor. If they track their dietary data for a week, they will have their final eligibility assessed using home/self-monitored American Heart Association guidelines for blood pressure measurement while on the video Zoom call (Visit 2) with research staff. Once they attend Visit 2 and are deemed eligible based on their blood pressure being in range, participants will be randomized and oriented to their study arm.

Randomization will be 1:1 and conducted at the participant level using a permuted block randomization method and stratifying by blood pressure risk category, an important predictor of the intervention effect on blood pressure, and whether or not taking blood pressure medications. Blood pressure risk category is defined using the current American Heart Association guidelines, based on the average of the 3 readings:

Normal: If SBP < 80 mm Hg
Hypertension stage 1: SBP 130-139 mm Hg or DBP 80-89 mm Hg
Hypertension stage 2: SBP 140-159 mm Hg or DBP 90-99 mm Hg

If average SBP is >160 mm Hg and/or DBP is >100 mm Hg, the participant will not be randomized at that time. Blood pressure will be taken again within the next 24 hours to determine final eligibility. If at the retake within 24 hours, the average BP it still above the range for study participation (160+ mm Hg for SBP and/or 100+ mm Hg DBP) and the participant is not currently on medications but plans on starting BP-lowering medications during the study enrollment period, they will told to reach out if they are interested in measuring their BP again once their BP has been stabilized by medications and appropriate follow-up from their PCP. All of the same data collection procedures will occur at that visit to take BP to assess final eligibility, prior to being randomized.

If the participant is on BP-lowering medications already and falls in the ineligible range as described above, they will be told they are ineligible for the study.

For all participants, appropriate follow-up (for adverse event reporting or referral to local organizations /resources if ineligible), will occur.

Stratification will ensure equal allocation between study arms for blood pressure category at baseline and whether taking blood pressure medications. The allocation tables with permuted blocks will be created by the study statistician and stored in a secure web application (REDCap) in such a way that only the statistician will be able to view it.

All participants will track their dietary intake daily using the Pattern Health app, which pulls in nutrient data from Nutritionix, a publicly available dietary-tracking app. Nourish Prompt will collect all foods and beverages entered by participants in the Pattern Health app via an API. Using these data, Prompt will perform the following functions:

1. Confirm foods, portion size, and process data, such as time of day entered
2. Calculate DASH adherence score for DASH target ranges for micronutrients (calcium, magnesium, potassium, sodium) and macronutrients (protein, saturated fat, fiber). Each nutrient has a target range of intake per day and participants will be grouped whether their calculated dietary intake was in the range or not for the day and for the week.
3. Calculate changes in nutrient adherence over time from the previous day, week, month and/or since baseline
4. Determine which nutrients met DASH thresholds and which foods contributed
5. Determine which nutrients were below DASH thresholds and suggest foods to boost intake

Using the above data, Prompt will then deliver automated feedback messages to participants daily via text message. In addition to the personalized texts, we will use an innovative strategy called responsive coaching using a 2-step protocol throughout the trial.

Step 1: Determine baseline DASH score during the first 2 weeks of tracking, after randomization.
Step 2: Categorize participants into progress zones each week in a fully automated manner based on nutrient intake. Starting in week 2, Prompt will place participants into 1 of 3 zones (green, yellow, or red), based on dietary change from baseline. The zones inform the frequency, intensity, and mode of counseling.

As such, coaching zones will be triggered based on the following targets (from their nutrient intake):
Green zone: Participants will continue to track their dietary intake and receive daily automated personalized texts and tailored skills training videos. They will receive no coaching.
Yellow zone: Participants will receive additional brief coaching via text message from our study dietitians if they are not hitting target ranges. The goal of text coaching is to raise awareness about changes in dietary intake, to enhance motivation and efficacy for behavior change, and/or to engage in problem-solving.
Red Zone: We will activate the red zone protocol for participants who are not in their target range for 3 weeks or more. When notified that a participant has entered the red zone, his/her coach (a registered dietitian trained in MI) will make a counseling call attempt within 24 hours using the preferred modality of choice - either video or phone (and text, at the coach's discretion). Each 15-20-minute counseling call will be designed to assess and enhance motivation and self-efficacy for behavior change, deliver in-depth behavioral skills training, and provide social support. On each call, coaches will: 1) review changes in DASH nutrient adherence and self-monitoring data; 2) discuss problem-solving strategies; 3) deliver skills training content, and; 4) discuss community resources, if applicable. The coaching dashboard system in Prompt automatically records coaching texts and process data (e.g., date/time).

Engagement texts (Orange Zone): If a participant does not track their daily food and beverage intake – indicating no engagement - s/he will be sent an automated text encouraging engagement (e.g., Hi Michelle, you didn't track your diet yesterday. Check out the video on tips to making tracking easier! Get back on track with tracking today!). If a participant does not engage for more than 3 days in a row, s/he will be sent a text from a coach asking how the coach can help encourage tracking. Coaches will also be prompted to follow up with participants who have not tracked for > 3 days via a separate re-engagement protocol.

Skills training: We created 2-3 minute animated videos to provide skills training on each of the DASH components and other behavioral strategies to change diet. Topics included: how to get more calcium and magnesium, dining out on DASH, getting more protein and fiber, how to be a fat detective, how to read a food label, menu planning on DASH, the balance between sodium and potassium, DASH on a budget, and maintaining DASH, etc. We will include additional skills training videos in the proposed intervention on theory- and evidence-based behavioral principles. This includes intuitive eating, self-compassion, stress management, social support, etc.. These videos will be sent via separate text messages with a link to a YouTube video and contained with the Nourish app.

We will provide participants with the NHLBI online booklet link describing DASH and sample meal plans and recipes from NHLBI. We will conduct follow-up assessment visits at 2, 4, 6, and 12 months. All study measurements will be performed by trained, certified study personnel online via Duke Zoom.

Aim 1 Measures: We will collect dietary intake data using the Automated Self-Administered 24-hour Recall (ASA24) system. We will collect 2 separate 24-hour dietary recalls (1 weekday and 1 weekend day) at multiple time points. (Baseline, 2, 4, 6 and 12-month follow-up).

Aim 2 Measures: We will ask participants to measure blood pressure on the Duke Zoom call on the upper arm (or forearm if arm circumference measured at Visit 2 is over 17") three times at 1-minute intervals after 5 minutes of quiet sitting. We will use a validated blood pressure machine (sent to participants after Visit 1) and the appropriate-sized cuff. We will use the average of second 2 blood pressure measures in analyses. (All timepoints starting at Visit 2 - randomization visit)
Aim 3 Measures:
Current medication use and adherence will be assessed using a method similar to that used in previous blood pressure trials (all timepoints) and the Voils blood pressure med adherence measure (baseline, 6 and 12- months)

Physical activity: Nordic Physical Activity Questionnaire-short form (NPAQ) (baseline, 6-months and 12-months)

Self-efficacy for healthy eating: will be measured using the Intuitive Eating Scale- 2 and Nutrition Self Efficacy Scale (baseline, 6-months and 12-months)

Engagement with the intervention will be measured as the proportion of days tracked over expected, and proportion of coaching encounters attended over the number expected in each zone. (baseline and 6-months; tracking will also be assessed at 12-months).

Psychosocial measures will be measured using the Patient Health Questionnaire (PHQ-8) a validated measure for assessing depressive symptoms in community populations, the BRFSS stress measure (baseline, 6- and 12-months); and experiences of discrimination (baseline)

Sociodemographics include items such as self-reported age, race/ethnicity, gender, health insurance, income, technology usage, employment status, education, household size, eating habits, and marital status, etc. (baseline). We will also ask about app usage and intent to lose weight during the active intervention phase (6-months and 12-months).

Intervention satisfaction will be assessed at 6-months.

Subject Selection:

MTurk: Participants will be recruited on Amazon Mechanical Turk (mTurk). Previous work using mTurk samples indicates that the sample is typically 55% female and 36% non-white with a mean age of 33 years . Our study sample will likely reflect these numbers, but may vary depending on who elects to participate in our project.

Participants on MTurk are called workers; these workers can select our study from a list of Human Intelligence Tasks (HITs) that are available to them. The study will be described briefly so they can decide whether or not to accept the HIT. The project will be available to mTurk workers who live in the United States. Sample selection via mTurk can be further refined by qualifications to more closely match the anticipated study group

recruited from the geographic area near Durham, North Carolina. Qualifications we will use to further refine the mTurk sample include: age, gender, parent status, exercise frequency, income level, rent home vs own home, and primary internet device.

The study description will include a request to participate only if they have ever had high blood pressure. A brief 2-question screener will assess blood pressure diagnosis and the questionnaire will be programmed to end if the participant has never been diagnosed with high blood pressure or does not take medication to control blood pressure.

Recruitment for Formative Research:
Inclusion criteria: We will include men and women who self-identify as black/African American (anywhere in the U.S.) with self-reported diagnosis of high blood pressure (systolic blood pressure of 120-159mmgHg or diastolic blood pressure of 80-99mmHg) whether or not they are taking medications.

Additional inclusion criteria: aged ≥18 years; self-reported body mass index ≥ 18.5 kg/m2; has a smartphone with a data plan; has a working email address; and speaks English as primary language.

Exclusion criteria: We will exclude those participating in a related blood pressure/dietary trial; had cardiovascular disease event (e.g. stroke, myocardial infarction) in prior 6 months; active malignancy; recent psychiatric-related institutionalization; pregnancy – current or planned during the study period; and documented dementia.

RCT:
We will randomize 300 men and women with a:

- normal blood pressure (systolic BP of <120 mmHg or diastolic BP: <80 mmHg with diagnosis of hypertension) and/or taking blood pressure medications
- systolic BP of 120-159 mmHg or diastolic BP: 80-99mmHg whether or not they are taking medications
- If the BP is above 140 mmHg for systolic or 90mmHg for diastolic and not taking medications, we will refer them to their physician for follow-up.
- If the BP is ineligible (160+ mmHg systolic and/or 100+ mmHg diastolic) and is not taking medications, but states that they plan to start taking BP-lowering medications (per their PCP's recommendation/prescription) within the study recruitment period, they can be offered to reach out the study team via phone/email when their BP has stabilized. The same protocols will apply (confirming BP for eligibility) at the visit. If they are still ineligible due to high BP at that point, no other follow-up will occur and they will not be randomized.

Additional inclusion criteria: Aged ≥18 years; BMI ≥ 18.5 kg/m ; has a smartphone with a data plan 2 and an email address; willing to receive daily text messages; willing and able to participate in 6 videoconferencing research visits over the 12 month period; speaks English as primary language; currently lives in the United States.

Additional exclusion criteria: not willing to update phone/device operating system; participating in another related clinical trial; cardiovascular disease event (e.g. stroke, myocardial infarction) in prior 6 months; active malignancy; recent psychiatric institutionalization; pregnancy– current or planned during the study period; documented dementia, lives in the same household as another participant already enrolled in Nourish (due to concerns about contamination if randomized to different arms), bariatric surgery in the last 12 months; currently on kidney dialysis; was told by healthcare provider to not eat a high-potassium diet; and/or investigator-discretion.

Subject Recruitment and Compensation

Formative Research Phase:
Participants for DIP into DASH will be identified via passive recruitment strategies. These will include social media advertisements (e.g. NextDoor, Reddit, Facebook, Twitter, Instagram), and ResearchMatch, as well as working through community organizations that serve diverse populations, such as Piedmont Health, churches and other community organizations via their social media posts or flyers. We aim to recruit 50% men and 50% women. Participants who complete an interview will be compensated $30 for their time. At the conclusion of the interview, participants will be asked if they would like to be contacted for the main RCT at a later date. If they say yes, they will be contacted by research staff and will follow all screening /consent procedures outlined for the main trial.

RCT:
Similar to the formative research, we will recruit participants using a multi-pronged strategy: 1) direct marketing; 2) local media; 3) social media; 4) community organizations; 5) primary care clinics; and 6) Duke MyChart recruitment messages will be sent to potentially-eligible participants using a computable phenotype based on our eligibility criteria within MyChart or email to patients without a MaestroCare account (see below). We have worked with the Maestro Care Optimization Team in DOCR and the Recruitment Innovation Center in the CTSI to ensure that both the computable phenotype and message are appropriate for our audience.

