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Rationale and study design of the MyHEART study: A young adult hypertension self-management randomized controlled trial

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ABSTRACT

Young adults (18–39 year-olds) with hypertension have a higher lifetime risk for cardiovascular disease. However, less than 50% of young adults achieve hypertension control in the United States. Hypertension self-management programs are recommended to improve control, but have been targeted to middle-aged and older populations. Young adults need hypertension self-management programs (*i.e.*, home blood pressure monitoring and lifestyle modifications) tailored to their unique needs to lower blood pressure and reduce the risks and medication burden they may face over a lifetime. To address the unmet need in hypertensive care for young adults, we developed MyHEART (My Hypertension Education And Reaching Target), a multi-component, theoretically-based intervention designed to achieve self-management among young adults with uncontrolled hypertension. MyHEART is a patient-centered program, based upon the Self-Determination Theory, that uses evidence-based health behavior approaches to lower blood pressure. Therefore, the objective of this study is to evaluate MyHEART's impact on changes in systolic and diastolic blood pressure compared to usual care after 6 and 12 months in 310 geographically and racially/ethnically diverse young adults with uncontrolled hypertension. Secondary outcomes include MyHEART's impact on behavioral outcomes at 6 and 12 months, compared to usual clinical care (increased physical activity, decreased sodium intake) and to examine whether MyHEART's effects on self-management behavior are mediated through variables of perceived competence, autonomy, motivation, and activation (mediation outcomes). MyHEART is one of the first multicenter, randomized controlled hypertension trials tailored to young adults with primary care. The design and methodology will maximize the generalizability of this study.
Trial registration: ClinicalTrials.gov Identifier: NCT03158051

Abbreviations: SDT, self-determination theory; EHR, electronic health record; WCHQ, Wisconsin Collaborative for Healthcare Quality; HEDIS, Healthcare Effectiveness Data and Information Set; AMBP, ambulatory blood pressure; PA, physician assistant; NP, nurse practitioner; REDCap, Research Electronic Data Capture; BECCI, Behavior Change Counseling Index; CARDIA, Coronary Artery Risk Development in Young Adults; ACG, Adjusted Clinical Group; AMA, American Medical Association; REALM-R, Rapid Estimate of Adult Literacy in Medicine-Revised; ASA24, Automated Self-Administered 24-hour Dietary Assessment Tool; DASH, Dietary Approaches to Stop Hypertension

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1. Introduction

Uncontrolled hypertension in young adults is an enormous public health burden in the United States [1–3]. Over 10 million 18–39 year-olds (1 in 5 men; 1 in 6 women) have hypertension [4–6], increasing their risk of premature heart failure, stroke, and chronic kidney disease [7,8]. Hypertension control reduces morbidity, mortality, and future healthcare costs [9–13]; yet, less than 50% of young adults with hypertension in the U.S. have achieved blood pressure control, even with the former blood pressure guidelines (< 140/90 mmHg) [4,14–17].

While hypertension self-management programs targeted towards adults ≥50 years old reduce blood pressure [18–36], they primarily focus on medication titration [37]. In contrast, lifestyle modifications are commonly the initial hypertension treatment step, rather than a medication, among young adults [4,38]. Therefore, young adults need tailored hypertension self-management (home blood pressure monitoring and lifestyle modifications) to lower blood pressures and reduce the amount of medication they may need over a lifetime [39–42]. In contrast to older adults, young adulthood is a time of frequent healthcare and vocational transitions, new life responsibilities, and less interest in health-related goals (*i.e.*, prevention of heart attack and stroke) [43,44]. Thus, the content and method of delivery of hypertension self-management must be individualized to young adults and address barriers specific to this population [45–47].

To address the unmet need in hypertensive care for young adults, we developed MyHEART (My Hypertension Education And Reaching Target), a multi-component, theoretically-based intervention designed to achieve self-management among young adults with uncontrolled hypertension [48]. MyHEART is a patient-centered program that uses evidence-based health behavior approaches to lower blood pressure. MyHEART was developed by young adults and other stakeholders [44,49], and differs from previous interventions by: 1) targeting barriers identified by young adults in our preliminary research, 2) tailoring the mode of delivery to preferences expressed by members of this age group, and 3) individualizing action plans to participants' motivations and behavior goals. MyHEART is founded on the self-determination theory (SDT) [50], which is used to support chronic disease self-management and lifestyle modifications. SDT acknowledges that young adults are more likely to adopt and maintain health behaviors with: 1) autonomous (internal) motivation, instead of external motivation (*i.e.*, external pressure), 2) relatedness (*i.e.*, supportive healthcare interactions), and 3) perceived self-competence (*i.e.*, perceived self-efficacy [51,52]; confidence in starting and maintaining behaviors to reach a goal) [50,53–59]. We successfully conducted a 3-month pilot study of MyHEART to establish feasibility and participant satisfaction [48], which informed the design of this multisite randomized controlled trial.

Therefore, the overall objective of this study is to evaluate MyHEART's impact on blood pressure among 310 geographically and racially/ethnically diverse young adults within two large, Midwestern healthcare systems. Our co-primary outcomes are changes in systolic and diastolic blood pressure after 6 and 12 months in young adults (18–39 year-olds) with uncontrolled hypertension. In this article, we report on the study design, procedures, and development of the *MyHEART* intervention protocol.

