Title

Reach Out 2: A Randomized Controlled Trial of a Text Message-Based Hypertension Intervention in a Safety-Net Emergency Department Population

Introduction

Background and rationale {6a}

With 121.5 million (47%) adults with hypertension, the U.S. is facing a hypertension epidemic.[1] Hypertension is the most important modifiable cardiovascular risk factor,[2-7] while blood pressure (BP) treatment reduces cardiovascular disease and all-cause mortality.[1,6] Approximately, 39% of hypertensive Americans are unaware that they have the conditiion.[1] Even with widespread availability of effective treatment, 78% of Americans with hypertension are uncontrolled.[1]

Racial and socioeconomical inequities are pervasive in hypertension.[8] Black Americans have the highest prevalence of hypertension in the US and are among the highest in the world.[1] By age 55 about 76% of Black individuals will have developed hypertension.[9] Black men have one of lowest rates of blood pressure control of any racial or ethnic group.[1] Hypertension disparities are also evident among those with low-income, uninsured and working-age populations. People with low socioeconomic status have a 2-fold higher odds of hypertension.[8] Uninsured Americans have a higher prevalence, less awareness, lower treatment rates, and lower control rates of hypertension than their insured counterparts.[10] Similarly, working-age Americans are less likely to have their hypertension controlled and more likely to have missed appointments than their older counterparts.[11-13]

One approach to addressing the hypertension epidemic is by going to where the people are in the community like barber shops and beauty salons,[14,15] or expanding into non-traditional chronic disease management settings like the Emergency Department (ED). The ED is a cornerstone for health care in most communities. There are over 136 million ED visits annually,[16] of which hypertension is identified in 45% of the individuals (60 million visits).[17] The ED is uniquely suited for addressing hypertension among Black Americans, those of low socioeconomic status, and working-age Americans. First, these populations are high-volume users of the ED.[18 19] Second, asymptomatic elevated BP during the ED visit is highly associated with persistent hypertension.[20] Finally, an ED visit might be a teachable moment – a health event that might motivate individuals to adopt health-promoting behaviors to get control of their BP.[21-23] ED guidelines recommend BP screening,[24] and there is consensus that patients with asymptomatic hypertension should we referred for outpatient follow-up.[25] While self-management and primary care are the mainstay of BP management, identifying hypertensive patients and initiating a mobile health (mHealth) program creates an opportunity for the ED to partner in BP management.

Given the extent of the hypertension epidemic, scalable strategies are needed. Text messaging is nearly ubiquitous as 96% of adult Americans have a mobile phone, and over 80% use it for text messaging.[26] Black

Americans are more likely to own a mobile phone than White Americans.[27] Text messaging is an appealing option for behavioral interventions, given its popularity in historically marginalized populations, low cost, ease of adoption, scalability, and ability to reach people in real-time. Additional advantages include that it is a 'push technology' intervention delivered without any effort from the individual, cannot be deleted, does not require upgrades, and the majority of people already use this technology.[28] mHealth interventions are endorsed by the American Heart Association.[29] A recent systematic review supports the promise of mHealth strategies for hypertension while also identifying limitations such as generalizability, short duration of follow-up, lack of information on the optimal delivery, and absence of rigorous clinical trial design.[30] Such limitations will be addressed in Reach Out 2.

The Reach Out 2 trial builds upon the success of the Reach Out 1 trial, aiming to further investigate the impact of a text message-based hypertension intervention in a safety-net ED population.

Objectives {7}

Aim 1: To determine whether an mHealth intervention results in lower BPs and more initiation of BP management than usual care among hypertensive safety-net ED patients likely to be discharged home.

Aim 2: Among participants randomized to the mHealth intervention, to assess BP control and long-term engagement with prompted SMBP monitoring from 6 months up to 3 years post-enrollment.

Aim 3: To contextualize Reach Out 2 findings, using real-world data and simulation analyses, we will explore the potential population-level reduction in myocardial infarction, stroke, and dementia associated with implementing Reach Out 2 across all eligible patients receiving care at individual safety-net EDs and across all safety-net EDs.

