Protocol and Statistical Analysis Plan

Youth-Led Intervention to Improve Blood Pressure

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INTERVENTIONAL RESEARCH PROTOCOL

(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  A Youth-Led Digital Education Intervention to Improve Blood Pressure for Hypertensive Adults Who Present to the Emergency Department

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1.0 Research Design

1.1 Purpose/Specific Aims

The proposed study will integrate user-centered design, community engagement, and implementation science, with a randomized controlled trial (RCT), to develop, test, and collect implementation data on a youth-led HTN education digital badge. The badge will act as an electronic tool to guide youth through learning and then teaching adults on how to achieve better HTN control. Adults with HTN and youth from the local community will be recruited for user-centered design sessions to provide input in the development of a youth-led HTN education digital badge. We will then recruit adult ED patients with uncontrolled HTN (BP ≥130/80 mm Hg) who have an existing relationship (such as family member) with a youth (14-24 years old) and the youth themselves for an RCT. The adult plus youth dyad will be randomized to either: 1) intervention arm- 6-week youth-led HTN education digital badge at home- or 2) control arm- 6-week youth job readiness digital badge at home. In addition to the primary study outcome of adult BP change 2-months post-intervention, we will collect secondary outcomes of HTN knowledge and youth self-efficacy, as well as implementation metrics of intervention acceptability, feasibility, and fidelity. Bringing health education to the patient's home, while simultaneously empowering youth is an innovative technology-driven model for improving BP for patients with uncontrolled HTN who may lack access to care. Outcomes of this project will result in a scalable and easily adoptable model to empower youth while simultaneously improving BP in a difficult to reach adult population.

Due to challenges recruiting youth through adults in the ED, we will be adding a cohort to the study. For this new cohort of the study, we will recruit interested youth from New Brunswick Health Sciences Technology High School (NBHSTHS). Students will be asked to pair themselves with an adult (18+) (preference for adult who has been diagnosed with hypertension, but not mandatory) with an existing relationship with the student where it would be feasible to complete an online module together 1 hour per week for 6 weeks. The adult must be fluent in English or Spanish and the student must be able to speak the fluent language of the adult. We will evaluate the youth-led digital hypertension (HTN) education intervention- an electronic tool to guide youth through learning and then teaching and supporting adults on how to control hypertension (for adults with hypertension) and how to avoid it (for adults without hypertension). Outcomes of interest are HTN knowledge, confidence in HTN management, and health behavior changes in participants, which will be obtained through pre- and post- intervention assessments. We will also be exploring outcomes of participant acceptability, feasibility, and fidelity of the intervention.

A. Objectives

Specific aims are:

Aim 1: Create a youth-led HTN education digital badge by means of user-centered design methods and community engagement with adults with HTN and youth to obtain input on the contents of the digital badge prior to implementation.

Aim 1a: The hypertension knowledge assessment being used in the study has not been used before on youth or Spanish-speaking populations, so we will obtain feedback on the assessment from these groups.

Aim 2: Evaluate the effectiveness of a youth-led HTN education digital badge intervention on the primary outcome of mean systolic BP (SBP) and diastolic BP (DBP) change in adults with uncontrolled HTN at 2-months post-intervention compared to the control group. Additionally, evaluate change in HTN knowledge and youth self-efficacy. Additionally, we will measure confidence in HTN management, and health behavior changes in participants.

Aim 3: Evaluate the implementation process of the youth-led HTN education digital badge by collecting qualitative and quantitative data on acceptability, feasibility, and fidelity of the intervention by participants.

B. Hypotheses / Research Question(s)

Research Question (Aim 1): *What are the most acceptable and easily understood ways to present HTN information to this population?*

Hypothesis 2abc (Aim 2): *(a) The mean SBP and DBP differences at 2-month post-intervention will show greater decreases for the intervention group than the control group. (b) HTN knowledge will increase from pre- to post-intervention in youth and adults in the intervention group and will not change in control group. (c) Youth self-efficacy will increase from the pre- to the post-intervention period in both the intervention and control groups.*

Hypothesis 3 (Aim 3): *The intervention will overall have high acceptability and feasibility (average scores of ≥4 on the Acceptability of Intervention Measure (AIM) and Feasibility of Intervention Measure (FIM) scales[1]) and fidelity (majority will complete entire digital badge playlist correctly).*

1.2 Research Significance

HTN is the leading risk factor for death and disability-adjusted life years.[2] In addition to being a risk factor for stroke[3] and renal dysfunction[4], HTN is also the primary risk factor for heart disease, which is the leading cause of death in the US and kills close to 650,000 people per year.[5] In the US, 33% of individuals have HTN[6] and for adults with HTN, BP control decreased from 54% in 2013-2014 to 44% in 2017-2018.[7] BP is elevated at 44% of all ED visits- compared to 27% of primary care doctor visits.[8] Data demonstrates that ED patients' elevated BP is from HTN, and not a result of pain or anxiety from the ED visit.[9,10] From 2006 to 2012, HTN-related ED visits made up 24% of all ED visits, and rose 5% per year.[11]

ED patients may have no interaction with the healthcare system outside the ED, and thus be difficult to reach for interventions. There are 139 million ED visits annually in the US,[12] and ED visits for primary-care needs are highest for uninsured and low-income patients, suggesting a lack of access to primary care for these patients.[13] EDs tend to serve in a safety net capacity for underserved patients.[14] The proportion of adults with uncontrolled HTN is greater for those without a usual care facility than those with one,[7] suggesting high rates for ED patients without a source of usual care. Controlled BP is also less likely for people with HTN and no insurance than those with private insurance.[7]

Compared to non-Hispanic whites, African Americans are 40% more likely to have high BP,[15] are less likely to have it under control,[7,15] are 20% more likely to die from heart disease,[15] and are more likely to have heart failure at a young age (<50 yrs).[16] Adults with limited English proficiency (LEP) are more likely to have poorly controlled HTN than adults with English proficiency,[17] and the management of asymptomatic HTN in the ED can be complicated by language and cultural differences between the patient and the provider.[18] Several studies have shown that a lack of HTN knowledge is a common barrier to HTN control,[19-21] and providing information that is culturally-sensitive and relevant is especially important.[21,22] Culturally relevant programs using community health workers (CHWs) have proven effective in controlling BP for people with HTN.[23,24] CHWs can provide culturally appropriate health promotion and health education and assist in accessing medical services.[25]

Youth can act in a CHW capacity for the adults with whom they live. A youth-led HTN education intervention can warrant benefits to both hypertensive adults and the youth themselves. *For adults*, a lack of HTN knowledge is a common barrier to HTN control,[19-21] while social support is a strong facilitator[19,21,26] especially for African Americans.[27] *Youth* have shown increased confidence when given the responsibility to provide health education and care navigation to others.[28-30] Guided by the Social Cognitive Theory[31] and findings from several studies, youth who contribute to health programs and services can also expand their own knowledge and increase their healthful decision making capacity.[30,32,33,34]

1.3 Research Design and Methods

A. Research Procedures

Aim 1 (Group 1): This aim will develop the intervention through community feedback and user-centered design methods.