2. Study design

2.1. Overview of study design

MyHEART is a randomized, controlled clinical trial, across two large, Midwestern healthcare systems: UW Health (Madison, WI; 25 academic and rural clinics) and Aurora Health Care (Milwaukee, WI; 31 urban community clinics). The primary objective is to evaluate the MyHEART intervention (hypertension self-management) compared to usual care on changes in systolic and diastolic blood pressure from baseline to 6 and 12 months in young adults (18–39 year-olds) with uncontrolled hypertension. The sites differ in patient demographics, races/ethnicities, and payor mix, supporting generalizability of the results. The study schema is presented in Fig. 1. Prior to initiating the protocol, all study sites received institutional review board (IRB) approval from the University of Wisconsin-Madison Health Sciences IRB and the Wisconsin IRB Consortium.

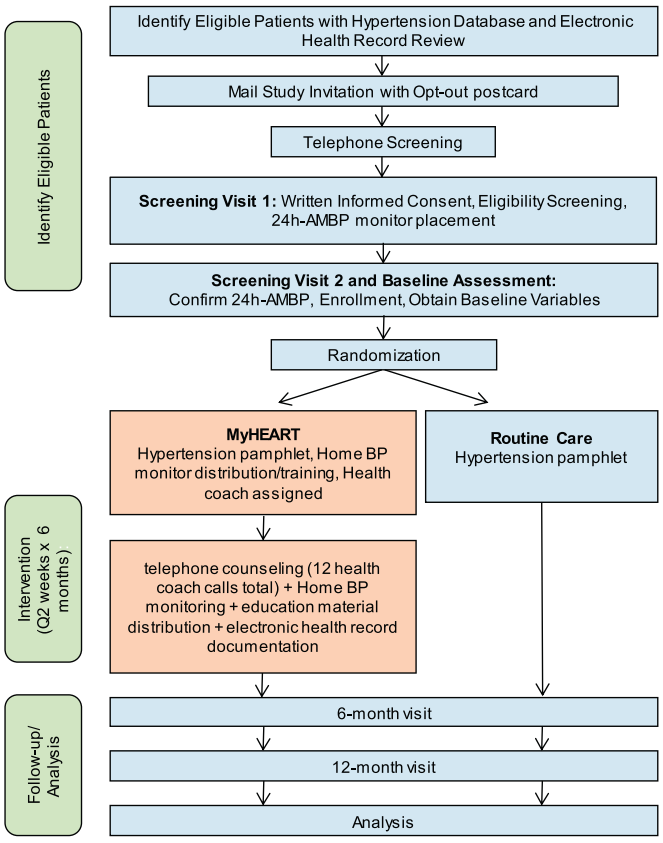

Fig. 1. Eligibility, enrollment, randomization, follow-up, and analysis.

2.2. Inclusion and exclusion criteria

Each healthcare system has an electronic health record (EHR) with a Wisconsin Collaborative for Healthcare Quality (WCHQ) hypertension registry that will be used to screen and identify potentially eligible patients [60]. Founded in 2003, WCHQ is a voluntary consortium of 37 Wisconsin healthcare organizations (physician groups, hospitals, health plans) that has led the nation in measuring and reporting healthcare quality. The WCHQ definition created for public reporting is based on the Healthcare Effectiveness Data and Information Set (HEDIS) metrics [60–62]. The research sites have reported metrics for complicated and uncomplicated hypertension to WCHQ since 2005.

The inclusion and exclusion criteria are summarized in Table 1. Potentially eligible patients in the EHR hypertension registry must: 1) be 18–39 years old at the start of the study, 2) have a minimum of two hypertension ICD-10 coded office visits with any provider (physician [MD or DO, including resident physician], physician assistant [PA], or nurse practitioner [NP]) on different dates in the last 24 months prior to eligibility assessment, with at least one code in the past 18 months, and 3) be medically homed (*i.e.*, receiving routine primary care within the healthcare system) within their specific healthcare site [63]. The last two clinic blood pressures will determine eligibility for a study invitation; the blood pressures must include a systolic ≥140 mmHg and/or diastolic ≥90 mmHg [9], and the last blood pressure must be within the last 90 days. If multiple blood pressures were recorded on the same day of service, the average of the last two blood pressures on that date

Table 1
Study eligibility criteria.

Inclusion criteria
1. Willing and capable of giving written informed consent
2. Willing to comply with all study procedures and be available for the duration of the study
3. Males and females ages 18–39 years old at the start of the study (inclusive)
4. A minimum of two hypertension ICD-10 coded visits with a provider (MD, DO, PA, NP) on different dates in the last 24 months, with at least one code in the past 18 months
5. Medically homed at UW Health or Aurora Health Care

Exclusion criteria
1. History of medically determined Congestive Heart Failure
2. Unable to provide informed consent (*i.e.,* activated healthcare power of attorney)
3. Unable or unwilling to travel to local clinic for research visits
4. Currently residing in a skilled nursing facility
5. Diagnosed with sickle cell anemia or cystic fibrosis
6. Diagnosed with stroke, myocardial infarction, and/or coronary artery revascularization in the past 2 years
7. Syncope while exercising or doing strenuous activity within past 12 months
8. Currently prescribed warfarin, novel oral anticoagulant, or insulin
9. Planned organ transplant or prior transplant in the past 5 years
10. Chemotherapy or radiation therapy within 6 the past months
11. Severely impaired hearing, vision, or speech, as determined by study staff responsible for enrollment
12. Current participation or planning to participate in another clinical trial in the next 12 months
13. Pregnant or planning to become pregnant in the next 12 months
14. Planning to leave the geographic area in the next 6 months
15. Health condition that will limit both increasing physical activity and changing diet
16. Illegal drug use (other than marijuana) in the past 30 days
17. Unable to read or communicate in English
18. Currently on dialysis or seeing a Nephrologist
19. Between-arm blood pressure difference ≥20 mmHg
20. White Coat Hypertension (24-hour ambulatory monitoring)
21. Inability to comply with or complete the protocol or other reasons at the discretion of the principal and site investigators
22. Currently residing in correctional facility

