Study Title: Reach Out: Randomized Clinical Trial of Emergency Department-Initiated Hypertension Behavioral Intervention Connecting Multiple Health Systems

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Not applicable

(Any modification to the protocol should be annotated on the coversheet or in an appendix. The annotation should note the exact words that are changed, the location in the protocol, the date the modification was approved by the Executive Committee, and the date it became effective.)

Listing of changes

Version No.	Date	Reviewer	Details of changes	IRB Status
2.0	9.19.2018	MRD	1. Uploading of instructions for BP and text messaging which have been done by a graphic designer. (appendix A; appendix E) 2. JNC-7 to JNC-88 outcomes based on recent revisions to blood pressure guidelines (page 8; page 19)	Approved
3.0	12.3.2018	MRD	1. Added a sentence regarding the option to keep participants up to date on progress of the study. (page 15) 2. Deleted incomplete sentence "; we will accomplish this via the following specific aims." (page 10) 3. Added clarification to consent process that the electronic pdf for may have the opportunity to be built into Redcap for more centralized and secure storage (page 14).	Approved
4.0	4.1.2019	MRD	1. Added sentences and appendix describing use and purpose of Reach Out Feedback sheet and Comic Book. (Page 13) a. Appendix F (Page 44) b. Appendix G (Page 45-57)	Approved
5.0	7.8.2019	MRD	1. Fix table of contents 2. Change subjects to participants throughout protocol 3. Correct provider transportation/appointment control standards from 140/90 to systolic 130. 4. Add clarification that participants may be contacted for technology checks after randomization if indications arise. (Page 18) 5. Language allowing contact in the case of lost data or consent documentation (Page 17)	Approved
6.0	8.13.2019	MRD	1. Add outcome sentence, "Outcomes may be built into REDCap. Outcomes may be visually modified, questions removed, rearranged, or re-worded as	Approved

			resources become available, but the messaging, and content will re-main consistent." (Page 19).	
7.0	9.12.2019	MRD	Adding explanation and appendix regarding provider appointment scheduling documentation if needed by provider office for scheduling permission. - Appendix H added (Page 48). - Sentence added "If a provider office indicates that they require proof of permission from participant regarding the ability to schedule appointments on their behalf, REACH OUT may provide that to them for their files, or complete the office's specific permission forms (Appendix H)." (Page 19).	Approved
8.0	12.5.2019	MRD	Adding FIM and AIM scales. Page 21 notes that general intervention feedback may include validated scales, Acceptability of Intervention Measure (AIM), and Feasibility of Intervention Measure (FIM). Added appendices to Pages 61-63 referencing a proposed study within the trial. Added Appendix I: Holiday Card Study within a Trial (Page 61-62) Added Appendix J: Holiday Card (Page 63) Updated Table of Contents with new Appendices (Page 4)	Approved
9.0	1.17.2020	MRD	Increase sample size estimates within the synopsis (Page 8) and the specific sample size section (Page 29). After accruing approximately 400 randomized participants, we noted lower than expected retention at 6 month visits. Therefore, we adjusted the maximum total number of enrollments and randomizations upwards by 50% each. The overall intention is to achieve approximately 240 protocol completers (attendees at 12-month visit). We will continue to monitor accrual and retention in order to achieve this target.	Approved
10.0	2.13.2020	MRD	Adding description and appendix of 1) Outcome reminder letter and 2) Newsletter outcome. Description of mailing of outcome reminder and newsletter added to Page 21. Added Appendix K: Outcome letter Added Appendix L: Newsletter Updated Table of Contents with new appendices.	Approved
11.0	3.16.2020	MRD	Amendment for tele-outcomes given COVID recommendations. Detailing tele-outcome protocols and materials (Page 21). Including materials to make tele-outcomes more accessible to participants including a Tele-outcome reminder (appendix M) and a tele-outcome guide (appendix N), as well as a link to a video guide.	Approved
12.0	4.14.2020	MRD	Supplemental appendix detailing extended 15 and 18 month outcomes with participant consent (appendix O). Addition of ability to do phone recruitment of ED patients. This involves calling ED patients (once discharged) that have	Approved

			met certain inclusion/ exclusion criteria for recruitment (page 17).	
13.0	10.8.2020	MRD	Supplemental Appendix changes (Appendix O) Clarification on where data will be stored regarding databases. Language was changes for Reach Out Cognition from exclusively Redcap, to equivalent databases. The feedback forms (neuro-qol/ sage) regarding the enrollment surveys will only be sent out to participants if they have completed the entire assessment. The mini MoCA was previously described as part of the enrollment, after the consent process. However, it seems most appropriate this is used as a screener prior to consent. A section was added describing screening processes, and a screening consent verbal was created and submitted to IRB.	Approved
14.0	08.1.2022	MRD	Adding subsection 3 of "Contemporary Control Group." This is detailed as a retrospective contemporary control group of Hurley ED patients who had an outpatient follow-up visit.	Pending

SYNOPSIS

Study Title:

Reach Out: Randomized Clinical Trial of Emergency Department-Initiated Hypertension Behavioral Intervention Connecting Multiple Health Systems

Objectives

Through Reach Out, a health system focused, multicomponent, health theory based, mobile health behavioral intervention to reduce blood pressure (BP) among hypertensive patients evaluated in a safety net ED. We aim to determine which behavioral intervention components or 'dose' of the components contribute to a reduction in systolic BP at one year (Aim 1). We will also determine the effect of primary care provider appointment scheduling and transportation on primary care follow up of hypertensive patients treated in an urban, safety net ED (Aim 2). Ultimately, by connecting ED patients to primary care providers, Reach Out can serve as a model for safety net hospitals and Federally Qualified Health Centers to improve chronic disease management in underserved communities.

Design and Outcomes

Reach Out is a health system focused, multicomponent, multiphase optimization strategy (MOST), health theory based, mobile health behavioral intervention to reduce BP among hypertensive patients evaluated in a safety net ED. This trial will take place in Flint, Michigan, an urban, under-resourced, predominately African American community with which the researchers have long-standing partnerships. Reach Out consists of three components, each with two levels: 1) healthy behavior text messaging (yes vs. no), 2) prompted home BP self-monitoring (weekly vs. daily), and 3) facilitated primary care provider appointment scheduling and transportation (yes vs. no). Participants will be randomized into one of the eight experimental arms and followed for 12 months.

The primary endpoint is the change in systolic BP from baseline to 12 months. By using multivariable modeling within the context of a 2x2x2 factorial design, we will learn about the relative contributions of each of the three components to BP reduction. Our overarching objective is to demonstrate that an ED initiated, multicomponent, health system intervention can meaningfully reduce BP in a traditionally underserved population.

Interventions and Duration

Reach Out consists of three, bi-level, mobile health components:

1) healthy behavior text messaging (yes vs.no)
2) prompted BP self-monitoring and associated tailored and targeted text messages (daily vs. weekly)
3) facilitated primary care provider appointment scheduling and transportation (yes vs. no).

After demonstrating persistent hypertension and responsiveness to texting, participants will be randomized into this 2x2x2 factorial design and followed for 12 months.

Sample Size and Population

We originally planned to enroll approximately 960 patients into the eligibility phase. From this group, we estimate that 480 participants will report qualifying BPs and will be randomized to one of the eight intervention arms. We anticipate 240 participants will fully complete the 12 month, in person follow up visits. However, after accruing approximately 400 randomized participants, we noted lower than expected retention at 6 month visits. Therefore, we adjusted the maximum total number of enrollments and randomizations upwards by 50% each. The overall intention is to achieve approximately 240 protocol completers (attendees at 12-month visit). We will continue to monitor accrual and retention in order to achieve this target.

STUDY ENDPOINTS AND OBJECTIVES

1.1 **Primary Endpoint**

Reduction in systolic BP from baseline (median of three qualifying SBP from eligibility phase) to 12 months.

1.2 **Primary Objective**

Estimate the expected change in 12-month SBP reduction associated with each level of the three interventions and determine the combination of elements that appears most promising for study in a future larger scale trial.

1.3 **Secondary Endpoints**

- Time from ED visit to arrival at first primary care visit (in days).

- Attendance at two or more primary care visits within 12 months of randomization.

1.4 **Exploratory and Process Endpoints**

BP

- Proportion of participants achieving BP control
    - JNC-8 targets for SBP/DBP
    - 2017 AHA guidelines targets for SBP/DBP
- Change in DBP and mean arterial pressure
- Change in 6 month SBP

Process

- Number of interactions (such as calls/texts) to schedule participant initial primary care visit
- Number of interactions to schedule all other primary care visits
- Proportion of BPs texted to the study team
- Proportion enrolled but not randomized

PCP

- Establishment of a primary care providers among those without
- Number and proportion of provider visits attended
- Proportion of transportation vouchers used

Utilization

- Frequency of Hurley ED and other healthcare visits
- Self-reported follow up of health system (Hurley, Hamilton, or other community clinics)

- Follow up outside of health system (urgent care, outside clinics, outside EDs)

Medications
- Changes/escalation in antihypertensive regimen through patient self-report
- Medication Adherence (Hill-Bone Scale, and modified Hill-Bone instrument asking, "How often do you forget to take your HBP medicine?")

Other
- Social Cognitive Theory (SCT) measures
    - Modified one-question self-efficacy measure, "I am confident that I can take my blood pressure and text it to the Reach Out Team")
    - Questions querying self-efficacy, motivation, social support and expertise.
        - I am confident that I can control my blood pressure
        - It is worthwhile for me to control my blood pressure
        - My friends and family care if I control my blood pressure
        - I know the right steps to take to control my blood pressure
- General intervention feedback

2 BACKGROUND

2.1 **Rationale**

Hypertension is the most important modifiable risk factor for cardiovascular disease, the leading cause of mortality in the United States. African Americans have the highest prevalence of hypertension of any race/ethnic group in the United States which largely contributes to their increased burden of stroke compared to non-Hispanic whites. In addition, uncontrolled hypertension is more common among socioeconomically disadvantaged populations than their counterparts.

The Emergency Department (ED) represents a missed opportunity to identify and treat hypertension in difficult–to-reach populations. Currently, there are 136 million ED visits per year and nearly all have at least one BP measured and recorded. African Americans and socioeconomically disadvantaged patients are disproportionally represented in the ED patient population and both are increasing. In the age of electronic health records (EHR) and mobile health, the ED can feasibly become an integral partner in chronic disease management by programming the EHR to identify hypertensive patients and dispense a mobile health behavioral intervention. Facilitating ED follow up at primary care clinics is a key feature of the proposed intervention. Through leveraging the strengths of the ED and its large patient volume of uncontrolled, difficult-to-reach, hypertensive patients, with the strengths of the primary care clinics' continuity of care, we aim to improve community wide utilization of health services.

We propose, Reach Out, a health system focused, multicomponent, health theory based, mobile health behavioral intervention to reduce BP among hypertensive patients evaluated in a safety net ED. This trial will take place in Flint, Michigan, an urban, under-resourced, predominately African American community with which the researchers have long-standing partnerships.

Reach Out consists of three components, each with two levels: 1) healthy behavior text messaging (daily vs. none), 2) prompted home BP self-monitoring (weekly vs. daily), and 3) facilitated primary care provider appointment scheduling and transportation (yes vs. no). Participants will be randomized into one of the eight experimental arms and followed for 12 months.

Our overarching objective is to demonstrate that an ED initiated, multicomponent, health system intervention can meaningfully reduce BP in a traditionally underserved population.

2.1.1 Management of hypertension in, and following, the ED

Given variable ED hypertension management and low ED follow up rates, ED visits are missed opportunities for the identification and management of hypertension. Each year there are over 130 million ED visits, of which hypertension is identified in about 45% (60 million visits). While ED guidelines recommend BP screening, the recommendations for management of asymptomatic hypertension in the ED vary widely from no intervention, referral for primary care follow up, or initiation of antihypertensive to be followed by primary care. However, adherence with recommended primary care follow up by ED patients in the United States is low; ranging from 26% and 56% depending on the community served. Strategies such as those proposed in Reach Out, which facilitate ED patient follow up with primary care providers via appointment scheduling and transportation, are vital given the burden of hypertension and disproportionate ED use in disadvantaged populations, as well as low rates of primary care follow up after an ED visit.

2.1.2 Mobile health technology offers ubiquity and scalability for hypertension treatment

Mobile messaging is nearly ubiquitous—ninety-two percent of adult Americans have a mobile phone with over 80% using their devices to send or receive text messages. Overall, African Americans are more likely to own a mobile phone than non-Hispanic whites. Text messaging, or short-message service (SMS), is a widely used technology that sends messages of up to 160 characters. Text messaging offers an appealing option for behavioral interventions given its popularity in underserved populations, low cost, ease of adoption, scalability, and ability to reach people in real-time yet remain flexible and convenient. Text messaging does not require costly smart phones or expensive data plans—adding to the practicality and generalizability of Reach Out.

2.1.3 Patient population

This trial will take place in Flint, Michigan, an urban, underserved, predominately African American community. Flint has a population of 102,434, of which 57% are African Americans; 37% live below the poverty level. About 40% of Flint residents self-report hypertension.

Hurley Medical Center is a 540-bed teaching hospital, and it is the only Level I Trauma Center and safety net hospital located in Flint (Genesee County). The Hurley ED cares for about 110,000 visits per year and recently more than doubled in space. There is disproportionate burden of hypertension among African Americans, those of low socioeconomic status, and working-age Americans. These populations are high volume users of the ED. In fact, 20% of working age Americans had an ED visit in the last year. African Americans have nearly twice the ED visits

compared to non-Hispanic whites; and individuals with Medicaid have the highest ED visit rate of any type of insurance.

Hamilton Community Health Network, a FHQC network in Flint, cares for over 30,000 patients, about 65% of whom are African American, in multiple clinics throughout the city.

2.1.4 Relevance and priority for this study

Hypertension experts have called for evaluation of multilevel interventions addressing barriers to hypertension care. In line with this request and informed in part by the theory, Social Ecological Model, Reach Out intervenes at the individual patient, health system, and community levels. At the individual level, Reach Out will increase identification of hypertension through ED screening, providing BP self-monitors, and encouraging healthy behaviors, all of which are barriers to hypertension management in urban, under-resourced populations. At the health system level, Reach Out leverages the EHR to identify potential participants. Reach Out will work to reduce health system barriers by scheduling primary care provider appointments. Cost of medications is also a barrier that will be addressed in Reach Out. For participants who establish care with the FQHC, medications are provided on a sliding fee scale. Additionally, healthy behavior text messages will provide information about pharmacies with $4 generic drug programs in the area.

2.2 **Supporting Data (Preliminary studies)**

The scientific premise of Reach Out is to test an innovative, mobile health, behavioral, health system intervention to reduce BP in hard-to-reach high-risk populations.

An American Heart Association scientific statement on the use of mobile health for cardiovascular disease prevention found only 13 trials of which only three (all performed outside of the US) used primarily text messaging to promote BP control. Two of the three trials showed a reduction in BP but the results were limited by low participant retention and absence of intention-to-treat analysis. The American Heart Association scientific statement also identified limitations in trials with short duration of follow up, interventions less than 6 months, lack of information on the optimal intervention components and their delivery, and an absence of rigorous clinical trial design. Furthermore, the reductions in BP were small in many of the trials, suggesting that interventions that combine text messaging with other behavioral approaches, such as self- monitoring and novel strategies such as primary care provider scheduling and transportation assistance, may be needed in underserved populations. Reach Out will specifically address these limitations.

Specifically, within our study team, in prior work, we have: 1) developed and tested health theory-based healthy behavior text messages and road map; 2) confirmed the feasibility of prompted BP self-monitoring; 3) created automated, real-time EHR alerts to identify possible eligible ED patients; 4) established a recruitment strategy and protocol; and 5) conducted behavioral clinical trials.

2.2.1 Reach Out-Flint Churches (HUM00082454)

Using a community-based participatory research (CBPR) approach, several mobile health components were developed including prompted BP self-monitoring, healthy behavior text messages,

and a text messaging roadmap. We then tested healthy behavior text messages and weekly prompted BP self-monitoring in three African American churches for 6 months. All text messages were delivered automatically through a text messaging platform developed by Mosio, who is also the vendor for this application.53 A total of 48 participants received the intervention with a mean age of 58 (sd=9.8) years, all of whom were African American. Notably, 15% of the participants did not have a primary care provider. Participants responded to BP prompts 587 (47%) of the available 1248 person-weeks. All (100%) participants reported satisfaction with the Reach Out intervention. Overwhelmingly, participants did not want the mobile health intervention supplemented with phone calls, workshops, cooking demonstrations or internet modules.

2.2.2 Reach Out-ED (HUM00091668)

This was a pilot trial of the healthy behavior text messaging and weekly prompted BP self-monitoring in the University of Michigan ED. In this study, we created real-time automated alerts using the EHR to identify potentially eligible participants. We also created procedures for recruitment of ED patients. Real-time automated EHR alerts identified patients with systolic BP ≥160 or a diastolic BP ≥100 (stage II hypertension) who were likely to be discharged from the ED. During the 7-month enrollment period, over 9,300 patients with elevated BP were identified through the alerts. Given that this was a pilot study that relied on volunteer undergraduate student research assistants, 163 patients were approached and 104 patients enrolled (64%), confirming the feasibility of automated real-time ED screening followed by research staff enrollment of eligible patients. Of the 104 enrolled participants, 55 had at least one elevated BP and were activated into the study.

3 CONTEMPORARY CONTROL GROUP

To better understand how the intervention will or has affected Reach Out participants, we will retrospectively create a contemporary control group. This control group will encompass HMC ED patients who had follow-up visit (outpatient or ED) within 12 months of their ED visit. Patients will be identified through review of the HMC EMR, during a similar period to when the Reach Out intervention was being conducted (March 2019-August 2020). If not possible to make adequate comparisons during the trial time period, it may be expanded. All data will be outgoing from HMC to the study team. We request a waiver of HIPAA authorization and waiver of consent. We will exclude all patients that were consented into the study, the contemporary control group will be de-identified following participant exclusion. We will collect the minimum amount of personal data possible to accomplish the comparison including similar variables to:

- Stratifying variables (sex, age, antihypertensive use)
- Demographics (race, ethnicity)
- Date of ED visit
- ED complaint
- ED BPs
- Date of follow-up
- BPs at follow-up
- Time to follow-up

4 STUDY DESIGN

As we did successfully through our two pilot studies (HUM00082454/ HUM00091668), we will integrate the two strategies together to now recruit participants from the emergency department of Hurley Medical Center in Flint, MI. We will conduct a randomized, controlled, 2x2x2 factorial design clinical trial that will allocate participants to eight different combinations of mobile health components (Table 2). The proposed trial will identify which mobile health components, or 'dose' of the components (healthy behavior text messaging, prompted BP self-monitoring and facilitated primary care provider appointments and transportation) contribute to a reduction in BP among hypertensive participants recruited from Hurley Medical Center, an urban, safety net ED (Table 1). A baseline assessment will occur at enrollment. Outcome assessments will also occur at 6 months and 12 months.