Duke patients will be recruited as follows:
1) MyChart messages: We will utilize the MyChart research messaging platform by having the DOCR Maestro Care Research Analyst we have contracted with send the approved Nourish research message to potentially-eligible patients. The Analyst will run the phenotype through MyChart and include adult patients (18+ yo) located anywhere with an active MyChart account and a recent/upcoming appointment who have a diagnosis of hypertension, speak English, and who are not marked as deceased or have a diagnosis of dementia. The Analyst will send the approved message in batches and the message will refer interested patients to click on the study website to review the content, and fill out the online REDCap screener, consent and enrollment and/or contact the research team with questions.

2)MaestroCare outreach: Because demographic diversity is a critical part of this study, we do not want to exclude patients who may be eligible and interested in our study, but for whatever reason, have not activated a MyChart account. Thus, for Duke patients without an active MyChart account, the same eligibility criteria above will apply and will be part of the computable phenotype and criteria above. However, because there is no way to message Duke patients without an active MyChart account, when the messages are sent via MyChart to active patients, the Analyst will also send a

secure email with a spreadsheet with a list of potentially-eligible patients from the MyChart list and their contact information to the study coordinator. This will immediately be saved within the study's protected drive. Bcc'ed emails will be sent from the Duke email address using the approved email template to direct people to the study website for information and how to screen/consent and enroll, if interested.

We will also advertise the study using online flyers on websites including ClinicalTrials.gov, Duke Clinical Trials website, and ResearchMatch. We aim to recruit a sample that is at least 30% male and 40% racial /ethnic minority (similar to the demographics of Durham, N.C.). On a regular basis, we will assess the racial/ethic and gender of current participants so that we can do targeted recruitment, if necessary.

We will offer participants up to a total of $160 in reimbursement via online Amazon gift cards, for the time spent taking surveys and participating in online research visits, over the duration of the study.

Risks/Benefits

Formative Research:
We anticipate minimal risk to the participant with the main risk being loss of confidentiality. The risk is detailed in the informed consent document for the participant. Risk will be minimized by assigning participants a study ID number that will be used on any forms in place of their name. Audio recordings will be captured with a recording via Duke Zoom or Duke WebEx on an encrypted computer and then immediately deleted from the computer once the audio files have been transferred to a Duke-provisioned Box account. All electronic files and the recordings will be securely stored behind the Duke firewall with access only granted to approved study staff. There is no direct benefit to the participant, but benefit to society may come from the study findings about how to approach hypertension treatment with a dietary approach and how to recruit more African American /black adults into clinical research trials.

RCT: Study personnel will not be responsible for the clinical care of participants and participants will be made aware of this delineation of responsibility. Participants will be referred to their primary care providers if any clinical problems are detected. Research assistants will be trained to detect clinical information that requires discussion with the PI and safety officer and that suggests referral to the provider. The informed consent will clearly describe all potential risks, including those specific to the use of the dietary tracking app.We anticipate minimal risk to the participant with the main risk being loss of confidentiality.

Potential benefits for study participants include improved diet quality, blood pressure and consequent reduction in cardiovascular risk. An additional benefit for some participants may be personal satisfaction in being part of a study that may have major public health implications for the community. No benefit from participation can be guaranteed. Potential benefits to others include the possibility that this research will help researchers evaluate the feasibility and efficacy of Nourish in promoting DASH dietary adherence. The minimal health risks to participants listed above are offset by the potential benefits to them and to society.

Disseminable interventions that promote improved diet quality and hypertension management in diverse communities can reduce the disproportionate impact of cardiovascular-related mortality and morbidity. This fully-powered 12-month randomized controlled trial aims to examine the efficacy of the Nourish intervention on changes in dietary quality and blood pressure among men and women with high blood pressure using the new blood pressure guidelines for nonpharmacological treatment. The findings from this study prepare us for a future pragmatic trial testing the implementation of Nourish in primary care. Our approach will also advance the science of digital health intervention dissemination. The minimal health risks to participants are offset by the potential benefits to them and to society, i.e., improved adherence to the DASH dietary appraoch and improved hypertension management, with consequent reductions in risk of comorbidities.

Data Analysis & Statistical Considerations

Formative Research:
Interview audio recordings will be transcribed verbatim by Datagain Services. Study staff will conduct rapid analysis on transcribed interviews and/or use NVivo software to process the data with thematic analysis using a codebook derived from an initial coding of the same transcripts. After the codes are agreed upon and defined, all transcripts will be analyzed to identify common themes. Each transcript will be independently analyzed by two study staff members and consensus reached.

RCT:
Power and sample size. Using data from the pilot study we anticipate systolic blood pressure changes in intervention vs control as follows: -3.4 (SD=8.6) mmHg and 2 (SD=9.3) mmHg which results in an effect size of 0.6. The effect size for diastolic blood pressure is 0.75 based on changes in intervention vs control of -3.8 (SD=7.9) mmHg vs. 1.6 (SD=6.4) mmHg. With 90% power and a type I error rate (alpha) of .01, we can detect the expected effect size with the proposed sample size of 300.

Demographic and baseline data will be examined for integrity of randomization scheme and the homogeneity of study arms. If any demographic and baseline data are not balanced between the two study arms and are believed to affect the outcome, we will consider adjusting these variables in the modeling process. All analyses will be based on intention-to-treat (ITT) principles.

Aim 1: To understand how DASH score improves over time from baseline to 6 months and sustains through 12-month follow-up between study arms, we will plot observed DASH score vs. time (baseline, 1- month, 2-month, 4-month, 6-month, 12-month) by two study arms. Linear mixed models will be built to test the primary hypotheses. If we observe a linear trend in the previous plot, our model will contain fixed effects including group variable (intervention vs. control), time, and intervention by time interaction. To account for the correlations within the same participant over time, we include a random intercept and random slope for time in the model. If there is a quadratic trend in time, we will also include a quadratic term in time in the model. If any of the demographic or baseline variables are statistically different between the two study arms, then these variables will be included in a step-wise model selection process for the linear mixed model. We will estimate model parameters using the SAS/STAT procedure MIXED (SAS Version 9, Cary, NC). We will evaluate the primary hypotheses by testing the null hypothesis that the time by intervention parameter is 0.

Aims 2 and 3: Similar analysis will be conducted for changes in blood pressure (Aim 2) and relevant clinical, behavioral and psychosocial variables (Aim 3). If the distribution of any of the outcomes is heavily skewed, then we will either appropriately transform the data so it's normally distributed or use a generalized linear mixed model with an appropriate link function.

Missing data: Although we do not expect any missing baseline data, we anticipate no more than 20% missing values in longitudinal outcomes owing to dropout, missed completed dietary recalls, or missed follow-up assessments. In the pilot trial, we had 10% attrition with diet and blood pressure outcomes. Our primary model estimates intervention effects while accounting for missing data.

Data & Safety Monitoring

Study personnel will not be responsible for the clinical care of participants and participants will be made aware of this delineation of responsibility. Participants will be referred to their primary care providers (PCPs) if any clinical problems are detected. Surveillance for adverse events and relevant clinical events will occur by the research visit blood pressure measurement protocol for our out-of-range measurements that require medical attention, as well as documenting any adverse events that are learned through research visits or interactions with participants, and/or coaching interactions.

Data confidentiality: We will use the standard operating procedures that have been used on our prior trials for survey conduct and data management. These procedures have been developed and used in many studies and we will adhere to these procedures for the proposed study. The privacy, security, and durability of accumulated personal health information are of paramount importance. Our existing practices meet or exceed the software industry's best practices for protecting personal data. Specifically: physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all databases are encrypted and access from the public Internet is precluded; all software and servers are encrypted, audited, and access is limited to skilled personnel; all communication between our software's application programming interface (API) and third-party software is encrypted using SSL. Personnel must have access to perform regular maintenance duties. However, this constituency is limited to senior system administrators and the project director. All paper files related to the study will be stored in a secure location at Duke University in a locked file cabinet accessible only to IRB-approved key study personnel.

Breach of confidentiality: All participant information collected in the context of this study, and even the fact that an individual is participating in the study, will be considered confidential. Confidentiality will be assured through several mechanisms. First, each participant will be assigned a study ID that will be used on all study forms and lab specimens. Second, all study forms and paper records that contain participant information will be kept in secured, locked areas or in encrypted databases (see security measures described above). In addition, such materials, when in use, will be kept away from public scrutiny. Materials that need to be discarded will be destroyed. Third, access to all participant data and information will be restricted to authorized personnel. In the case of computerized study data, access to data will be password protected and staff members will be assigned individualized passwords that allow them access to only those elements of the data management system to which they are authorized. In addition, all study personnel will maintain certification with the Duke IRB that they have completed training in research ethics, which includes training on

confidentiality. Finally, participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.

All information obtained in the course of the study that identifies an individual will be treated as confidential in accordance with section 903C of the Public Health Service Act (42 U.S.C.299a-1). We will strip all identifiers from analytic data sets after data merging and will keep all personal identifiers in a separate location from the analytic data. No individual participant will be identified in any reports from the study. Data storage will involve computer files that will be password protected and encrypted and will be accessible only to personnel who need to contact participants.

Adverse event reporting: This is a minimal risk intervention and it is highly unlikely that we will encounter any adverse events (AE) or serious adverse events (SAE). However, Dr. Svetkey or Dr. Tyson, our safety officers, will review, collate, and evaluate adverse events in real-time. The safety officers and the PI will evaluate all adverse events within 72 hours; serious adverse events will be evaluated within 24 hours. Any study-related serious adverse event will be reported to the NIH IC and to the Duke IRB within 2 weeks; all others will be included in the annual report to the NIH IC.

We will compile an aggregate AE report from all study groups annually. These data will be blinded in the summary reports that will be provided to the study biostatistician, PI, and safety officer. Given the nature of the intervention, we would expect the rate of AEs to be low. In the present study, we expect that most, if any, reported injuries would result from activities unrelated to the intervention. Nevertheless, any adverse event rate over 50% during the 12-month observation period will be reported both to the Duke University IRB and the NIH IC.

Informed Consent Process:
MTurk: Participants will fill out an initial eligibility survey and if deemed eligible will continue with online questionnaires. Because participants are completing the consent online within their own time frame, they will have as much time as they need to consider whether they want to participate.

Formative Research: Participants will undergo eligibility screening via REDCap to determine if they qualify for the study and if they qualify, to review the online consent form. Participants could choose to consent at that time or if desired, could wait and return to the form at a later time, including overnight. They will also have an option to check that they would prefer to talk with a study staff before signing the online consent form.

RCT: Participants will fill out an initial eligibility survey and if deemed eligible, will be able to review a quick video explaining the study and then will fill out the online consent form (all part of REDCap). Because participants are completing the consent online within their own time frame, they will have as much time as they need to consider whether they want to participate. Participants will be also allowed to take as much time as they need to read through the consent form and ask questions. If participants need to decide, they can speak to a study staff member to ask questions before they consent.

Where will the consent process occur?
The consent processes will occur online in the privacy of the participant's home or other location they deem fit.

What steps will be taken in that location to protect the privacy of the prospective participant?
Participants will be encouraged to choose a location they deem private enough to review the online consent form and to conduct the interview, if they provide e-consent. Since the location is based on participant preference, we cannot guarantee full privacy protection.

How much time will be allocated for conducting the initial consent discussion, including presenting the information in the consent document and answering questions, with each prospective participant?
Because participants are completing the consent online within their own time frame, they will have as much time as they need to consider whether they want to participate and can come back to the REDCap consent document. Participants will be also allowed to take as much time as they need to read through the consent form and ask questions. If participants need to decide, they can speak to a study staff member to ask questions before they consent. Study contact information is listed throughout all materials.

What arrangements will be in place for answering participant questions before and after the consent is signed?
Because participants are completing the consent online within their own time frame, they will have as much time as they need to consider whether they want to participate. Participants will be also allowed to take as much time as they need to read through the consent form and ask questions. If participants need to decide, they can speak to a study staff member to ask questions before they consent. Study contact information is listed throughout all materials. Describe the steps taken to minimize the possibility of coercion or undue influence.

MTurk: Because participants are completing the consent online within their own time frame, they will have as much time as they need to consider whether they want to participate. Participants will be also allowed to take as much time as they need to read through the consent form and ask questions. If participants need to decide, they can speak to a study staff member to ask questions before they consent. The consent includes language that will make it very clear that the subject does not need to participate. Payment is kept at a rate that will not be coercive, $5.