will be used. At the time of study design and protocol implementation, the diagnostic blood pressure threshold for hypertension was ≥140/90 mmHg [9,15], which will be continued throughout the study. After publication of the 2017 AHA/ACC Guidelines [4], there were implementation delays across some health systems; therefore, a diagnostic threshold of ≥140/90 mmHg will be maintained for consistency. Blood pressures from inpatient, emergency room, and urgent care visits and self-reported blood pressures are excluded. Patients who are currently using antihypertensive medication or have initiated lifestyle modifications are also included. Due to limitations with administrative data [64], some exclusion criteria will be assessed by manual chart abstraction and self-report. Illegal drug use will not be reported.

2.3. Participant recruitment and eligibility screening

The names and contact information of potentially eligible patients were made available to the respective study coordinators at each site. The site coordinators will mail an introductory research packet, which was designed by racially/ethnically diverse patient stakeholders, approved by primary care leaders, and used in the pilot study [48]. The introductory packet includes a flyer summarizing MyHEART and a prepaid opt-out postcard. If an opt-out response is not received 2 weeks after the mailing, research staff will call patients to assess eligibility and subsequently invite them for a face-to-face visit at the research clinic within their medically homed region. Participants who answer the phone will be asked to provide verbal consent solely for the phone screening. We will recruit a total of 310 participants over 27 months. Additional IRB-approved recruitment efforts include community flyer distribution, print advertising, clinical panel review, and social media.

Potential participants who completed the telephone screen will be invited for a screening visit (Visit 1) for additional eligibility assessment. Written informed consent for this study will be obtained at the start of this in-person visit, which will include authorization for additional screening/eligibility assessment [65]. After obtaining written informed consent, blood pressures will be measured during the visit after the patient rests for 5 minutes in the seated position. An appropriately sized [66] blood pressure cuff will be connected to an automated sphygmomanometer (Dinamap; GE). Each site will have the following cuff sizes available: small adult (for arm circumference of 17–22 cm), regular adult (22–32 cm), large adult (32–42 cm), and extra-large adult (42–50 cm). A blood pressure will be obtained on the right upper arm, then the left upper arm, for the initial assessment. Right arm blood pressures will be subsequently used for the initial and follow-up visits unless the left arm systolic blood pressure is ≥10 mmHg higher. If a participant's body habitus is not compatible with the cuff sizes, the individual will be excluded. The average of the second and third systolic and diastolic pressures will define the baseline clinic blood pressure [67]. The primary care provider will be notified if the between-arm blood pressure difference is ≥20 mmHg [68], and the participant will be excluded. All remaining eligible patients who complete clinic blood pressures will receive their clinic blood pressure in written format from Visit 1 and will then receive an ambulatory blood pressure (AMBP) monitor (SpaceLabs 90277) [69] for 24-hour blood pressure monitoring. AMBP monitoring is recommended to confirm a hypertension diagnosis (*i.e.*, exclude white coat hypertension) [4,17,70,71]. The U.S. Preventive Services Task Force noted up to 65% of patients with high office blood pressures were not diagnosed with hypertension after AMBP monitoring [71].

2.4. Participant enrollment and randomization

Patients will return the AMBP monitor the next business day (Visit 2). Patients are eligible if the mean 24-hour AMBP is a systolic ≥130 mmHg and/or diastolic ≥80 mmHg and/or the mean awake AMBP is a systolic ≥135 mmHg and/or diastolic ≥85 mmHg [71,72]. If there is white coat hypertension, the patient is ineligible and their primary care provider will be notified; the patient is also ineligible if on blood pressure medication(s) with controlled hypertension. Remaining eligible patients will be enrolled, randomized to MyHEART or usual care, and will complete the baseline assessment. The primary care provider will also be notified of all enrolled patients via the EHR; provider permission for study participation is not needed given the broad exclusion criteria, lack of device/medication administration, and ongoing follow-up assessment. All participants will receive copies of their baseline, 6-, and 12-month average clinic blood pressures to share with their provider [31].

Randomization assignments will be generated by the University of Wisconsin-Madison Biostatistics Data Coordinating Center using permuted block in random block sizes, stratified by health system to ensure equal allocation. Study data will be collected and managed using the REDCap system hosted at the University of Wisconsin-Madison [73,74]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry, 2) audit trails for tracking data manipulation and export procedures, 3) automated export procedures for seamless data downloads to common statistical packages, and 4) procedures for importing data from external sources. The REDCap system will be used to verify eligibility prior to randomization.

To reduce bias, MyHEART assessors will be blinded to treatment assignments [75,76]. Assessors will be trained to treat patients in both study groups identically per protocol [77]. Ambulatory monitoring will be the gold standard for blood pressure measurements. Primary care providers cannot be blinded since health coaches will document in the participants' EHRs.