First, we will first create an outline of a prototype for a youth-led HTN education digital badge. A digital badge is a type of credential[35] that serves as a virtual resume of knowledge and competencies for stakeholders such as peers, schools, or potential employers.[36] The digital badge will have a playlist of 6 online experiences (XPs) on HTN information. Each XP will be self-guided with step-by-step instructions to learn material, complete a task, and submit evidence of completion (e.g. photographs). Information that contributes to the playlist XPs will come from reputable health sources, such as the Centers for Disease Control and Prevention[37] and American Heart Association,[38] and will include information on local federally qualified health centers to establish primary care. The digital badge at this stage will be a skeleton outline of possible content for inclusion in the eventual digital badge intervention.

Second, design sessions will be held (led by the PI for English sessions and a Spanish-speaking RA for Spanish sessions) with community members to get feedback on the digital badge prototype. These sessions will be in the format of focus groups or individual interviews. At the start of each session, participants will complete a brief questionnaire, then participants will be provided a menu of possible digital badge content areas and various possible content within each area to provide their input on which they would prefer to see be included in the digital badge. Participants will also discuss acceptability, feasibility, obstacles and solutions for digital badge implementation. Participants will be asked to comment in an open-ended style with prompts used to guide the discussion. Design sessions are expected to last about 1.5 hours and will be audio recorded. The digital badge intervention will then be refined to reflect the input of discussion session participants prior to being used in Aim 2.

Aim 1a: The hypertension knowledge assessment being used in the study has not been used before on youth or Spanish-speaking populations, so we are looking for participants from the design sessions to take part in one-on-one Zoom cognitive interview sessions about their feedback on the assessment. (Spanish documents will be added as a future modification prior to Aim 1a taking place with Spanish-speakers.)

1. Prior to the youth cognitive interviews, a health literacy expert will run the assessment through software for health literacy. Next, members of the study team, including experts in pediatrics and health literacy will look over the assessment. This group will meet to go through the wording of the instructions, items, and responses for appropriateness at the teenager level.
2. We will recruit a subset of interested youth from the design session participants (Aim 1) for the one-on-one youth cognitive interviews, which will take place over Zoom. The participant will complete a brief demographic survey and then complete the hypertension knowledge tool and will provide overall reactions and feedback. Then they will provide feedback on each question one at a time on wording, understandability, clarity, and relevance of instructions, items, and responses. Youth must sign an additional consent form (and parental permission form if under 18 years old) and will receive a $10 gift card for their time.
3. The group from step #1 will meet again and discuss what should be changed in the assessment tool based on feedback from the youth. The refined assessment will then be used in Aim 2.
4. Spanish-speaking sessions will also take place implementing one-on-one cognitive sessions as explained in step #2 above. These sessions will not take place until Spanish documents are submitted for IRB approval in a future modification.

Aim 2 (Group 2): One cohort will be recruited out of the ED. This cohort implements a two-arm randomized controlled trial to test the effectiveness of the intervention.

1. A member of the study team (usually the research assistant (RA)) will determine initial eligibility by checking the patient's chart/ED board for their BP. The RA will ask patients with BP ≥130/80 mmHg if they have a history of HTN. If yes, the RA will ask the patient: 1) If they have an existing relationship (such as family member) with a 14-24-year-old, and 2) If the youth has access to internet or a data plan, as well as a smart phone or computer (to complete the digital badge intervention).

2. If the patient is eligible and interested in participating in the study, the RA will discuss the study with the patient, answer questions, and obtain written consent.

3. The RA will then collect the patient's BP using the study BP cuff (which is then used for patient follow-up visits so that there is no variation in BP instrument measurements) and follows the BP measurement protocol. Adult completes baseline assessments including hypertension knowledge.

4. The RA will give the patient a study flyer to bring home to the potential youth participant and will collect the patient's contact information. The patient will be asked to share the information with the youth and call the study team if both adult and youth are interested in participating. If the adult is willing to provide the youth's contact information, we will collect it.

5. If the team does not hear from the patient after 3 days, they will contact (call, email, and/or text) the patient to follow-up about participation. If we have the youth's contact information from the adult, we will contact the youth directly and tell them that we received their information from the adult (see youth recruitment script). The adult patient and youth must both agree to participate in the study for the dyad to participate.

6. After a member of the study team discusses the study with the youth (and parent or legal guardian if youth is 14-17), answers questions, and obtains written consent (including parental/legal guardian consent if youth is 14-17 years old).

7. Youth completes baseline assessments including hypertension knowledge and self-efficacy scales.

8. Each dyad will be randomized into one of two arms- either intervention or control arm:
   Arm 1- Intervention: Participants in the intervention arm will receive the youth-led HTN education digital badge to complete, which will be comprised of a 6-week playlist of one module per week comprising the playlist. Youth will learn from the module and will teach the adult in their dyad about hypertension education in each week's themed module.

   Arm 2- Control: For dyads that are randomized into the control arm, the youth will complete job readiness digital badges. These will include a Career & Job Readiness digital badge playlist, with such playlists as, "Interview Preparation", "Resume Ready", and "Professionalism". While this group may complete multiple digital badges, the total time needed to complete the badges will be approximately equivalent to that of the intervention group (eg. one hour per week for each arm).

9. For both arms, youth must submit evidence of completion (eg. photograph, document) as specified in the playlist's instructions. Evidence will be reviewed by the study team and a digital badge is received if all XPs are satisfactorily completed. If not satisfactorily completed, then a note will be sent back to the youth on how to fix or improve the evidence and resubmit.

10. Adult participants in both arms return to RWJUH for follow-up BP check and complete follow-up assessments- blood pressure self-care scale, hypertension knowledge assessment, and self-efficacy to manage hypertension scale. They will receive an incentive for returning at 1 week and 2 months after completion of digital badge. Youth will complete follow-up assessments of hypertension knowledge and confidence in managing blood pressure of adults at the same timepoints but will be done remotely/electronically.