We will monitor the efficacy and resources required for the intervention using system level data obtained from the ED, the FQHCs, and clinics.

Table 1: Reach Out Intervention Components to Decrease BP

Texts	Stratification Levels	Tailoring variables	Mechanism for BP Reduction
Healthy behavior	Daily vs. None	No	Decrease salt intake Increase physical activity Increase fruit and vegetable intake
		Medical provider BP medication Self-efficacy	Discuss with provider Increase medication adherence
Prompted BP self-monitoring	Daily vs. Weekly	BP change (most recent self-reported BP) BP control	Participant activation Participant autonomy Participant competence
Provider scheduling and transportation	Yes vs. None	Medical Provider BP control	Improve access to medical care Opportunities for medication optimization

5 SELECTION AND ENROLLMENT OF PARTICIPANTS

Participants will be recruited from Hurley Medical Center in Flint, MI by trained research assistants who will be notified by real-time alerts from EPIC.

5.1 **Inclusion Criteria**

- Age of 18 or greater
- At least one BP with SBP ≥ 160 or a DBP ≥ 100 (criteria 1)
- If the patient has repeated measurements after achieving Criteria 1, at least one of the repeat BP remains SBP ≥ 140 or a DBP ≥ 90
- Must have cell phones with text-messaging capability and willingness to receive texts

- Likely to be discharged from the ED

5.2 **Exclusion Criteria**

- Unable to read English (<1% at study site)
- Prisoners
- Pregnant
- Pre-existing condition making one year follow-up unlikely
    - Terminal illness with death expected within 90 days
- Current use of 3 or more antihypertensive agents
- Patients with other serious medical conditions that prevent self-monitoring of BP
- Critical illness with placement in resuscitation bay
- Dementia/cognitive impairment

5.3 **Study Enrollment Procedures**

5.3.1 Identification of Cases

As we did through EPIC at the University of Michigan in HUM00091668, we will implement an automated screening algorithm used by the electronic medical records of the ED, to identify patients with blood pressures over a threshold. The threshold for activation is established by a systolic BP (SBP)≥160, or a diastolic BP (DBP)≥100. We may adjust this screening threshold if the proportion of patients with persistent hypertension in follow up texting is towards either extreme (for example, less than 40% or above 80%). This threshold activation will alert the study team member(s) a patient meets the BP eligibility criteria, and should be further screened.

Patient BP is obtained during normal patient screening during any ED visit. We will use this alert through their EMR to automatically notify the study team members to the presence of potentially eligible patients. If the alert system is not functional at any point, it may be supplemented by manual chart review of the daily ED patient log for recruitment and screening purposes. Automated identification of patients may commence up to 3 months prior to the opening of enrollment to work out errors and optimize the EMR screening algorithm within Hurley.

We will request a waiver of consent to maintain a screening log of patients that trigger the alert system, and also at times when completing remote recruitment, and through chart review collect demographics such as, age, gender, race/ ethnicity, reason for ineligibility or refusal and ED BP.

Research assistants will be based in the Hurley emergency department, and thus familiar and comfortable with their system. Flyers/ announcements may be made to the emergency department staff at events such as, staff meetings, or common area board, to notify them of study purpose and recruitment (Appendix C). This document may be visually modified as resources become available, but the messaging, and content will remain consistent.

5.3.1 Consent procedures

All adults meeting the inclusion/exclusion criteria will be approached for consent, if a study team member is available. Research staff will then perform in-person screening of these patients based on the remaining enrollment criteria (see inclusion/ exclusion criteria). Cognitive ability will be assessed through the question, "Are you able to stay home alone for 24 hours?" Patients will receive routine clinical care at the local emergency departments, and eligibility will be confirmed as previously described. We will use an informational flyer to help provide information about the study (Appendix C, Appendix E). If possible, the consent process will be performed in a private room or sectioned area as to provide the most privacy possible. This process will always be performed in person, however we may use electronic pdf forms of the consent document (may build this into Redcap), and collect electronic signatures through a secure mechanism. A copy of the informed consent document with signature will still be supplied to the participant. Following consent, participants will receive a validated, automated, oscillometric BP monitor (XREXS Automatic Digital monitor or similar), and be asked to complete a baseline assessment. We will collect baseline characteristics, including the data needed for targeting and tailoring the text messages. The research staff will teach the participant how to use the BP cuff and text the readings to the study team, including the timing of BP self-monitoring, body position, and resting prior to testing (Appendix A). Participants may also be given a comic book (Appendix G) to improve understanding of the study and hypertension, as well as a Reach Out BP Feedback sheet (Appendix F). Additionally, these documents may be visually modified as resources become available, but the wording, and content will remain consistent. Participants will be given $20 in compensation for their time. We may have a study newsletter that is available to participants so they remain updated on the study.

5.3.2 Telephone Recruitment

As an alternative to in-person recruitment and consent procedures, remote recruitment may also be utilized instead of in-person. We may screen ER patients that meet age range and blood pressure inclusion criteria via EMR, and then call to complete eligibility screening. The research staff will follow a phone screening and recruitment script for remote recruitment (Appendix O). We may also mail letters to these patients, letting them know if their potential eligibility (Appendix P). We will attempt to call ER patients once they are discharged home, within the next week, given patients often do not have their own telephone in the ER. The research staff will contact the patient via the contact information available in HMC's ED medical records (same records viewed as during in-person recruitment).

5.3.3 Telephone Consent Procedures

If adults are found to be eligible by via telephone screening , we will proceed to a telephone consent process, and will follow a phone consent script (Appendix O), this may be done with whatever means best possible for participant (telephone, video, etc). The research staff will ask for the last name, and month and year of birth as confirmation that we are speaking to expected patient. Only once confirmed, will the research staff begin the process of consent. The consent process will be performed by the research staff in a private environment to provide the most privacy possible The research staff will explain the study to participants during the consenting process. Interested participants will be enrolled in the study after providing verbal consent (for remote recruitment). The research staff will discuss questions with the participant, and research would only begin after informed consent is obtained.

For feasibility reasons, within our already approved waiver of hipaa authorizing we add waiver of documentation of informed consent to allow for the study enrollment consenting to be obtained in multiple ways (i.e., in-person when feasible, or verbal consent for those completing remotely).

We will attempt to provide a copy of the consent to potential participant at beginning of obtaining consent via email, text message to download, or texted link to website. If requested, we will give the participant a copy of the informed consent document via postal mail. Following consent, participants will be asked to complete a baseline assessment. We will collect baseline characteristics, including the data needed for targeting and tailoring the text messages. The research staff will postal mail a validated, automated, oscillometric BP monitor (XREXS Automatic Digital monitor or similar), and will teach the participant how to use the BP cuff and text the readings to the study team, including the timing of BP self-monitoring, body position, and resting prior to testing (Appendix A). This training may be done after participant has receive BP cuff. Participants may also be mailed all training materials noted in the in-person consent process. Participants will be given $20 or cash equivalent in compensation for their time after informed consent is received by the research staff. We may have a study newsletter that is available to participants so they remain updated on the study. All following enrollment training discussed would then be done over the phone or through video services, and materials (incentive, blood pressure cuff, instructions sheet(s), swag, etc) would be either emailed, texted, or postal mailed to participant.

5.3.4 Eligibility phase

Following consent, because some participants will have isolated hypertension in the ED, participants will undergo a 3-week eligibility phase (beginning after informed consent, and participant has received blood pressure cuff) to determine if they have persistently elevated BP. All participants enrolled in the study will be given an automated BP cuff, American Heart Association or American College of Cardiology information about high blood pressure (Appendix B), and receive a text message one day in a week asking to text in their own BP. If a participant has not responded by the end of week 2 of the eligibility phase, a study team member may contact up to 2 times to assure it is not a technical issue. This is based on feedback from our previous studies, where participant's primary reported reason for unresponsiveness was unaddressed technical complications.

If participants have 1) persistent high blood pressure (any self-reported BP (SBP)≥140 or a BP (DBP)≥90), and 2) responded to texts at least once, they will be randomized into the trial. If participants do not meet both criteria, they will receive no further communication from the study team following the eligibility phase. These participants may be texted a final text message thanking them for participation.

5.3.5 Randomization

Table 2: Reach Out ED Intervention Arms

The overall study period will be approximately 12 months. After the 3-week eligibility phase, assessing for persistent hypertension and responsiveness to text messages, participants who meet all eligibility criteria will then be randomized.

Participants will be randomized via 2x2x2 block randomization. Participants will be randomized into an experimental arm containing one of the two levels of the three interventions (eight unique combinations) (Table 2).

Arm	Healthy Behavior Text	Prompted BP self-monitoring frequency	Facilitated Primary Care appointment scheduling and transportation
1	No	Low	No
2	Yes	Low	No
3	No	High	No
4	Yes	High	No
5	No	Low	Yes
6	Yes	Low	Yes
7	No	High	Yes
8	Yes	High	Yes

Importantly, the intervention components may have important associations with participants' baseline characteristics. We are most interested in three baseline characteristics: age, sex, and antihypertensive use. Thus, to ensure scientific rigor, in randomization we will reduce imbalance within our treatment arms by stratifying randomization with these variables: 1) age (<64, ≥65); 2) sex, as reported by participant; 3) taking an antihypertensive within the last 6 months (yes vs. no).

In the instance of any lost data, including but not limited to proof of consent through signature, participant responses, assessment data, or anything necessary for study procedures and/or IRB protocol, the participant will be contacted for completion. Because this is not an FDA regulated study, we desire to do what is least burdensome for the participant, the IRB, as well as most equitable as to not deprive the participant of the opportunity to have access to the study. If this instance arises, and they chose, or the study team is not able to contact them in a reasonable time, we may consider them withdrawn and submit this to the IRB.

6 STUDY INTERVENTIONS

6.1 Intervention and strategy components

As stated, Reach Out tests three intervention components: 1) healthy behavior text messaging (daily vs. none); 2) prompted BP self- monitoring (daily vs. weekly); 3) facilitated primary care provider scheduling and transportation (yes vs. no). Participants will be randomized into one of eight arms (Table 2) for the 12-month intervention. For example, in arm 1, the participants will not receive healthy behavior based texts. They will receive weekly prompted BP self-monitoring. Arm 1 is the lowest intensity group (weekly prompted self-monitoring and reporting of BP) and will serve as the effective control group. There is no "untreated" control group given the efficacy of prompted blood pressure self-monitoring and feedback from the community following the preliminary studies. In all of these intervention groups, throughout the duration of the study, if a participants seems to be consistently unresponsive or responding in error, we may attempt to

contact them via phone, text message, or their preferred means, to ensure they are not in need of technology or study assistance.

Additionally, if any requests are sent in by the participant to modulate, pause, or stop any of their intervention components, we will give the participant the option if they may still be contacted for outcome assessments or appropriate other intervention components, if possible. Certain intervention components deemed not possible because of coronavirus or institutional guidance, may not be able to be implemented.

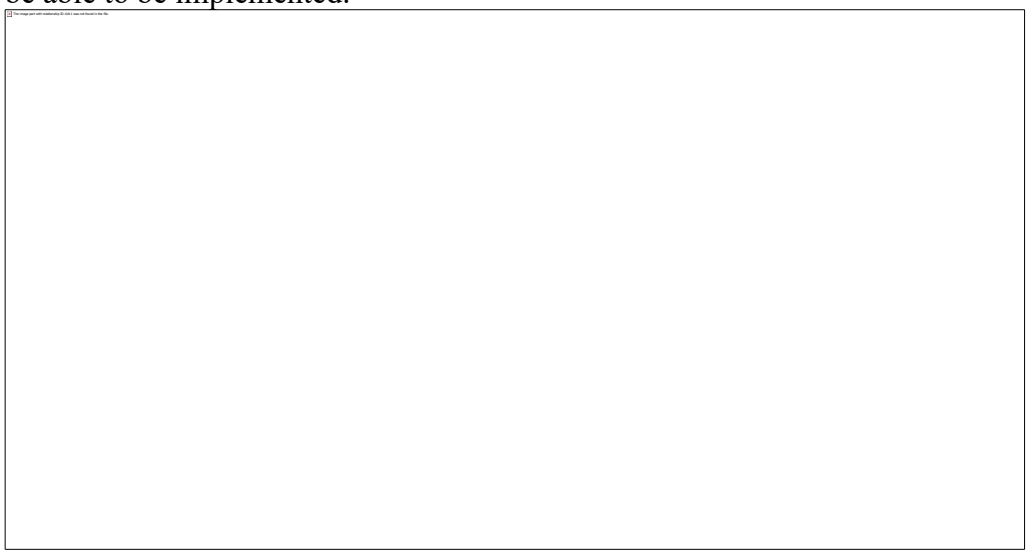


Figure 1 Reach Out Study Design and Incentives (within the randomization table, - boxes indicate low intensity, + boxes indicate high intensity)

6.1.1 **Text messages**

Text message frequency will be dependent on the randomization of the participant. Participants randomized to receive healthy behavior text messages will receive them daily.

Text messages will be both tailored and targeted. Tailoring and targeting are health behavior strategies to increase the personal relevance and therefore the efficacy of behavioral interventions. Targeting refers to the creation of materials focused on shared characteristics of a group of people. In contrast, tailoring refers to materials focused on characteristics of individuals. Studies have shown that tailored and targeted communications are more effective than generic messages. The messages address the most important lifestyle interventions to reduce BP such as, salt reduction, increased fruit and vegetable intake, and increased physical activity. Our team, partnering with the community, created the content for these text messages based on social cognitive theory. Appended are generic, targeted, and tailored text messages. Based on community and hospital feedback, additional text messages may be added, but they will be in the same participant and style of the appended messages.

In addition to these generic health messages, tailored and targeted text messages-based on whether the participant takes an antihypertensive medication, medication adherence level, self-efficacy level, and has a primary care physician will be used. For example, for participants taking

antihypertensive medications, text messages will also address medication adherences (e.g., pill boxes, schedules, etc.).

6.1.2 **Prompted BP self-monitoring**

All participants will have received a BP self-monitoring device at enrollment in the ED, and training for use and text-message response formatting. Participants will be randomized into either a high intensity or low intensity.

- The high intensity group will receive message reminders to check and text their BP back daily
- The low intensity group will be asked to check and text it weekly

By texting their BP, participants have a record of their BPs that they can bring to their primary care provider appointments. They may also be able to prompt the text messaging system to acquire a list of their self-reported blood pressures from the text messaging system. Participants will receive a monthly picture graph of their self-reported blood pressures for feedback. Our platform will allow the participants to provide preferences regarding the time of day for the BP reminders, and the ability to adjust these as needed.

The text-messaging system may make up to a total of 3 attempts until the participant responds with a BP. Some messages for that week may then be tailored on that BP recording.

Please note this will be the only Reach Out research specified outbound message that will be permissible from the participants to the research team. Otherwise, messages sent by the participant will trigger an automated response saying that the response is automated and that for emergencies, the participant should call 911. Participants who have a BP >180/120 will be sent an automated message telling them to call their doctor right away, as they likely need more or different medication, and if they have symptoms such as chest pain, weakness, difficulty talking, or confusion to call 911.. Additionally, if a message is sent to the system that doesn't make sense in the context of a BP reading, an automated error message will be sent back for them to resubmit their BP in the previously taught method.

Participants will have the option to modulate their own reminder frequency by texting prompts to either receive daily BP message reminders, weekly message reminders, or setting them back to where they were assigned at baseline.

6.1.3 **Facilitated primary care provider appointment scheduling and transportation**

Recognizing the importance of primary care provider visits and transportation, Reach Out will facilitate primary care provider appointment scheduling and transportation. Participants will be randomized to receive either facilitated scheduling and transportation, or passive reminders.

Participants randomized to the facilitated group will be able to schedule appointments with their primary care provider via phone call or text capability, which may be facilitated by the research team depending on the capability of our scheduling system. If a provider office indicates that they require proof of permission from participant regarding the ability to schedule appointments

on their behalf, REACH OUT may provide that to them for their files, or complete the office's specific permission forms (Appendix H).

For participants without a primary care provider, medical care will be established at a Hamilton Community Health Center within about 6 weeks of discharge from the ED. After initial enrollment, for all randomized participants, our research team will initially identify up to 3 available appointments that will be texted to the participant who will reply with his/her selected appointment. If a participant does not identify an available appointment time of the 3 selected, a member of the research staff may call to confirm availability and troubleshoot with participant by assessing barriers.

Preceding the appointment, automated text messages may be sent to the participant to remind him/her of the appointment. On, or prior, to the day of the appointment, a transportation credit will be issued to the participant via a driving service, which is most readily available in that targeted neighborhood (taxi, public transportation, or ride share services are all possibilities). Though rare, a study team member may contact the participant (phone call or text message) through this process if necessary to clarify or complete appointment scheduling.

These appointment and transportation procedures will occur monthly (on average) until BP control is achieved. Following BP control, which is defined by a certain number of instances of self-reported <130 systolic, we will reduce the frequency of recommended provider visits. Following control, appointments will be scheduled about every 3 months thereafter.

Participants who are not randomized to facilitated primary care provider appointment scheduling and transportation will receive text messages encouraging participants to contact their primary care provider to schedule an appointment. Transportation will not be provided.

7 OUTCOMES AND EVALUATIONS

7.1 Outcome Assessments

7.1.1 Outcomes

A baseline assessment will occur at enrollment. Outcome assessments will also occur at 6 months and 12 months. Outcome assessments will occur at a provider office to coincide with a scheduled provider appointment, in the ED research space, or a mutually convenient location (e.g. home, library, or restaurant). The primary endpoint is the change in systolic BP (SBP) from baseline to 12 months. At baseline, BP will be measured by the research team using a validated blood pressure cuff, in accordance with national standards for measurement. BP will also be taken with the participant's home blood pressure cuff measurement and compared to the outcome assessment measurements to assess accuracy of the home device. Participants will be given $25 for completing the 6 month outcome assessment, and $30 for completing the 12 month outcome assessment.