Trial design {8}

Reach Out 2 is a prospective, randomized open-, blinded-endpoint (PROBE) controlled trial. Patients will be recruited from the Hurley Emergency Department (ED). Participant will be randomized in the ED to the mHealth intervention or usual care (Table 1). There will be in-person, incentivized outcome visits at 3- and 6-months. The primary outcome is a reduction in systolic BP at 6 months. Participants in the intervention arm will be followed from 6-months to 3-years in an extended follow-up observational cohort of prompted SMBP monitoring.

As we did successfully through our previous studies (HUM00082454/ HUM00091668/ HUM00138470/ HUM00200541), we will integrate the various strategies together to now recruit participants and partners from the ED of Hurley Medical Center in Flint, MI.

Table 1

Person	Texts	Frequency Levels dependent on BP Control	Tailoring variables
Participant	Prompted BP self-monitoring and feedback (SMBP)	Weekly vs. 3x/week	BP change (most recent self-reported BP) Enrollment BP BP control
	Provider scheduling reminder and transportation	None vs. Yes	Medical Provider BP control
Optional Partner	Reminder for patient SMBP	Weekly vs. 3x/week	Participant text in BP
	Reminder for participant upcoming provider appointment	None vs. Yes	Participant BP control Participant medical provider

Methods: Participants, interventions and outcomes

Study setting {9}

Patients will be recruited from the Hurley Medical Center ED by our team of research assistants.

This is a clinical trial of one-enrolling site (Hurley Medical Center), with multi-investigators from different sites. Other site involvement include Northwestern University, The University of Michigan, and Ohio State University. Drs. Skolarus (Northwestern University) and Meurer (University of Michigan) will each occupy the role of PI. Study staff and coordinators conducting participant recruitment at the site of enrollment will be employed by the University of Michigan.

Hurley Medical Center

- Site of Recruitment

Northwestern University

- Dr. Skolarus, multiple PI, will, along with Dr. Meurer, provide overall leadership to the entire project. Northwestern University is the primary grant recipient.

Ohio State University

- Dr. Burke's primary role in the design and execution of aim 3 analyses. Dr. Lin will execute the trial analysis with the support of Drs. Meurer and Kidwell and assist in execution of the aim 3 under the support of Dr. Burke.. All of this will be de-identified data, no identifiable data will be shared with OSU.

University of Michigan

- Dr. Meurer, multiple PI, will, along with Dr. Skolarus, provide overall leadership to the entire project. IRBMED will also serve as the sIRB of record.

Eligibility criteria {10}

Inclusion Criteria for Main Trial Participants

While in the ED, the patient must meet all of the following:
-Adult (≥18 y/o)
-At least one BP with Systolic BP ≥160 or a Diastolic BP ≥100 (criteria 1)
-If the patient has repeated measurements after achieving Criteria 1, at least one of the repeat BP remains systolic BP ≥140 or a diastolic BP ≥90
-Must have cell phones with text-messaging capability
-Likely to be discharged from the ED

Exclusion Criteria for Main Trial Participants:
- Critical illness
- Unable to read English (<1% at study site)
- Incarcerated
- Pregnant
- Pre-existing condition making 6-month follow-up unlikely