Due to challenges recruiting youth through adults in the ED, we will be adding a cohort to the study. For this new cohort of the study, we will recruit interested youth from NBHSTHS. Students will be asked to pair themselves with an adult (18+) (preference for adult who has been diagnosed with hypertension) with an existing relationship with the student where it would be feasible to complete an online module together 1 hour per week for 6 weeks. The adult must be fluent in English or Spanish and the student must be able to speak the fluent language of the adult. For this cohort, study procedures are as follows:

1. We will recruit students at NBHSTHS for information sessions (see youth recruitment flyer).

2. We will hold information sessions at the school about the study.

3. After info session, student decides if they want to participate and determines if an adult in their life also wants to participate. Student will give their adult a recruitment flyer and will then complete a Redcap form with their info and adult's info including best time to reach adult to complete consent form and parent info for parental permission (if adult is not parent) on Zoom (could also complete at school if needed).

4. Student consent, adult consent, and parental permission forms will be obtained using e-consent in Redcap.

5. Students will be grouped into a training session at school. At the start of the session, students will complete study assessments including demographics and hypertension knowledge in Redcap. (Adults will also complete their pre-intervention assessments remotely this week via Redcap.)

6. The following week, the student group will have a second in-school session to evaluate their knowledge on to implement the intervention on their adult at home by implementing it on a "practice adult" (one of the research assistants) who will have a checklist where they check off that the student is able to complete the intervention correctly and teach them anything that they have questions about or do not do correctly. Youth completes a HTN knowledge assessment at the end of this session.

7. For the following 6 weeks, students will implement the digital hypertension education intervention with their adult at home- completing one module per week (each module will take about one hour). (Participants will complete feedback assessments at the end of each module.)

8. At the end of the 6 weeks, adult and youth participants will again complete the assessments that they completed before the 6-week intervention (with the exception of demographics).

9. Halfway through the 6-week intervention and at the end of the intervention, any participants (youth or adult) who is interested (not required) can complete interviews about feedback on the intervention (on Zoom or in person).

10. 4 weeks after the end of the 6-week intervention, adult and youth participants will complete the assessments a final time.

Aim 3 (Group 2):
Questionnaire: At the conclusion of each hypertension education module in the intervention, all participants in the intervention group will be asked to complete a questionnaire on the intervention's acceptability and feasibility as part of the requirement for module completion. Participants must complete the questionnaires to receive their study incentive.

Interviews: We will also conduct one-on-one phone interviews with interested participants from the intervention group for more in-depth information on intervention acceptability, feasibility, and fidelity. These will take place halfway through the intervention and at the end of the intervention. Interviews will be available in English and Spanish, and be audio recorded.

B. Data Points

Aim 1 (Group 1): Participation will be a one-time design session that will take place prior to the start of the RCT.

Aim 1a: Participation will be a one-time cognitive interview session.

Aim 2 (Group 2): For the first cohort, BP will be collected at baseline in the ED and at 1 week and 2-month post-intervention follow-ups at RWJUH. Pre- and post-intervention change in HTN knowledge, adult BP self-care, adult self-efficacy to manage HTN and youth confidence in managing adult BP will be collected during the same timepoints.

For the school cohort, youth and adult participants will complete study assessments after consent is signed. Fidelity of the intervention will be collected on youth the following week, and youth will complete a HTN knowledge assessment at the end of this session. At the end of each of the 6 intervention modules, participants will complete module feedback assessments. At the end of the 6 week intervention and then 1 month after the end of the 6 week intervention, all participants will complete study assessments.

Aim 3 (Group 2): Implementation data points will be collected at the end of each module (surveys) and at the midpoint and end of the intervention period (6 weeks post-baseline) (interviews).

C. Study Duration
Aim 1 (Group 1): Participation will be a one-time design session that will last approximately 1.5 hours.
The duration of this aim is expected to be about 3 months.

Aim 1a: Participation will be a one-time cognitive interview session that will last approximately 30 minutes. The duration of this aim is expected to be about 3 months.

Aim 2 (Group 2): For the first cohort, participation duration will be 3.5 months (6 weeks for digital badge intervention plus 2 months for final follow-up after completion of intervention). Baseline data collection is expected to take approximately 20 minutes. During the 6-week digital badge intervention, participants will spend approximately 1 hour per week on the digital badge. Follow-up data collection is expected to take approximately 20 minutes per session (with sessions at 1 week and 2 months).

For the school cohort, youth participation duration will be 12 weeks (about 3 months) (2 weeks for training, 6 weeks for digital badge intervention plus 4 weeks for final follow-up after completion of intervention). Two training sessions at weeks 1 and 2 are expected to take about 40-60 minutes each. Baseline data collection is expected to take approximately 20 minutes. During the 6-week digital education module, participants will spend approximately 1 hour per week on the module. Follow-up data collection is expected to take approximately 20 minutes per session (with sessions at 8 week and 12 weeks).

Adult participation duration will be 10 weeks (6 weeks for digital badge intervention plus 4 weeks for final follow-up after completion of intervention). Baseline data collection is expected to take approximately 20 minutes. During the 6-week digital education module, participants will spend approximately 1 hour per week on the module. Follow-up data collection is expected to take approximately 20 minutes per session (with sessions at the end of the intervention and 1 month later).

Aim 3 (Group 2): The quantitative implementation data questionnaire is expected to take approximately 5-10 minutes to complete. The qualitative interviews will last approximately 30-45 minutes each.
The duration of Aims 2 and 3 are expected to be 1.5 years total for the study.

D. Endpoints

Aim 1: Participation will be a one-time design session that will last approximately 1.5 hours.

Aim 1a: Participation will be a one-time cognitive interview session that will last approximately 30 minutes.

Aims 2 and 3: For the first cohort, participation ends 2 months after the end of the 6-week intervention (3.5 months after baseline). For the school cohort, participation ends after 12 weeks for youth and after 10 weeks for adults.

1.4 Preliminary Data

The PI is a co-founder of the CHAMPIONS NETWork program for high school students in underserved Chicago neighborhoods. Youth are trained as health advocates and then act as health educators for ED patients and family members at home. Youth participants have shown significant increases in empowerment and health knowledge.[28] In 2017, the CHAMPIONS NETWork received funding to implement a cardiovascular health digital badge, where youth learned and educated adult family members about cardiovascular health. After completion, youth focus groups indicated their overall positive response to the experience, and appreciation of the badge's active learning and its long-term benefits.[41] However, any impact of the health education provided by the students on health changes for the adult was not measured and is currently unknown. This study builds upon this work to implement a youth-led digital health education intervention to improve hypertension (HTN) disparities in adult ED patients.