Usual care participants will receive hypertension clinical care per their primary care provider. This includes the possibility of receiving

untailored self-management resources (*i.e.,* dietician referral) at their provider's discretion, but this is not systematically tailored to young adults' needs. We will assess the number of healthcare team contacts in the usual care arm based on the number of primary care and specialty visits and dietician and exercise referrals after study enrollment [38,43]. Usual care participants will receive a handout providing an overview of high blood pressure based upon the American Heart Association [77,78]. It is usual care for patients to receive hypertension educational material when presenting for a hypertension visit. They will not receive home blood pressure monitors. Usual care participants will have the same 6- and 12-month assessments as the intervention arm.

3. The MyHEART intervention

3.1. MyHEART theoretical framework

The conceptual model of MyHEART (Fig. 1) is founded on the self-determination theory (SDT), which has been used in behavioral interventions across races/ethnicities and with young adults [79,80]. To reduce the risk of negative sequelae from long-term hypertension, the goal is to not only initiate behaviors for blood pressure control, but also foster maintenance of new behaviors. Therefore, MyHEART incorporates important hypertension education components implemented by a health coach (Fig. 2): 1) telephone-based self-management counseling, 2) home blood pressure monitoring, and 3) young adult-focused hypertension education. These components are recommended by the Institute of Medicine [81] and the American Heart Association [1]. Health coaching provides informational and emotional support for chronic disease management [82–84]. Telephone interventions increase contacts between patients and their healthcare teams [85–88]. MyHEART uses telephone as the primary mode of communication between participants and coaches because young adult community stakeholders indicated a preference for this mode of delivery compared to text messaging [44]. Young adults felt that it was easier to control the location and time of day they received health coaching by phone, in contrast to text messaging [44]. MyHEART will not initiate or titrate blood pressure medication. Participants randomized to the MyHEART intervention will continue to receive hypertension care from their primary care provider, including medication initiation and adjustments as clinically indicated. Intervention participants will receive the same hypertension overview [77] handout as the usual care participants.

3.2. MyHEART health coach

There will be four health coaches (two for each site) for telephone-based self-management counseling. MyHEART health coach certification options include an exercise physiologist (American College of Sports Medicine certification) with outpatient cardiovascular rehabilitation experience, or a cardiovascular registered nurse with at least 3 years of clinical experience including chronic disease management and adult education/counseling. The health coach will perform telephone counseling every 2 weeks over 6 months (12 calls total).

Based upon the self-determination theory, the interpersonal interaction between the coach and participant in MyHEART promotes relatedness and humanistic principles consistent with motivational interviewing [89]. The coaches' goal over the 6 months of calls is to help participants establish self-management skills and maintain behaviors after MyHEART, *i.e.*, sustainability of MyHEART. The content of coach-participant interactions will focus on: 1) highlighting discrepancies between participants' current health behaviors and their desired behavior goals to promote internal motivation, 2) sharing reference points for guideline-recommended behaviors to lower blood pressure, and 3) discussing short-term goals and developing congruent action plans [90]. Coaches will promote autonomy by individualizing the order and depth of educational content based on the behavioral goals chosen by the participant [91–94]. Participants will have practical skill-building (*e.g.*, label reading [95]) and coaches will encourage patients to set goals that are motivating but not overwhelming.

3.3. MyHEART hypertension education modules

There are ten hypertension self-management modules (Table 2) for MyHEART that are based on our young adult focus groups [44], pilot study [48], previous interventions [21,93,96,97], and hypertension guidelines [4,9,17]. All intervention participants will start with the home blood pressure monitoring module during the initial health coach session. The first follow-up phone call will address hypertension knowledge and review home blood pressure monitoring. Home blood pressure monitoring education will also be provided during all follow-up phone calls. The order of the remaining modules will be guided by participant's choice and tailored to their goals [98,99]. Fewer modules than calls allows some topics to be repeated as needed and per the participants' requests. Current tobacco users will be referred to the Wisconsin Tobacco Quit Line (http://www.ctri.wisc.edu/quitline.html) when ready to attempt cessation and their primary care provider will be notified of their intention to quit via the EHR. The primary care provider will also be notified if the participant consumes > 14 alcohol beverages/week for referral and follow-up [85]. The MyHEART team created handouts to include specific topics requested by our young adult focus groups [44]; additional handouts are from national organizations (*e.g.*, NIH, American Heart Association, etc.). The MyHEART handouts were formatted with a Flesch-Kincaid readability of ≤6th grade [100]; the MyHEART modules and handouts were tailored to address cultural differences [101] given the higher prevalence of hypertension in Black young adults [102,103].

Following each health coach call, hypertension education handouts and personalized goal sheets with stepwise action plans will be available via email [108] and/or postal mail according to the participant's preference [22]. Distribution of written educational materials is effective in multi-component interventions by reinforcing verbal discussions and supporting learning style differences [109]. Telephone encounters between the health coach and participants will be documented by the coach using our piloted EHR template. This is accessible by primary care providers and the patient's care team [110] to review home blood pressures and lifestyle modifications which may reinforce participation.

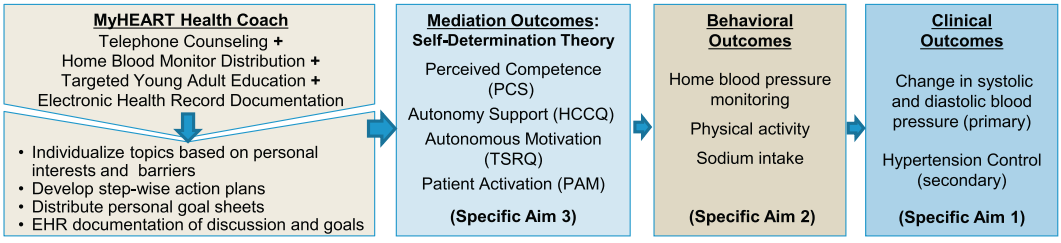

Fig. 2. MyHEART conceptual model

Table 2
MyHEART educational modules.