At these 6 and 12 month assessments, text messages and/or phone calls will be sent to all participants to facilitated the outcome assessment scheduling of the 6 and 12 month. Reminder text

messages may be sent the 2 days before and the day of the outcome assessment. In striving for equity within our study population, we may also offer transportation credit to participants via a driving service, which is most readily available in that targeted neighborhood (taxi, public transportation, or ride share services are all possibilities), to be able to assess our primary outcomes of BP in person. Outcomes may be built into REDCap. Outcomes may be visually modified, questions removed, rearranged, or re-worded as resources become available, but the messaging, and content will remain consistent. Outcomes will be assessing such topics as contact/tailoring information, provider topics, medication, medication adherence, hospital use, the impact of coronavirus, and Reach out study feedback/ utilization. To increase retention for outcomes, and as already addressed within our enrollment process with participants, we may also be mailing 6/12 outcome reminders (Appendix K), and/or newsletters (Appendix L). Outcome reminders will be updated for either 6 or 12 month outcomes as needed. These materials are included as appendices in the protocol, and will be submitted to the IRB as outlines of materials. However, the dates, time sensitive information, and content may change as needed to better communicate and stay up to date with participants. For example, within the newsletters that may be periodically sent out and updated, it will always contain topics such as recruitment updates, 6/12 outcome visit information, study staff spotlights, end of study instructions, and any other relevant, time-sensitive informational updates. Given the topics and theme of the content will remain consistent, we will not submit changes to the IRB unless there are significant additions or deviations from topics.

7.1.2 **Tele-Outcomes**

Given recent COVID-19 precautionary contact recommendations or when unable or not recommended to conduct in-person 6 and 12 month outcome assessments, we have devised tele-outcomes to mitigate in-person contact. These outcome assessments would replace in-person assessments during COVID-19 precautions. We may resume in-person outcomes once COVID-19 recommendations are lifted.

We would ask participants to send a picture or video confirmation that they are taking their blood pressure with their blood pressure cuff. Around these 6 and 12 month assessments, text messages and/or phone calls will be sent to participants to facilitated the tele-outcome assessment scheduling. Participants may be mailed a reminder, and instructions sheet of how to complete this assessment appropriately, with the least amount of PHI possible (Appendix M and N). These materials may be mailed out by a HIPAA compliant mail service. Participants may also be directed to a video through text message link or website which is demonstrating how to take a picture of cuff, and sending it in (https://www.youtube.com/channel/UCup3LoqlxtMw9sYHQEX7AIA available at reachouted.com). These resources may be visually modified, rearranged, or reworded as resources or COVID-19 standards change, but the messaging, and content will remain consistent. These materials are included as appendices or links in the protocol, and will be submitted to the IRB as outlines of materials. However, time sensitive information, and content may change as needed to better communicate and stay up to date with participants. Given the topics and theme of the content will remain consistent, we will not submit changes to the IRB unless there are significant additions or deviations from topics.

In these tele-outcomes, participants may complete outcome assessments in the following ways. We may ask the participant to include a picture, or video of themselves taking their blood pressure when they text in their BP. This could be texted, emailed, postal mailed, or another means available to the participant, as we are attempting to be equitable between participants according to their availability for method. We will utilize all secure means to assist in these outcomes and promote equity in completion between participants (this may include phone, text, facetime, bluejeans, text link to youtube tutorial, etc). Participants will also be instructed to text message in 3 consecutive measures and adhere to the American Heart Association best practices for measuring blood pressure. Reach Out will attempt to complete the outcome survey via phone, mail, or similar means. If participants are unable to send pictures based on their phone service, we may use methods such as mailing a disposable camera with returned mailing for their use, or having them ask a friend to text it to us.

Once outcome is completed, we will send a confirmation of completion to participants, and ask them to confirm their current mailing address. Incentives may be mailed or texted (link to equivalent value for gift card) out upon receiving these tele-outcomes.

7.2 **Exploratory and Process Endpoints**

BP

- Proportion of participants achieving BP control
    - JNC-8 targets for SBP/DBP
    - 2017 AHA guidelines targets for SBP/DBP
- Change in DBP and mean arterial pressure
- Change in 6 month SBP

Process

- Number of interactions (such as calls/texts) to schedule participant initial primary care visit
- Number of interactions to schedule all other primary care visits
- Proportion of BPs texted to the study team
- Proportion enrolled but not randomized

PCP

- Establishment of a primary care providers among those without
- Number and proportion of provider visits attended
- Proportion of transportation vouchers used

Utilization

- Frequency of Hurley ED and other healthcare visits
- Self-reported follow up of health system (Hurley, Hamilton, or other community clinics)
- Follow up outside of health system (urgent care, outside clinics, outside EDs)

Medications

- Changes/escalation in antihypertensive regimen through patient self-report
- Medication Adherence (Hill-Bone Scale, and modified Hill-Bone instrument asking, "How often do you forget to take your HBP medicine?")

Other

- Social Cognitive Theory (SCT) measures
    - Modified one-question self-efficacy measure, "I am confident that I can take my blood pressure and text it to the Reach Out Team")
    - Questions querying self-efficacy, motivation, social support and expertise.
        - I am confident that I can control my blood pressure
        - It is worthwhile for me to control my blood pressure
        - My friends and family care if I control my blood pressure
        - I know the right steps to take to control my blood pressure
- General intervention feedback
    - Acceptability of Intervention Measure (AIM)
    - Feasibility of Intervention Measure (FIM)

	Baseline	Screening			Randomization	Tech F/U	Med/ PCP Survey	Med/ PCP Survey	Med/ PCP Survey	Med/ PCP Survey	Med/ PCP Survey	6 month follow-up	Med/ PCP Survey	Med/ PCP Survey	Med/ PCP Survey	Med/ PCP Survey	Med/ PCP Survey	Med/ PCP Survey	12 month follow-up	Close-out
Time point	0	1	2	3	4	6	8	12	16	20	24	28	32	36	40	44	48	52	56	
					(+/- 7d) Monday							(+/- 6 weeks)							(+/- 30d)	
Measures to be collected																				
ENROLLMENT:																				
ID ED "user" status	X																			
Informed consent	X																			
Eligibility screen	X	X	X	X	X															
Incentive	X											X							X	
Cognitive screen	X																			
ED Measured BPs	X																			
Competence w/BP cuff	X					X														
Competence with text messaging	X					X														
ASSESSMENTS:																				
Contact Information	X											X							X	
Demographics	X																			
Medical History	X																			
Tobacco/ Alcohol	X																			
Insurance Status	X																			
Transportation	X																			
SCT measures	X											X							X	
Self- efficacy modified							X	X	X	X	X		X	X	X	X	X	X		
SCT modified	X											X							X	
Self- reported BP measurement		X	X	X																
Study taken BP measurement	X											X							X	
PCP:																				
PCP	X											X							X	
First PCP visit time												X							X	
PCP attendance	X						X	X	X	X	X	X	X	X	X	X	X	X	X	

Transportation vouchers used												X							X	
Utilization:																				
Frequency of ED visits												X							X	
Frequency of hospitalizations												X							X	
Medications:																				
Changes in anti-hypertensive treatment												X							X	
Medications	X											X							X	
Antihypertensives	X											X							X	
Pill text												X (+1 day)							X (+1 day)	
Hill-Bone	X											X							X	
Hill-Bone modified							X	X	X	X	X		X	X	X	X	X	X		
Intervention Feedback (AIM/ FIM)																			X	
Qualitative interviews																				X

BP medication adherence will be assessed using several different methods: 1) Hill-Bone and one-question modified Hill-Bone question; 2) pharmacy and provider notes; 3) text participants to message pictures of their medication prior to the 6 and 12 month follow-ups. We will also ask participants to bring their medication to the 6 and 12 month follow-ups. For participants that have not done either, they will be reminded at the follow-up appointments, and texted once more afterwards. In an attempt to further monitor medication adherence, we will look for medication fill rates within the Hurley EHR, and Hamilton pharmacy records, and if there are linkages to commercial pharmacy, we will scan electronic record to assess. We will evaluate the impact of the interventions, and a brief survey regarding participant feedback on the specific intervention components they received (will be added in a future amendment).

7.2.1 Incentives

In appreciation of participants' time all participants will be given a blood pressure cuff at enrollment (about $20 value), and $20 at the completion of baseline data collection. Participants will be given $25 for completing the 6 month outcome assessment and $30 for completing the 12 month outcome assessment.

Participants randomized to receive facilitated primary care provider appointment scheduling will also be provided transportation for their necessary appointments (about $15-30/ ride). All participants will be offered facilitated transportation in order to reach outcome assessment appointments. We will track all incentives allocated to participants through the intervention.

Participants may be given a variety of items designed to help promote enthusiasm and obvious contact information for the project including nominal gifts such as pens, a project t-shirt, and other assorted "stuff" with the Reach Out logo. The additional project stuff is pending available funds.

7.3 **Estimation of resources necessary to implement protocol**

We will track the operational aspects of conducting the intervention. This will include: 1) the number of contacts to providers for the research team to schedule the appointments; 2) time required from the research team to schedule follow up; 3) optimal methods to contact participants to schedule follow up. In addition, our research team will actively develop and optimize our manual of procedures and the design of the subsequent follow up study.

8 MANAGEMENT OF ADVERSE EXPERIENCES

Several types of safety issues and serious adverse events may occur in REACH-OUT and participants will be monitored for these regularly throughout the study.

8.1 **Definition of Adverse Event and Serious Adverse Event and Scope of AE reporting**

An adverse event (AE) is any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medical treatment or procedure regardless of whether it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable, or definite). Each AE is a unique representation of a specific event used for medical documentation and scientific analysis.

A serious adverse event (SAE) is an AE that is fatal or life threatening, is permanently or substantially disabling, requires or prolongs hospitalization, results in a congenital anomaly, requires intervention to prevent permanent impairment or damage, or any event that the treating clinician or internal medical monitor judges to be a significant hazard, contraindication, side effect, or precaution. Reporting serious adverse events (SAEs) are based on the guidelines of the International Conference on Harmonization (ICH).

We will only track adverse events definitely, probably, or possibly related to the intervention.

8.2 Unexpected (Unanticipated) Adverse Event

An unexpected AE is defined as an event that is not anticipated or known to occur as an established risk of either the study intervention or the participant's underlying medical condition. Expected events include, but are not limited to, those specifically identified and described or listed in the study protocol and/or informed consent document.

8.3 Severity of an Adverse Event

'Severity' is not the same as 'serious.' Serious is based on patient/event outcome or action criteria usually associated with events that pose a threat to a patient's life or health. The term 'severe' is often used to describe the intensity (severity) of a specific event (as in mild, moderate, severe myocardial infarction); the event itself, however, may be of relatively minor medical significance (such as severe headache). Seriousness (not severity) serves as a guide for defining regulatory reporting obligations. Most AEs include clinical criteria that describe patient/event outcomes or indicated interventions to more clearly substantiate seriousness.

8.4 Classification of an Adverse Event

All serious adverse events occurring during study participation will be documented on the AE case report form. Adverse events will be documented using the NCI Common Terminology Criteria for Adverse Events Version 3.0 (CTCAE). The CTCAE provides descriptive terminology that will be used for recording and reporting adverse events that occur. The CTCAE provides a grading (severity) scale for each AE term and AEs are listed alphabetically within categories based on anatomy or pathophysiology. The CTCAE (v 3.0) displays Grades 1-5 with unique clinical descriptions of severity for each AE based on this general guidance:

- Grade 1: Mild AE
- Grade 2: Moderate AE
- Grade 3: Severe AE
- Grade 4: Life-Threatening or Disabling AE
- Grade 5: Death related to AE

Note: Severity is not equivalent to seriousness. A serious adverse event (SAE) would be any event in category 4 or 5, and any event in category 3 that required or prolonged hospitalization.

8.5 Relationship to Study Treatment

At the time that an AE is reported, the PI is responsible for designating the likelihood that the AE is caused by the study intervention. This determination requires clinical judgment, but for purposes of this study, an algorithm is used to help the investigator report in a manner that is consistent across the trial and done as objectively as possible.

Modified for Reach Out, based upon: Adverse Events Reporting Requirements SOP (NIH-NIAID http://www.niaid.nih.gov/ncn/sop/adverseevents.htm, accessed 11-30-04).

Not related: The temporal relationship between treatment exposure and the adverse event is unreasonable or incompatible and/or adverse event is clearly due to extraneous causes (e.g., underlying disease, environment)

Unlikely: May have reasonable or only tenuous temporal relationship to intervention. Must meet both of the following conditions:

- Could readily have been produced by the participant's clinical state, or environmental or other interventions.
- Does not follow known pattern of response to intervention.

Possibly: Must meet any 2 of the 3 following conditions

- Has a reasonable temporal relationship to intervention.
- Could not readily have been produced by the participant's clinical state, environmental, or other interventions.
- Follows a known pattern of response to intervention.

Probably: Must meet all 3 of the following conditions

- Has a reasonable temporal relationship to intervention.
- Could not readily have been produced by the participant's clinical state or have been due to environmental or other interventions.
- Follows a known pattern of response to intervention.

Definitely: Must meet all 3 of the following conditions

- Has a reasonable temporal relationship to intervention.
- Could not possibly have been produced by the participant's clinical state or have been due to environmental or other interventions.
  Follows a known pattern of response to intervention.

8.6 **Adverse Event Recording and Reporting**

We will only record AEs and SAEs that are possibly, probably, or definitely related to the study interventions.

All AEs reported to the research team and all serious adverse events (SAEs) occurring until participation in the study has ended are recorded on the AE case report form. The PI or Study Coordinator or designee is responsible for entering any and all AEs and SAEs into the database as soon as he/she becomes aware of the event and updating the information (e.g., date of resolution, action taken) in a timely manner. All non-serious AEs must be recorded on the electronic AE CRF within 5 days from the time it was discovered by the study personnel. All SAEs and non-serious AEs must be entered by the end of study for that participant. These will be reported to the IRB per their policy preferences.

The PI is responsible for the monitoring and follow-up of AEs until resolution or the end of study for that participant, and appropriate documentation in the participant research record. In

addition to performing protocol specified follow up, the participating PI must review all previously reported ongoing AEs to evaluate the status. If an AE that was previously reported on the Adverse Event CRF fully resolves and then recurs later, the second occurrence is considered a new AE and a new Adverse Event CRF must be completed. Likewise, if an SAE that was previously reported and subsequently fully resolved later recurs at a level requiring expedited reporting, the SAE must be reported as a new SAE on the Adverse Event CRF.

Upon completion of the study protocol by the participant, premature withdrawal from the study by the participant, or participant's death, all information regarding each AE must be completed, if not already done so.

8.7 Serious Adverse Event Recording and Reporting

All Serious Adverse Events (SAEs) occurring during a participant's study participation will be recorded. These will be reported to the IRB per their policy preferences.

8.8 Formal Definitions of Selected or Anticipated Adverse Events and Safety Outcomes

Our team does not anticipate any specific adverse events related to the study intervention.

9 STATISTICAL CONSIDERATIONS

9.1 Data analysis

The primary analysis (aim 1) will fit a linear regression model with the outcome of SBP change (baseline minus 12 months) and main effect-coded binary predictors of healthy behavior texts (yes vs. no), prompted BP self-monitoring frequency (high vs. low), and primary care provider visit scheduling and transportation (active vs. passive). Initial analyses will focus on the main effects. Additional analyses will include all the two-way interactions of the three intervention components (only considering interactions where at least one of the factors in the interaction demonstrates a sufficiently large main effect). As the goal of this exploratory trial is to find interventions and combinations with activity, we will use an alpha level of 0.10 for all main effects and 0.20 for interactions. We plan to include elements meeting that bar for statistical significance in the subsequent multicenter trial. If significant interactions exist (i.e. the combination of facilitated transportation and high frequency home BP monitoring), we plan to implement the combination of elements that has the highest expected reduction in SBP – assuming we achieve significance at the p=0.1 (main effects) or 0.2 (interaction) level for the components. In the event of an overall "null" trial, we would examine the expected change in SBP for arm 1, which would be represented by the intercept. If this was significantly greater than 0 at the p=0.1 level we would propose a very simple subsequent multi-center trial using only weekly prompted BP self- monitoring.

The main secondary analyses (aim 2) will use time-to event (Cox Proportional Hazards) and logistic regression. For the endpoint of interest, (either time to first primary care visit, or the binary variable indicating attendance at two or more primary care visits within 1 year of randomization), we will fit an adjusted regression model. The main predictor of interest for these models is assignment to the active primary care provider scheduling and transportation arm (50% of all

participants randomized in the trial), while adjusting for the assignment into other groups similar to aim 1 (healthy behavior text messages and prompted BP self-monitoring).

We will conduct additional exploratory analyses using the stratification factors (age, sex, and antihypertensive use) as covariates. As uncertainty exists on the distribution of enrolled participants within these strata (e.g. young men taking antihypertensive medication), we cannot estimate the preliminary statistical power for these exploratory aims. Thus, we will estimate the power based on the strata sizes prior to conducting the exploratory analyses. Interaction terms (e.g. age with behavioral interventions, sex with behavioral interventions, etc.) will be utilized to determine if specific groups respond well to specific intervention elements. Baseline BP may also play an important role. We will examine its impact by dividing the cohort into tertiles. We will repeat the above primary and exploratory modeling within each of the three initial BP strata to determine if there is heterogeneity of effect (e.g. do patients with the highest baseline BPs get the most benefit from the intervention components?). We will similarly assess the impact of the intervention components on the exploratory and process outcomes using linear, Poisson, logistic, or ordinal regression depending on the distributions. In addition, we will conduct longitudinal analyses that include all BP measurements over time (including those by text and at the in-person visits) to assess the temporal profiles of response in the intervention components.

9.2 **Endpoints**

- Average change in systolic BP from baseline to 12 months
- Time from ED visit to arrival at first primary care visit (in days)
- Attendance at two or more primary care visits within 12 months of randomization

9.3 **Sample Size and Accrual**

We originally planned to enroll approximately 960 patients into the eligibility phase. From this group, we estimate that 480 participants will report qualifying BPs and will be randomized to one of the eight intervention arms. We anticipate 240 participants will fully complete the 12 month, in person follow up visits.