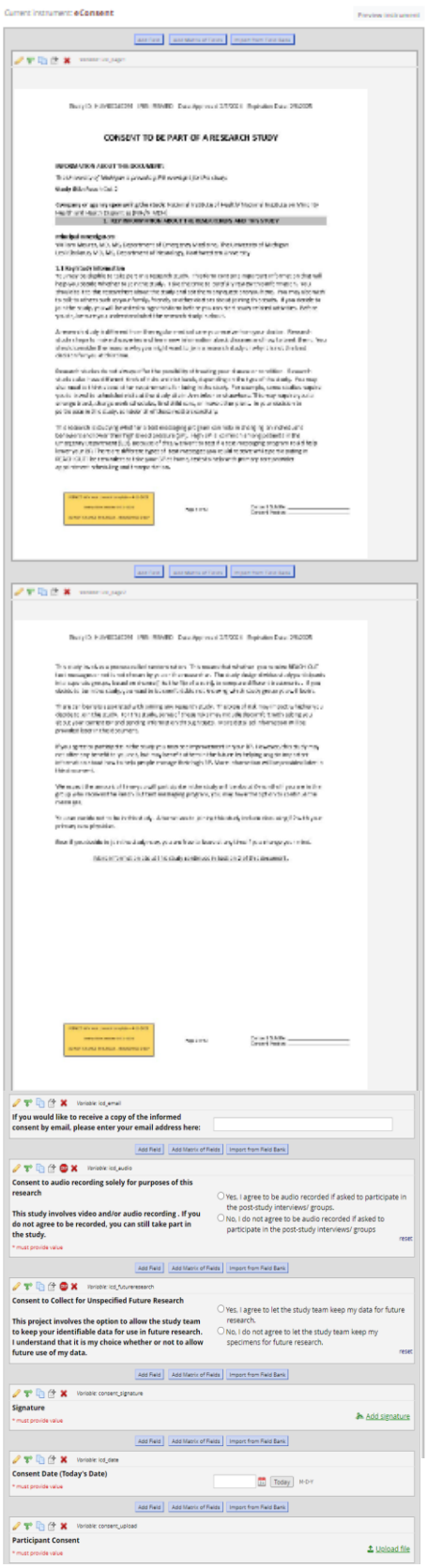
Inclusion Criteria for Partners (Partners are not research subjects, but will still only be possible partners with the following criteria)
-Adult (≥18 y/o)
-Must have cell phones with text-messaging capability
Exclusion Criteria for Partners:
- Critical illness
- Unable to read English (<1% at study site)
- Incarcerated
- Pre-existing condition making 6-months unlikely

Recruitment {15}

As we did through Reach Out 1 in Hurley Medical Center's EMR, we will utilize an automated screening algorithm used by the EMR 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. 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.

We request a waiver of HIPAA authorization to maintain a screening log of patients that trigger the alert system, and also at times if ever necessary in completing recruitment (for example, virtual recruitment), and through chart review collect demographics such as, age, gender, race/ ethnicity, reason for ineligibility or refusal and ED BP. Medical records of the patients will only be used for these purposes. Alternative virtual recruitment protocols are noted in appendix K.



Who will take informed consent? {26a}

Adults meeting the inclusion/exclusion criteria will be approached for consent, if a study team member is available. Research staff will then perform screening of these patients based on the remaining enrollment criteria.

If possible, the consent process will be performed in a private room or sectioned area as to provide the most privacy possible. For patients the process will be performed in person but we will either present paper informed consents, or utilize REDCap to present the approved informed consent document via electronic means (computer, tablet, or similar). We will configure REDCap to present the pages of PDF of the IRB-approved and stamped informed consent form. If for any reason the electronic system REDCap, is not function, we will utilize the identical approved paper informed consent document with the patient to complete the informed consent process. We will incorporate the informed consent document questions into redcap (for example, This study involves video and/or audio recording. If to participate in the post-study interviews/ groups you do not agree to be recorded, you can still take part in the study.Yes/No, etc). We will archive a PDF of the eConsent instrument, responses, and signature. A copy of the informed consent document will be offered to the participant through paper or electronic means. Examples are included as to how the eConsent is built into Redcap.

Participants will be informed during the consent process that if they pay per text message with their cell phone company, regular text messaging costs apply. Additionally, doctor's appointments are not paid for by the study team, and normal insurance, or coverage process will occur.

All consented, interventional participants will be given an Omron BP7 series or similar style validated BP cuffs. The blood pressure cuff is not the object of the study.

All consented participants will receive $25 at enrollment. This will be given in cash or gift card equivalent.

Pending study financial availability, we will also supply participants with pens, bags, magnets, or similar materials branded with study logo and/or pertinent study information like outcome timing. Alternative virtual consent protocols are noted in appendix K.

Partners

A participant does not have to include a partner, but may do so if they choose. Only intervention participants have the opportunity to have a partner. Partners will not complete consent as they are not research subjects, and no measures or outcomes are completed for partners. We will need to maintain the phone number of the partner, in order to send them the text messages. The research team will seek mutual understanding and agreement of partners to receive reminder text messages alongside consented participants. This mutual agreement will be sought for selected partners if they are present and available with the participant in the ER at the time of participant consent. The partner may or may not be present with the participant at the time of enrollment. One partner per participant will be chosen and participants have the option to not identify any partner. If a partner is chosen, they will be contacted (in-person or virtually) within about 1 week of enrollment of participant. The participant will provide first name, last name, age, gender, race, relationship to participant, and contact information (phone number, email, best time to contact, etc) for partner. If the partner declines the participant will be notified, and considering research assistant capacity, a participant may be offered the opportunity to include another partner. Regardless of partner involvement, the participant can still participate in the study, a partner is never necessary, simply optional.