Module	Topics
Home blood pressure monitoring	How to measure blood pressure, **include members in household to avoid isolation**
Hypertension knowledge	Define blood pressure, goal blood pressure, **long-term health consequences**
Low sodium	Reading labels, effects of sodium on blood pressure, culturally appropriate cooking alternatives, **eating with peers**, meal planning, shopping on a budget
Dietary approaches to stop hypertension (DASH) eating plan	DASH components, meal planning, **grocery shopping on a budget, DASH with peers;** Cultural and personal food preferences; Discuss cultural meaning of dietary practices
Weight loss/maintenance	Relationship of weight with hypertension, dietary and activity options to lose weight, time management, **social support to assist with weight loss, fitness apps**
Smoking cessation[a]	Negative effects of tobacco on heart health, **social/peer influence**
Moderate alcohol consumption	**Binge drinking**[b], negative effects on heart health; define quantity for types of alcohol [104]
Blood pressure medicine	Why medications may be needed, side effects, **adherence, possible lifelong commitment,** remembering medication, cost
Social support	Local resources for support, **reducing clinic no-shows, peer/social support** [105]
Stress management [106]	Identifying ways to reduce stress, **stress with life's transitions and new challenges**

Bold = young adult focused topics.
[a] Only for active tobacco users.
[b] Only for participants identified as having alcohol consumption beyond AHA guidelines [107].

3.4. MyHEART home blood pressure monitoring

Intervention participants will be provided an Omron BP760N home blood pressure monitor with an appropriate cuff size [111,112]; it has been validated in young adults and across BMI categories [113]. Participants will receive training and practice on proper cuff placement and monitor use [24]. They will be asked to take their blood pressure at least three days a week, 2 measurements each time [19,24]. To decrease missing data, participants will be able to read the recorded blood pressures to their health coach during phone calls [114] for entry into their EHR. Although all clinics have an EHR, automatic upload of home blood pressures into the EHR is not an active functionality with either healthcare system. Health coaches will review and discuss blood pressures during each telephone call. MyHEART coaches will also encourage clinic follow-up [115] based on the 2-week average home blood pressure. Participants will keep the blood pressure monitor after study completion. Malfunctioned monitors will be replaced during the study.

4. MyHEART health coach training

Health coaches will receive training that builds on their prior education in motivational interviewing [89] and hypertension management, using self-determination theory concepts. Training intensity is based on prior studies [116] and resources from our pilot [48]. Trainers will observe health coaches with role playing and score adherence according to an *a priori* skills checklist, followed by problem solving and debriefing [117–119]. All health coaches will train together via in-person (8-hour session) and web-based (1-hour) sessions [120]. There will be two health coach trainers; the same trainers will be at all sessions to avoid degradation of instructional information, bias, and to accommodate trainee differences [117]. As with our pilot, required credentials of the lead health coach trainer include a doctorate-level degree in areas of behavior theory and motivational interviewing, with at least 3 years of clinical experience.

5. Study fidelity

To ensure fidelity and reproducibility, research staff fidelity of data acquisition will be assessed by audits of clinic and ambulatory blood pressure techniques and review of REDCap data entry. Health coach fidelity will be evaluated using digital audio-recordings [121] of the coaches' communications and review of their study documentation. Our health coach fidelity evaluation will include assessment of intervention delivery (content and dose), adherence to protocol, and the use of MyHEART's coaching manual [122,123]. Randomly, 10% of each type of call (*i.e.*, baseline, follow-up, final) will be selected for assessment. Coaches will be evaluated using a modified Behavior Change Counseling Index (BECCI) to assess "how" the coach related to participants [124], a critical component of MyHEART. Questions were added from the Motivational Interviewing Treatment Integrity Measure 3.0 to include variables known to correlate with behavior change (*i.e.*, goal setting, monitoring) [125,126]. Fidelity will be assessed by doctorate-level nursing students. Fidelity assessment training will include one month of weekly meetings, with additional review of materials between meetings and practice with coding existing audio-visual files. Health coaches and research staff will receive monthly feedback to maintain or improve fidelity and minimize drift from protocol adherence [117–119,124,127–130].

6. Study outcomes

6.1. Specific aims and hypotheses

The overall objective of this study is to evaluate MyHEART's impact on blood pressure among 310 geographically and racially/ethnically diverse young adults. The co-primary outcomes are changes in systolic and diastolic blood pressure after 6 and 12 months in young adults (18–39 year-olds) with uncontrolled hypertension. The specific study aims are as follows:

6.1.1. Specific Aim 1

To evaluate the effect of MyHEART (home blood pressure monitor distribution and heath coaching) on clinical outcomes, the change in systolic and diastolic blood pressure (primary) and hypertension control (secondary) after 6 and 12 months, compared to usual clinical care. We hypothesize that MyHEART will significantly decrease systolic and diastolic blood pressures (clinic and 24-hour ambulatory) and increase hypertension control in young adults, compared to usual clinical care.

6.1.2. Specific Aim 2

To evaluate the effect of MyHEART on hypertension self-management behavior (behavioral outcomes) at 6 and 12 months, compared to usual clinical care. We hypothesize that MyHEART will increase the frequency of home blood pressure monitoring and lifestyle modifications (increased physical activity, decreased sodium intake).