However, after accruing approximately 400 randomized participants, we noted lower than expected retention at 6 month visits. Therefore, we will adjust the maximum total number of enrollments and randomizations upwards by 50% each. The overall intention is to achieve approximately 240 protocol completers (attendees at 12-month visit). We will continue to monitor accrual and retention in order to achieve this target.

In the work by Collins and others, methods for sample size estimations for factorial design, MOST based interventions, have previously been reported. It is important to note, that the primary hypotheses driven by these designs is not in the pairwise comparisons of each of the interventions, but instead is the overall estimate of the effects of each of the individual intervention components, and their combinations. This smallest standardized effect size of 0.35 corresponds to a BP change of 1 mm Hg and standard deviation of 2.8 mm Hg for each parameter. We believe this is the minimal clinically significant change for each component; and to achieve improvements of 3-4 mm Hg over the course of a year, our chosen regimen for the next phase

would need a component or combination of components to perform better than an expected 1 mm Hg change. For 80% power to detect the smallest main expected effect of 0.35 based on the Collins method of a 3-factor experiment analyzed using a second order model (i.e. main effects and 2-way interactions), we require 196 participants. Assuming 480 randomized participants, and allowing an additional 50% loss to follow up after the eligibility phase, we expect at least 240 participants, exceeding 80% power with an alpha level of 0.10 (inflated to reduce likelihood of dismissing active components with modest BP reducing effect) – we used the FactorialPower-Plan SAS macro to calculate power. For the secondary analyses, considering an alpha of 0.05 and a baseline proportion attending 2 or more primary care provider visits within one year of 40%, with a total sample size of 240 evenly distributed between the active appointment scheduling and passive appointment, we have 87% power to detect an increase to 60% attending 2 or more visits. The time to event analysis (considering an alpha of 0.05, power of 99%, and 240 participants enrolled over 720 days, followed for 30 days) can detect a change from 20% of participants in the non-facilitated group to 20.4% of participants in the facilitated group. This high power allows ample room to adjust for covariates and loss to follow up. Sample size calculations for secondary outcomes performed with STPLAN (version 4.5).

The challenges of recruiting racial minorities and people with socioeconomic disadvantage for clinical research studies are well documented. Reach Out participant recruitment will be facilitated by several factors: 1) the study is no more than minimal risk; 2) culturally and community sensitive recruitment materials were created using a CBPR approach; 3) enrollment in an urban, safety net ED; and 4) monetary incentives.

9.4 **Data Monitoring**

The trial does not employ formal efficacy or futility stopping rules. An independent medical monitor (IMM) will be appointed with responsibility to monitor data and oversee participant safety. IMM will be approved by the NIMHD to provide oversight of the trial. The Reach Out IMM will be an expert in the care of hypertension and may either be an emergency medicine physician or a primary care physician. The frequency of IMM meetings will be determined by the IMM, IC, and PI. Given the planned period of data collection we anticipate about 8-10 meetings, in which to advise about study progress and performance, and to make recommendations regarding study continuation and protocol changes.

10 DATA COLLECTION, SITE MONITORING, AND ADVERSE EXPERIENCE REPORTING

10.1 **Records to Be Kept**

Some data may be abstracted from the medical record into the participant's research chart. Identifying information will be collected for each individual in the study (phone numbers, name, age, address and additional contact information). This will be used to coordinate the outcome assess-

ments and text message tailoring. We will maintain a link between the study dataset and the patient identifiers to monitor for recurrent events and potential pharmacy information. This linkage file will be retained until the end of data analysis.

Limited access, HIPPAA compliant databases on secure servers will be utilized for all data storage and collection. Every effort will be made to protect the confidentiality of participants enrolled in this study. HIPAA regulations will be followed. Each patient will be assigned a unique study identification number, which will be used on all data collection forms. All identifying information recorded on paper will be stored in individual research files for each participant and will be kept in a locked file that is accessible only to study staff. All data stored electronically will be maintained in databases stored on a password protected network drive.

10.2 **Role of Data Management**

A subset of study participant data outcomes will undergo additional review to assess data quality. A second assessor, will review a random subset. Range checks and content validation will be utilized in the database to ensure high quality data entry.

10.3 **Quality Assurance**

When applicable, source documents will be uploaded for remote verification. Based on the results of the additional review, retraining of the abstractors will occur if issues with accuracy arise.

11 HUMAN PARTICIPANTS

In general, the research team will adhere to the following principles:

- We will protect and safeguard HIPAA defined Protected Health Information.
- We will respect the confidentiality of the medical providers and health care facilities.
- There will not be public disclosure of identifiable medical provider performance.
- There will not be disclosure or publication of identifiable hospital level performance.
- Identities (patient, provider, and hospital) will be coded in research databases with the linkage file being removed after data analysis.

11.1 **Risks**

11.1.1 **Data risks**

The main potential risk to patients in this study is breach of confidentiality of medical records and survey responses that could result in psychological distress. The likelihood of this risk is estimated to be rare. The seriousness to the participant is estimated to be low. We have methods in place to prevent this occurrence. Data obtained for participants will be held strictly confidential in locked facilities and password protected computers. Trained abstractors will enter pertinent information into the database using REDCAP or similar secure online database. Each abstractor is restricted to only the data they collect or have a need to access. Reach Out will use a secure, password-protected web-based application to enter necessary contact information. The text messages are within a SSL encrypted web-based application with secure log-ins to access. A DUA is

in process. We have also obtained a Certificate of Confidentiality from the National Institutes of Health. The Certificate can be used to legally refuse to disclose information that may identify a participant.

11.1.2 **Vulnerable populations: pregnant women, prisoners, and children**

We are not enrolling vulnerable populations (pregnant women, children, and prisoners). Hypertension is a different disease in pregnancy and in childhood. Prisoners will not generally have access to text messaging, a BP monitoring cuff, or appointments with outside primary care physicians and thus they would not be able to participate or benefit from the study interventions.

All patients of childbearing age will be screened for pregnancy at the time of enrollment. For those who may be pregnant, a pregnancy test may be performed in the Emergency Department (ED) as part of their routine medical care. We are performing research procedures and screening patients in the ED who are visiting for a variety of medical problems and cannot mandate that the clinical care teams perform pregnancy tests. However, in the screening and enrollment process, our research staff will ask potential participants if they could be pregnant. If pregnancy testing has not been done by the clinical team, the research team will inform the clinical team that the patient may be pregnant. The research team will not enroll this patient unless there is a negative pregnancy test. The study would not be dangerous for a pregnant woman; however, the results would not be scientifically relevant.

Once enrolled, participants of childbearing age will be instructed to notify the research team if they become pregnant. Additionally, we will ask participants whether they might be pregnant during the research visits. If the research team learns the participant is pregnant at the research visits or is notified at other times during the intervention, the intervention elements would be discontinued, and we will work with their usual medical care provider to help them establish prenatal care. This will be done because hypertension management differs in pregnancy. In general, by the intention to treat principle, we will keep pregnant women in our cohort to monitor and collect outcomes; we will not use the active intervention components.

Enrolled patients may become prisoners while in our study. The study team will not actively screen for this, however if we learn this during the course of participation we will place study procedures on hold while the patient is a prisoner. We may resume their participation after the period of incarceration, assuming the one-year follow up period has not been expended. We will not extend the follow up window in these cases.

While not a traditionally defined vulnerable population, the people of the city of Flint have faced unique challenges recently given the water crisis. The University of Michigan Department of Emergency Medicine has a long-standing relationship with Hurley Medical Center and the city of Flint. Our faculty group has staffed the emergency department there for almost 20 years. We have an active research infrastructure there and work to reduce the burden of substance abuse and violence in this community. We anticipate that the community will be distrustful of government-funded research, and we will be extremely diligent including working with our community advisory board and employing research staff sensitive to diverse populations. In fact, the research assistants will be part of Dr. Cunningham's infrastructure at Hurley Medical Center and

thus have extensive experience recruiting and enrolling this patient population and setting. This research proposal involves limited risks to the community and is truly designed to provide methods of getting better access to hypertension treatment, so it should not be controversial.

11.2 **Adequacy of Protection Against Risk**

11.2.1 Physical risks

The BP cuffs could cause skin irritation or bruising – this is unlikely given the FDA approved devices used and will most likely be of low seriousness. In addition, it is possible that the participants will experience a medical emergency and elect to text the research number instead of seeking care. All text messages sent into the Reach Out system will receive a standard message similar to, "Remember: this is an automated messaging system, and texts other than your BP are not read. If you have questions, ask your Dr. If this is an emergency call 911."

If BP received is outside of parameters, participants will receive something akin to the following message, "You sent a BP that is very high or low. If this is right, please contact a Dr. very soon to check your BP. If you sent it by accident, please text us a new BP."

11.2.2 Psychological risks

We do not anticipate our intervention will induce psychological risks. We provide positive text messages and referrals to primary care providers. There is a small risk that our study team will lose or release private personal health information and that this could induce psychological harm. We are not collecting sensitive health information that could lead to psychological harm if disclosed to unauthorized individuals.

11.2.3 Financial risks

Text-messaging charges could create a financial burden on participants. We plan to minimize this risk by specifically discussing this during the enrollment process. In addition, our previous work demonstrates that the majority of eligible patients will have unlimited text messaging plans. We do not use any sort of app or data (which is more likely to incur costs for participants). Additionally, we believe it will be unlikely that anyone will have limited minute mobile voice plans, and thus it will be unlikely that our study protocol will induce overage fees for participants. Additional financial risks would include identity theft due to the loss of sensitive information by the study team; we are minimizing the personal data that we collect to what is necessary for our research strategy so this should be unlikely.

11.2.4 Legal risks

We are not collecting location-based data relating to text messages and we do not anticipate that our research protocol will induce any additional legal risks for participants. Alternative procedures that may confer less risk: we are conducting a prospective, clinical trial of several low risk interventions to improve BP. Alternatives to our research strategy would generally be for the participants to self-monitor their BP and follow up with their doctors outside of our protocol. This will be included as an alternative to participation during the informed consent process.

11.3 **Institutional Review Board (IRB) Review and Informed Consent**

This protocol and the consent and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

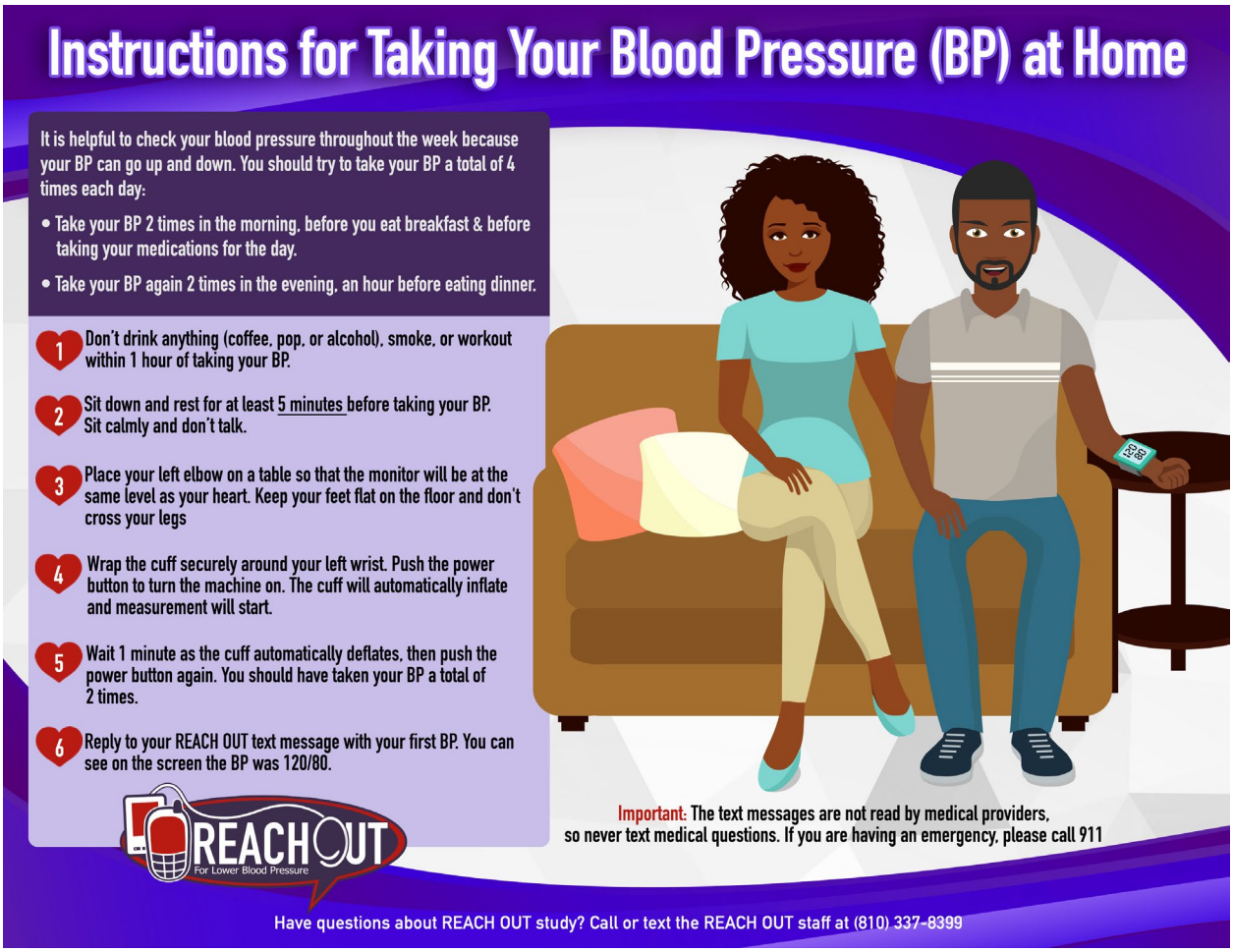
11.4 **Participant Confidentiality / Data Retention**

All records will be kept in a locked file cabinet or on secure computer systems. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, or the NIMDH. In accordance with NIH regulations, we may create a permanent de-identified, public use database. We will remove linkages to protected health information, hospital identifiers and patient identifiers. The purpose of the retention of this data is for future research and to comply the NIH regulations for datasets created during the conduct of NIH funded research grants.

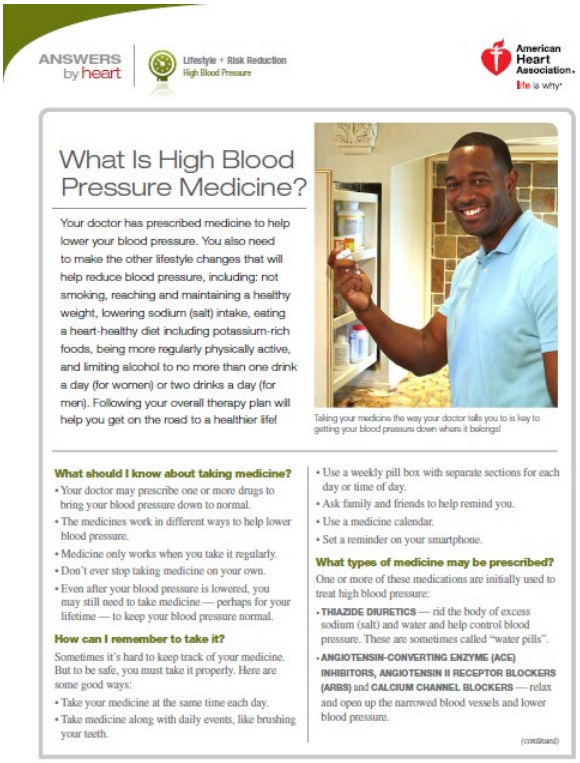
11.5 **Study Modification/Discontinuation**

The study may be modified or discontinued at any time by the IRB, the NIMDH, or other government agencies as part of their duties to ensure that research participants are protected.

Appendix A – Flyer for taking your BP at Home



Appendix B – Blood Pressure Informational flyers



ANSWERS by heart | Lifestyle + Risk Reduction: High Blood Pressure

American Heart Association. Life is why

What Is High Blood Pressure Medicine?

Your doctor has prescribed medicine to help lower your blood pressure. You also need to make the other lifestyle changes that will help reduce blood pressure, including: not smoking, reaching and maintaining a healthy weight, lowering sodium (salt) intake, eating a heart-healthy diet including potassium-rich foods, being more regularly physically active, and limiting alcohol to no more than one drink a day (for women) or two drinks a day (for men). Following your overall therapy plan will help you get on the road to a healthier life!

Taking your medicine the way your doctor tells you to is key to getting your blood pressure down where it belongs!

What should I know about taking medicine?

- Your doctor may prescribe one or more drugs to bring your blood pressure down to normal.
- The medicines work in different ways to help lower blood pressure.
- Medicine only works when you take it regularly.
- Don't ever stop taking medicine on your own.
- Even after your blood pressure is lowered, you may still need to take medicine — perhaps for your lifetime — to keep your blood pressure normal.

How can I remember to take it?

Sometimes it's hard to keep track of your medicine. But to be safe, you must take it properly. Here are some good ways:

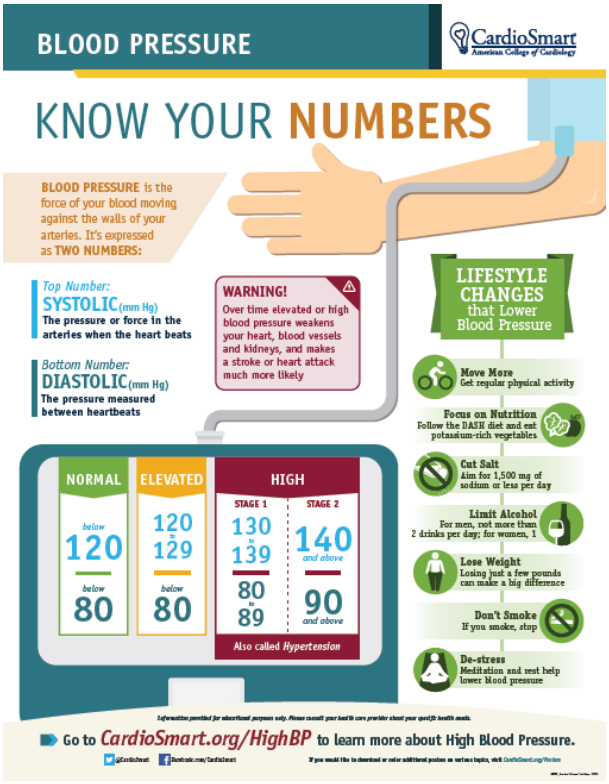
- Take your medicine at the same time each day.
- Take medicine along with daily events, like brushing your teeth.
- Use a weekly pill box with separate sections for each day or time of day.
- Ask family and friends to help remind you.
- Use a medicine calendar.
- Set a reminder on your smartphone.