Formative Research/RCT: Because participants are completing the consent online within their own time frame, they will have as much time as they need to consider whether they want to participate. Participants will be also allowed to take as much time as they need to read through the consent form and ask questions. If participants need to decide, they can speak to a study staff member to ask questions before they consent. The consent includes language that will make it very clear that the subject does not need to participate. "You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled." Payment is kept at a rate that will not be coercive but will compensate participants for the time burden involved with participating. Before consented we will give ample time to ask questions and decline participation. They will also be given Dr. Bennett's and/or Dr. Blackman Carr's contact information for any questions or concerns for the formative research and/or the main RCT.

Waiver of Informed Consent/HIPAA Authorization:
Formative Research: We request to waive all elements of the informed consent and HIPAA authorization for screening and recruitment purposes. We will access PHI submitted by potential participants for screening and follow-up for questions related to consent and the interview.

RCT: While the screening survey does not have identifiers until the participant provides online informed consent to participate, we request to waive all elements of the informed consent and HIPAA authorization for screening and recruitment purposes as follows for ResearchMatch and Duke (no MyChart account) patients. We will access PHI submitted by potential participants for screening and follow-up for questions related to consent and participating in the main trial who are identified by ResearchMatch and Duke patients who are potentially-eligible and who are identified who do not have an active MyChart account. This includes people who have opted-in from ResearchMatch recruitment messages (who authorize to share their contact information with us) and those Duke patients identified via the MyChart analyst for recruitment (only those without a MyChart account who are active Duke patients) and whose contact information we will receive from the Duke MyChart recruitment team to send a follow-up email (using the email provided in our supporting documents). Note that we will not receive PHI from the MyChart messages that are sent by the Analyst on our behalf. We will only be able to identify those participants if they screen and consent via our REDCap processes.

MTurk: We ask to waive all elements of the informed consent and HIPAA authorization to conduct of the research project without obtaining verbal or written consent and authorization. MTurk is previously described and we will not receive participant PHI: -Names of the participants are never collected, so no names will be recorded on the survey materials. Therefore, no member of the research team will be able to identify which data elements correspond to which participant. All data will be marked, stored, and organized by a unique participant ID assigned to each worker by Mechanical Turk. -We would like to ask participants for some basic demographic information, including age, education, ethnicity, occupation and gender. These responses will only be linked with subject IDs, not with names. We will have access to their IP address, but that is the only identifier. -Unless participants choose to email us about the study using a personal address or otherwise include personally identifiable information (PII), we will never know their names. Even in that case, we will not be able to link names to data. In our records of the data, each participant will be identified only by a random subject ID. -The data will only be reported to us from the MTurk study is aggregated across cases. No PHI is reported.

PHI Collected/Source:
Formative Research: Name City State Email address Phone numbers (all available) Basic screening information provided in screener

All of the information will be submitted by participants via a Duke REDCap survey and online consent process.

RCT: For the main trial, we will receive the following information pre-consent as follows:
ResearchMatch:
Name
Available contact information (phone numbers, email address, mailing address)

Demographics (race, ethnicity, gender, age, health information they shared with ResearchMatch) to allow us to reach demographic targets and makes sure our sample contains diversity

Duke MaestroCare (non-MyChart account) patient recruitment:
MRN (this is the ensure we located the right person when we register the patient in OnCore, in order to match participants with similar names)
Name
Available contact information (phone numbers, email address, mailing address)
Demographics (race, ethnicity, gender, age, insurance plan) to allow us to reach demographic targets and makes sure our sample contains the appropriate diversity

MTurk: None. Unless participants choose to email us about the study using a personal address or otherwise include personally identifiable information (PII), we will never know their names or identifiers prior to consent. Even in that case, we will not be able to link names to data and the only identifier (postconsent, which is mentioned in the consent form is the IP address). In our records of the data, each participant will be identified only by a random subject ID.

Criteria for Waiver:

a) The research or clinical investigation involves no more than minimal risk to subjects:

Formative Research: Identification process for potential participants involves no more than minimal risk to participants, mainly the risk of loss of confidentiality.

RCT: Identification process for potential participants involves no more than minimal risk to participants, mainly the risk of loss of confidentiality.
MTurk: The MTurk study is no more than minimal risk. Participants sign up as workers generally, not specifically for this study. No PHI will be collected and we are only asking about their message preferences. Unless participants choose to email us about the study using a personal address or otherwise include personally identifiable information (PII), we will never know their names. Even in that case, we will not be able to link names to data. In our records of the data, each participant will be identified only by a random subject ID.

b) The waiver or alteration will not adversely affect the rights and welfare of the subjects. Include a description of any measures to be taken to ensure that the rights and welfare of subjects will be protected:

Formative Research: Identifying information submitted by the subject for recruitment will be stored within a Duke REDCap project. These data are password-protected and only available to approved study staff and investigators. Participant welfare and rights are not negatively affected by this process.

RCT: Identifying information submitted by the subject for recruitment will be stored within Duke Box, Duke REDCap project, Nourish study protected drive that is restricted and accessed via Duke Health VPN, or MaestroCare (as necessary for the lists we will run- but will not be accessed by the study team, only by the Duke MaestroCare Research Analyst at DOCR). These data sources are password-protected and only available to approved study staff and investigators. Participant welfare and rights are not negatively affected by this process. MTurk: The MTurk study is no more than minimal risk. Participants sign up as workers generally, not specifically for this study. Only the IP address will be collected via Duke Qualtrics (for consented individuals), and we are only asking about their message preferences. Unless participants choose to email us about the study using a personal address or otherwise include personally identifiable information (PII), we will never know their names. Even in that case, we will not be able to link names to data. In our records of the data, each participant will be identified only by a random subject ID. c)

c) Whenever appropriate, the subjects will be provided with additional pertinent information after participation:
Formative Research and RCT: Whenever appropriate, subjects will be provided with additional pertinent information.
MTurk: This is not applicable as we will have no way to individually contact participants.

d) If this research activity relates to research involving deception, explain how subjects will be provided with additional pertinent information after study participation and what information will be provided.
N/A

e) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements (e1. and e2.) Demonstrate that the use or disclosure of PHI involves no more than minimal risk to the privacy of subjects by describing the plans requested below: e1) An adequate plan to protect the identifiers from improper use and disclosure. Describe the plan (how protection will be accomplished) and indicate where the PHI will be stored and who will have access:

Formative Research: PHI identifiers will be stored within a Duke REDCap project with access restricted only to approved research staff. Data will be stored with a corresponding study ID.

RCT: Identifying information submitted by the subject for recruitment will be stored within Duke Box, Duke REDCap project or MaestroCare (as necessary for the lists we will run), with access restricted to only approved research staff.
MTurk: No identifiers will be collected or stored

e2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Describe the plan (how and when identifiers will be destroyed and by whom). If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, provide the reason to retain identifiers:

Formative Research and RCT: Identifiers will be maintained for 6 years after the completion of the study in accordance with Duke policy. After this date, electronic study records will be destroyed. In addition, for the Maestro Care (non Duke MyChart users), the spreadsheets with their information in the protected drive will be deleted as soon as the recruitment phase for the study is over and the entire sample has been recruited. The reason to store these spreadsheets on an ongoing basis is that that we want to ensure we do not email the same patients multiple times as they will likely show up on multiple lists and we will compare the lists to make sure we are not contacting them again.

MTurk: No identifiers will be collected or stored.

e3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule. By electronically signing this submission, the PI provides this written assurance: True.

f) The research could not practicably be conducted or carried out without the waiver or alteration: Explain why informed consent/authorization can not be obtained from subjects.
Formative Research: Participants are self-screening for eligibility for the study. The information is necessary to identify eligible participants. We are recruiting from the community and potential participants would not have the opportunity to participate without first self-screening.

RCT: For active Duke MaestroCare patients (with non My Chart accounts) and for ResearchMatch, we need a way to follow up with patients who are potentially eligible and/or interested in participating by reaching out to them via email. We are utilizing all online and remote recruitment methods we have for this digital health study to reach our target sample and to ensure diversity, one of requirements for the funder. We will make sure we remove participants who express they are not interested/opt-out or whom we have already emailed.

MTurk: Participants are self-screening for eligibility for the study. We will have no information on these participants aside from their MTurk profile.

g) The research could not practicably be conducted or carried out without access to and use of the protected health information:
Formative Research and RCT: Since we are recruiting from the community, there would be no way to contact/screen potential participants without this information.
MTurk: We won't be accessing PHI.

h) For research using biospecimens or identifiable information, the research could not practicably be carried out without access to and use of the protected health information:
Formative Research and RCT: Since we are recruiting from the community, there would be no way to contact/screen potential participants without this information, and we need identifiable information to reach them and follow up with their interest (for the formative interviews, Duke patients without MyChart account access, and opted-in ResearchMatch participants).

Nourish: Using digital health to improve diet quality among adults at risk for cardiovascular disease (NCT03875768)

MTurk: We won't be accessing PHI.

Ensuring Subject Privacy & Confidentiality

MTurk: Amazon Mechanical Turk follows the same information practices as Amazon, and information we collect is subject to the Amazon Privacy Notice. Workers accessing Amazon Mechanical Turk have already accepted the practices described in the Amazon Privacy Notice and are not doing this specifically for our study. All participants are assigned an ID.

-Names of the participants are never collected, so no names will be recorded on the survey materials. Therefore, no member of the research team will be able to identify which data elements correspond to which participant. All data will be marked, stored, and organized by a unique participant ID assigned to each worker by Mechanical Turk.

-We would like to ask participants for some basic demographic information, including age, education, ethnicity, occupation and gender. These responses will only be linked with subject IDs, not with names.

-Unless participants choose to email us about the study using a personal address or otherwise include personally identifiable information (PII), we will never know their names. Even in that case, we will not be able to link names to data. In our records of the data, each participant will be identified only by a random subject ID.

-The data will only be reported to us from the MTurk study is aggregated across cases. No PHI is reported.

Formative Research: Audio recordings will be recorded via Duke WebEx and/or Duke Zoom and name and identifying information will be removed from the subsequent transcripts that are received from the transcription company. These transcripts will be stored within a restricted folder on Duke Box.

RCT: We will use a restricted Duke REDCap project, Duke Box, Duke protected drive via Duke health VPN access, and Pattern Health for intervention/survey data with restricted access. Data security documents for Pattern Health are attached to this IRB application. Study records that identify patients will be kept confidential as required by law. All data will be marked with a unique code number for storage at Duke University Health System in accordance with Duke's Institutional Review Board's guidelines and policies. All data collection will occur in private settings where patient survey responses cannot be seen or heard by others. Patients are able to refuse to answer any of the questions or stop participation in this study at any time. During the online screening process, each potential participant will be assigned a study participant number for tracking purposes. All other participant forms (e.g. AEs, SAEs, etc) will be identified by study participant number only.