6.1.3. Specific Aim 3

To examine whether MyHEART's effects on self-management behavior are mediated through variables of perceived competence,

autonomy, motivation, and activation (mediation outcomes). Based on our pilot study and theoretical framework, we hypothesize that MyHEART's effects will be mediated through perceived competence, autonomy, motivation, and activation.

6.2. Primary outcome (Aim 1) assessment

The co-primary clinical outcomes (Table 3) are a change in systolic and diastolic blood pressure at 6 and 12 months [9,24]. The secondary clinical outcome is hypertension control at 6 and 12 months. Hypertension control will be defined using 24-hour ambulatory blood pressures as the gold standard (< 130/80 mmHg), otherwise a clinic blood pressure of < 140/90 mmHg. To reflect the 2017 ACC/AHA Hypertension Guidelines publication [4], we will include a secondary clinic blood pressure outcome of < 130/80 mmHg. Follow-up clinic blood pressures will be measured per the screening visit protocol. The 6-month outcome assesses the end of the 6-month MyHEART intervention [31]. This follows guideline recommendations [4,17], and adherence to lifestyle interventions usually peaks at 6 months [31]. The 12-month outcome (*i.e.*, 6 months post-intervention) [131] assesses maintenance of blood pressure and sustainability of behavior change after study completion. In contrast to the baseline assessment, follow-up questionnaires and physiologic measurements will be conducted during Visit 1 to decrease missing data.

6.3. Primary outcome (Aim 1) power estimates

A total of 310 eligible young adults will be enrolled into the study (155 participants per randomized arm) to result in an effective sample size of 264 under the assumption of 15% random drop-out at 6 months following randomization [136]. In Nidich *et al.* [137], the 3-month transcendental meditation program showed a mean difference of 6.3 and 4.0 in systolic and diastolic blood pressure change with a standard deviation of 13.6 and 9.7, respectively, as compared to usual care among young adults at hypertension risk. With an effective sample size of 264, there is power of 0.94 and 0.87 for systolic and diastolic blood pressure, respectively, for the same differences, each at a two-tailed 0.025 test for an overall significance level of 0.05.

6.4. Primary and secondary outcome (Aim 1) statistical analysis plan

Data will be analyzed by intent to treat. Missing data will be imputed using multiple imputations along with sensitivity analyses for missingness according to the recommendations given in the National Research Council report [138,139]. The primary comparisons for the co-primary outcomes of systolic and diastolic blood pressure change from baseline to 6 months will be done using analysis of covariance with MyHEART and baseline blood pressure as independent covariates. The primary comparisons for the secondary outcome of hypertension control at 6 months will be based on Fisher's exact tests. If differences exist, they are likely to be largest at 6 months. Sequential hypothesis testing will be performed for hypertension control if blood pressure changes are shown to be statistically significantly different. Likewise, sequential hypothesis testing will be performed comparing the 6-month blood pressure change and hypertension control and only comparing 12-month success rates if the 6-month blood pressure change and hypertension control rates are shown to be statistically significantly different, using an alpha re-use approach [140]. The 12-month analysis will focus on *maintenance* of behavior change, to assess whether significant differences seen between baseline and 6 months are sustained. This will be achieved through a test for no difference between the baseline to 6-month change and the baseline to 12-month change [141]. Linear (for blood pressure) and generalized linear (for hypertension control) mixed-effects regression models will be fit to better understand the effects of MyHEART over time using longitudinal measurements. We will also assess the differential effectiveness of the intervention across subgroups (gender, race/ethnicity), which will guide future interventions, by developing exploratory regression models with interactions between MyHEART and baseline subject characteristics.

7. Explanatory variable assessment

Baseline explanatory variables, including demographic, clinical, and psychosocial variables, will be obtained for intervention and usual care participants (Table 4). The biological variables were selected based on our young adult studies [38,43,142,143] and previously identified barriers and predictors of hypertension control and self-management [144–147]. For body mass index (kg/m^2), weight will be measured to the nearest 0.1 kg in light clothing without shoes; height will be measured to the nearest 0.1 cm using a single, wall-mounted stadiometer [136,148]. All scales will be calibrated quarterly by trained study personnel using standard weights. The selected questionnaires have been validated in young adults and across races/ethnicities [149,150]. Alcohol consumption will be evaluated by alcohol beverage type and quantity as performed in the CARDIA (Coronary Artery Risk Development in Young Adults) study [151].

Participants will report their financial situation by selecting whether they: a) had enough money after paying bills for extra things (*e.g.*, dining out), b) enough to pay bills but not to purchase extra things, c)

Table 3
Baseline assessment, 6-month, and 12-month outcomes for all participants (intervention & usual care).

Time commitment = combined total across Visits 1 and 2	Baseline assessment (2½ hours)		6-month[a] outcomes (1½ hours)		12-month[a] outcomes (1½ hours)	
	Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2
Aim 1. Clinical Outcomes: Change in Systolic and Diastolic Blood Pressure (primary); Hypertension Control (secondary)						
Study visit blood pressure	x		x		x	
24-hour Ambulatory Blood Pressure (gold standard)		x		x		x
Aim 2. Behavior Outcomes						
24-hour dietary recall [132] (in-person and phone administration)		x	x		x	
7-Day Physical Activity Recall[b]		x	x		x	
Home Blood Pressure Monitoring Frequency[b] [133]		x	x		x	
Weight (kilograms, kg) and Body mass index (kg/m^2) [134]		x	x		x	
Aim 3. Mediation Outcomes						
Perceived Competence Scales[b] (PCS)		x	x		x	
Health-Care Climate Questionnaire[b] (HCCQ)		x	x		x	
Treatment Self-Regulation Questionnaires[b] (TSRQ)		x	x		x	
Patient Activation Measure[b] (PAM) [135]		x	x		x	

Visits 1, 2 are consecutive days.
[a] 6- and 12-month visits are within 1 week after last phone call.
[b] Completed in-person at visit.