1.5 Sample Size Justification

This is a pilot study. All sample sizes for this study will provide adequate initial information for the development, effectiveness, and implementation metrics on this novel intervention. Future larger studies on the intervention will include a sample size calculation to determine appropriate sample for appropriate power to fully test the intervention.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

Aim 1: Not applicable

Aim 1a: Not applicable

Aim 2: For the first cohort, outcomes will be compared for dyads randomized to the intervention arm versus those randomized to the control arm, where youth participants in the intervention arm will complete the youth-led HTN education digital badge with their hypertensive adult and youth participants in the control arm will complete job readiness digital badge(s).

For the school cohort, we will be looking at changes before and after the 6-week intervention in adult and youth participants.

Aim 3: Not applicable

B. Dependent Variables or Outcome Measures

Aim 1: Not applicable

Aim 1a: Not applicable

Aim 2: For the first cohort, the primary outcome is change in BP (in mm Hg) from baseline to 1 week and 2 months later. We will also collect secondary outcomes of pre- and post-intervention change in HTN knowledge, adult BP self-care, adult self-efficacy to manage HTN and youth confidence in managing adult BP during the same timepoints.

For the school cohort, outcomes of interest are HTN knowledge, confidence in HTN management, and health behavior changes in participants. (Same outcomes as the first cohort except for the BP change.)

Aim 3: Not applicable

1.7 Drugs/Devices/Biologics

Not applicable

1.8 Specimen Collection

Not applicable

1.9 Data Collection

A. Primary Data Collection

- **Location**:

Aim 1: Design sessions will take place on a remote platform such as Zoom.

Aim 1a: Cognitive interview sessions will take place on a remote platform such as Zoom.

Aim 2: For the first cohort, initial blood pressure reading for adult participants will take place in the emergency department at RWJ University Hospital in New Brunswick. The PI is faculty in the department and will discuss with the Chair of Emergency Medicine to determine the best method for collecting this information.
For the school cohort, questionnaires will be completed in person at the school (youth) or remotely (adults) via Redcap.

Aim 3: A questionnaire will be completed remotely, via digital badge platform, email, or phone.

In-depth interview data will be collected over the phone/Zoom.

- **Process of Data Collection**:
  Aim 1: At the start of each design session, participants will complete a brief questionnaire, then participants will discuss the acceptability, feasibility, obstacles and solutions for digital badge implementation. Because sessions will be complete remotely, questionnaires will be completed electronically by participants directly on RedCap.
  Design sessions will be led by the PI and participants will be asked to comment in an open-ended style with prompts used to guide the discussion. Prompts will help explore how long the intervention is likely to last, clarity of instructions, and likely reactions of participants. Each participant will be assigned a random study ID that will be associated with their responses so that their responses are de-identified. Design sessions are expected to last about 1.5 hours and will be audio recorded. The audio recording will then be transcribed by the RA.

  Aim 1a: The participant will complete a brief demographic survey and then complete the hypertension knowledge tool on RedCap and will provide overall reactions and feedback. Then they will provide feedback on each question one at a time on wording, understandability, clarity, and relevance of instructions, items, and responses. Sessions will be led by the PI and RA. Sessions will last approximately 30 minutes and will be audio recorded. The audio recording will be transcribed by the RA.

  Aim 2: For the first cohort, BP data will be collected when the potential participant is in the ED by the recruiter- either the RA or PI and will be entered into the RedCap study database. It will then be collected at 1 week and 2 months post-intervention when the adult participant returns to RWJUH for follow-up BP readings which will be entered into RedCap. HTN knowledge, self-efficacy, and self-care data will be collected electronically via RedCap. Participants will be sent a link to the appropriate questionnaires to be completed at baseline, 1 week post intervention, and 2 months post intervention.

  For the school cohort, data collection will be done through Redcap. Questionnaires will be completed in person at the school (youth) or remotely (adults).

  Aim 3: All participants in the intervention group will be asked to complete a questionnaire at the end of each intervention module through the digital badge platform, which will allow them to complete the questionnaire in RedCap. Participants must complete the questionnaires to receive their digital badge incentive.

  We will also conduct one-on-one phone/Zoom interviews with interested participants for more in-depth information on intervention acceptability, feasibility, and fidelity. Interviews will last approximately 30-45 minutes each, be available in English and Spanish, and be audio recorded. The audio recording will then be transcribed by the RA.

- **Timing and Frequency**:
  Aim 1: Participation will be a one-time design session.

  Aim 1a: Participation will be a one-time design session.

  Aim 2: For the first cohort, BP will be collected at baseline in the ED and at 1 week and 2-month post-intervention follow-ups at RWJUH. HTN knowledge, self-care, and self-efficacy will be collected at the start of the intervention, and at 1 week and 2 months post-intervention.

  For the school cohort, youth and adult participants will complete study assessments after consent is signed. Fidelity of the intervention will be collected on youth the following week, and

youth will complete a HTN knowledge assessment at the end of this session. At the end of each of the 6 intervention modules, participants will complete module feedback assessments. At the end of the 6-week intervention and then 1 month after the end of the 6-week intervention, all participants will complete study assessments.

Aim 3: Implementation outcomes will be collected at the end of each module (questionnaires) and the end of the intervention period (6 weeks post-baseline). Interviews will take place at the halfway point and end of the intervention.

- **Procedures for Audio/Visual Recording**:
Aim 1: The design sessions will be audio recorded. This acknowledgement will be included in the consent/assent/parental permission form for participants of this aim (Group 1).

Aim 1a: The design sessions will be audio recorded. This acknowledgement will be included in the consent/assent/parental permission form for participants of this aim.

Aim 2: Not applicable

Aim 3: For intervention participants in who agree to participate in the in-depth interviews, the interviews will be audio recorded. This acknowledgement will be included in the consent/assent/parental permission form.

- **Study Instruments**:
Aim 1: *Quantitative*: Participants will complete a brief questionnaire of demographic information, HTN history (for adults), HTN family history, Williams et al. (1998)'s hypertension knowledge tool, and the Self-Reported Health Literacy Questions Among Diverse English and Spanish-Speaking Populations (Sarkar et al. 2011).

Qualitative: Design sessions will explore the acceptability and feasibility of the prototyped digital badge and web-based implementation process, including potential obstacles and solutions.