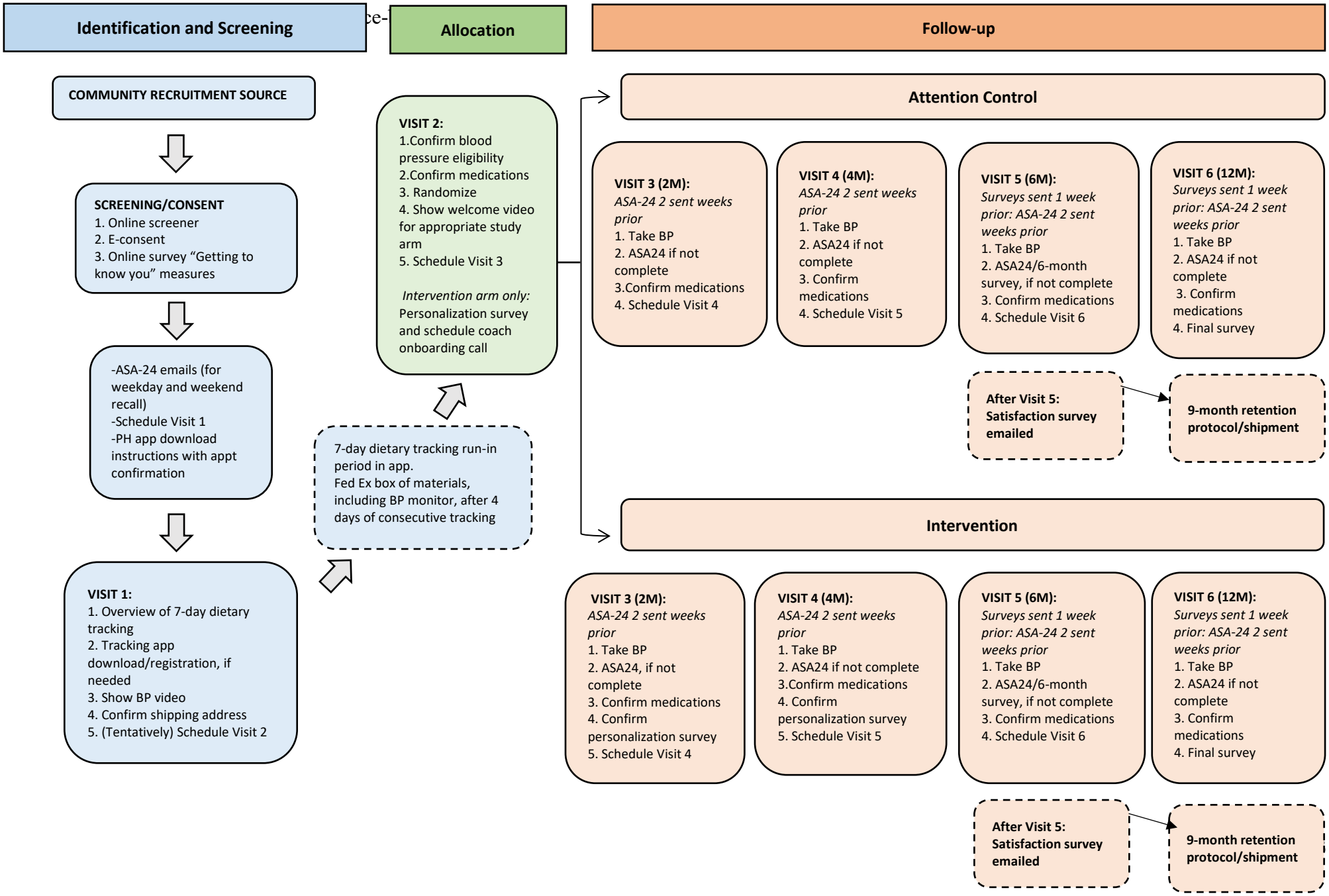
Formative Research: All online data (screening information and informed consent documents) will be stored in a Duke REDCap project, and downloaded to Duke Box, with restricted access to appropriate research staff. Recorded interview data will be collected via phone or videoconference through Duke-provisioned Zoom and/or WebEx accounts. These audio recordings will be recorded via Duke WebEx or Duke Zoom, provided via a contract with Datagain Services, and subsequent transcripts will be stored on Duke Box.

MTurk: Amazon Mechanical Turk follows the same information practices as Amazon, and information we collect is subject to the Amazon Privacy Notice. Workers accessing Amazon Mechanical Turk have already accepted the practices described in the Amazon Privacy Notice and are not doing this specifically for our study. All participants are assigned an ID. Names of the participants are never collected, so no names will be recorded on the survey materials. Therefore, no member of the research team will be able to identify which data elements correspond to which participant. All data will be marked, stored, and organized by a unique participant ID assigned to each worker by Mechanical Turk. The data will only be reported to us from the MTurk study is aggregated across cases. No PHI is reported.

RCT: Electronic study data storage: A Duke REDCap project will be used for screening, consent, survey and subject management with appropriate restriction only to authorized research staff. A study protected drive folder with Duke Health VPN access and restricted to authorized personnel will also be utilized for storage of sensitive information. A Pattern Health console will be created with restricted access only to select key personnel on this study. All output data and/or analyses from REDCap or Pattern Health will be stored on a secure Box folder created for the purpose of this study and with access restricted to key personnel. Electronic data files will be password-protected and maintained on a password-protected Duke server, with access only available to approved study staff and investigators. This includes REDCap and the Pattern Health console, which contains the link of study identification numbers to identifying information. All data will be retained for 6 years and then will be destroyed according to Duke guidelines.

Nourish: Using digital health to improve diet quality among adults at risk for cardiovascular disease (NCT03875768)

STUDY FLOW:



Nourish measures/constructs

Construct or Measure	Online eligibility screener	Online survey after consent ("Getting to Know you")	Visit 1: Dietary tracking confirmation/ orientation	Visit 2: Randomization occurs	Follow-up visits (by month)			
					Visit 3: (2 Mo)	Visit 4: (4 Mo)	Visit 5: (6 Mo)	Visit 6: (12 Mo)
Dietary Intake								
• ASA-24*			x*		x	x	x	x
• Food allergies/restrictions (5-items)		x						
Blood pressure								
• Hypertension screener	x							
• Blood pressure *(Zoom call-verified)*				x	x	x	x	x
• Blood pressure tendency to run high		x						
• Blood pressure home self-monitoring		x					x	x
Anthropometrics								
• Self-reported Weight	x							
• Self-reported Height	x							
Medication use								
• Current blood pressure meds/dosage**		x		x	x	x	x	x
• Voils blood pressure med adherence (3 items)^		x					x	x
Smoking								
• HINTS smoking questions (3 items)		x					x	x
Physical activity:								
• NPAQ		x					x	x
Self-efficacy for healthy eating:								
• Nutrition Self Efficacy Scale		x					x	x
• Intuitive Eating Scale-2 (IES-2)		x					x	x

Psychosocial:								
• Stress		x					x	x
• Sleep		x					x	x
• PHQ-8		x					x	x
• Every day discrimination		x						
• Experiences of discrimination		x						
Technology use:								
• Smartphone type		x						
• Cell phone usage frequency		x						
• Text messaging frequency		x						
• Unlimited texting plan		x						
• Internet access and usage (3 items)		x						
• Time owning a smartphone		x						
• Smartphone App usage (4 items)		x						
Demographics:								
• Gender (2-items)	x^^	x^^						
• Age (from DOB at PH app registration)			x					
• Age (self-reported on survey)		x						
• Race/ethnicity		x						
• Education		x						
• Household income		x						
• Employment (3 items)		x						
• Marital status		x						
• Household composition (4-items)		x						
• Home ownership		x						
• Car ownership		x						
• Public assistance (2-items)		x						

• Insurance status		x						
• Personalization survey *(Ix arm only)*				x	x	x		

x* ASA 24 collection occurs during 2-week period prior to visits (Visit 1, Follow-up visits Visit 3-6). After Visit 1, if participant tracks for 4 consecutive days on the Pattern Health app, will receive a box with materials. If eligible in BP range, will be randomized at Visit 2.

x** Medications are asked on the screener (if taking BP meds) but specifics/dosages are on the pre-visit surveys and confirmed during the visits

x^ Voils et al's 3-item adherence

x^^ Gender on the screener asks about sex at birth, self-identified gender asked on online evaluation survey

Descriptions:

Current medication use will be assessed using a similar protocol from Voils et al.

Physical activity: Nordic Physical Activity Questionnaire-short form (NPAQ)

Engagement with the intervention will be measured as the proportion of days tracked over expected, DASH nutrient adherence, and number/proportion of coaching encounters attended over the number expected in each zone.

Self-efficacy for healthy eating will be measured using the Nutrition Self Efficacy Scale and Intuitive Eating Scale- 2 (IES-2)

Depression will be measured using the Patient Health Questionnaire (PHQ-8); a validated measure for assessing depressive symptoms in community populations.

Sociodemographics include measures such as race/ethnicity, health insurance, income, employment status, education, household size, technology use, etc.

[REDCap eligibility screening landing page]

Welcome and thank you for your interest in the Nourish study!

What is Nourish?
Nourish is a research study that investigators at Duke University are doing to help adults with high blood pressure follow an eating pattern that can lower blood pressure and improve health.

What's involved?
If you join Nourish, you will be asked to track what you eat and drink every day through a smartphone app and to participate in study visits over one year. You will receive information on how to improve your eating habits using the DASH (Dietary Approaches to Stop Hypertension) eating pattern. You will be compensated for your time, starting at the second visit.

How do I participate?
To see if this study is right for you and if you are eligible, click "Next" below and answer a few questions. If you are eligible for the study, we'll give you some more information before you decide if you would like to join.

Questions?
If you have any questions, please contact us at nourish@duke.edu or call 919-613-1591.

Screening Survey

At the bottom of each screening question page below, there is a footer that says:
Questions? Contact us at nourish@duke.edu or 919-613-1591

Question	Options	Skip logic	Exclusion rules
1. How did you hear about this study?	____Facebook ____ Clinical trials website (Clinicaltrials.gov) ____Researchmatch.org ____Duke MyChart message ____ Community forum or listserv (e.g. Nextdoor) ___Craigslist ___Community organization post/email ___Duke website or listing ____Twitter ____Reddit ____Someone told me about it ____Don't know ____Other:_____ 1a. Please describe how you heard about the study:	If "Other" is selected, go to 1a Otherwise skip to 2	
2. 2a. Have you ever been told by a doctor or other health professional that you have high blood pressure, also called hypertension?	_____ Yes _____ No _____ Not sure/I don't know_____	All responses – ask 2b	**Exclude if answer No to ALL 2 (2a, 2b, 2c AND 2d) If answer yes to any of them, still eligible.**
2b. Are you currently taking medication to control your blood pressure?	_____ Yes _____ No	If yes to 2a OR 2b, skip to 3	

(*Include any medication meant to help control your blood pressure, including diuretics or "water pills.*		If no/don't know, ask 2c	
If no or Not sure/I don't know to question 2a AND No to 2b ask 2c: 2c. Think about the last time you got your blood pressure tested. Was the top number, also known as systolic blood pressure, in this range: 120-159?	_____ Yes _____ No _____ I don't know/I don't remember	If yes to 2c, skip to 3 If no or I don't know/I don't remember, ask 2d	
If no or I don't know/I don't remember to question 2c: 2d. Think about the last time you got your blood pressure tested. Was the bottom number, also known as diastolic blood pressure, in this range: 80-99?	_____ Yes _____ No _____ I don't know/I don't remember		
3. Do you have a smartphone with a data plan?	_____ Yes _____ No		Exclude if no
4. If needed, would you be willing to update your smartphone operating system to the most recent version? (For example, this might mean changing your operating system from version 10 to version 10.1. We are **not** asking you to update your actual smartphone/device).	_____ Yes _____ No		Exclude if no
5. To participate in Nourish remotely, you will need to complete at least 6 visits with our research team on a videoconference platform, such as Zoom. Are you willing and able to do this?	_____ Yes _____ No		Exclude if no
6. Do you have an email address?	_____ Yes _____ No		Exclude if no

7. Are you able to write and speak English fluently?	_____ Yes _____ No		Exclude if no
8. Are you currently 18 years old or older?	_____ Yes, I'm 18 or older _____ No, I'm younger than 18		Exclude if no
9. What was your sex assigned at birth?	_____ Male _____ Female	If male, skip to 10 If female, continue to 9a	
9a. If female ask: Are you pregnant or planning to become pregnant in the next 12 months?	_____ Yes _____ No	Continue to 10.	Exclude if yes
10. Have you ever been told by a doctor or other health professional that you had a heart attack, also called a myocardial infarction?	_____ Yes _____ No	If No, skip to 11 If Yes, continue to 10a	
10a. If yes, was it in the last 6 months?	_____ Yes _____ No		Exclude if yes
11. Have you ever been told by a doctor or other health professional or a stroke, also called an ischemic attack?			Exclude if yes
11a. If yes, was it in the last 6 months?	_____ Yes _____ No		
12. Do you have cancer?	_____ Yes _____ No	If No, skip to 13 If Yes, continue to 12a	
12a. If yes, is it in remission?	_____ Yes _____ No		Exclude if no
13. Have you had bariatric surgery (also called weight loss surgery) in the last 12 months *or* are you planning on having bariatric surgery in the next 12 months?	____ Yes, had surgery in the last 12 months ____ Yes, planning on surgery in the next 12 months ____No		Exclude if yes (past or planned bariatric surgery)
14. Are you on dialysis?	_____ Yes _____ No		Exclude if yes
15. Have you been told by a healthcare provider to lower the amount of potassium you eat?	_____ Yes _____ No		Exclude if yes

16. Have you ever been hospitalized for a psychiatric condition or event?	_____ Yes _____ No	If No, skip to 17 If Yes, continue to 16a	
16a. If yes, was it in the last 6-months?	_____ Yes _____ No		Exclude if yes
17. Have you been diagnosed with dementia?	_____ Yes _____ No		Exclude if yes
18. What is your height?	_____ feet _____ inches		Calculate **BMI** = 703 × weight (lbs) / [height (in)]^2
19. What is your current weight?	_____pounds		and exclude if less than 18.5
20. Are you currently participating in another study or clinical trial to change what you eat, your blood pressure or overall heart health? *This includes drug trials as well as studies to help you improve your health habits or behaviors.*	_____ Yes _____ No		Exclude if yes
21. Do you know anyone else participating in the Nourish study?	_____ Yes _____ No		If Yes, ask Question 21a. If No go to 22.
21a. Does the person participating in the Nourish study live with you?	_____ Yes _____ No		If yes to Question 21 and yes 21a, exclude
22. Do you currently live in the United States?	_____ Yes _____ No		If yes, go to end of screener. If No exclude.