Table 4
Baseline biological & explanatory variables.

	Data source
Age, Gender	EHR
Race/ethnicity, Marital Status, number of children in home	Self-report
Body mass index (kg/m^2) [152,153]; Waist circumference (cm)	Screening Visit 1
Alcohol consumption [151]	Self-report
Highest level of education attained [154]	Self-report
Tobacco status [155] (current, former, never); cigarette packs/day [156]; e-cigarette use (yes/no)	Self-report
Employment (full-time, part-time, other)	Self-report
Financial Status [20]; Annual household income [152]	Self-report
Self-rated health status [157–159]	Self-report
Health literacy [21,160,161]	Self-report
Comorbidities: dyslipidemia [162], anxiety [163–165], depression [166], diabetes mellitus [167], chronic kidney disease [168]	EHR [34]
Medical Outcomes Study Social Support Survey [169]	Self-report
John Hopkins Adjusted Clinical Group (ACG) Risk Score [170]	EHR
Primary care, specialty and urgent care visits over past 12 months prior to enrollment	EHR
Medication Adherence (Morisky) [171]	Self-report
Blood pressure medication classes (0,1,2,3, ≥4) and dose	EHR [34]
All other medication classes (i.e., oral contraceptives)	EHR

EHR, electronic health record; AMA, American Medical Association.

enough money to pay bills by cutting back on things, or d) difficulty paying bills no matter what was done. The first two answer choices are categorized as “adequate income” and the last two choices as “inadequate income” [20]. This financial assessment accounts for varying income, which is more reflective of young adulthood. Single-item assessments of self-rated health status have a strong association with health outcomes and provide a broad assessment of health [157–159]. Self-rated health will be measured using the question: "In general, would you say your health is Excellent, Very Good, Good, Fair, or Poor?", which has been used in nationally representative samples [157–159]. Health literacy (*i.e.*, the ability to obtain, process, and understand basic information to make appropriate health decisions [172,173]) will be evaluated using the Rapid Estimate of Adult Literacy in Medicine-Revised (REALM-R) instrument [160,161]. Baseline comorbidities will be assessed using established administrative data algorithms per our previous research [38,43,142,143]. The Medical Outcomes Study Social Support Survey [169] is a brief multi-dimensional evaluation validated for patients with chronic illnesses [159,169,174,175]. Healthcare utilization will be evaluated using the Johns Hopkins Adjusted Clinical Group Case-Mix System (version 10.0), which assesses morbidity burden based on patient age, gender, and patterns of disease [38,43,142,170]; we will also measure the number of clinic visits. To account for varying hypertension treatment at baseline, we will adjust for number of antihypertensive medication classes. In addition to using the EHR, participants will be asked to report all prescription and non-prescription medications. Global medication adherence will be assessed using the 4-item Morisky Scale [171,176]. Provider characteristics will be obtained from the EHR, human resources, and the American Medical Association Masterfile data [38,43].

8. Secondary outcome (Aim 2: Self-management behavior) assessment

Dietary intake data for 24-hour recalls will be collected and analyzed using the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool, version (2016), developed by the National Cancer Institute, Bethesda, MD [177]. We will use the 7-Day Physical Activity Recall [178–183] to assess baseline and change in physical activity. Accelerometers will not be used due to compliance limitations in young adult populations [148]. Frequency of home blood pressure monitoring (defined as taking your own blood pressure or having someone check your blood pressure outside of your usual primary care clinic) will be assessed by a single response: at least once a day, once or twice a week, once a month, or less than once a month [133]. The accuracy and reliability of the intervention arm’s self-responses will be evaluated by comparing automatically stored home blood pressure monitor readings with self-report entries to analyze deletion (under-reporting), addition (over-reporting), and reporting precision [184]. The accuracy and reliability of the intervention arm will be applied to the usual care arm. Physiologic secondary endpoints (weight [kg] and body mass index [kg/m^2]) will also be assessed.

8.1. Secondary outcome (Aim 2: Self-management behavior) statistical analysis plan

Behavioral outcomes will be analyzed in a similar manner as with the clinical outcomes depending on whether they are continuous or categorical. Unlike the clinical outcomes, there is no reason to control for multiplicity of testing, and so no adjustment will be made, and any p-values < 0.05 will be noted. For Aim 2, there are three continuous variables: dietary recall (focused on grams of sodium/day and number of fruit & vegetable servings/day per the DASH-sodium diet [185,186]), 7-day physical activity recall, and one count variable (home blood pressure monitoring frequency). Missing data will be handled in a similar manner as with clinical outcomes above. Thus, the effective sample size of 264 subjects will provide 90% power to detect a difference in the mean change from baseline to 6 months between treatment groups of about 0.4 times the standard deviation of the differences (moderate effect size). Analyses (t-tests or Wilcoxon tests and ANCOVA for continuous variables; Fisher’s exact test for the categorical variable) will be performed for comparison of change from baseline to 6 months between treatment groups. Linear or generalized linear mixed-effects regression models will be fit to describe longitudinal behavioral measurements over time.