Aim 1a: A brief demographic survey and Williams et al. (1998)'s hypertension knowledge tool

Aim 2: For the first cohort, the primary outcome of the study is change in BP (in mm Hg). For both cohorts, we will collect secondary outcomes of pre- and post-intervention change in HTN knowledge, self-efficacy, and self-care (for adults) Additionally, we will ask adult participants to complete the Self-Reported Health Literacy Questions Among Diverse English and Spanish-Speaking Populations (Sarkar et al. 2011).Assessments are attached in eIRB. Assessments must be completed in order for participants to receive their study incentives.

Aim 3:
Quantitative: Participant outcomes will be measured from two sources: participant questionnaire and information pulled by the study team from the digital badge platform.

1. Participant questionnaire will include the following measures:
    a. 4-item Acceptability of Intervention *Measure* (AIM) scale[1] to measure intervention acceptability by participants
    b. 4-item Feasibility of Intervention Measure (FIM) scale[1] to measure intervention feasibility by participants
    c. Amount of time spent for hypertension education module completion
    d. Feedback on the hypertension education module.

2. Data pulled from the digital badge platform will measure intervention fidelity. This information will include:
    a. Measures of adherence to program protocol: 1) # of participants who completed the entire digital badge, 2) Number of days between each XP (as XPs are meant to be administered weekly), 3) # pieces of submitted evidence rejected by the program reviewer for each XP

    b. Measures of dose of intervention delivered: 1) Number of XPs completed in the playlist, 2) Which XPs were completed by participants who did not complete the entire digital badge

- *Qualitative:* Phone/Zoom interview participants will describe obstacles and successes that they encountered with the digital badge. We will also ask participants about acceptability and feasibility of the digital badge, including asking them to explain reasoning behind their favorite and least favorite module and most and least informative module.

- **Ethnographic Studies, Interviews, Or Observation**:
  Aim 1: Design sessions will explore the acceptability and feasibility of the prototyped digital badge and web-based implementation process, including potential obstacles and solutions.

  Aim 1a: We will recruit a subset of interested youth from the design session participants (Aim 1) for the one-on-one youth cognitive interviews, which will take place over Zoom. The participant will complete a brief demographic survey and then complete the hypertension knowledge tool and will provide overall reactions and feedback. Then they will provide feedback on each question one at a time on wording, understandability, clarity, and relevance of instructions, items, and responses.

  Aim 2: Not applicable.

  Aim 3: Phone/Zoom interview participants will describe obstacles and successes that they encountered with the digital badge. We will also ask participants about acceptability and feasibility of the digital badge, including asking them to explain reasoning behind their favorite and least favorite modules and most and least informative modules.

- **Subject Identifiers**:
  Aim 1: No identifiers will be collected. Questionnaires and audio recordings from design sessions will be de-identified and each participant will have a random study ID that will be used for both questionnaires and design session transcripts.

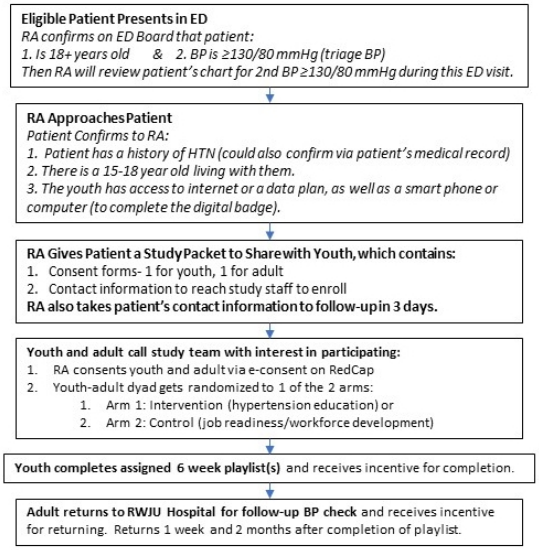
  Aim 1a: No identifiers will be collected. Questionnaires and audio recordings will be de-identified and each participant will have a random study ID that will be used for both questionnaires and design session transcripts.

  Aims 2 and 3: Data will be collected in REDCap (Research Electronic Data Capture)- a password protected, secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 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 data integration and interoperability with external sources. Redcap allows for removal of identifiers when research data is exported from Redcap for analysis, so we will remove identifiers prior to analysis.

B. Secondary Data Collection

Not applicable

1.10 Timetable/Schedule of Events (Aim 2- First cohort (ED recruitment))



(Please note that when RA approaches patient, they will ask patient if they know a 14-24 year old (not have a 15-18 year old living with them).)

2.0 Project Management

2.1 Research Staff and Qualifications

All members of the research team are faculty, staff, or students at Rutgers. The PI has years of experience planning and implementing research studies. Additionally, because this study is part of a career development grant, a highly qualified mentorship team of senior faculty members is in place to provide mentorship to the PI on all study aspects.

2.2 Research Staff Training

All research staff have completed requisite Collaborative Institutional Training Initiative requirements, and will obtain familiarity with the research protocol prior to any interactions with the study. This familiarity will be tested to determine readiness prior to interactions with the study and participants.

2.3 Resources Available

The study will recruit patients out of the emergency department (ED) at Robert Wood Johnson University Hospital (RWJUH). Uncontrolled hypertension is a prevalent condition in ED patients, and this ED sees 70,000 patients a year, so recruitment at this site can provide a large pool of eligible patients from which to recruit for this study. The PI is faculty in the department and has the support of the department chair to conduct this study in the RWJUH ED.

For the school cohort, we will recruit youth from NBHSTHS. The PI has worked with the school for one year for other projects and has the support and enthusiasm of the school's principal to conduct this study.

Additionally, this is a funded study and such funding supports hiring of a research assistant (RA), who will be a valuable asset to help the PI with such tasks as recruitment and data collection.

2.4 Research Sites

Robert Wood Johnson University Hospital- 1 Robert Wood Johnson Place, New Brunswick, NJ 08901
New Brunswick Health Sciences Technology High School- 165 Bayard St, New Brunswick, NJ 08901

3.0 Multi-Center Research

Not applicable

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Aim 1: We will partner with the New Jersey Alliance for Clinical and Translational Science (NJ ACTS) community engagement core as a resource to help recruit participants for the user-centered design sessions from relevant community organizations. Community organizations will share the study and eligibility criteria with their constituents and will be asked to contact the PI for eligibility screening and scheduling into a design session. Youth will be recruited for design sessions from Rutgers youth summer programs, the CHAMPIONS program and Urban Health Program (which take place remotely from Chicago), and New Brunswick Health Sciences Technology High School. Leadership for the program/school will be given a flyer to distribute to students/program participants. Youth interested in participating in the study will contact the PI for eligibility screening (must be age 15-18 years), consent or assent + parental permission obtainment, and scheduling into a session. The recruitment flyer has been submitted as an attachment.