At the end of the screener, after they answer all the questions, score the questions such that they are excluded if they answer any question as indicated by the last column in the table above.

*** For all ineligible participants web page will state:**

Thank you for your interest in the Nourish study and for taking the time to answer these questions. Unfortunately, based on your responses, you are not eligible to join Nourish at this time.

If you would like us to keep your information on-file for any future studies we may have, please email us at nourish@duke.edu.

****For all eligible participants web page will state:**

[Thank you for answering our survey.
Based on your responses, this study might be right for you.

Please press "Submit" to watch a short video about what Nourish is all about. After the video, you will have the chance to learn more about the study and your part in it, so you can decide if you want to participate. We will ask you to review and sign a form that lists out all the risks and benefits of Nourish study activities.

You can contact us with questions at nourish@duke.edu or (919) 613-1591 or sign the form if you are ready to participate.]

After REDCap e-consent form signed, participant will receive an emailed copy with this information:

[Welcome to Nourish! First, we'll need some more information about how we can reach you and where we can send our study materials to you]

[Collect phone numbers, mailing address to ship study materials]

[Over the next month, we will need to schedule 2 online meetings with you. We will contact you to make these appointments when we get to that step, but it will help us to know some days and times when you generally might be available]

[List of days/times with checkboxes]

“Getting to know you” Survey (BASELINE SURVEY)

[Thank you. We will reach out to schedule your first appointment after you complete your surveys.]

The survey questions we are about to ask you will help us find out more about people who join the Nourish Study.

- There are no "right" or "wrong" answers to any of these questions.
- This survey should take 30-45 minutes to complete.
- All aspects of the study are *voluntary* and you can quit at any time.
- This survey must be completed before the next step of the study.
- If you can't finish all at once, you can stop and start again at any time by clicking the Save & Return Later button below.]

We'd like to know about how you use technology in your daily life.

1. What kind of smartphone do you have?
   _____ Apple iPhone
   _____ Android (Google)
   _____ Windows Phone
   _____ Something else

2. How often do you use your cell phone?
   _____ Often
   _____ Sometimes
   _____ Rarely

3. How often do you send text messages?

_____ Often
_____ Sometimes
_____ Rarely

4. Do you have an unlimited texting plan?
_____ Yes
_____ No
_____ Don't know

5. Do you currently subscribe to internet service at home? *This does not include your data plan for your smartphone.*
_____ Yes
_____ No
_____ Don't know

6. If "No", Please tell me whether any of the following are reasons why you do not have high-speed internet at home.
_____ The monthly cost of a home broadband subscription is too expensive
_____ The cost of a computer is too expensive
_____ Your smartphone lets you do everything online that you need to do
_____ You have other options for internet access outside of your home
_____ Broadband service is not available where you live, or is not available at an acceptable speed
_____ Some other reason____

7. How do you access the internet most frequently?

_____ Cell phone
_____ Desktop/laptop
_____ Tablet

8. Over how many months or years have you had a smartphone?
   _____ < 6 months
   _____ 6-11 months
   _____ 1-2 years
   _____ More than 2 years
   _____ Not sure

9. Do you use apps?
   _____ Yes
   _____ No

If yes, they do you use apps:

10. On a scale of 0-10, with 0 being “Not at all comfortable” and 10 being “very comfortable,” how comfortable are you using applications ("apps") on your smartphone?

    _____ (0-10)

If yes, they do you use apps:

11. Have you ever used an app to track the following? (Select all that apply)
    _____ Blood pressure
    _____ Weight
    _____ Physical activity
    _____ Diet
    _____ Medication
    _____ None of these

If yes, they do you use apps:

12. Have you ever used an electronic or wearable device to track the following? (Select all that apply)
    _____ Blood pressure
    _____ Weight
    _____ Physical activity

_____ Diet
_____ Medication
_____ None of these

Now, we'd like to ask you about your demographic information.

13. What is your current age?
_____years

14a. How would you describe your gender?
_____ Male
_____ Female
_____ Prefer to self-describe
_____ Prefer not to say

12b.If “prefer to self-describe” is selected:
How would you describe your gender?
_____

14. Do you identify as transgender?
_____ Yes
_____ No
_____ Prefer not to say

15. Do you consider yourself to be Hispanic or Latino?
_____ Yes, Hispanic or Latino
_____ No, not Hispanic or Latino
_____Prefer not to say

16. What race do you consider yourself to be? Please mark all the categories that you identify with
_____ American Indian or Native American

_____ Asian
_____ Native Hawaiian or Pacific Islander
_____ Black or African American
_____ White
_____ Another race
_____ Prefer not to say

17. If “another race” is selected: “Which other race?: _____

18. What is the highest level of schooling you completed?
_____ Never attended school or only attended kindergarten
_____ Grades 1 through 8 (Elementary school)
_____ Grades 9 through 11 (Some high school)
_____ Vocational or trade school after high school
_____ Some college or university
_____ Associate degree from college or university
_____ College, 4 years or more (College graduate)
_____ Post-graduate degree

19. Which of these categories best describes your total combined household income for the past 12 months? This should include gross income (before taxes) from all sources, wages, rent from properties, social security, disability, and/or veteran's benefits, unemployment benefits, workman's compensation, help from relatives (including child payments and alimony) and so on.
_____ Less than $5,000
_____ $5,000 through $11,999
_____ $12,000 through $15,999
_____ $16,000 through $24,999
_____ $25,000 through $34,999
_____ $35,000 through $49,999
_____ $50,000 through $74,999
_____ $75,000 through $99,999
_____ $100,000 or greater
_____ Don't know

20. Which of the following best describes your current main daily activities and/or responsibilities? Select all that apply.
_____ Working full time
_____ Working part-time
_____ Student
_____ Unemployed or laid off
_____ Looking for work
_____ Keeping house or raising children full-time
_____ Retired

21. (If answer unemployed or laid off, or looking for work) How long have you been out of work? Please enter number of week or months

_____ Weeks

_____ Months

22. (if answer working full time or working part-time) Are you satisfied with the number of hours you are working?
_____ Yes
_____ No, too few hours
_____ No, too many hours

23. Are you currently living with a spouse or partner?
_____ Yes
_____ No

24.
a. How many people are currently living in your household, including yourself?
_____ Number of people
b. Of these people, how many are children 18 years or younger?
_____ Number of children
c. Of these people, how many are adults, including yourself?

_____ Number of adults

d. Of the adults, how many bring income into the household?
_____ Number of adults

25. Is the home where you live:
_____ Owned by you or someone in the household with a mortgage or loan? Include home equity loans.
_____ Owned by you or someone in the household free and clear (without a mortgage or loan)?
_____ Rented?
_____ Occupied without payment of rent?
_____ Other, please specify: _____

26. Do you own a car?
_____ Yes
_____ No

27. Has your family received any support from the SNAP Program (food stamps)?
_____ Yes
_____ No

28. Has your family received any support from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)?
_____ Yes
_____ No

29. What type of health insurance do you have?
_____ Private insurance (such as Blue Cross Blue Shield, CIGNA, Health America, Aetna)
_____ Medicaid
_____Medicare
_____None, I pay out of pocket
_____ Other, please specify: _____

30. Does your blood pressure tend to run high?
_____ Yes
_____ No

31. Have you ever had a blood pressure reading where the systolic blood pressure (the top number) was over 160, or the diastolic blood pressure (the bottom number) was over 100?
_____ Yes
_____ No

32. Do you ever measure your blood pressure outside of appointments with your health care provider?
_____ Yes
_____ No

If Yes ask next 3 questions:

33. Where do you measure your blood pressure? (select all that apply)
_____ At home
_____ At a pharmacy
_____ At a friend or relative's house
_____ At a community fair or event
_____ Other, please specify: _____

34. How often do you measure your blood pressure in any of these places?
_____ 3 or more times per day
_____ 1 to less than 3 times per day
_____ Sometimes, but less than once per day

35. Do you regularly transmit, via e-mail, Internet, phone or fax, blood pressure readings to a health care provider for feedback?
_____ Yes
_____ No

Medication Use							
Are you currently taking any prescription medication?						☐ yes	☐ no
Please list any prescription medications that you are taking:							
Medication Name	Dose	Times per Day	Is this medication for blood pressure?			Have you taken this medication regularly for at least 1 month?	
1.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
2.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
3.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
4.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
5.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
6.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
7.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
8.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
9.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no
10.			☐ yes	☐ no	☐ not sure	☐ yes	☐ no

36. In order for blood pressure medication to work best, people should take it according to the doctor's instructions. For one reason or another, people can't or don't always take all of their pills as prescribed. We want to know how often you have missed your blood pressure medication. Please rate your agreement with the following statements.

On how many days over the past 7 days did you miss at least one dose of your blood pressure medication?

Over the past 7 days....

I took all doses of my blood pressure medication.

_____Never
_____Rarely
_____Sometimes
_____Often
_____Always

I missed or skipped at least one dose of my blood pressure medication.

_____Never
_____Rarely
_____Sometimes
_____Often
_____Always

I was not able to take all of my blood pressure medication.

_____Never
_____Rarely
_____Sometimes
_____Often
_____Always

37. Have you smoked at least 100 cigarettes in your entire life?

NOTE: 5 packs = 100 cigarettes

_____ Yes
_____ No
_____ Don't Know/Not sure

Food Allergies

1. Do you currently have any food allergies, food intolerances or do not eat certain foods?
____Yes
____ No

2. Which foods? (Select all that apply to you)
____ Milk or dairy
____ Meat
____ Eggs
____ Fish or shellfish
____ Nuts or seeds
____ Wheat, gluten, corn or other grains
____ Fruits or vegetables
____ Beans or legumes
____ Other foods**

3. If "Other foods" selected: What other food types? _____

4. Are you vegetarian?
____Yes
____ No

5. Are you vegan?
____Yes
____ No

Nutrition Self-Efficacy Scale

How certain are you that you could overcome the following barriers? Please respond from 0-100 where 0 is not at all certain and 100 is completely certain.	
I can manage to stick to a dietary pattern that is rich in fruits and vegetables, legumes, beans, nuts, low-fat dairy, and lean protein foods…..	0-100
…even if I need a long time to develop the necessary routines.	
…even if I have to try several times until it works.	
… even if I have to rethink my entire way of nutrition	
… even if I do not receive a great deal of support from others when making my first attempts	
… even if I have to make a detailed plan	

For the next set of questions, please tell us how much you agree with the following statements about your eating habits.