What types of medicine may be prescribed?

One or more of these medications are initially used to treat high blood pressure:

- **THIAZIDE DIURETICS** — rid the body of excess sodium (salt) and water and help control blood pressure. These are sometimes called "water pills".
- **ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS, ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS)** and **CALCIUM CHANNEL BLOCKERS** — relax and open up the narrowed blood vessels and lower blood pressure.

(continued)



Appendix C – Recruitment flyer

REACH OUT is a research project to help you to reduce your high blood pressure. We'll work with you to lower your blood pressure through text messages, send reminders to check your blood pressure, and team up with doctors in the Flint community.

By joining REACH OUT, you will help **build a program that works toward improving how** people manage their blood pressure, in hopes of preventing future health problems such as strokes, heart disease, and kidney disease.

To participate in the REACH OUT project, you will need to…

- ☐ Be 18 years or older
- ☐ Have high blood pressure
- ☐ Have a cell phone that can send and receive text messages
- ☐ Be willing to receive and send text messages (Any text messaging costs will not be paid for by REACH OUT)
- ☐ Take your blood pressure and text it to REACH OUT staff
- ☐ Be willing to come to 2 follow-up visits over the next year – one in 6 months, the other in 12 months.

Will I be paid for my time?

-When you sign up, you will be given a FREE blood pressure cuff and $20.

- At 3 weeks you will be sent a text message letting you know if you will continue in REACH OUT, or will no longer get text messages

-Those that continue in REACH OUT can earn an additional:

- $25 at the 6-month follow-up

-And-

- $30 at the 12-month follow-up

Who should I contact?

For more information, contact Reach Out at reachoutED@med.umich.edu or (810) 337-8399.

Appendix D – Sample text messages

	Theory	Construct	Category	Subcategory	Text Message
1.	Social Cognitive Theory (SCT)	COGNITIONS (Knowledge/Skills)	DIET	Substitutions	If you're trying to limit your sugar, try switching soda, lemonade, and other juices for water! Carrying a water bottle throughout the day can help you drink more!
2.	SCT	COGNITIONS Knowledge/Skills	DIET	Substitutions	Canned products can have a lot of salt! Look for "lower sodium" or "salt-free" varieties at the grocery store instead!
3.	SCT	COGNITIONS Knowledge/Skills	DIET	Culinary Knowledge	Rinsing canned veggies and beans with water after you open them can help remove extra salt!
4.	SCT	COGNITIONS Self-Efficacy	DIET	Eating/ Ordering out	Salads are a healthy option especially when eating out. Beware of the extra toppings though and try asking for the dressing and cheese on the side so you can choose how much to add!
5.	SCT	COGNITIONS Self-Efficacy	DIET	Planning	Planning your meals can be a great way to help you stay on track! Start with planning one of your meals for the week like lunch or dinner!
6.	SCT	COGNITIONS Self Efficacy	DIET	Eating/ Ordering Out	Try asking your server when out restaurants if you can substitute steamed vegetables or fruit for French fries and chips
7.	SCT	COGNITIONS Self Efficacy	DIET	Snacks	We all have cravings once in a while. Try a piece of fruit or yogurt with granola as a healthy substitute for ice cream or cookies!
8.	SCT	COGNITIONS Self Efficacy	DIET	Eating/ Ordering Out	Find yourself struggling to find healthy options at fast food restaurants? Try to choose baked or grilled options over items that are fried to keep calories from fat down!
9.	SCT	COGNITIONS Outcome Expectations	DIET	Eating/ Ordering Out	Portion sizes at restaurants can be really large. Try asking your server to box up half of your meal before it gets to the table!
10.		COGNITIONS Outcome Expectations	DIET	Food Access	If you find fruits and veggies going bad before you use them, opt for buying frozen ones! Frozen has the same amount of nutrients as fresh!

11.	SCT	SOCIOENVIRON-MENTAL Social Support	DIET	Encouragement	Stress can make it hard to eat healthy and exercise, try talking with friends and family about your health goals to help keep you on track! ☺
12.	SCT	SOCIOENVIRON-MENTAL Social Support	DIET	Food Access	Check out your local farmers market for fresh fruits and veggies! Follow this link to find the closest market to your home –
13.	SCT	SOCIOENVIRON-MENTAL Social Support	DIET	Food Access	Did you know some farmers markets accept SNAP EBT vouchers? Check with your local market and vendors to see if you can use your benefits to buy fresh produce!
14.	SCT	BEHAVIORAL Reinforcement	DIET	Encouragement	Eating healthy is hard! You are doing a great job, keep at it! ☺
15.	SCT	BEHAVIORAL Reinforcement	DIET	Culinary Knowledge	Cooking at home not only helps you save money, but is generally healthier than eating out because you decide how much sugar, salt and fat to add!
16.	SCT	Reinforcement	DIET	Encouragement	All of us here on the REACH OUT team are proud of the progress you have made. Keep up the great work! ☺
17.	SCT	Reinforcement	DIET	Encouragement	Stress can make eating healthy seem overwhelming and hard. Keep at your health goals and try to take it one day at a time! ☺
18.	SCT	BEHAVIORAL Reinforcement	DIET	Eating/ Ordering Out	Eating healthy at restaurants can be challenging. Most restaurants have their menus available online so try checking these out beforehand so you can plan for success even when eating out! ☺
19.	SCT	Reinforcement	PHYSICAL ACTIVITY	Exercising regularly is hard! You are doing a great job, keep at it! ☺	
20.	SCT	Social Support	PHYSICAL ACTIVITY	Accountability helps with sticking to eating healthy and being active! Find a friend, family member, or significant other that you can share your goals with to help keep you on track!	
21.	SCT	Social Support	PHYSICAL ACTIVITY	Work days are long and exhausting! Try turning your lunch hour into a daily walk! Bring along a co-worker and turn it into a social hour!	

22.	SCT	Knowledge	PHYSICAL ACTIVITY	An easy way to get more steps into your day is by opting to take the stairs over the elevator when you can!
23.	SCT	Outcome Expecta-tions	PHYSICAL ACTIVITY	Weight loss can be challenging! But maintaining a healthy weight can make it easier to do things like cook, work, and even play with your kids/grandkid! ☺
24.	SCT	Knowledge	PHYSICAL ACTIVITY	Winter can make getting outside challenging. If you find yourself struggling to be active outdoors, con-sider trying a new winter activity with friends like skiing, ice skating, or snow shoeing!
25.	SCT	Outcome Expecta-tions	PHYSICAL ACTIVITY	If your job involves a lot of sitting, try to schedule 15 minutes every couple of hours to walk around! Take the longer route to the bathroom, the stairs, or even a lap around the building!
26.	SCT	Reinforcement	PHYSICAL ACTIVITY	Stress can make exercise seem overwhelming and hard. Keep at your health goals and try to take it one day at a time! ☺
27.	SCT	Knowledge	PHYSICAL ACTIVITY	Try using commercial breaks while watching TV as a time to get up and get moving! Try doing some, lunges, jumping jacks or jogging in place!
28.	SCT	Knowledge	PHYSICAL ACTIVITY	Don't forget that being active can be more than going for a run or hitting the gym! Try gardening, biking, or even a walk to get yourself up and moving!
1.	SCT		MEDICATION ADHER-ANCE	It is very important to regularly take your BP medication, get help by asking people close to you to remind you. Often the more support you have the better!
2.	SCT		MEDICATION ADHER-ANCE	Don't forget to regularly take your BP meds, and do not stop any medications without talking to your health care provider first. Consistency is very important!
3.	SCT		MEDICATION ADHER-ANCE	Remember to take your BP meds every day. If you don't feel like your meds are making a difference, or you're having side-effects, your Dr can help, go see them!
4.	SCT		MEDICATION ADHER-ANCE	Often cost of BP meds are a challenge, but there are discount, BPmeds at many stores, such as Kmart, Mei-jer, Walmart, CVS, and Walgreens.
5.	SCT		MEDICATION ADHER-ANCE	Many stores like Kmart, Meijer, Walmart, CVS, and Walgreens provide discounted BP meds. Save money by checking to see if your BP meds are cheaper there.

6.	SCT	MEDICATION ADHER-ANCE	If you find yourself having trouble remembering to take your BP meds, use a beeping alarm or watch to remind you when a dose is due, and to keep consistency!
1.	SCT	Med Encouragement	It's not always easy to decide when it's time to start taking BP meds, but most people need meds in addition to exercise and diet to lower their high BP.
2.	SCT	Med Encouragement	Often cost of BP meds are a challenge, but there are discount, generic meds at many stores, such as Kmart, Meijer, Walmart, CVS, and Walgreens.
3.	SCT	Med Encouragement	Think about how important it is to you to lower your BP, then start taking small steps towards change. One important step may be beginning BP medication.
4.	SCT	Med Encouragement	If your healthy habits aren't enough to bring your BP below 140/90, you may need to take BP medication, and this is something a Dr can help you decide.
5.	SCT	Med Encouragement	It is important to consider talking about BP meds with a Dr. Most people who take pills for high BP need to take 2 or more kinds of pills that work together.
6.	SCT	Med Encouragement	If you are like most people with high BP, meds can play a major part in lowering your BP. It is between you and a Dr to determine the right plan.
7.	SCT	Med Encouragement	Though healthy life changes are key to lower your BP, it may also be key to take BP meds with a Dr. If you don't have one, you can call Hamilton 810-406-4246.
8.	SCT	Med Encouragement	Many stores like Kmart, Meijer, Walmart, CVS, and Walgreens provide discounted BP meds. Save money by checking to see if your BP meds are cheaper there.
9.	n/a	Coronavirus Impact	Have you been diagnosed with COVID-19 (i.e., coronavirus infection)? Have any of your family or friends been diagnosed with COVID-19 (i.e., coronavirus infection)? Have you had fevers, cough, runny nose, shortness of breath, cold-like symptoms, or flu-like symptoms in the last week? Have you received your flu shot this year?

Special Messages		
Welcome to REACH OUT- first text sent out to everyone	156	Welcome to REACH OUT! You will text in your BP once a week and get feedback/tips on how to better manage your high BP. Save this number into your contacts!
Weekly BP Survey Collection	157	This is your weekly reminder to take your BP and reply back to this message. If you have questions see your BP cuff instructions, and the REACH OUT handout.
Not real BP number- an unrealistic number was sent in.	153	The BP you sent in does not seem to be right. Your BP should setup like xxx/xxx. Refer to your BP cuff instructions, and the home BP measurement handout.
Reminder: Did not text in BP reading (After waiting 3 hours)	124	Remember to text in your weekly BP reading so we can create personalized messages for you this week based on your progress.
	152	Don't forget to text in your BP this week. If you have any questions about taking your BP see your BP cuff guide, and the REACH OUT handout we gave you.
	159	Remember to text in your BP reading so we can create personalized messages for you this week based on your progress. This is your last reminder for this week.
Text something other than BP	160	Remember: this is an automated messaging system, and texts other than your BP are not read. If you have questions ask your Dr. If this is an emergency call 911
Success Response: what to send back	159	REACH OUT has received your BP of **$current-blood-pressure.** Thank you for your response, now you can get personal messages on your most current BP for the week!

when they do enter a valid BP		
BP greater than 180/110	148	You recently reported a BP greater than 180/110, which is very high. Please contact a Dr. soon (at least within a few days) to have your BP checked. Note: Bottom number (diastolic) larger than top number (systolic) Parameters: top number (systolic) less than 70 or greater than 250 Bottom number (diastolic) less than 50 or greater than 140
If they were outside the BP parameters	158	You sent a BP that is very high or low. If this is right, please contact a Dr very soon to check your BP. If you sent it by accident, please text us a new BP.
If diastolic bigger than systolic	159	The BP you sent in does not seem to be right. Your BP should be like xxx/xxx. Refer to your BP cuff instructions, and the home BP handout. Please text new BP.
If they text back the same number	155	You recently sent a BP that is extremely high or low. If this was the actual reading given by the machine, please contact a Dr very soon to check your BP.
Closing		You have been in the research study, REACH OUT, for about 4 months. Please send in your final blood pressure through text message!

Appendix E – Flyer for Text Message Instructions

Appendix F – Reach Out Feedback

Name: _____ Date: _____

We took your blood pressure today as a part of your participation in the REACH OUT project.
Your blood pressure was: _____/_____.

What does your blood pressure mean?

Blood Pressure Categories			
$\frac{120}{80}$ or lower	$\frac{121-129}{80 \text{ or lower}}$	$\frac{130-179}{80-119}$	Above $\frac{180}{120}$
Normal Blood Pressure	Borderline Blood Pressure	High Blood Pressure	Hypertensive Emergency
Awesome! Keep up the good work!	Talk to your doctor about your BP at your next appointment. Consider eating less salt, more fruits/veggies and exercising more to lower your BP.	See your Dr about your BP within the next month. You may need to start or change medications to help lower your BP. Consider eating less salt, more fruits/veggies and exercising more to lower your BP.	You need to call your Dr right away! You likely need to start, change or take more of your BP medications If you have you have symptoms such as chest pain, weakness, difficulty talking or confusion call 911

Some things I can do to manage my blood pressure better/Goals I can set for managing my BP:

1) _____

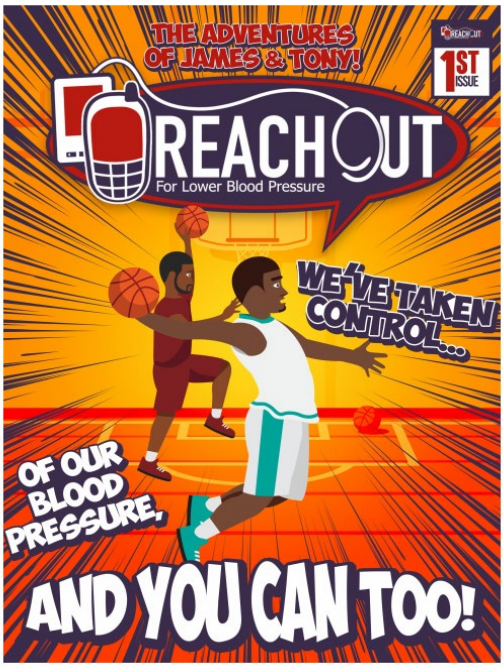
2) _____

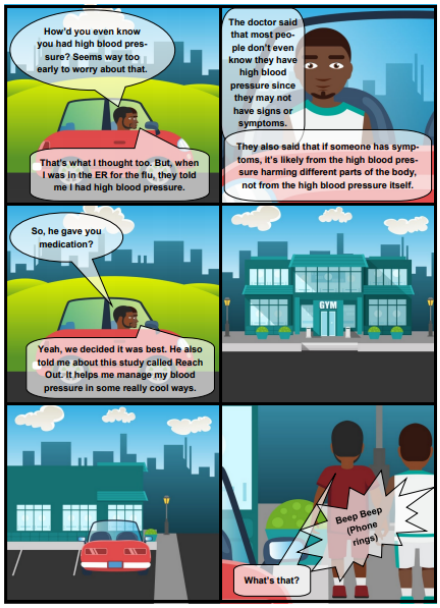
3) _____

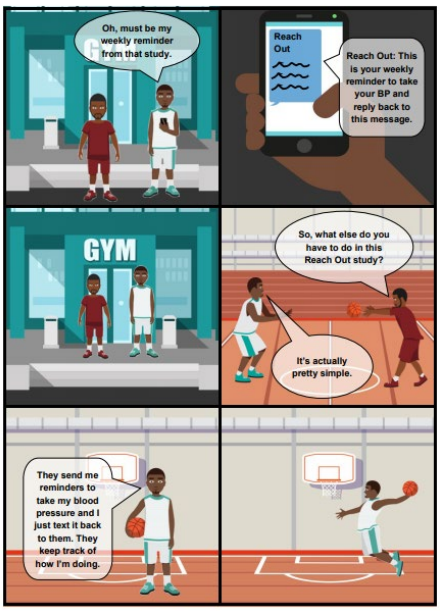
If you have questions about your blood pressure you should talk to your doctor. Your doctor will be able to answer your questions and set up blood pressure goals and treatments that are right for you.

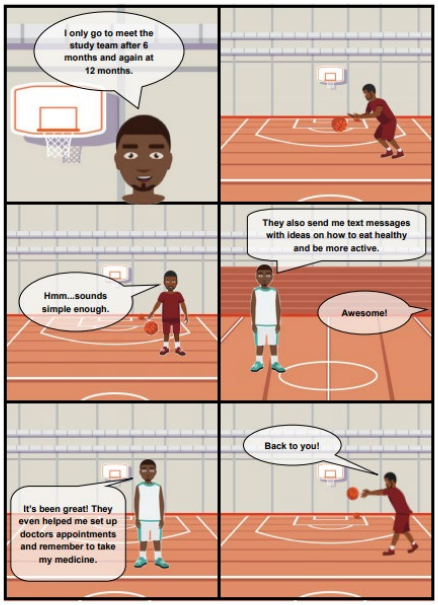
If you have REACH OUT study questions, contact (810)-337-8399.

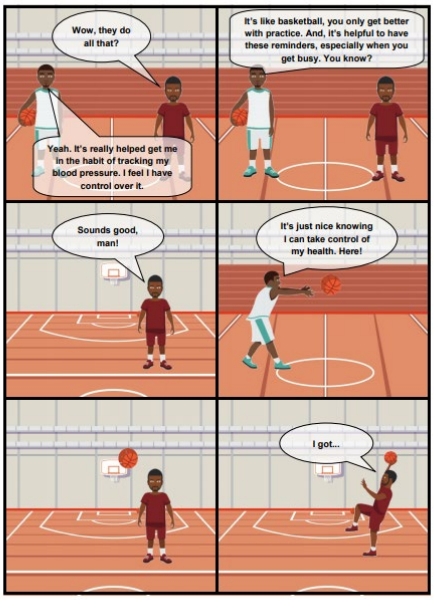
Appendix G – Comic Book

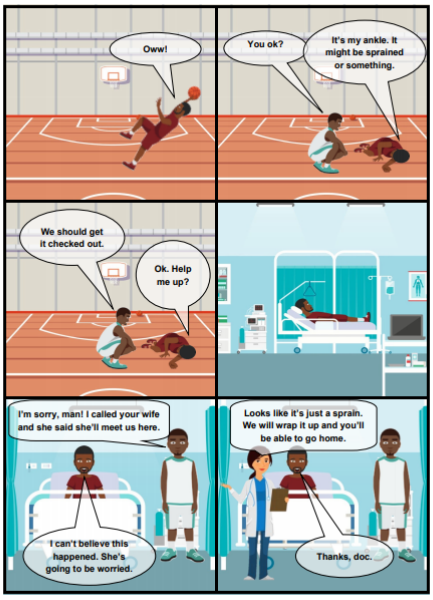







I only go to meet the study team after 6 months and again at 12 months.
Hmm...sounds simple enough.
They also send me text messages with ideas on how to eat healthy and be more active.
Awesome!
It's been great! They even helped me set up doctors appointments and remember to take my medicine.
Back to you!