9. Secondary outcome (Aim 3: Mediation analysis) assessment

To complement the primary findings, we will explore how treatment effects occur. Mediators are the constructs that the intervention (MyHEART) works through to affect behavior change [187]. Results from this Aim will examine the intervention components that provide the greatest support for sustainable behavior change.

The Perceived Competence Scale will evaluate participants’ beliefs of their abilities to change behavior [118,188]. Participants’ perceptions of their healthcare team’s autonomy support will be measured using the modified Health Care Climate Questionnaire [118]. The Treatment Self-Regulation Questionnaire will assess autonomous motivation (self-determined), external motivation, and amotivation. Based on SDT, we expect an increase in autonomous motivation and a decrease in external motivation [189]. The Patient Activation Measure [190–194] will assess participants’ knowledge, skill, and confidence in managing their health [195]. All surveys are validated in young adults [118,188,189].

9.1. Secondary outcome (Aim 3: Mediation analysis) statistical analysis plan

Analyses will examine four hypothesized mediators of the MyHEART intervention: (i) autonomy support, (ii) motivation, (iii) perceived competence [196], and (iv) activation. We will estimate mediation effects in multilevel models [197–201] where mediation is assessed by fitting two models. Similar to Aim 2, Model 1 estimates MyHEART’s intervention effect on the outcome (behavior change) but also includes the mediating variable as a time-dependent covariate. Model 2 estimates MyHEART’s effect on the mediator itself over time using linear mixed-effects modeling, with the same condition by time

interactions. We will estimate a separate model for each mediation variable. Dividing the mediation effect by the overall intervention effect estimated in Aim 1 yields the percent mediated (the proportion of the intervention effect that is mediated by the mediator). Standard errors and 95% confidence intervals for the mediation effect and percent mediated estimates will be calculated using bootstrapping [202]. This analysis will be pivotal to guide future replication and dissemination of MyHEART.

10. Potential study limitations

As with any randomized controlled trial, potential problems may arise. These potential pitfalls will help guide study dissemination [203]. Our design limits our ability to analyze MyHEART's effect compared to the effect of participants solely receiving greater attention from health coaches (*i.e.*, greater number of care encounters). We believe this is reasonable, as usual care has proven ineffective for controlling hypertension in young adults. Lack of primary care provider blinding [204] could increase referrals in the usual care arm to hypertension self-management resources not targeted to young adults which may underestimate MyHEART's effect. We will adjust for this by collecting data on all ambulatory visits for the usual care and intervention arms. Recruitment of young adults is an established challenge when conducting research studies [205]. In addition to our above methods, additional recruitment steps will include partnering with primary care providers to review weekly panels, posting announcements within primary care clinics, targeting more ethnically diverse clinics, communication venues (*e.g.*, community boards, churches), and social media (*e.g.,* Facebook, Instagram) [206,207]. We will assess for attrition bias by analyzing for significant differences between usual care and intervention participants [208]. Low return of home blood pressures is a concern; however, we have provided multiple modalities to return blood pressure data. In addition, we have included incentives every three months to encourage program participation. Loss to follow-up is a concern in longitudinal studies. Young adults are a mobile population; some loss to follow-up is expected and accounted for in our sample size. We will minimize this risk with scheduled assessments, re-try calls, and participant-directed communication [209]. At enrollment, we will ask participants to provide contact information for two people who are close friends or family and would be aware of their location. We will contact all participants by telephone every 2 months to verify contact information [209]. Length of follow-up: Our study (intervention + maintenance) concludes after 12 months based on prior studies [77]; in addition, our preliminary data demonstrated changes in healthcare systems among young adults after a mean 15 months [77]. Self-report and recall bias [210] are limitations with surveys and questionnaires [211]. However, more robust assessment will likely result in greater missing data. We tried to avoid response burden; similar assessments have been conducted with this age range [212] and with comparable estimated completion times. EHR utilization is a limitation. All of the clinics in the included healthcare systems for this proposal use an EHR system. Finally, we require a diagnosis of hypertension to capture a population with known hypertension and ongoing uncontrolled blood pressures. Future studies will include young adults without a hypertension diagnosis to increase awareness.

11. Conclusion

The growing prevalence of uncontrolled hypertension among young adults is a significant public health burden in the United States. Although hypertension self-management (home blood pressure monitoring and lifestyle modifications) is recommended to lower and control blood pressure, current hypertension self-management programs do not meet the needs and barriers specific to young adults. MyHEART is the first multicomponent, theoretically-based randomized controlled trial tailored to diverse young adults with an established primary care team. This trial will provide data on the impact of MyHEART vs. usual care, and inform future dissemination and implementation initiatives in other healthcare systems.

Trial status

Enrollment into this randomized controlled trial began in October 2017 and will conclude in June 2020.

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Author contributions

H. Johnson, L. Sullivan-Vedder, K. Kim, P. McBride, M. Smith, J. LaMantia, J. Fink, M. Knutson Sinaise, L. Zeller, and D. Lauver developed the study design and methodology.

H. Johnson and J. LaMantia were involved in the primary draft of the manuscript.

H. Johnson, L. Sullivan-Vedder, K. Kim, P. McBride, M. Smith, J. LaMantia, M. Knutson Sinaise, L. Zeller, and D. Lauver were involved in substantial edits and contributions to the final manuscript.

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