If the participant selects a partner that is not present and available with the participant in the ER at the time of participant consent, they will be contacted within about 2 weeks for a confirmation and conversation of agreement. This may be done with whatever means best possible (telephone, video, etc). For the partner, we will ask for relationship to the participant, first and last name (information will be known from participant, it may be possible the participant does not know the birthday of their selected partner), and contact information (phone number and email). The participant may be given an informational flyer that outlines partner involvement to help explain the partner support throughout the study.

If at the end of the participant's intervention, a partner is asked for Reach Out feedback through interview and/or focus groups, the partner will complete a process of informed consent in the same means and methods as already described for the participants (in-person or virtual).

Randomisation

Randomization is at the participant level and will take place after consent and the baseline data collection. We will use three baseline factors for stratification: 1) race (Black vs. other); 2) sex; 3) taking an antihypertensive medication within the last 6 months (yes vs. no).

Interventions

Explanation for the choice of comparators {6b}

Without a control group, Reach Out 1 findings were promising but may be, at least in part, due to regression to the mean or other temporal trends. Other hypertension interventions initiated in the ED also show potential to lower BP.[36-40] Yet, these studies shared some of the limitations of Reach Out 1 including being limited by small sample size, lack of control group, unblinded assessments, and adaption of the intervention during the study. Thus, Reach Out 2 will include a usual care group.

Intervention description {11a}

Participants will be asked to provide an email address and cell phone number for texting and will be asked for permission to use these means of communication for scheduling the outcome assessment. We will also collect contact information for family member(s) and/or friend(s) as an alternative contact should we have difficulty reaching the participant.

Participants randomized to the intervention group will have the option include a partner, friend, or family member with text-messaging capability who could support them on their BP journey. The partner will receive Reach Out materials and text messages to remind the participant to engage in SMBP and of their upcoming appointments.

After consent but before randomization, participant BP will be measured by the research team using the Omron BP7 series or similar device, according to the research standards to ensure consistent technique across baseline and outcomes. Three consecutive BPs will be taken, and the 2nd and 3rd BP readings will be averaged to generate the baseline measurement unless they are over 10 mmHg apart in systolic. In that case a 4th BP will be measured, and the average taken of the 2 closest measurements. If it is not possible to physically take BPs with participants, ED BPs may be abstracted from the medical record. Additionally, baseline information will be abstracted from the medical record including ED BPs, age, sex, and current medications. We will ask additional information during baseline, such as race/ethnicity (self-report), gender (self-report), medical health literacy, self-rated health, hypertension awareness (prior diagnosis of hypertension, taking antihypertensive medications and medication adherence), health-related social needs, medications, whether they have a primary care provider, and recent health visits.