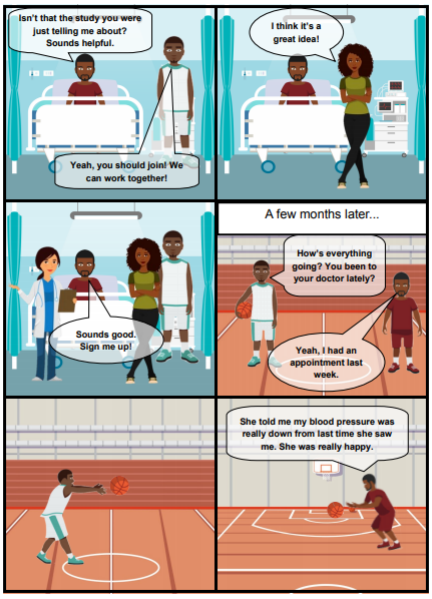

Wow, they do all that?
Yeah. It's really helped get me in the habit of tracking my blood pressure. I feel I have control over it.
It's like basketball, you only get better with practice. And, it's helpful to have these reminders, especially when you get busy. You know?
Sounds good, man!
It's just nice knowing I can take control of my health. Here!
I got...

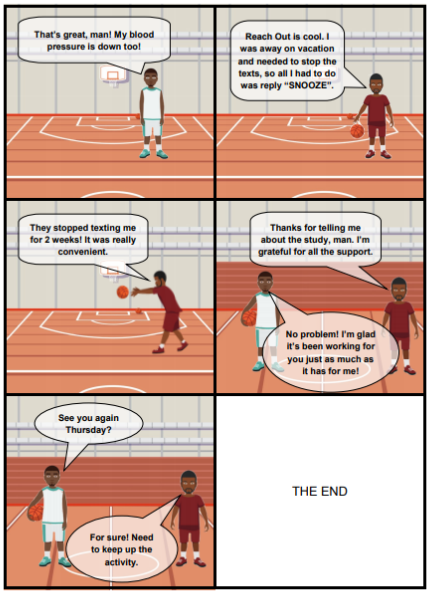

Oww!
You ok?
It's my ankle. It might be sprained or something.
We should get it checked out.
Ok. Help me up?
I'm sorry, man! I called your wife and she said she'll meet us here.
I can't believe this happened. She's going to be worried.
Looks like it's just a sprain. We will wrap it up and you'll be able to go home.
Thanks, doc.


Tony, you ok?!
I'm fine, Mary. It's just a sprain.
Is that true, doctor?
Yes, the ankle should heal quickly.
I did want to talk to you about something else though. I noticed that your blood pressure is higher than it should be.
How can that be? He's always been healthy.
Unfortunately, high blood pressure doesn't always show symptoms, but it's important to keep it under control.
Has your regular doctor ever talked to you about this?
Yeah, she has mentioned it. My friend was just telling me he has high blood pressure, but we're both so young...and I feel just fine.


What's so bad about having high blood pressure?
High blood pressure increases your risk for stroke and heart disease.
Wait, am I going to get sick? I have to stay healthy so I can be around for my kids!
The good news is that there's a lot you can do to help bring your blood pressure down.
Being more physically active is a good first step, but if you can make it a regular part of your routine, it would help even more.
I guess I can try to work out more often.


Another thing you could do is eat a healthy diet with more fruits and vegetables, less salt, and less foods high in fat.
If you smoke, quitting is a way to improve your health.
Also, if you drink alcohol, limiting to 1-2 drinks each day is another way to work towards getting your blood pressure back into the healthy range.
I'd also like to talk to you about this research study that's looking for participants.
They can help give you some tools and motivation to make healthy changes to lower your blood pressure.
REACH OUT
It's called Reach Out.


Isn't that the study you were just telling me about? Sounds helpful.
I think it's a great idea!
Yeah, you should join! We can work together!
Sounds good. Sign me up!
A few months later...
How's everything going? You been to your doctor lately?
Yeah, I had an appointment last week.
She told me my blood pressure was really down from last time she saw me. She was really happy.


That's great, man! My blood pressure is down too!
Reach Out is cool. I was away on vacation and needed to stop the texts, so all I had to do was reply "SNOOZE".
They stopped texting me for 2 weeks! It was really convenient.
Thanks for telling me about the study, man. I'm grateful for all the support.
No problem! I'm glad it's been working for you just as much as it has for me!
See you again Thursday?
For sure! Need to keep up the activity.
THE END

Appendix H – Provider Authorization

Provider Scheduling Authorization

Name _____ Date of Birth _____

Address _____ Phone Number _____

I am part of a research study, REACH OUT, which aims to lower blood pressure. One aspect of the study, is that REACH OUT may assist in scheduling appointments for me with my primary care provider.

By signing below, I hereby acknowledge that I am allowing study team members of REACH OUT permission to call my primary care provider on my behalf, and schedule appointment. I acknowledge that this form may also be given to my primary care provider office and be kept on file as documentation of this permission.

Participant's Signature _____ Date _____

Appendix I- Holiday Card Study Within A Trial

Introduction and Background

Holiday cards are frequently sent to research participants, yet the impact of this practice is not clear. The intended result is to maximize retention and maximize the amount of follow up data collected from participants on protocols. The trials group at the University of York, UK has organized the Christmas Card study within a trial (SWAT). Professor David Torgenson is the lead investigator. This SWAT has been registered as "SWAT 82: Sending Christmas cards to trial participants to improve retention – studies within trials (SWATs)" and has the Prometheus reference MR/R013748/1/SWAT 82 and was approved by the Yorkshire & The Humber – Leeds West Research Committee under project ID 27054.

Within the main protocol of REACH-OUT, sending retention materials is allowable. We propose to use this SWAT methodology to send holiday cards (Appendix J) to a random sample of participants currently active on the REACH-OUT protocol.

No data with protected health information or personal identifiers will be transferred outside of the REACH-OUT. Aggregate response rates per arm of the SWAT will be shared to the organizers of the SWAT in York.

Design

Inclusion:

The launch date is pending approval of this amendment, but we anticipate sending the cards in Winter 2020. All subjects currently active on the REACH-OUT protocol are eligible.

Exclusion:

Participants who have withdrawn from follow up visits.

Intervention:

We will create a randomization list of the current REACH-OUT participants, stratified by randomization group assignment (groups 1-8 will each have 1:1 randomization to holiday card versus no holiday card). In addition, within each of the 8 treatment groups, we will further stratify randomization of the holiday card by gender and age (<65 versus >65). Cards will be mailed.

Analysis – From SWAT:

The primary endpoint is retention – defined attendance at the next follow up visit. The secondary endpoints are cost per participant retained and response rate.

Subgroups will be identified for reporting, including those with an appointment within 30 days of expected delivery of the card, those who have 1st or 2nd visit next, and those who did not return the previous 4-week survey.

We will report proportions and differences in proportions with 95% confidence intervals for the primary endpoint and repeat this for all subgroups, including gender and age.

Analysis – Additional Specific to REACH-OUT

We will estimate additional subgroups using the defined stratification variables of REACH-OUT

The REACH-OUT specific primary endpoint is text-messaging engagement. This is a count variable, which for the 4 weeks prior to and after the expected card delivery is defined as the number of blood pressures reported by text over the number of blood pressures that were requested. Participants near the beginning (less than 4 weeks in) or end (less than 4 weeks from final visit) of REACH-OUT will be excluded from this analysis. The main analysis of this will be using repeated measures binary logistic regression with a random effect. Each participant will have a line of data for each eligible blood pressure request. We will include an indicator variable for REACH-OUT assigned frequency of texts (weekly versus every other day) and SWAT group assignment (will be one in participants who were sent a card, for the eligible BPs that occurred after estimated receipt of card, and will be zero in all participants not randomized to card, and will be zero for all pre-delivery texts in the group randomized to card.) A random intercept for individual will be included. In addition, we will add a variable to account for the number of weeks before or after the estimated delivery of the card. Depending on model fit and number of observed outcome events, we will add in adjustment for the other two main REACH-OUT interventions (healthy behavior texts versus none, PCP facilitated transportation versus none), along with the gender, age, and pre-existing hypertension medications baseline stratification variables from the main REACH-OUT study.

Appendix J- Holiday Card

Appendix K- Outcome Reminder

Version 1.0 1.31.2020

Hello from Reach Out!

Thank you so much for taking part in Reach Out! We are delighted to walk with you on your journey to reduce your blood pressure.

It is time for your 6-Month Reach Out visit. This is a meeting with someone from our study team where we will take your blood pressure and complete a survey. It will take about 20 minutes, and you will be given $25 for your time. Please drop in anytime:

Flint Farmer's Market XXAM-XXPM DATE.

If you are unable to meet on DATE, we will contact you to schedule another time and location to meet.

Please call or text 1-810-337-8399
to pick a day and time!

These visits are important for our study, so that we can know how you are doing. Thank you for your time and participation in Reach Out!

Sincerely,

Lesli, Will, Mackenzie, Zahera, Candace, Adam, Deborah, Louis

Appendix L- Newsletter Outline

REACH OUT
For Lower Blood Pressure

February 2020
Volume 1, Issue 1

Dear Reach Out Participant,

We want to update you on the progress of the Reach Out study and thank you from the bottom of our hearts for your continued support and participation. This newsletter contains info about:

- Outcome Visits
- Staff spotlight

Reach Out began recruitment in 2019. We have had an overwhelming response. We have enrolled over 800 participants. We are beginning doing 6 and 12 month outcomes.

Outcomes: Call us!

Please remember that we would love to meet with you after 6 months and again at 12 months to have a 20 minute visit to see how you are doing. At 6 months you will get $25, and at 12 months you will get $30. These visits are important for our study, so that we can know how you are doing. Please drop in anytime:

Please call or text 1-810-337-8399 to pick a day and time!

Flint Farmer's Market XXAM-XXPM DATE

If you are unable to meet on DATE, please call or text to pick a day and time!

Staff Spotlight: Candace!

It's amazing to see how awesome Reach Out is being received by the Flint Community. During a routine visit to my local Flint nail salon, I was chatting with my nail tech about work and how things had been going since moving to the area.

Another customer in the salon, overheard our conversation and been expressing her appreciation for Reach Out and how much she enjoyed the program.

She detailed the text messages received and the healthy life style tips she acquired. Her testimony sparked more conversation amongst others in the salon, and before I knew it everyone was asking me how they could sign up! It was incredible to hear how much we were influencing one particular person, but also to see the potential impact we could have on the community.

J U F V R N M Y T B P F B
M E D I C A T I O N L L S
N N L Y V Z O X F I O Y E
N D O P H M H K N O U R L
T O F I R T A T D F E E B
S C V X T R L P V X X A A
K T K O M A R A E V Z C T
N O I S N E T R E P Y H E
O R S S S R C I N H V O G
N Z P S R I S I D D S U E
C C U M S H U R L E Y T V
A R J E T X E T W J M U B
E B O J T A E R G C G Y L

BLOODPRESSURE
DOCTOR
EXERCISE
FLINT
GREATJOB
HEALTHY
HURLEY
HYPERTENSION
MEDICATION
MEDITATION
REACHOUT
TEXT
VEGETABLES

Appendix M- Tele Outcome Reminder

Version 1.0 3.20.2020 HUM00138470/ 1199877

Hello from Reach Out!

Thank you so much for taking part in Reach Out! We are delighted to walk with you on your journey to reduce your blood pressure. The COVID-19 pandemic has caused Reach Out to change the way we are going to check-in with you. For your safety, we are going to collect your outcomes via picture and text message rather than in-person.

It is time for your 6-Month Reach Out outcome measurement. It will only take a few minutes and you will get $25 for your time! Detailed instructions are on the next page.

These outcomes are really important for our study. They help us understand how you are doing and learn your thoughts on how Reach Out works for you.

Thank you for your time and participation in Reach Out!

Please call or text 1-810-337-8399 with questions!

Sincerely,

Lesli, Will, Mackenzie, Zahera, Candace, Adam, Deborah, Louis

Version 1.0 3.20.2020 HUM00138470/ 1199877

Hello from Reach Out!

Thank you so much for taking part in Reach Out! We are delighted to walk with you on your journey to reduce your blood pressure. The COVID-19 pandemic has caused Reach Out to change the way we are going to check-in with you. For your safety, we are going to collect your outcomes via picture and text message rather than in-person.

It is time for your 12-Month Reach Out outcome measurement. It will only take a few minutes and you will get $30 for your time! Detailed instructions are on the next page.

These outcomes are really important for our study. They help us understand how you are doing and learn your thoughts on how Reach Out works for you.

Thank you for your time and participation in Reach Out!

Please call or text 1-810-337-8399 with questions!

Sincerely,

Lesli, Will, Mackenzie, Zahera, Candace, Adam, Deborah, Louis

Appendix N- Tele Outcome Guide

Instructions for Outcomes

It is time for your 6– month outcome! It will only take a few minutes. You will be mailed $25 for completing the outcome. For assistance, questions, concerns or you would like a Reach Out Team member to walk you through the outcome, feel free to call Reach Out at (810) 337-8399.

What you need to do!

1 Step 1: Take a photo of yourself wearing the blood pressure cuff!

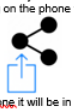
1. Open your camera app.
2. Place the blood pressure cuff on the inside of your wrist.
3. Aim the camera towards your wrist with the cuff on it.
   i. We only need to see your wrist and that the cuff is on your wrist. We do NOT need to see your face.

4. When you're ready to take a photo, tape the shutter button located in the middle of the screen to take the photo.

Version 1.0 3.20.2020 HUM00138470/ 1199877

2 Step 2: Send us that photo!

1. Open your camera app.
2. Tap the picture you'd like to text.
3. Tap the share button on your screen. This looks different depending on the phone you are using.



   i. If iphone it will be in the lower left corner
   ii. If android it may be in the middle of the top of your screen.

4. **Send your photo to (810) 498-2266.**

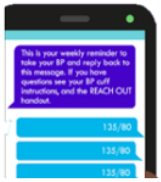
If you have any trouble at all, call us! (810) 337-8399

3 Step 3: Text us 3 different blood pressures (xxx/xxx)!

1. Take your blood pressure using your blood pressure cuff. Follow the instruction sheet for taking your BP.
2. Text your BP to (810)- 498-2266 as XXX/ XXX.
3. Follow the instructions sheet for text messages.
   a. This is a text message and does not have to be a picture.

Version 1.0 3.20.2020 HUM00138470/ 1199877

4. Do this 3x so you are sending us a total of 3 blood pressures to Reach Out!



You will receive a confirmation that your outcome was completed within 24 hours.

Congratulations, you are all done!

Thank you for completing your 6-month outcome with Reach Out! You will receive your $25 incentive within 10-20 business days. To confirm your address, call or text Reach Out at (810) 337-8399.

If you have any trouble at all, call us! (810) 337-8399

Thank you!

Lesli, Will, Mackenzie, Zahera, Candace, Adam, Deborah, Louis

Appendix O- Telephone Consent Script

Screening Phone Recruitment Script:

Hello, my name is _____ from the University of Michigan and Hurley Medical Center. Am I speaking to _____?

I'd like to tell you about a research study that uses text messaging to help you lower your blood pressure (BP), and then ask you a few questions to see if you are interested and eligible to participate in the study.

Taking part in this study is completely **voluntary**. You do not have to take part if you don't want to. Your medical treatment will not be affected in any way if you choose not to take part. You may also leave the study at any time. If you leave the study before it is over, you will not lose any benefits to which you are owed.

(Purpose of the study) We are asking you to be in this study because you were a patient in the ER of Hurley Medical Center recently, and while you were there, had elevated BP. Many people have high blood pressure. We are doing this study because we want to know if sending text messages and reminding people to check their blood pressure can help people to lower their blood pressure. People who volunteer to be in this research study will be asked to complete some surveys about yourself, and you'll be asked to take your own blood pressure throughout the study while receiving text messages.

Would you be interested in hearing more about our study and how you can help? *[If yes, continue with script. If no, thank the patient and code him/her as a screen refusal]*
Great!

I have a few simple questions to ask to first.

Can you confirm your last name? And the month and year you were born?

Thank you!

[If PT gives information that matches the medical record, continue with script. If the information does not match/ the person on the phone is NOT the patient, ask the person on the phone if they know the patient, and a better time or way to contact them]

Are you 18 year of age or older?
[If yes, continue with script. If no, thank the patient and code him/her as ineligible]
Do you have a cell phone with the ability to text-message and willingness to receive texts?

[If yes, continue with script. If no, thank the patient and code him/her as ineligible]

Are you able to stay home alone for 24 hours?

[If yes, continue with script. If no, thank the patient and code him/her as ineligible]

Unable to read English

[If no, continue with script. If yes, thank the patient and code him/her as ineligible]

Prisoners

[If no, continue with script. If yes, thank the patient and code him/her as ineligible]

Pregnant

[If no, continue with script. If yes, thank the patient and code him/her as ineligible]

Pre-existing condition making one year follow-up unlikely

[If no, continue with script. If yes, thank the patient and code him/her as ineligible]

Current use of 3 or more antihypertensive agents

[If no, continue with script. If yes, thank the patient and code him/her as ineligible]

Any other serious medical conditions that prevent self-monitoring of BP

[If no, continue with script. If yes, thank the patient and code him/her as ineligible]

Dementia/cognitive impairment

[If no, continue with script. If yes, thank the patient and code him/her as ineligible]

You qualify for the study, are you interested in hearing more?

Informed Consent Phone Script:

(Information about Study Procedures) If you agree to participant in the study, you will start by completing a survey telling the research team about yourself.