Intuitive Eating Scale- 2 (IES-2)					
	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
1. I try to avoid certain foods high in fat, carbohydrates or calories.	☐	☐	☐	☐	☐
2. I find myself eating when I'm feeling emotional (e.g. anxious, depressed, sad), even when I'm not physically hungry.	☐	☐	☐	☐	☐
3. If I'm craving certain foods, I allow myself to have it.	☐	☐	☐	☐	☐
4. I get mad at myself for eating something unhealthy.	☐	☐	☐	☐	☐
	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**
5. I find myself eating when I am lonely, even when I'm not physically hungry.	☐	☐	☐	☐	☐
6. I trust my body to tell me when to eat.	☐	☐	☐	☐	☐
7. I trust my body to tell me what to eat.	☐	☐	☐	☐	☐

8. I trust my body to tell me how much to eat.	☐	☐	☐	☐	☐
9. I have forbidden foods that I don't allow myself to eat.	☐	☐	☐	☐	☐
10. I use food to help me soothe my negative emotions.	☐	☐	☐	☐	☐
11. I find myself eating when I am stressed out, even when I'm not physically hungry.	☐	☐	☐	☐	☐
12. I am able to cope with my negative emotions (e.g. anxiety, sadness) without turning to food for comfort.	☐	☐	☐	☐	☐
13. When I am bored, I do NOT eat just for something to do.	☐	☐	☐	☐	☐
14. When I am lonely, I do NOT turn to food for comfort.	☐	☐	☐	☐	☐
15. I find other ways to cope with stress and anxiety than by eating.	☐	☐	☐	☐	☐
16. I allow myself to eat what food I desire at the moment.	☐	☐	☐	☐	☐
17. I do NOT follow eating rules or diet plans that dictate what, when, and/or how much to eat.	☐	☐	☐	☐	☐
18. Most of the time, I desire to eat nutritious foods.	☐	☐	☐	☐	☐
19. I mostly eat foods that make my body perform efficiently (well).	☐	☐	☐	☐	☐
20. I mostly eat foods that give my body energy and stamina.	☐	☐	☐	☐	☐
21. I rely on my hunger signals to tell me when to eat.	☐	☐	☐	☐	☐
22. I rely on my fullness (satiety) signals to tell me when to stop eating.	☐	☐	☐	☐	☐
23. I trust my body to tell me when to stop eating.	☐	☐	☐	☐	☐

Nordic Physical Activity Questionnaire-short form (NPAQ)

On a typical week, how much time do you spend in total on moderate and vigorous physical activities where your heartbeat increases and you breathe faster (e.g. brisk walking, cycling as a means of transport or as exercise, heavy gardening, running or recreational sports). Only include activities that lasted at least 10 minutes at a time.

_____ Less than ½ an hour (less than 30 minutes)
_____ ½ an hour – 1½ hours (30-90 minutes)
_____ 1½ hours – 2½ hours (90-150 minutes)
_____ 2½ hours – 5 hours (150-300 minutes)
_____ more than 5 hours (more than 300 minutes)

Sleep

I would like to ask you a few questions about your sleep patterns.

1. Over the last 2 weeks, how many days have you had trouble falling asleep or staying asleep or sleeping too much?
_____ 0-14 days

2. On average, how many hours of sleep do you get in a 24-hour period?
_____ Number of hours [0-24]

Stress

Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?
_____ Number of days [0-30]

Personal Health Questionnaire Depression Scale (PHQ-8) Over the last 2 weeks, how often have you been bothered by any of the following:	0 Not at all	1 Several Days	2 More than half the days	3 Nearly every day
Little interest or pleasure in doing things?	☐	☐	☐	☐
Feeling down, depressed or hopeless?	☐	☐	☐	☐

Trouble falling or staying asleep, or sleeping too much?	☐	☐	☐	☐
Feeling tired or having little energy?	☐	☐	☐	☐
Poor appetite or overeating?	☐	☐	☐	☐
Feeling bad about yourself-or that you are a failure or have let yourself or your family down?	☐	☐	☐	☐
Trouble concentrating on things, such as reading the newspaper or watching television?	☐	☐	☐	☐
Moving or speaking so slowly that other people could have noticed? Or the opposite— being so fidgety or restless that you have been moving around a lot more than usual?	☐	☐	☐	☐

Expanded Everyday Discrimination Scale In your day-to-day life, how often do any of the following things happen to you?	Almost everyday	At least once a week	A few times a month	A few times a year	Less than once a year	Never
You are treated with less courtesy than other people are.	☐	☐	☐	☐	☐	☐
You are treated with less respect than other people are.	☐	☐	☐	☐	☐	☐
You receive poorer service than other people at restaurants or stores.	☐	☐	☐	☐	☐	☐
People act as if they think you are not smart.	☐	☐	☐	☐	☐	☐
People act as if they are afraid of you.	☐	☐	☐	☐	☐	☐
People act as if they think you are dishonest.	☐	☐	☐	☐	☐	☐
People act as if they're better than you are.	☐	☐	☐	☐	☐	☐
You are called names or insulted.	☐	☐	☐	☐	☐	☐
You are threatened or harassed.	☐	☐	☐	☐	☐	☐
You are followed around in stores.	☐	☐	☐	☐	☐	☐
Follow-up Question (Asked only of those answering "A few times a year" or more frequently to at least one question.): What do you think is the main reason for these experiences?	_____ Your Ancestry or National Origins _____ Your Gender _____ Your Race _____ Your Age _____ Your Religion _____ Your Height _____ Your Weight _____ Some other Aspect of Your Physical Appearance _____ Your Sexual Orientation _____ Your Education or Income Level _____ A physical disability _____ Your shade of skin color _____ Your tribe _____ Other (SPECIFY) _____					

Experiences of discrimination

This next section is going to ask about how you and others like you are treated, and how you typically respond.

1) If you feel you have been treated unfairly, do you usually: (please select the best response)

   ☐ accept it as a fact of life
   ☐ try to do something about it

2) If you have been treated unfairly, do you usually: (please select the best response)

   ☐ talk to other people about it
   ☐ keep it to yourself

Have you ever experienced discrimination, been prevented from doing something, or been hassled or made to feel inferior in any of the following situations because of your **race, ethnicity, or color**?

3) At school?

   ☐ no (Go to 4)
   ☐ yes

   a) How many times did this happen?

      ☐ once
      ☐ two or three times
      ☐ four or more times

4) Getting hired or getting a job?
   ☐ no (Go to 5)
   ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

5) At work?

- ☐ no (Go to 6)
- ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

6) Getting housing?

- ☐ no (Go to 7)
- ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

7) Getting medical care?

- ☐ no (Go to 8)
- ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

8) Getting service in a store or restaurant?

- ☐ no (Go to 9)
- ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

9) Getting credit, bank loans, or a mortgage?

- ☐ no (Go to 10)
- ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

10) On the street or in a public setting?

- ☐ no (Go to 11)
- ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

11) From the police or in the courts?

- ☐ no (Go to end)
- ☐ yes

a) How many times did this happen?

- ☐ once
- ☐ two or three times
- ☐ four or more times

[END OF SURVEY text]:

Great work!

Your survey has been submitted. A member of the Nourish team will email you in the next few days with instructions for the next step of the study.
Thank you for participating in Nourish!

Intervention Arm: Personalization Survey

[This is first administered after randomization – during Visit 2, for intervention arm only to personalize the intervention – and then at Visits 3 and 4 for 2-month and 4-month visits via the Pattern Health (Nourish) app where the intervention is delivered]

1. Do you have any children under age 12 in the home? (kids<age12)
   ____Yes (1)
   ____No (0)

2. What is your employment status (work):
   ____full time (1)
   ____part time (2)
   ____not at all (3)

3. How would you describe your gender?
   ____Female (1)
   ____Male (2)
   ____Non-binary (3)

4. Are you married or do you live with a partner (support)?
   ____Yes (1)
   ____No (0)

5. In the last month, how often have you felt nervous and stressed? (stress)
   ____Never (1)
   ____Almost never (2)
   ____Sometimes (3)
   ____Fairly often (4)
   ____Very often (5)

6. Which eating pattern best describes your eating habits (eatingpersona):

____Three square meals and 2 snacks (1)
____Constant grazing (2)
____Skip breakfast and eat later (3)
____Fuel eating, joy eating, fog eating, storm eating (these are just eating personas)
____Eat to live, Live to eat?

7. How would you describe your smartphone use (techroutine):
____Constant Use: As soon as I wake, several times throughout the work day, in the evening, and before bed (1)
____Only When I Need It: It's always with me, but I only check in with news or social media a couple times a day (2)
____Absent-minded User: I often don't remember where my phone is/I'm always leaving it in my purse or on the dresser. Out of sight, out of mind. (3)

8.

b. Do you often cook your own meals (cook)?
____Yes (1)
____No (0)

c. If no, then ask, does someone else often cook meals for you (cookother)?
____Yes (1)
____No (0)

9. Do you have any of the following food allergies or food intolerances? Check all that apply (allergy)
____Peanuts (1)
____Tree nuts (2)
____Eggs (3)
____Milk (4)
____Shellfish (5)

10. How often do you dine out at restaurants? (dineout)
____Every day (1)
____Approximately 3 times per week (2)
____Once a week (3)
____Approximately 2 times per month (4)

____Never (5)

11. Which of the following food pattern preferences applies to you? (foodpref)
    ____Kosher/halal (1)
    ____Vegetarian/vegan or avoid meat (2)
    ____None of the above (0)

12. Which of the following DASH friendly meals would you try? Check all that apply?
    ____Image 1
    ____Image 2
    ____Image 3
    ____Image 4
    ____Image 5
    ____Image 6
    ____Image 7

REMOTE DATA COLLECTION PROTOCOL

STEP 1: Screening, Registration and Consent

- Participant finds out about the study somewhere and clicks on link about study on www.nourishstudy.org
  - When recruitment for study is nearing completion, notice will ask to email if interested.
    - When recruitment is done, note on the website will say "Thank you for your interest. We have finished recruiting for Nourish."
  - Fills out eligibility screener via REDCap survey
    - *When recruitment is done, REDCap survey will be closed.*
    - Participant screens for the study (Using self-reported BP/BP medications to confirm eligibility)
- If eligible and interested, e-consents in REDCap
    - Email received with attached consent form and directions for filling out V1 (baseline) survey
- Fills out V1 survey (baseline survey)
  - 2nd email explains how to complete ASA-24 assessments (sent 8 am the day after completing the baseline survey)
  - Completes online evaluation measures *(see measures/constructs chart)*

STEP 2: Complete ASA-24 via https://asa24.nci.nih.gov/

- Needs to complete 2 ASA-24 dietary assessments within 14 days of completing 1st ASA
    - Requested days will be unannounced days - 1 weekend and 1 day.
- Study staff monitoring progress with reminders (automated prompt emails from RC), throughout the 14 days, per protocol
- **To continue being eligible to move forward in the study, participant must:**
    - **Complete 2 ASA-24 unscheduled tracking within 14 days that includes:**
        - **1 weekend day**
        - **1 weekday**

ASA-24 Protocol:

- Study team will assign ASA-24 login credentials for each participant based on the pre-coded list in REDCap
- Study team will log into ASA-24 website daily to confirm participant has completed ASA-24 measurements
- Study team will check ASA-24 website to confirm completion of survey and enter into ASA-2
    - Dates between 2 ASA-24 submissions must be within 14-day window:
        - They have 3 attempts for each recall type (weekend or weekday)

- **If participant completes 2 ASA-24 measurements within the 14-day period,** the study team will receive automatic scheduling request email from RC to schedule a Zoom Visit 1 (Continue to STEP 3).
- **If participant** does not complete 2 ASA-24 measurements within the 14-day period, participant is **ineligible.**

STEP 3:

VISIT 1: Dietary Eligibility/PH Tracking Orientation Zoom Visit
[ONLY if completed 2 ASA-24s]

- After completing second ASA-24 dietary assessment, team will schedule 20-30 minute Zoom appt for the following
    - Overview of:
        - Nourish study purpose, answer Q&A about study
        - Orient participant to PH tracking app to track for next 7 days
            - Explain they will need to track in app for next week
            - Confirm download (if not done via email)
            - Brief overview of how to track
            - Confirm timing of BP medications, if applicable, for scheduling Visit 2
    - **Participant asked to track for 7 day**s

- Schedule (tentative) Visit 2 for 8-10 days later
- **Confirm shipping address so can ship box after 4 consecutive days out of 7 (STEP 4)**
  - Participant will be sent a box with Omron BP monitor/instructions
    - Visit 2 average BP measurement confirms BP for final eligibility (see below).
- Appt reminder 1 day before will include link to download the app to register with PH
    - Will need to ensure that they have downloaded it, registered and logged in
    - Will need to have enabled text messages
  - Link to resources in the app/online

- After Visit 1 visit, check PH console each day for the next 7 days (and to track if 4 consecutive days are tracked (STEP 4) to see if Pattern Health task deployed to confirm 4 days of tracking.
  - Need at least 4 consecutive days of tracking.
    - Will give an opportunity to do it another week if participant explains reason for not completing and it is approved by project director and/or PI.
  - Ex: if Wednesday appointment schedule on the next Thursday or later
  - Make sure participant has contact information for questions about tracking.