We will recruit adults with hypertension for the design sessions (Aim 1) from the Robert Wood Johnson University Hospital Emergency Department. Recruitment flyers will be displayed in the ED and ED providers will be given recruitment flyers to distribute to any adult patient who presents to the ED with elevated BP. Also, members of the study team will approach ED patients to inform them about the study, assess eligibility, and collect contact information into the interest form on Redcap (already approved).
Additionally, the East Brunswick Public Library will post the adult recruitment flyer. Interested people will contact the PI- Dr. Heinert- if interested in participating in a focus group. After reaching out, we will confirm eligibility with the potential participant. If eligible, we will then schedule them into a focus group or one-on-one interview session.

Aim 1a: Participants for this aim will be a subset of Aim 1 participants. Aim 1 participants who are youth or Spanish-speaking will receive a recruitment email about participation in Aim 1a, and can participate if interested.

Aim 2: For the first cohort, a member of the study team (usually the research assistant (RA)) will determine initial eligibility by checking the patient's chart/ED board for their BP. The RA will ask patients with BP ≥130/80 mmHg if they have a history of HTN. If yes, the RA will ask the patient: 1) If they know a 14-24-year-old, and 2) If the youth has access to internet or a data plan, as well as a smart phone or computer (to complete the digital badge intervention).

For the school cohort, all students at NBHSTHS are eligible to participate if an adult in their life also wants to participate in the study.

Aim 3: All participants randomized to the intervention arm in the first cohort of Aim 2 and all participants in the school cohort will complete the implementation questionnaires for Aim 3, and those who are interested will participate in in-depth interviews after completing appropriate written consent for this element of the study.

B. Recruitment Details

Aim 1: We will partner with the New Jersey Alliance for Clinical and Translational Science (NJ ACTS) community engagement core as a resource to help recruit participants for the user-centered design sessions from relevant community organizations. Youth will be recruited for design sessions from Rutgers youth summer programs, the CHAMPIONS program and Urban Health Program (which take place remotely from Chicago), and New Brunswick Health Sciences Technology High School. Leadership for the program/school will be given a flyer to distribute to students/program participants. Youth interested in participating in the study will contact the PI for eligibility screening (must be age 15-18 years), consent or assent + parental permission obtainment, and scheduling into a session. The recruitment flyer has been submitted as an attachment.

We will recruit adults with hypertension for the design sessions (Aim 1) from the Robert Wood Johnson University Hospital Emergency Department. Recruitment flyers will be displayed in the ED and ED providers will be given recruitment flyers to distribute to any adult patient who presents to the ED with elevated BP. Also, members of the study team will approach ED patients to inform them about the study, assess eligibility, and collect contact information into the interest form on Redcap (already approved).

Additionally, the East Brunswick Public Library will post the adult recruitment flyer. Interested people will contact the PI- Dr. Heinert- if interested in participating in a focus group. After reaching out, we will confirm eligibility with the potential participant. If eligible, we will then schedule them into a session.

Aim 1a: Participants for this aim will be a subset of Aim 1 participants. Aim 1 participants who are youth or Spanish-speaking will receive a recruitment email about participation in Aim 1a, and can contact the PI to participate if interested.

Aim 2: For the first cohort, if the patient is eligible and interested in participating in the study, the RA will give the patient a study packet to bring home to the potential youth participant and will collect the patient's contact information. The patient will be asked to share the information with the youth and contact the study team if both adult and youth are interested in participating. If we have the youth's contact information from the adult, we will contact the youth directly and tell them that we received their information from the adult (see youth recruitment script) and see if they are interested in participating.

If the team does not hear from the patient or youth after 3 days, they will contact the patient to follow-up about participation. The adult patient and youth must both agree to participate in the study for the dyad to participate.

For the school cohort, we will recruit students at NBHSTHS for information sessions (see youth recruitment flyer). We will hold information sessions at the school about the study. After info session, student decides if they want to participate and determines if an adult in their life also wants to participate. Student will give their adult a recruitment flyer and will then complete a Redcap form with their info and adult's info including best time to reach adult to complete consent form and parent info for parental permission (if adult is not parent) on Zoom (could also complete at school if needed).

Aim 3: For recruitment of in-depth interviews, participants from the intervention group of the RCT (Aim 2 first cohort) and all participants in the school cohort will receive an email from the PI that describes the opportunity to participate in this additional study and how to contact the PI if interested in participation.

C. Subject Screening

- **Inclusion Criteria**

Aim 1: Participants will be youth (15-18 years) and adults (18+ years old) with self-reported HTN diagnosis.

Aim 1a: Participants will be youth (15-18 years) and Spanish-speaking adults (18+ years old) with self-reported HTN diagnosis.

Aim 2: First cohort**:** Eligible adult participants will be 18+ year old ED patients with a history of HTN and two high BP (≥ 130/80 mmHg) readings during their ED visit who have an existing relationship with a 14-24-year-old. The eligible youth participants (14-24-year-old) must have access to the internet or data plan and a smart phone or computer.

School cohort: Youth Eligibility: Any interested student at New Brunswick Health Sciences Technology High School.

Adult Eligibility: Adult (18+) (preference for adult who has been diagnosed with hypertension) with an existing relationship with the youth where it would be feasible to complete an online module together 1 hour per week for 6 weeks. Fluency in English or Spanish (youth must be able to speak fluent language).

Aim 3: Everyone who randomized to the intervention group for the RCT (first cohort) and all participants in the school cohort will be asked to complete a brief questionnaire after completing each module.. Interested participants from the intervention arm(first cohort) and anyone from the school cohort will be recruited for the in-depth interviews.

- **Exclusion Criteria**
  Aim 1: Age <15 years, inability to speak fluently in English or Spanish

  Aim 1a: Age <15 years, inability to speak fluently in English or Spanish

  Aims 2 and 3: First cohort: Age <14 years, inability to speak fluently in English or Spanish, no access to the internet or a data plan and a smart phone or computer.

  School cohort: People who cannot take part in the study are people who are not able to speak fluently in English or Spanish (youth and adult must be able to speak the same language), and youth with no access to the internet or a data plan and a smart phone or computer.