Once in the study, you will also be given materials about BP. A BP monitor will be given to you to use to take your BP at home. You will be taught how to take your own BP using the monitor given, and how to text these results back to the study team

On a weekly basis for 3 weeks you will receive text messages reminding you to take your BP. You will then take your own BP and to text the results back to the study team. If during the 3-week period you still have high BP, the REACH OUT Program will start. There are three different types of text messages you could receive while participating in the REACH OUT program 1) healthy behavior texts; 2) reminder texts to take your BP at home; 3) texts to help with primary care provider appointment scheduling and transportation.

It is possible that you might receive all of the types of text messages, or only one type. The type of texts and how often you receive them will depend on what grouping you have been randomly assigned to. You may receive several messages from the study team in one day.
Follow-up visits will occur at 6 months and 12 months and may be in-person or virtual. At these visits, your BP will be measured by the REACH OUT team. You will also be asked to complete additional surveys.
At the end of the study period, some participants may be asked to participate in a focus group so we can learn about your opinions on REACH OUT. We may ask you by telephone, or in person to participate. We may record and will write down notes about what is said during these interviews so that we have a record and can accurately remember your opinions about Reach out.
This program does not replace your usual health care. If you have a problem or question about your blood pressure or medical problems, you will still need to contact your healthcare team.
We expect the amount of time you will participate in the study will be about 12 months.
(Risks and Potential Benefits of the Study) There can be risks associated with joining any research study. For this study, some of these risks may include asking you about your current recorded BP. The messages are meant to be motivational, but there is a small chance you may be distressed by them. You do not need to answer any question that you don't want to, and you can stop the text messages at any time. There is a small chance that participants in this study could have information about their health status, such as information about their BP levels, or general health activities, given to people they don't want to know.
You also need to understand that all information received from you will be confidential and will be kept under lock and key or secure, password protected documents and computers. Your name will not be kept with your answers. Your name will not appear in any reports.

As with any research study, there may be additional risks that are unknown or unexpected.

This study may not offer any benefit to you , but may benefit others in the future by helping us gain important information about how to help people manage their high BP.
(Financial Information) You will be given an automated BP cuff and $20 at your enrollment. You will be given $25 after completion of your 6-month follow-up visit, and $30 after completion of your 12-month follow-up visit. REACH OUT will provide transportation, if needed, to the 6 month and 12 month visits. Some participants may also be provided transportation to their primary doctor for REACH OUT appointments. Participants asked to participate in the focus groups may receive food and up to $20 following completion of the session. Payments will be in the form of cash or a gift card.
(Confidentiality) You may be worried about the confidentiality of your information. We won't share answers with anyone except the researchers of this study. The risks to participating are minimal, but there is risk associated with transmitting data, including loss of confidentiality.

Taking part in this study will involve collecting private information about you. If there are physical copies of your information, it will be stored in a locked area, accessible only to research staff, and will not be made part of your medical record. Your research information will be entered into a password protected computer and your name will be separated from the data. We will not share data that identifies you with anyone outside of the study. The study uses a SSL encrypted web-based application with secure log-ins to access. There is a very small risk that someone could obtain your contact information from the study website.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research, or for any purpose you have consented to in this informed consent document.

Consenting to this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results and dental records
- Any records relating to condition, the treatment received, and response to the treatment
- Demographic information
- Personal identifiers

The results of this study could be published in an article, but would not include any information that would let others know who you are.
(Contact Information) I will provide you with our study cell phone, email and other direct contact information if you have any questions about the study or if you want to withdraw from the study. I will also provide you with contact information for the University of Michigan Institutional Review Board and Hurley Medical Center's Institutional Review Board if you have any questions about your rights and responsibilities as a research participant. This contact information is on the copy of the Consent form which has been texted, emailed, or mailed to you.

(Consent) Do you have any questions, comments or concerns? Remember, your participation is voluntary.

(*If patient consents to participate in the study with no further questions, pursue consent*)
Great, so the final thing is getting your consent as documentation that you have heard the informed consent for this study, and are agreeing to participate.
If you agree to participant in this study, please reply "yes" to the question. I will record your answer.
(*If patient says yes, record answer; legal name; date; time)*
Please answer the following questions. I will record your answer.

I have had the opportunity to ask questions and have those questions answered to my satisfaction.
(*Record answer)*
I would like to receive follow-up newsletters and information regarding Reach Out after completion of the study.
(*Record answer)*

If asked to participate in the post-study focus group, I agree to being recorded during discussion.
(*Record answer)*
How would you prefer to receive a copy of this consent document (email, postal mail, etc)?
(*If patient says email, record this email address and send consent form to participant. If patient says address, record this address and send consent form to participant)*

Appendix P- Remote Recruitment Letter

Version 1.0 4.20.2020

HUM00138470/ 1199877

Dear _____,

You are invited to participate in a new study called Reach Out for the University of Michigan and Hurley Medical Center REACH OUT is a research project to help you to reduce your high blood pressure through text messages.

You were selected to help because you are 18 years or older, and were recently a patient at Hurley's ER. Participation in this study is completely voluntary and confidential.

To see if you qualify for the study, give us a call at (810)-337-8399

To participate in the REACH OUT project, you will need to…

- ☐ Be 18 years or older
- ☐ Have a cell phone that can send and receive text messages

After calling (810)-337-8399, and finding out if you are eligible for the study and if you agree to join the study, there are a few more activities that we would ask you to do over the next 12 months. You will receive more information once you qualify about what the study will involve, but to briefly summarize…

You will receive payment for participation in the study, which includes:

- ☐ Survey at enrollment
- ☐ Follow-up visit at 6 months and 12 months
- ☐ Be willing to receive and send text messages
- ☐ Take your blood pressure and text it to REACH OUT

Will I be paid for my time?

When you sign up, you will be given a free blood pressure cuff and $20.

- o At 3 weeks you will be sent a text message letting you know if you will continue in REACH OUT, or will no longer get text messages.

Those that continue in REACH OUT can earn an additional:

- o $25 at the 6-month follow-up
- o $30 at the 12-month follow-up

If you have any questions about the study or are interested in enrolling, please call/text us at 810-337-8399!

Sincerely,
[Staff Member's Name and Job Title]
Phone: 810-337-8399

Appendix Q- Supplement: Reach Out Cognition

Introduction and Background

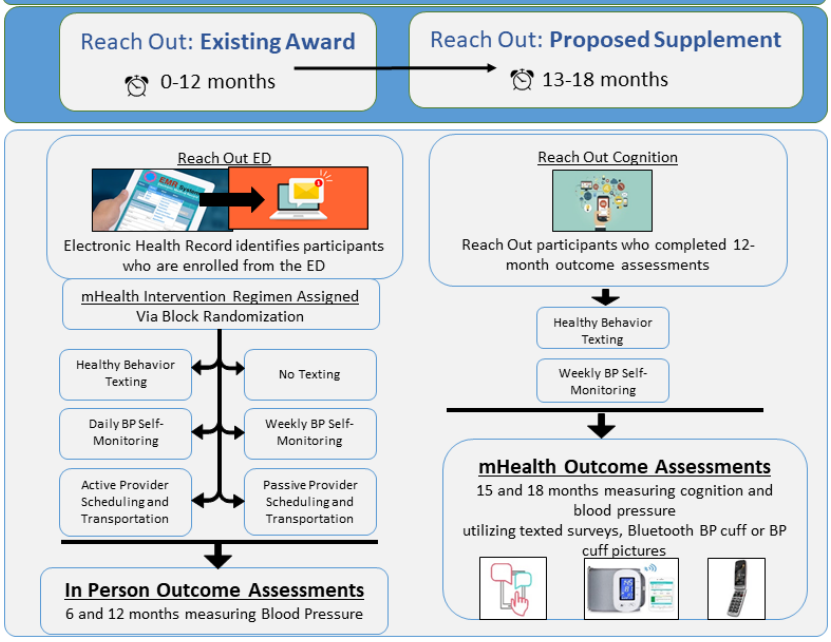
We propose Reach Out Cognition which will extend Reach Out data collection past the current 12 months to 15 and 18 months. During Reach Out Cognition, we aim to assess novel approaches to mobile health (mHealth) self-administered cognition and blood pressure (BP) measurements. These approaches may include cognitive assessments via mobile applications (apps) and Web-based surveys, and wireless BP measurements via Bluetooth-enabled blood pressure cuffs and apps. The launch date is pending approval of a supplement and/or amendment and participant completion of the parent study 12-month outcome assessment (we anticipate July 2020).

Design

Recruitment:

The study population for Reach Out Cognition will be drawn from Reach Out participants who complete the Reach Out intervention and are defined as: participants who complete the 12-month outcome assessment. We anticipate about 240 participants will have completed Reach Out's 12-month outcome assessment and will be eligible for Reach Out Cognition. At the time of the final (12-month) outcome assessment, participants will be introduced to the opportunity of continuing for another ~6 months with the added mHealth measures.

Figure 1: Overview of Reach Out Existing Award and Proposed Supplement



Inclusion:

Participants of the Reach Out protocol that are no more than 6 months after completion of their 12-month outcomes are eligible. A subset of Reach Out participants will not have smartphones. However, our goal is inclusivity and generalizability and will allow for inclusion of all cell phones with the capability to send picture text-messages. Thus we designed Reach Out Cognition with the capability to include these participants, albeit outcome assessments procedures will differ.

Exclusion:

Participants who have withdrawn or not completed follow up visits.

Screening:

Prior to consent, participants may be screened for baseline cognition via the mini-Montreal Cognitive Assessment (MoCA) or similar. This would be preceded by verbal screening consent (Appendix V). Participants may either be given a feedback sheet in person, via postal mail, or text message to link regarding their MoCA score if fully completed (Appendix S). If score <11, or similar test specific cognitive threshold, we will state the MoCA suggested response to this range, and participant will not be consented for the study. It will be suggested that participant may wish to share the MOCA score with their doctor to discuss memory and thinking. Participant's doctor will be able to answer questions and decide whether more testing or treatments are right. These tests are not diagnostic.

Consent:

If 12-month outcome is in-person, and the participant agrees to continued participation, an informed consent will be signed (may be electronic and built into redcap as previous informed consent) by the participant before any study procedure is done.

However, in the time of COVID-19, the consent process and subsequent surveys may also be done virtually, if performing a 12-month outcome via tele-outcome per Reach Out protocol. In this circumstance, we would perform remote recruitment and consent. The research staff will follow a phone consent script (Appendix R), this may be done with whatever means best possible for participant (telephone, video, etc). The research staff will ask for the last name, and month and year of birth as confirmation that we are speaking to expected patient. Only once confirmed, will the research staff begin the process of consent. The consent process will be performed by the research staff in a private environment to provide the most privacy possible. The research staff will explain the study to participants during the consenting process. Interested participants will be enrolled in the study after providing verbal consent (for remote recruitment). The research staff will discuss questions with the participant, and research would only begin after informed consent is obtained.

For participants who are within 6 months of their 12 month visit but have completed their 12 month outcome visit prior to approval of this amendment, we may attempt to re-contact them to perform remote recruitment and consent.

For feasibility reasons, within our already approved waiver of hipaa authorization, we add waiver of documentation of informed consent to allow for the study enrollment consenting to be obtained in multiple ways (i.e., in-person when feasible, or verbal consent for those completing remotely).

We will give the participant a copy of the informed consent document. Given this is a study of no more than minimal risk of harm, and seeking in-person written consent may prove more harmful to participants, we will also seek a waiver of documentation of consent in the case tele-outcomes are being done. In this circumstance, we would read an informed consent script over the phone, discuss questions with the participant, and research would only begin after participant

verbally consents. All following enrollment training discussed would then be done over the phone or through video services, and materials would be either emailed, texted, or postal mailed to participant.

Enrollment:

After enrollment participants may complete a brief survey assessing their eHealth literacy via the eHealth Literacy Scale or similar and baseline cognition via the Self-Administered Gerocognitive Exam (SAGE). Participants will either be given a feedback sheet in person, via postal mail, or text message to link regarding score, which may only be sent out if the survey is fully complete, or it is determined than an appropriate score can be calculated based on missing values (Appendix S). If score <17, we will state the SAGE suggested response to this range. It will be suggested that participant may wish to share the SAGE score with their doctor to discuss memory and thinking. Participant's doctor will be able to answer questions and decide whether more testing or treatments are right. These tests are not diagnostic.

Participants will receive a BP arm cuff and incentives for completing the outcome assessments. They may also receive materials helpful in technology assistance and instructions. These may be mailed or emailed to participants if performing tele-outcomes.

At enrollment, participants will undergo about a 60-minute technology introduction tailored to if they have a smart phone or a feature phone. Reach Out Cognition assessments will differ based on whether the participant has a feature phone or smartphone (Table 1). If participant phone capabilities change throughout the duration of the study, we will work with them to re-train on their new phone.

- Feature phones include capabilities such as built-in cameras.
- Smartphones, in comparison, have touch-input and advanced computing software, in addition to built-in cameras, apps, and Web-browsers.

Participants will receive a Bluetooth-compatible BP monitor, the Omron Evolv Wireless Upper Arm Home BP Monitor or similar model which may depend on phone capability.

Table 1: Overview of Reach Out Cognition and BP Assessments

Data	Smartphone	Feature Phone
SAGE	Texted survey for phone-use	Texted survey URL for browser-use
Neuro-QoL	Texted survey for phone-use	Texted survey URL for browser-use
BP	App and Bluetooth BP cuff	Texted BP with photograph

We will review procedures and trainings for all groups and phone capabilities. Those with smartphones may download the necessary app associated with the Bluetooth-compatible BP monitor. This will allow participants' blood pressures to directly sync the BP cuff to the app.

Participants with feature phones will be trained on how to photograph the process of obtaining BP measurements and how to submit the picture via text to the study team. While, ideally it would include the BP measurement, we are most interested in confirming the BP cuff is on the participant's arm as a measure of validity of the measurement. The picture does not have to include the persons face or any identifiers.

We will also review best practices for BP measurements. Participants will receive a text to an online survey link for survey questions. This link can be used directly, or typed into a web-browser. The participant and the study coordinator may complete a mock round of cognitive and BP measures in the practice environment to identify and solve any technological issues. If enrollment is not able to be done in-person, training would then be done over the phone or through video services, and materials would be either emailed, texted, or postal mailed to participants. We will have participants download the app (if able) while we are communicating with them, so we may train them in set-up and use of both app, text messages. We will postal mail the blood pressure monitor to participants, and then may also have another virtual training with participant in blood pressure monitor use.

We will also have resources and trainings available on the Reach Out website (reachouted.com) accessible to participants (for example, Appendix T and Appendix U).

Intervention

Participants who agree to continue in Reach Out Cognition will continue to receive the Reach Out intervention at a moderate intensity; this may include daily healthy behavior text messages and weekly prompted blood pressure self-monitoring. We elected to forego facilitating the primary care appointment scheduling and transportation as that was not automated and thus requires substantial study team resources and is not consistent with Reach Out Cognition's solely mHealth intervention.

Reach Out Cognition, will extend data collection to include 15 and 18 month assessments +/- 45 days for contact for outcomes. These assessments may include mHealth cognition and blood pressure assessments (Figure 1). Cognitive measures may be assessed using two different validated measures (or similar methods): 1) SAGE; and 2) Neuro-QoL-Cognition (Quality of Life in Neurological Disorders). Self-reported blood pressure outcomes will be based on either pictures or a Bluetooth-enabled BP cuff.

Outcomes (smartphone and feature phones)

At around 15 and 18 months, participants will receive reminder text message(s) and/or email(s) to complete a survey link and/or variations of computer adaptive assessment, or paper copies of survey, to either be mailed back or take a pictures and text/ email to return. In either scenario, the survey information does not contain sensitive information, and our attempt is to be flexible in receiving outcomes as is preferable and feasible from participants. The survey link may directly import data into RedCap or another equivalently secure database. Participants may also be

mailed and called as reminder(s) for these outcomes, and to assist with technology troubleshooting.

Participants with smartphones will be sent a reminder text message to complete a Bluetooth enabled BP measurement. In order to get the data, we will train participants on how to download their data via the Bluetooth app, and send the data to the study team either text or email to a secure study team email. If the sending of data method is unavailable, or is found to be too difficult for participants, the study team will conduct an in-person or virtual outcome visit to download final blood pressures from the Bluetooth app or collect BP measurements over the phone.

Participants with feature phones will be sent a reminder text message prompting the photograph blood pressure procedure. We will ask the participant to include a photograph of themselves taking their blood pressure when they text in their BP. We will instruct participants to send the picture, and text message 3 blood pressure measurements. Participants will be instructed to take 3 consecutive measures and adhere to the American Heart Association best practices for measuring blood pressure. This will be done via secure texting via Mosio. If the sending of data method is unavailable, or is found to be too difficult for participants, the study team will conduct an in-person or virtual outcome visit to for assistance or collect BP measurements over the phone.

Participants who do not respond to outcome requests or indicate technical difficulties, may be contacted by the study team via phone or text to troubleshoot.

Participants may be contacted to invite them to participate in other mHealth or stroke prevention trainings, if interested.

Throughout the duration of the intervention, the study team will attempt to support and connect with the participants as able. All resources, materials, and methods of contact are included as appendices or standards in the protocol, and will be submitted to the IRB as outlines. However, time sensitive information, and content may change as needed to better communicate and stay up to date with participants, especially given COVID-19, and the changing standards of interactions. Given the topics and theme of the content will remain consistent, we will not submit changes to the IRB unless there are significant additions or deviations from topics or methods.

Data Security

Reach Out will use a secure, password-protected web-based application, REDCap and/or qualtrics, for data collection and surveys. The text messages and picture messages are within a SSL encrypted web-based application with secure log-ins to access. The Bluetooth app is subject to the terms and conditions of the particular company, which will be presented to the participant. The data being utilized on these apps (blood pressures) will only be connected with personal information if the participant chooses to use their name and email in the profile description and sharing capability. Regardless, additional personal identifiable information will not be associated with the blood pressures or the app from Reach Out. Additionally, any data submitted by participants via direct download from BP app and sent to study team by email correspondence will be through a secure study team email. Only Reach Out study team members will have access to the study email account. All data submissions received on the study email account will

be transferred to the password-protected database. All Reach Out study team members will receive data security training.

Outcomes

We will measure acceptability, feasibility and satisfaction which are necessary for large scale use of mHealth BP and cognition measures. We will use these scales or similar validated measures of acceptability, feasibility and satisfaction.

Acceptability is the perception among participants that the mHealth assessments are achievable and agreeable. Acceptability will be assessed by the proportion of Reach Out 12-month outcome participants who continue into Reach Out Cognition.