STEP 4: PH DIETARY TRACKING FOR 4 CONSECUTIVE DAYS (OUT OF 7 DAYS)

- **IF PARTICIPANT TRACKS CONSECUTIVELY FOR 4 DAYS in a 7-day PERIOD**
  - Once have 4 consecutive days of tracking out of a 7-day period task will be created in PH app (check console)
    - Ship box (follow Fed Ex shipping protocol)
    - Email will be sent to let person know that BP will be verified for final study eligibility during Visit 2
    - Instructions to participant:
      - Need to have box opened: and on-hand for the visit with measuring tape and batteries installed
      - Pick a convenient time (45-60 mins) when not likely to drink caffeine/smoke cigarettes/exercised (last 30 minutes) or taking BP medications in the last 1 hour, preferably at least 2-3 hours later
      - Need to sit still, quiet space
      - Will need Zoom on phone, tablet or computer with reliable wifi and video

- **IF PARTICIPANT DOES NOT TRACK CONSECUTIVELY FOR 4 DAYS in a 7-day PERIOD (WEEK 1):**
  - Check Pattern Health console and see if dietary tracking data coming in

- At end of Week 1, if haven't tracked at least 4 consecutive days, will receive automated email asking them to reschedule Visit 2. Will continue to monitor console to make sure tracking data are coming in.

- **IF PARTICIPANT DOES NOT TRACK CONSECUTIVELY FOR 4 DAYS in a 7-day PERIOD (WEEK 2):**
  - Check Pattern Health console and see if dietary tracking data coming in
    - ***At end of Week 2, if did not track for 4 consecutive days within a 7-day period, will become ineligible for the study.***

STEP 5: VISIT 2 (including randomization, if eligible based on BP)

- 1 day before the visit, will confirm date/time via email with tips/reminders:
  - Don't drink caffeine/smoke/exercise for at least 30 minutes before the visit
  - Have BP monitor ready and unpackaged to use (batteries installed, etc)
  - Send this link as a reminder to watch how to take the BP: https://www.heart.org/en/health-topics/high-blood-pressure/understanding-blood-pressure-readings/monitoring-your-blood-pressure-at-home

- **Conduct 45-60 minute Zoom appt to:**

1. **Answer any further questions**

2. **Confirm BP is in-range** *(see below for remote BP instructions*):*
   Out-of-range:
   - Follow BP re-measurement protocol (see below)
   - *If BP is still out-of-range, say they are ineligible, share resources and pay participant $40 for the first 2 visits*

   In-range:
   - Continue to baseline measurements

3. **Collect baseline measurements**
   - Confirm medication and dosages

4. **Randomize**
   - Show DASH overview video while putting in information in the Pattern Health console, have participant watch onboarding video for arm
   - If randomized to Intervention, will administer personalization survey for participant to fill out in the app

5. **Orientation**:

- What to expect
- Get them set up with onboarding with RD via Zoom video call (Check Coach's Outlook calendar)
- Schedule Visit 3 (2 months from now)
    - Remind about the importance of tracking daily and filling out the dietary recalls (ASA24) on the day they are sent or visit may be rescheduled.

***Remote BP Measurement**

- Explain to participant that blood pressure measurement will determine eligibility for the study and that you are asking them to take their blood pressure 3 times to get the most accurate reading
- Start visit by with checking in with participant- ask how they have been doing the last week?
- Remind participant to relax, make themselves comfortable, take a deep breath, etc
- Verify the participant received the study materials package and answer any questions the participant has about Nourish so far.

Confirm left or right arm for protocol

- The participant should use their left arm if possible.
- Confirm with participant what they told us at visit 1 about using their left or right arm.
- "Before we get started, can you please confirm that we can/cannot take your blood pressure in your left arm?"

Cuff Placement

Walk the participant through measuring their upper arm

- **"Please get out the measuring tape that was provided in the box of materials so you can measure your upper arm and to get it and the monitor/batteries if not nearby. This is to ensure we get the right fit on the cuff for accurate blood pressure reading."**
- **If the participant is wearing a shirt that covers the upper arm area, say**
    - **"Please roll up the sleeve so your upper arm is bare."**
    - **"Now, please stand and find the part of the upper arm that is about halfway between the shoulder and elbow."**
- **Once the participant is standing, say**
    - **"Please wrap the measuring tape around the midpoint of your arm and tell me the measurement in inches around the entire upper arm, rounded up to the nearest inch is fine."**
- **Record the circumference measurement in inches, rounding up to the nearest tenth of an inch, i.e. 14.5 inches becomes 15 inches.**

- If you find the BP monitor doesn't fit correctly on the upper arm below, or the circumference measurement > 17 inches, participant should use left forearm measurement (preferably, unless cannot -- then use right forearm as last resort), as described.

(Upper arm Cuffs fit 9"-17" circumference or 22 to 42 cm in circumference.)

- All readings will be recorded to the nearest digit.
- Variables to record:
  - Blood Pressure 1, Blood Pressure 2, Blood Pressure 3, Average (systolic/diastolic)
- Confirm if participant has had caffeine/smoked/exercised in the last 30 minutes.
- Confirm if date/time of last dose of BP medications
  - If yes, let the participant know that we will need to wait until 30 minutes after their caffeine, exercise or smoking to take blood pressure measurements.
  - If yes to recent BP medications, will need to wait at least 1 hour after last dose.
- If the above apply, ask to connect on Zoom in 30-60 mins, if available, or within the next 24 hours if not available soon.

LEFT UPPER ARM PROTOCOL

- "We are going to take your blood pressure, which will determine the last step of eligibility to continue in Nourish. We are going to ask you to take your blood pressure 3 times, in order to get the most accurate reading."

"I'm going to give you some directions about taking your blood pressure and what to expect."

"We will start with a 5-minute relaxation period. Then, I will ask you to take your first blood pressure reading, and then wait for 1 minute in between each of the next 2 readings."

1. **"Please be seated with your back supported, legs uncrossed, in a quiet room. You'll sit with your left elbow and forearm resting comfortably on the arm of your chair and the palm of your hand turned upward."**
2. **"Please apply the cuff around your upper left arm."**
3. **"The tubing should be centered and aligned with the brachial artery, which is right in the middle of your arm."**
4. **"The edge of the cuff nearest the tubing should be about half an inch above the crease of your elbow."**
5. **"The mid-height of the cuff should be at your heart level."**

6. **"Please wrap the cuff tightly around the arm, tight enough that you can insert only one finger between the cuff and arm. The cuff should be of uniform pressure against the arm."**
7. **"Please make sure you are sitting with both feet flat against the floor (use a box if feet dangle), back straight to back of chair, and palm facing upwards."**
8. **"Is it okay to play some relaxing spa-like music for you?"**
    - **If participant says yes,** click here for playlist**.**
9. **"I'm going to ask you not to talk during this period of time or look at your phone. I just hope you can relax and take some time for yourself, to sit quietly and breathe."**
10. **"Feel free to sit with your eyes closed, feet uncrossed and arms resting in the right position. I will be turning off my video so you can relax and not be distracted." (if on video).**
    - **Set a silent (ie phone) timer for ~5 minutes. When the timer goes off, say:**
11. **"Please turn on BP monitor by pressing the start button, Then please hold up the monitor with your other hand to your camera so I can see the screen and you won't have to talk. If I can't see it, I'll let you know to read it out loud to me."**
12. **Tell participant to take the first measurement of 3 readings (with 1 minute in between- use a timer to measure the 1 minute and tell them when to take the next 2 readings) and to hold up the monitor and show you the reading on the screen (or read it on the phone if no video).**

OR

LEFT FOREARM PROTOCOL

- "We are going to take your blood pressure, which will determine the last step of eligibility to continue in Nourish. We are going to ask you to take your blood pressure 3 times, in order to get the most accurate reading."

"I'm going to give you some directions about taking your blood pressure and what to expect."

"We will start with a 5-minute relaxation period. Then, I will ask you to take your first blood pressure reading, and then wait for 1 minute in between each of the next 2 readings."

1. **"Please be seated with back supported, legs uncrossed, in a quiet room with your left elbow and forearm resting comfortably on the arm of the chair and the palm of the hand turned upward."**
2. **"For your blood pressure reading, you will use the largest section of your forearm that is closest to your elbow."**

3. **"The cuff will be actually flipped around from the direction you would have it if you were using the upper arm cuff - the tubing will run up toward the upper arm and not down toward the hand."**
4. **"Please make sure the tubing is facing the inner crease of the elbow (the brachial artery)."**
5. **"The edge of the cuff nearest the tubing should be about half an inch away from the crease of your elbow."**
6. **"The cuff should be at your heart level, which might mean you need to raise raising your arm off the chair arm. (Note, this might mean bringing the forearm and the hand up and toward your head)."**
7. **"Please wrap the cuff tightly around the arm, tight enough that you can insert only one finger between the cuff and arm. The cuff should be of uniform pressure against the arm."**
8. **"Please make sure you are sitting with both feet flat against the floor (use a box if feet dangle), back straight to back of chair, and palm facing upwards."**
9. **"Is it okay to play some relaxing spa-like music for you?"**
    - **If participant says yes,** click here for playlist**.**
10. **"I'm going to ask you not to talk during this period of time or look at your phone. I just hope you can relax and take some time for yourself, to sit quietly and breathe."**
11. **"Feel free to sit with your eyes closed, feet uncrossed and arms resting in the right position. I will be turning off my video so you can relax and not be distracted." (if on video).**
    - **Set a silent (ie phone) timer for ~5 minutes. When the timer goes off, say:**
12. **"Please turn on BP monitor by pressing the start button. Then please hold up the monitor with your other hand to your camera so I can see the screen and you won't have to talk. If I can't see it, I'll let you know to read it out loud to me."**
13. **"Please turn on BP monitor by pressing the start button and tell me what the reading says when it appears" [if you can't see the monitor].**
14. **Tell participant to take the first measurement of 3 readings (with 1 minute in between- use a timer to measure the 1 minute and tell them when to take the next 2 readings) and to hold up the monitor and show you the reading on the screen (or read it on the phone if no video).**

- Record the 3 readings with 1 minute in between readings #2 and #3.

1. SBP/DBP _ _ _ /_ _ _
2. SBP/DBP _ _ _ /_ _ _
3. SBP/DBP _ _ _ /_ _ _

Avg. SBP/DBP _ _ _ /_ _ _

- If avg. is SBP ≥ 160 *OR* DBP ≥100, tell participant you will call back in next 30-60 minutes and retake blood pressure, if available
    - If unable to take BP within 30 minutes, try to reschedule appt for the next day (within 24 hours if possible) and try again.
        - If BP is still too high, ineligible. See below

4. SBP/DBP _ _ _ /_ _ _
5. SBP/DBP _ _ _ /_ _ _
6. SBP/DBP _ _ _ /_ _ _

Avg. SBP/DBP _ _ _ /_ _ _

Avg. SBP 120-159 OR DBP 80-99 OR BOTH for eligibility

- Note: Will follow separate AE protocol if average BP readings are:

SBP ≥ 180 mm/Hg
OR
DBP ≥ 110 mm/Hg
OR
SBP ≤ 90

If second blood pressure is out of range, inform participant s/he is unfortunately not eligible for the study and provide community resources (DASH information, hypertension clinic information at Duke, other resources in their area).

Pay participant $40 Amazon gift card incentive if ineligible based on BP

If participant is ineligible due to high BP and is not currently on BP meds but states that they plan to start taking BP-lowering medications (per their PCP's recommendation/prescription) within the study recruitment period, they can be offered to reach out the study team via phone/email when their BP has stabilized. The same protocols will apply (confirming BP for eligibility) at the visit. If they are still ineligible due to high BP at that point, no other follow-up will occur and they will not be randomized.