  Aim 3: Participants from the control arm in the first cohort will not be eligible for the in-depth interviews or questionnaires.

4.2 Secondary Subjects

Not applicable

4.3 Number of Subjects

A. Total Number of Subjects

Aim 1: Participants for the design sessions will be 10-15 adults in total and 10-15 youth in total. Each design session will be a focus group of approximately 5-8 people or one-on-one interview and we anticipate 2 design sessions for each group (adults and youth). One adult session will be in Spanish to be inclusive of participants with limited English proficiency.

Aim 1a: 15 participants

Aim 2: 100 participant dyads (1 youth + 1 adult = 1 dyad), 200 total

Aim 3: 10 adults and 10 youth will be recruited for phone interviews. In the first cohort, all members of the intervention group and in the school cohort all participants will complete questionnaires. ().

B. Total Number of Subjects If Multicenter Study

Not applicable

C. Feasibility

In the US, 33% of individuals have HTN[6] and for adults with HTN, BP control decreased from 54% in 2013-2014 to 44% in 2017-2018.[7] BP is elevated at almost half (44%) of all ED visits- compared to 27% of primary care doctor visits.[8] Data demonstrates that ED patients' elevated BP is from HTN, and not a result of pain or anxiety from the ED visit.[9,10] From 2006 to 2012, HTN-related ED visits made up 24% of all ED visits, and rose 5% per year.[11]

Based on the high prevalence of uncontrolled HTN in the US, and especially in ED patients compared to patients in other settings, we anticipate that it will be feasible to recruit our study sample size of 100 patients for Aim 2 given we are recruiting from a large ED of 70,000 patients. (Aim 1 sample size of 20-30 participants is also feasible given the prevalence of HTN in the community.)

For the school cohort, there are about 200 students at the school, so we anticipate that recruiting enough students for the study will be feasible, especially because all study procedures will take place at school or at home.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**

  Aim 1: Participants will receive an information letter about the study, and their consent to participate will be their participation in the discussion. Parental permission will take place electronically through RedCap for participants 15-17 years old, and will be required in order for 15-17 year olds to participate.

  Aim 1a: Participants will receive an information letter about the study, and their consent to participate will be their participation in the discussion. Parental permission will take place electronically through RedCap for participants 15-17 years old, and will be required in order for 15-17 year olds to participate.

  Aim 2: For first cohort: Adult consent by the ED patient will take place in the ED through RedCap so that the study team can collect their baseline BP and other characteristics at baseline. Assent and parental permission for youth participants will take place electronically through RedCap. A member of the study team will walk the youth participant and their parent/legal guardian through the study and appropriate form via phone or Zoom.

  School cohort: Adult and youth consents and parental permission forms will be completed electronically through Redcap. A member of the study team will describe the study, answer questions about the study, and will consent the participant in person or on Zoom while the participant signs the form on Redcap.

  Aim 3: Interview: Participants will receive an information letter about the study, and their consent to participate will be their beginning the interview. Parental permission will take place electronically through RedCap for participants 14-17 years old, and will be required in order for 14-17 year olds to participate.

For the school cohort: The interview will be included in the consent form for the rest of the study.

- **Ongoing Consent**
  Not applicable

- **Individual Roles for Researchers Involved in Consent**
  Participants will be consented by the PI (Heinert) and research assistants. (

- **Consent Discussion Duration**
  It is expected that the consent/assent/parental permission process (for each Aims) will take approximately 5 minutes each.

- **Coercion or Undue Influence**
  For first cohort: In order to minimize the possibility of coercion or undue influence on potential subjects, subjects in Aim 2 will only be approached for study consent after they have completed their evaluation in the emergency department and their care team has approved of them being approached by the study team . Subjects in all Aims will also be informed that participation is voluntary and will not affect their relationship with the university/hospital if they decline to participate.

  For school cohort: It will be stressed to potential subjects that participation in the study is voluntary.

- **Subject Understanding**
  Participants will be given ample opportunity to ask any questions they may have about the study, and a trained member of the study team will answer their questions.

B. Waiver or Alteration of Consent Process
Not applicable

C. Documentation of Consent

- **Documenting Consent**
  For the first cohort, Aim 2 adult participants will be consented for the study in person in the ED, at which time they will complete an electronic consent in RedCap or sign a paper consent document. All other participants (parents/legal guardians in Aims 1, 1a, and 3, and youth and parents/legal guardians in Aim 2, adults in the school cohort) will sign their consent/assent/parental permission document electronically in RedCap.

- **Waiver of Documentation Of Consent (i.e., will not obtain subject's signature)**
  For Aims 1, 1a, and 3 (first cohort), participants will receive an information letter about the study, and their consent to participate will be their participation in the discussion. For the school cohort, the interview will be included in the study consent form.

4.5 Special Consent/Populations

A. Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  Parental permission will be obtained for study participants who are less than 18 years old for all Aims.

- **Non-Parental Permission**

Legal guardians can provide parental permission. Proof of legal guardianship will be shown to the study team, and it is expected that this will not be a problem to exhibit because they need this proof for school.

- **Assent Process**
  No assent forms will be used in this study.
  Participants who are 14-17 years old will follow the same consent process as adults for Aims 1, 1a, and 3. Participants who are 14-17 years old will follow the same consent process as 18 year olds in the "Youth" group. (Each cohort for Aim 2 will have 2 consent forms- one for the adults, and one for youth pair in their dyad.)

- **Documentation of Assent**
  Not applicable
  Aim 2 youth will sign a consent form electronically in RedCap. A member of the study team will walk the participant through the study and appropriate form via phone or Zoom.

- **Reaching Age of Majority During Study**
  Not applicable

B. Wards of the State
Not applicable

- **Research Outside of NJ Involving Minors**
  Not applicable

C. Non-English-Speaking Subjects
In addition to English, participants who are Spanish-speaking will also be eligible for the study.

- **Process for Non-English-Speaking Subjects**
  Research assistants Kelvin Guzman, and Ananya Penugonda have translated all patient-facing documents (consent, recruitment script, etc) into Spanish. Research assistants (RA) Ananya Penugonda and Kelvin Guzman, and Kaylee Grullon are fluent Spanish-speakers and will interact with Spanish-speaking patients for research tasks such as consenting and focus groups and interviews for Aims 1, 1a, and 3.

- **Short Form Consent for Non-English Speakers**
  The English consent form is translated into Spanish for Non-English Speakers.