Feasibility is the extent to which the mHealth assessments can be successfully carried out. Feasibility will be assessed by the proportion of participants who complete the mHealth cognitive assessment and the BP assessments separately. We will declare feasibility if greater than 50% of participants provide at least one cognitive measure.

Satisfaction is the perception that upon completion of the mHealth assessments participants found them agreeable. Satisfaction will be measured with a text survey to all participants. The satisfaction survey is 4-item, written at a 5th grade reaching level and takes less than 5 minutes to complete. Responses are a 5 item likert scale. In addition, we may invite a subset of participants to participate in a focus group.

Focus Groups

To assess participant satisfaction with mHealth self-administered cognitive and blood pressure measures, we may conduct up to 4 focus groups of about 10 participants each of Reach Out Cognition. We anticipate the focus group to last about 60 minutes and will be conducted at a location convenient to the participants or virtually via secure means provided by the University of Michigan (https://safecomputing.umich.edu/dataguide/?q=home). Focus groups will be based on a semi-structured interview guide. Given this is minimal risk, and conversational, this will not be submitted to the IRB. During the focus group team members will assist in taking structured notes. Participants will be given $25 in appreciation of their time.

Analysis

Descriptive statistics will be used to evaluate acceptability, feasibility and satisfaction. The denominator is the number of Reach Out participants who complete the 12 month assessments. Regarding feasibility, we will separately determine the feasibility by mHealth measure (i.e. cognition vs. BP), phone type (i.e. smartphone vs. feature phone) and operating system type (iOS vs. Android vs. Windows) as a continuous and dichotomous (>50% completion of each assessment type) measure. The satisfaction scale will be assessed for all participants. Given the difference in procedures by phone type, we will compare satisfaction between the smartphone and feature phone users using a Kruskal-Wallis test.

Minorities and women: Per NIH policy, the primary outcomes will be analyzed for evidence of differential treatment effects in subgroups determined by sex/gender, race, and ethnicity.

Upon recruitment during the parent study final outcome visit, we may collect a Montreal Cognitive Assessment (MoCA). We anticipate that approximately 10-20% of our participants will have previously undiagnosed mild cognitive impairment. In addition, using the Neuro-QOL cognition battery, we will determine how much the Reach-Out Cognitive cohort differs from the expected values for the patient reported outcomes. Using existing data on trajectory of change in MoCA based on age, we will develop estimates of the likely cognitive status of ED patients with hypertension 12 months prior to enrollment in Reach Out Cognitive (i.e. at the time initially seen in ED and enrolled in the parent Reach Out trial).

Appendix R- Supplement: Telephone consent script

Screening Phone Recruitment Script:

Hello, my name is _____ from the University of Michigan and Hurley Medical Center. Am I speaking to _____?

I'd like to tell you about a way that you could continue to participate in Reach Out for about another 6 months. In this research study, you will continue to receive some texts from Reach Out and will be asked to take your blood pressure weekly.

(Purpose of the study) The purpose of this study is to see whether mHealth (mobile health) interventions can help lower blood pressure. High blood pressure, can lead to a stroke and heart attack and affects about 78 million Americans. We are asking you to be in this study because you were a participant in Reach Out.

People who volunteer to be in this research study will be asked to complete some surveys about themselves, and to take their blood pressure using a Bluetooth blood pressure cuff or by taking a picture of your blood pressure cuff. They will also receive text messages.

Would you be interested in hearing more about our study and how you can help? *[If yes, continue with script. If no, thank the patient and code him/her as a screen refusal]*

Great!

I have a few simple questions to ask to first.

Can you confirm your last name? And the month and year you were born?

Thank you!

[If PT gives information that matches the medical record, continue with script. If the information does not match/ the person on the phone is NOT the patient, ask the person on the phone if they know the patient, and a better time or way to contact them]

Do you have a cell phone with the ability to send picture text messages?
[If yes, continue with script. If no, thank the patient and code him/her as ineligible]

You qualify for the study, are you interested in hearing more?

(Information about Study Procedures) After consent, you willcomplete a baseline survey about yourself, your knowledge of technology, and how you process through thoughts and decisions (cognition).

Once in the study, you will continue to receive some of the text messages and reminders to take your blood pressure that you received during Reach Out.

If you have a smart phone, you will receive a new bluetooth-compatible blood pressure cuff and will be asked to download the blood pressure cuff app to your cell phone and trained on how to use the app. You will be asked to take your blood pressure weekly using the new bluetooth-compatible blood pressure cuff.

At around 3 and 6 months, you will receive reminder text message(s) to complete a survey link. You may also be mailed and called as reminder(s) for these outcomes, and to assist with technology troubleshooting.

If you have a smartphone, you will be sent a reminder text message to complete a Bluetooth enabled BP measurement. In order to get the data, we will train you on how to download data via the Bluetooth app, and send the data to the study team either via email or a similar secure means. If unavailable, the study team will conduct an in-person or virtual outcome visit to download final blood pressures from the Bluetooth app.

Participants without apps or Bluetooth capable phones will be sent a reminder text message prompting a photograph blood pressure procedure.

Please note- this program does not take the place of your doctor. Doctors will **not** be evaluating all of the information participants report during their automated text messaging system, and no one will be reviewing blood pressure or survey data in real-time. If you have any urgent questions, health problems, or dangerous BP levels they should be addressed with your doctor, or call 911.

You may be contacted to be invited to participate in other mHealth or stroke prevention trainings, if interested.

You may also be asked to participate in a focus group.

We expect the amount of time you will participate in the study will be about 6 months.

(Risks and Potential Benefits of the Study) There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include:

(1) Discomfort with monitoring or potentially sending a picture of your blood pressure.
(2) You will receive survey links to complete questionnaires, directly connected to secured database(s). Reach Out will use a secure, password-protected web-based application for data collection and surveys.
(3) Depending on your phone capability you may transmit your BP over Bluetooth app. The risks associated with these apps are stated in their terms and conditions, as with any app you download. You should read these terms and conditions. The app may collect data and information including account information, user data, usage information, cookie information,

third party services for basic services, third party services for data sharing, third party data, and additional information provided to app. Some of these features can be changed in account settings. This is not Reach Out, but company data and privacy policies.

(4) This study contains risks associated with transmitting data online, including loss of confidentiality. We have protections in place to minimize these technical risks.

You also need to understand that all information received from you will be confidential and will be kept under lock and key or secure, password protected documents and computers. Your name will not be kept with your answers. Your name will not appear in any reports.

As with any research study, there may be additional risks that are unknown or unexpected.

This study may not offer any benefit to you not, but may benefit others in the future by helping us gain important information about how to help people manage their high BP.

(Financial Information) You will be given a blood pressure cuff and $20 after completing 3-month outcome, and $30 after completing the 6-month. Participants asked to participate in the focus groups may receive food and up to $20 following completion of the session. Payments will be in the form of cash or a gift card.

(Confidentiality) You may be worried about the confidentiality of your information. We won't share answers with anyone except the researchers of this study. The risks to participating are minimal, but there is risk associated with transmitting data, including loss of confidentiality.

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways. If there are physical copies of your information, it will be stored in a locked area, accessible only to research staff, and will not be made part of your medical record. Your research information will be entered into a password protected computer and your name will be separated from the data. We will not share data that identifies you with anyone outside of the study. The study uses a SSL encrypted web-based application with secure log-ins to access. There is a very small risk that someone could obtain your contact information from the study website.

The research team will have printed terms and conditions available for the apps that are asked to be downloaded to your phone, so that you may understand the policies of those specific apps, which are not created or supported by Reach Out. The app is possibly partnered with selected third party services, in which thye

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about

yourself or your involvement in this research, or for any purpose you have consented to in this informed consent document.

Consenting to this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Demographic information
- Personal identifiers

The results of this study could be published in an article, but would not include any information that would let others know who you are.

(Contact Information) I will provide you with our study cell phone, email and other direct contact information if you have any questions about the study or if you want to withdraw from the study. I will also provide you with contact information for the University of Michigan Institutional Review Board and Hurley Medical Center's Institutional Review Board if you have any questions about your rights and responsibilities as a research participant. This contact information is on the copy of the Consent forms.

(Consent) Do you have any questions, comments or concerns? Remember, your participation is voluntary.

(*If patient consents to participate in the study with no further questions, pursue consent*)

Great, so the final thing is getting your consent as documentation that you have heard the informed consent for this study, and are agreeing to participate.

If you agree to participant in this study, please reply "yes" to the question. I will record your answer.

(*If patient says yes, record answer; legal name; date; time)*

Please answer the following questions. I will record your answer.

I have had the opportunity to ask questions and have those questions answered to my satisfaction.

(*Record answer)*

I would like to receive follow-up newsletters and information regarding Reach Out after completion of the study.

(*Record answer)*

If asked to participate in the post-study focus group, I agree to being recorded during discussion.

(*Record answer)*

How would you prefer to receive a copy of this consent document (email, postal mail, etc)?

(*If patient says email, record this email address and send consent form to participant. If patient says address, record this address and send consent form to participant)*

Appendix S- Supplement: Feedback forms

1.0 3.11.2020

Reach Out Cognition

Cognitive Screening

Date:

We did a cognitive test today as a part of the Reach Out Cognition Project. Your score on the Montreal Cognitive Assessment (MoCA test) was:_____out of 30.

What does your cognitive test score mean?

If your score was	Comment and Action
26 or above	Your Montreal Cognitive Assessment (MoCA test) score today is **within the normal range.** You don't need to do anything right now.
Less than 26	Some people with scores in this range have normal memory and thinking, and others have had changes in their memory and thinking. You may wish to share this score with your doctor to discuss whether you have had changes with your memory and thinking.

Based on the Montreal Cognitive Assessment Administration and Scoring Instructions (2010) available at: http://www.mocatest.org.

You should talk to your doctor if today's cognitive test score is less than normal or if you have questions about your cognitive test score. Your doctor will be able to answer your questions and decide whether more testing or treatments are right for you.

1.0 3.11.2020

Reach Out Cognition

Cognitive Screening

Date:

We did a cognitive test today as a part of the Reach Out Cognition Project. Your score on the Self-Administered Gerocognintive Exam (SAGE test) was:_____out of 22.

What does your cognitive test score mean?

If your score was	Comment and Action
17 or above	Your Self-Administered Gerocognintive Exam (SAGE test) score today is **within the normal range.** You don't need to do anything right now.
15 and 16	Individuals with these scores are likely to have mild memory or thinking impairments. Further evaluation by a physician is recommended.
14 and below	Individuals with these scores are likely to have a more severe memory or thinking condition. Further evaluation by a physician is recommended.

Reference: Scharre DW, Chang S-I, Murden RA, Lamb J, Beversdorf DQ, Kataki M, Naharaja HN, Bornstein RA: Self-administered Gerocognitive Examination (SAGE): A brief cognitive assessment instrument for Mild Cognitive Impairment (MCI) and early dementia. Alzheimer Dis Assoc Disord 2010:24:64-71

Please note that SAGE screening is not a diagnostic test of any condition. You should talk to your doctor if today's cognitive test score is less than normal or if you have questions about your cognitive test score. Your doctor will be able to answer your questions and decide whether more testing or treatments are right for you.

Appendix T- Supplement: Instructions for taking your BP

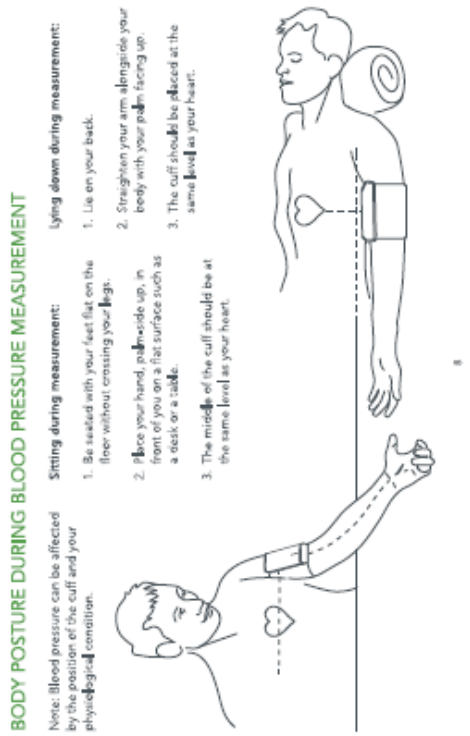
DETAILED INSTRUCTIONS ON TAKING A BLOOD PRESSURE MEASUREMENT

Taking a blood pressure measurement with the CardioArm is easy and is done in a few simple steps:

1. Open the Cardio App on your iOS or Android device.
2. Unwrap the cuff from around the CardioArm to switch on the device and pull the tab to open the cuff loop.
3. Fit the CardioArm cuff around your upper arm. You can review the instructions for proper cuff placement at any point.
4. Press the green START button on the Cardio App to start measuring. The cuff will inflate automatically. Relax, do not move and do not tense your arm muscle until the measurement result is displayed.

Breathe normally and do not talk. When the correct pressure is reached, the inflation stops and the pressure gradually decreases. If the required pressure was not reached, the device will automatically inflate additional air into the cuff.

5. The result, comprising of the systolic and the diastolic blood pressure and the pulse rate, is displayed on the Cardio App.
6. When the device has finished measuring, remove the cuff and wrap it around the CardioArm to switch off the device. If the cuff is left unwrapped, for a few minutes CardioArm switches off automatically. In this case, you will have to switch the cuff around the CardioArm and open it to switch on the device.



BODY POSTURE DURING BLOOD PRESSURE MEASUREMENT

Note: Blood pressure can be affected by the position of the cuff and your physiological condition.

Sitting during measurement:

1. Be seated with your feet flat on the floor without crossing your legs.
2. Place your hand, palm-side up, in front of you on a flat surface such as a desk or a table.
3. The middle of the cuff should be at the same level as your heart.

Lying down during measurement:

1. Lie on your back.
2. Straighten your arm alongside your body with your palm facing up.
3. The cuff should be placed at the same level as your heart.

Appendix U- Supplement: Instructions guide for tele-outcomes

Feature phone:

Instructions for Outcomes

It is time for your x-- month outcome! It will only take a few minutes. You will be mailed $xx for completing the outcome. For assistance, questions, concerns or you would like a Reach Out Cognition Team member to walk you through the outcome, feel free to call Reach Out at (810) 337-8399.

What you need to do!

1 Step 1: Take your blood pressure using the app!

1. Open the Qardio App on your iOS or Android phone.
2. Ensure you are sitting as indicated in the BP Measurement instruction sheet.
3. Take your blood pressure using your blood pressure cuff. Follow the instruction sheet for taking your BP.
   a. Do this 3x so you are taking a total of 3x blood pressures, 1 minute a part!

2 Step 2: Send us your blood pressures!

1. Open the Qardio App on your iOS or Android phone.
2. Click the HISTORY button on the bottom of your screen.
3. Select the upload icon in the upper right hand corner.
4. It will take you to a new screen where you can enter the study email address reachouted@med.umich.edu.
   a. Press send!

3 Step 3: Complete survey link!

1. You will receive a link to complete a few questions. This could come in a text message or email.
   a. If your phone has internet, you could click on the link, and complete the following questions.
   b. If your phone does not have internet, you would copy and paste the link to your internet browser and complete the following questions.

Thank you for your interest in this study.
Demographics
This link is unique to you and should not be forwarded to others.

You will receive a confirmation that your outcome was completed within 24 hours.

Congratulations, you are all done!

Thank you for completing your x-month outcome with Reach Out! You will receive your $xx incentive within 10-20 business days. To confirm your address, call or text Reach Out at (810) 337-8399.

If you have any trouble at all, call us! (810) 337-8399

Thank you!

Lesli, Will, Mackenzie, Zahera, Candace, Adam, Deborah, Louis

Smart phone:

Version 1.0 4.10.2020 HUM00138470/ 1199877

Instructions for Outcomes

It is time for your x– month outcome! It will only take a few minutes. You will be mailed $xx for completing the outcome. For assistance, questions, concerns or you would like a Reach Out Cognition Team member to walk you through the outcome, feel free to call Reach Out at (810) 337-8399.

What you need to do!

1 Step 1: Take a photo of yourself wearing the blood pressure cuff!

1. Open your camera app.
2. Place the blood pressure cuff on the inside of your wrist.
3. Aim the camera towards your wrist with the cuff on it.
   i. We only need to see your wrist and that the cuff is on your wrist. **Please take the picture from about your elbow to the end of your fingers.** We do NOT need to see your face.
4. When you're ready to take a photo, tap the shutter button located in the middle of the screen to take the photo.

Version 1.0 4.10.2020 HUM00138470/ 1199877

2 Step 2: Send us that photo!

1. Open your camera app.
2. Tap the picture you'd like to text.
3. Tap the share button on your screen. This looks different depending on the phone you are using.

   i. If iphone it will be in the lower left corner
   ii. If android it may be in the middle of the top of your screen.

4. **Send your photo to (810) 498-2266.**

If you have any trouble at all, call us! (810) 337-8399

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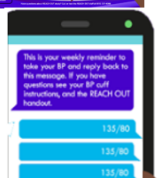
3 Step 3: Text us 3 different blood pressures (xxx/xxx)!

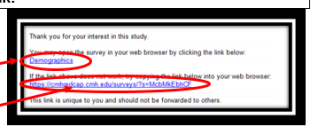
1. Take your blood pressure using your blood pressure cuff. Follow the instruction sheet for taking your BP.
2. Text your BP to (810)- 498-2266 as XXX/ XXX.
3. Follow the instructions sheet for text messages.
   a. This is a text message and does not have to be a picture.
4. Do this 3x so you are sending us a total of 3 blood pressures to Reach Out!



Version 1.0 4.10.2020 HUM00138470/ 1199877

4 Step 4: Complete survey link!

1. You will receive a link to complete a few questions. This could come in a text message or email.
   a. If your phone has internet, you could click on the link, and complete the following questions.
   b. If your phone does not have internet, you would copy and paste the link to your internet browser and complete the following questions.



You will receive a confirmation that your outcome was completed within 24 hours.

Congratulations, you are all done!

Thank you for completing your x-month outcome with Reach Out! You will receive your $xx incentive within 10-20 business days. To confirm your address, call or text Reach Out at (810) 337-8399.

If you have any trouble at all, call us! (810) 337-8399

Thank you!

Lesli, Will, Mackenzie, Zahera, Candace, Adam, Deborah, Louis