IF AVERAGE BP IS IN-RANGE (SBP: 120-159 *OR* DBP: 80-99 *OR* BOTH)

- **Once AVERAGE BP is verified as being in-range:** (SBP 120-159 OR DBP 80-99 OR BOTH), Staff continue with randomization and orientation to the treatment arm, as described above
- **At the end of the visit, pay the participant $40 Amazon gift card incentive.**

Follow-up Visits 3, 4, 5, 6 (Follow-up Months 2, 4, 6, 12)

- 2 weeks before each scheduled follow-up visit, ASA24 prompts are sent with reminders to be completed with reminders (as described above)
    - If both ASA24s are not complete, can still do visit and prompt participant to complete the recall while in the visit:
        - Take BP
        - Ask ppt to log into ASA system with their information
        - Confirm medications and dosage
        - Administer surveys, if appropriate
        - Schedule next visit
    - At end of visit, pay participant incentive (Amazon e-gift card):
        - $20 for 2-month visit (Visit 3)
        - $20 for 4-month visit (Visit 4)
        - $40 for 6-month visit (Visit 5)
        - $40 for 12-month visit (Visit 6)
- Automated reminders (REDCap emails)
    - Appt needs to be confirmed with reminders for remote BP collection
- Send out online surveys for months 6 and 12 months to save time at appt:
    - BP adherence med measures
    - Physical activity
    - Self-efficacy for healthy eating
    - Psychosocial measures (sleep, depression, stress, intuitive eating, etc)
    - Personalization survey (months 2 and 4 only as intervention ends at month 6) for Ix arm only
- 6-month visit protocol will include reminders about not receiving any more feedback and satisfaction (see 6-month protocol)
- 9-month retention protocol (see 9-month protocol)
- 12-month visit protocol will include closing out participation in the study:
    - Thank them for participating over the last year.
    - Share free dietary tracking app resources (Nourish app is turned off)- e.g. Nutritionix, My Fitness Pal, that have nutritional data, etc.

INFORMED CONSENT

DUKE UNIVERSITY HEALTH SYSTEM

DUHS IRB
IRB Pro00101689
IRB Reference Date: 02/09/2022
IRB Expiration Date: 03/05/2023

Online Consent to Participate in a Research Study
Nourish: Using digital health to improve diet quality among adults at risk for cardiovascular disease

The purpose of this research study is to use digital technologies like your smartphone and mobile apps to disseminate an evidence-based intervention to improve blood pressure and reduce cardiovascular disease risk.

Participants will undergo a screening to confirm they have high blood pressure and have completed surveys and dietary tracking using the Pattern Health app. If deemed eligible during a videoconference call to check blood pressure, participants will be randomized to a 6-month technology-based dietary intervention. All participants will keep track of everything they eat and drink, and some participants will receive daily feedback via text message and coach support. All participants will have follow-up videoconference research visits at 2, 4, 6 and 12- months. The study will last 12 months.

The greatest risks of this study include loss of confidentiality.
If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have high blood pressure and may be at-risk for cardiovascular disease. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. Please ask the study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) sponsors this study. The principal investigator for this study is Dr. Gary Bennett. Portions of Dr. Bennett’s and his research team’s salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Laura Svetkey and/or Dr. Crystal Tyson will be your doctors for the study and, if needed, will be in contact with you and/or your regular health care provider throughout the time that you are in the study and afterwards.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the effectiveness of a program that uses digital technologies such as a dietary tracking smartphone app, as compared to a control group, on 6- and 12- month changes diet quality, blood pressure and other outcomes.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 300 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You will then complete some questionnaires about your eating habits, lifestyle, depression, medication use, and other background information about you. You will also be asked about your usual eating patterns and to track your food intake on a mobile app; we will give you instructions on how to do so. We will also mail you a digital blood pressure monitor so you can measure your blood pressure with our study staff during online visits. You can keep this blood pressure monitor during and after the study duration.

Once all of these items are completed, we will schedule a Zoom (videoconferencing call) to make sure you are eligible to participate, based on your blood pressure readings. If you are eligible, you will then be randomly assigned (like the flip of a coin) to receive one of two programs using your smartphone to promote a healthy eating pattern. You have an equal chance of being assigned to either program. We will then give you a brief orientation to the study.

For one year, both groups will be asked to track their foods and beverages daily using a dietary tracking app called Pattern Health. One group will receive daily feedback through text messages and may also receive coaching support from text messages, phone calls and/or videoconferencing sessions. In addition, both groups will receive video and online educational materials about adopting a healthy eating pattern.

We will ask you to participate in online (Zoom) videoconferencing appointments at 2, 4, 6, and 12 months. At these visits, we will collect similar measures that we did at the baseline visits.

Some Important things to note*:*

- Your participation is voluntary.
- Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.
- If you want to end your study participation you can email, write or call us.
- If you do not sign this consent form, you will continue to receive care, but not as a part of

  this study.

HOW LONG WILL I BE IN THIS STUDY?

Your total study participation will be for one year. We are asking you to track your food and beverage intake every day for the entire year. One group will receive 6 months of added feedback and support.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

Breach of confidentiality: While we cannot completely guarantee confidentiality during your study participation, we have taken several precautions to prevent any disclosure. Additional information is listed in the "WILL MY INFORMATION BE KEPT CONFIDENTIAL?" section below.

All electronic files will be securely stored with access will only be granted to approved study staff. Electronic files will be kept multiple places 1) a secure REDCap database at Duke University; 2) our Nourish study digital platform at Duke; and 3) with an outside digital company called Pattern Health. We will integrate the Pattern Health system and our Duke systems using an application programming interface (API). Information collected by Pattern mobile app is subject to the terms of use. The Duke REDCap system will store your personal information (such as your contact/demographic information, your survey information, study visits, and information we need to track your safety in the study). The Nourish study platform at Duke is processed and stored on Heroku, a cloud application server platform. This platform will support the following Nourish services: the Nourish database, software logging, and file serving. The Pattern Health environment will be used for tracking your dietary data, survey information about you, and sending and receiving text messages. We will collect names, phone number, gender, date of birth, study ID, and nutritional information as part of the Pattern Health database. Nourish will receive nutrition information via the Pattern Health API on different nutrients. The data will be automatically analyzed daily according to algorithms we embed. Study staff use a password-protected database to view all identifying, demographic and nutritional information for each participant. We will use Twilio to send text messages from Pattern Health to participants. We will use Heroku to

process data analysis for the Prompt engine. These are companies outside of Duke that will have access to your personal information, including name, phone number, and any data you enter as part of your dietary tracking or text messages you send and/or receive as part of this study.

For the purposes of this study, you will be assigned a study ID that will be used on all study forms. All study forms that contain participant information will be kept in secured and encrypted databases. In addition, such materials, when in use, will be kept away from public scrutiny. Materials that need to be discarded will be destroyed.

Access to all participant data and information will be restricted to authorized personnel. In the case of computerized study data, access to data will be password protected and staff members will be assigned individualized passwords that allow them access to only those elements of the data management system to which they are authorized. In addition, all study personnel will maintain certification with the Duke IRB that they have completed training in research ethics, which includes training on confidentiality. You will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.

There may be risks or discomforts that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. Using a smartphone app to keep track of your dietary intake every day may result in improved blood pressure and lower cardiovascular risk. If you are in the group receiving extra feedback and support, that information may similarly help you improve your diet and overall health. We hope that in the future the information learned from this study will benefit other people with similar conditions.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

Instead of being in this study, you have the following alternatives: commercial digital programs, for example Livongo, Omada Health, and the NHLBI website that includes information about the DASH dietary pattern and high blood pressure. Please talk to your doctor about these and any other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may

be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related data, and procedures may be reported to the National Institute of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board and others, as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

One of the questionnaires we include in this study is the PHQ-which measures depressive symptoms. If your score is high on this measure, we will suggest that you follow-up with your primary care physician or a mental health specialist.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of Duke University, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at Duke University. Any research information in your medical record, if applicable, will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in scientific journals, your name or other identifying information will not be revealed.

WHAT ARE THE COSTS TO YOU?
The study sponsor National Institute of Health has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to a total of $160 in Amazon electronic gift cards for the time you spend filling out online surveys and participating in online videoconferencing research visits. This includes: $40 through the baseline visit; $20 for each of the 2-, and 4-month follow-up visits; and $40 for each of the 6- and 12-month follow-up visits.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study, please contact Miriam Berger, the study project director, at 919- 613-8398 or nourish@duke.edu. For a research-related injury, contact Dr. Gary Bennett at 919- 617-1020 during regular business hours and at gary.bennett@duke.edu after-hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, please contact the principal investigator in writing and let him know that you are withdrawing from the study. The mailing address is:

Nourish Study, Duke University, 417 Chapel Drive, Room 048, Durham, NC 27708. You can email nourish@duke.edu.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include adverse events affecting your cardiovascular health. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Gary Bennett at 919-617-1020 during regular business hours and at gary.bennett@duke.edu after-hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668- 5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ REDCap E-signature and Date

STATISTICAL ANALYSIS PLAN

Power and Sample Size[1]

We hypothesize that the intervention will lead to an increase in average DASH score of 2 units at 6 months and the control arm will achieve a 1-unit increase in DASH score. These estimates are based on the pilot study we conducted where both intervention and control arms achieved a 1-unit increase in DASH adherence from baseline to 3 months. Given the Nourish intervention is more intensive than what was delivered in the pilot, we anticipate a greater increase in DASH adherence. We estimate a standard deviation of 2 units for both intervention and control arms. This results in an effect size of 0.5, which is considered a medium effect size by Cohen's d. With 90% power and a type I error rate (alpha) of .01, a sample size of 242 will allow us to detect a difference of 1 unit in DASH adherence mean change score between study arms. We conservatively assume 20% attrition for this length of follow-up, resulting in the final analytic sample size of 300 total participants. With this sample size, we will also have power to examine intervention effects in systolic and diastolic blood pressure. Using data from the pilot study we anticipate systolic blood pressure changes in intervention vs control as follows: −3.4 (SD=8.6) mmHg and −2 (SD=9.3) mmHg respectively, which results in an effect size of 0.6. The effect size for diastolic blood pressure is 0.75 based on changes in intervention vs control of −3.8 (SD=7.9) mmHg vs. −1.6 (SD=6.4) mmHg, respectively. With 90% power and a type I error rate (alpha) of .01, we can detect the expected effect size with the proposed sample size of 300.

Statistical analysis plan

Demographic and baseline data will be examined for integrity of randomization scheme and the homogeneity of study arms. If any demographic and baseline data are not balanced between the two study arms and are believed to affect the outcome, we will consider adjusting these variables in the modeling process. All analyses will be based on intention-to-treat (ITT) principles.

We will assess the overall intervention effect on change of DASH score from baseline to 6 months by a two-sample t-test. To understand how DASH score improves over time from baseline to 6 months, and sustains through 12-month follow-up between study arms, we will plot observed DASH score vs. time (baseline, 2-month, 4- month, 6-month, 12-month) by two study arms. Linear mixed models will be built to test the primary hypotheses. If we observe a linear trend in the previous plot, our model will contain fixed effects including a group variable (intervention vs. control), time, and intervention by time interaction. To account for the correlations within the same participant over time, we will include a random intercept and random slope for time in the model. If there is a quadratic trend in time, we will also include a quadratic term for time in the model. To account for the stratified block randomization design, our models will also include our randomization stratification variables, blood pressure risk category and blood pressure medication status. If any other demographic or baseline variables are statistically different between the two study arms, then these variables will be included in a stepwise model selection process for the linear mixed model. We will evaluate the primary hypotheses by testing the null hypothesis that the time by intervention parameter is 0. Similar analysis will be conducted for changes in blood pressure and relevant clinical, behavioral and psychosocial variables. If the distribution of any of the outcomes is heavily skewed, then we will either appropriately transform the data so it's normally distributed or use a generalized linear mixed model with an appropriate link function.

Our linear mixed models will be fitted with a full maximum likelihood estimation using all available data to address missing data. These models allow for responses to be missing at random (MAR), where the missing mechanism may be related to either observed covariates or response variables, but not related to the unobserved data. Linear mixed models provide valid estimates of the intervention effect under the MAR mechanism and allow for a broad array of possible reasons for missingness.

[1] Miller HN, Berger MB, Askew S, et al. The Nourish Protocol: A digital health randomized controlled trial to promote the DASH eating pattern among adults with hypertension. *Contemp Clin Trials*. 2021;109:106539. doi:10.1016/j.cct.2021.106539