D. Adults Unable to Consent / Decisionally Impaired Adults
Not applicable

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
Participants will incur no expenses for study participation.

B. Compensation/Incentives
Aim 1: Participants will receive a $20 gift card.

Aim 1a: Participants will receive a $10 gift card.

Aim 2: In the first cohort, youth in both arms will receive a $20 gift card after completing baseline assessments, a $20 gift card after completing the first 3 weekly modules (halfway

through the intervention), a $20 gift card after completing all 6 weekly modules (end of intervention) and questionnaires one week later, and a $10 gift card after completing questionnaires two months after the end of the intervention.
Adults in both arms will receive a $20 gift card after completing baseline assessments and a $40 gift card at each follow-up visit for BP check (1 week and 2-months). Adults will also receive transportation vouchers (for either parking or public transit) for follow-up visits.

In the school cohort, adults and youth will receive $80 in gift cards total if they complete the study. Youth will receive: a $20 gift card after completing the second in-school session, a $20 gift card after completing the first 3 weekly modules (halfway through the intervention), a $20 gift card after completing all 6 weekly modules (end of intervention) and questionnaires, and a $20 gift card after completing questionnaires 1 month after the end of the intervention. Adults will receive: a $20 gift card after completing the second in-school session, a $20 gift card after completing the first 3 weekly modules (halfway through the intervention), a $20 gift card after completing all 6 weekly modules (end of intervention) and questionnaires, and a $20 gift card after completing questionnaires 1 month after the end of the intervention.**Aim 3:** Interview participants will receive a $10 gift card per interview for their time.

C. Compensation Documentation
To document compensation, we will keep a master list of date, subject name, amount and type of compensation received.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  This is a minimal risk study. The only foreseeable risk of harm is a possible loss of confidentiality, however procedures will be in place to minimize risks of harm.

- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  Not applicable

- **Other Foreseeable Risks of Harm**
  None

- **Observation and Sensitive Information**
  Not applicable

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
Not applicable

C. Risks of Harm to Non-Subjects
Not applicable

D. Assessment of Social Behavior Considerations
Not applicable

E. Minimizing Risks of Harm
The PI is responsible for protecting the confidentiality of subjects' data. All data will be entered into electronic database (RedCap). RedCap is a secure, web-based application. There will be no paper charts/data entry. This will minimize the potential for loss of information and breech of privacy. Patient confidentiality will be maintained through secured, password protection computerized data collection. All documents and information about this study will be kept confidential in accordance

with federal, state, and local laws and regulations. The results of this study will be published. If results are published, no subject will be identified by name.

- **Certificate of Confidentiality**
  Not applicable

- **Provisions to Protect the Privacy Interests of Subjects**
  Patient confidentiality will be maintained through secured, password protection computerized data collection. All documents and information about this study will be kept confidential in accordance with federal, state, and local laws and regulations. The results of this study will be published. If results are published, no subject will be identified by name.

F. Potential Benefits to Subjects
It is possible that adult participants with uncontrolled hypertension in the intervention arm of the randomized controlled trial (RCT) (Aim 2 first cohort) may experience a decrease in their blood pressure. We have also hypothesized that youth in both arms of the RCT (Aim 2 first cohort) may experience increased knowledge and self-empowerment. First the school cohort, participants may show an increase in hypertension knowledge, confidence in HTN management, and/or health behavior changes.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
HIPAA authorization language will be included in the consent for Aim 2 first cohort, as we will collect information from the patient's medical record.

5.2 Family Educational Rights and Privacy Act (FERPA)
Not applicable

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
A. Special Populations
- Children

5.4 General Data Protection Regulation (GDPR)
Not applicable

5.5 NJ Access to Medical Research Act (Surrogate Consent)
Not applicable

6.0 Data Management Plan

6.1 Data Analysis
Aim 1: *Quantitative:* Questionnaire data will be analyzed descriptively. *Qualitative*: Audio recordings will be transcribed verbatim, and will be analyzed using Gale's Framework Method.[42] As such, three members of the study team will conduct open coding for all transcripts and will meet to agree on a working analytical framework. Categories will be grouped into subsequent themes as related to the digital badge. The PI will then refine the digital badge based on findings from the design sessions with input from mentors.

Aim 1a: Qualitative data will be collected from youth on their feedback on the hypertension knowledge assessment tool. In addition, we will analyze item discrimination and internal reliability of the tool based on their completion of the tool in its entirety. Data from a brief demographic survey will be analyzed descriptively.

Aim 2: Descriptive statistics will be used to assess participant characteristics and covariate balance across study arms. To determine balancing of important measures that may influence outcome variables, the analysis will implement t-tests for continuous variables and chi-square tests for categorical variables. STATA will be used to carry out all statistical analysis. Analysis will include mean BP change from baseline to 2-month follow-up for each arm using a t-test. Multivariate linear regression analysis will also be used to compare the two groups, including a dummy variable for group, baseline BP, and any covariates found to be unbalanced across arms. For youth empowerment, pre- and post-intervention data will be compared with significance testing via t-test.

Aim 3: *Quantitative:* Quantitative data will be analyzed descriptively. *Qualitative*: Interviews will be analyzed using Gale's Framework Method[42] (see Aim 1 for more details).

6.2 Data Security

The PI is responsible for protecting the confidentiality of subjects' data. All participant data will either be de-identified or will use a coded list of identifiers prior to analysis (will remove identifiers prior to analysis). list of identifiers will be destroyed at the end of the study.

All data will be entered into electronic database (RedCap). RedCap is a secure, web-based application. There will be no paper charts/data entry. This will minimize the potential for loss of information and breech of privacy. Patient confidentiality will be maintained through secured, password protection computerized data collection. All documents and information about this study will be kept confidential in accordance with federal, state, and local laws and regulations. The results of this study will be published. If results are published, no subject will be identified by name.

6.3 Data and Safety Monitoring

Not applicable

6.4 Reporting Results

A. Individual Subjects' Results

Not applicable

B. Aggregate Results

Not applicable

C. Professional Reporting

Study methods and findings will be submitted as peer-reviewed abstracts to national conferences and manuscripts to professional journals.

D. Clinical Trials Registration, Results Reporting and Consent Posting

This research qualifies as a clinical trial and will be registered in clinicaltrials.gov.

6.5 Secondary Use of the Data

Not applicable

7.0 Research Repositories – Specimens and/or Data

Not applicable

8.0 Approvals/Authorizations

RUG form has been uploaded.
The cooperation letter from the school has also been uploaded.

9.0 Bibliography

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