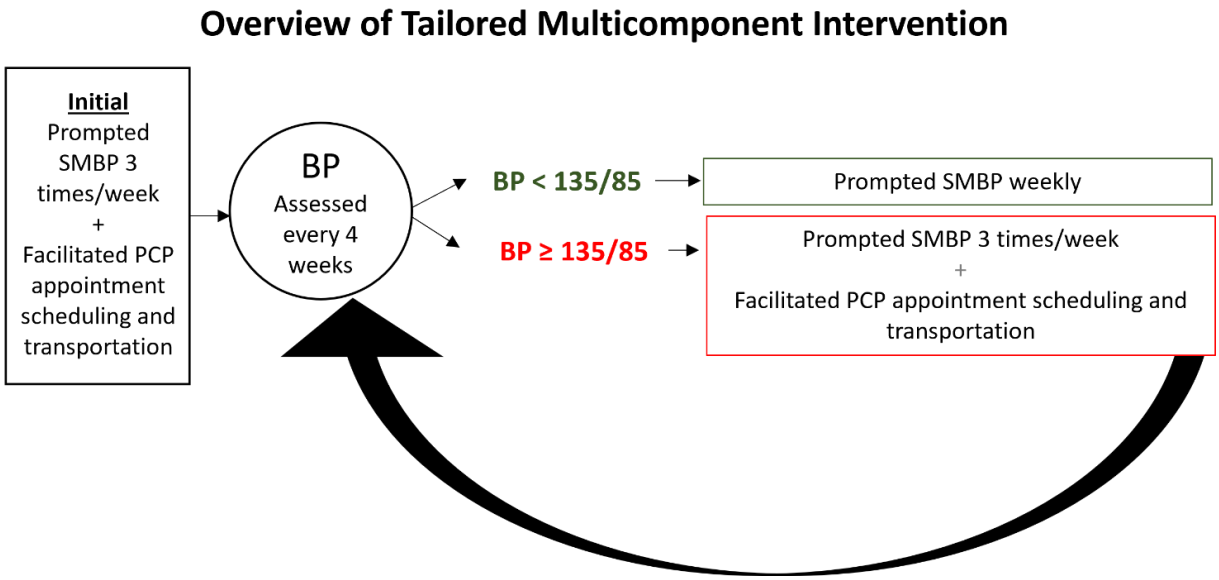
Usual care group

The usual care group is standard of care, they will receive the standard ED discharge materials available as recommended by their ED physician. These materials recommend lifestyle changes, dietary changes,

medication as directed, and follow-up with a PCP as directed. They will not receive the Reach Out intervention as described below.

Intervention group

Figure 1



BP monitoring skills session

Participants will be given a validated, automated, oscillometric BP monitor (Omron BP7 series or similar). The research assistants will teach the participant how to use the BP cuff. They will also be taught how to text message their BP through Mosio. They will be given instructions for BP and texting, used in Reach Out 1 (Appendix A and B). Participants will be given appropriate literacy-level, community hypertensive participant co-created materials (Appendix C).

Given the fluidity of text message interventions and communication, we have thoroughly outlined the text message intention and content throughout the protocol. We also provide sample messages (Appendix D). Text message themes, content, and intent will remain consistent, text message wording may be changed, added or removed throughout the study as feedback or need arises. We will not submit IRB amendment unless significant messaging content is altered.

Tailored Reach Out 2 mHealth components

Prompted SMBP with tailored feedback and provider scheduling and transportation frequency will be tailored based on BP control (Figure 1). Control is defined as SMBP <135/85 based on the median of 3 most recent observations. We may adjust this definition of control if we find need. Reach Out 2 will begin with prompted SMBP monitoring 3 days/week and facilitated provider scheduling and transportation monthly. Every 4 weeks SMBP measurements will be assessed and mHealth components will be escalated, de-escalated, or remain the same. If BP is controlled, SMBP prompts will be sent once a week and there will be no facilitated appointments. If BP is uncontrolled, SMBP prompts will be sent three times per week and facilitated provider scheduling and transportation will occur. Partners will be sent weekly or 2x/weekly text messages encouraging them to remind the participant to engage in SMBP and, if applicable, of their upcoming

appointments. The frequency of the partner's text messages will match the frequency of the participant's text messages. Depending on technological capability, the partner may also receive information about the participant's SMBP responsiveness, and messages with ideas of support and connection. If participants are unresponsive meaning they do not have 3 observations or more and have not responded with at least 1 observation in the last 4 weeks, we will do a technology check with the participant and potentially also with the partner. If the participant remains unresponsive after the technology check he/she will begin receiving the lowest intensity of the intervention (weekly SMBP prompts).

A technology check involves the study team calling the participant or partner to help with any known or unknown barriers that may be present with SMBP engagement. Technology checks may be requested by the participant or partner, deemed helpful by the study team due to perceived SMBP confusion, or due to participant unresponsiveness as described previously. The technology check may include personalized text messages, phone calls, emails, or letters.

Prompted SMBP with tailored feedback

Participants will receive texts (administered through Mosio), prompting SMBP at their selected time of day and day of the week. After texting their BP, the participant receives automated feedback tailored on specific criteria. For example, whether their BP is elevated, have a PCP, and/or whether their BP is greater than or lower than their enrollment BP, among possible other tailoring features. Participants may also be texted monthly graphs of their BP so they can see their BP trends and can share with their PCP (Figure 2).

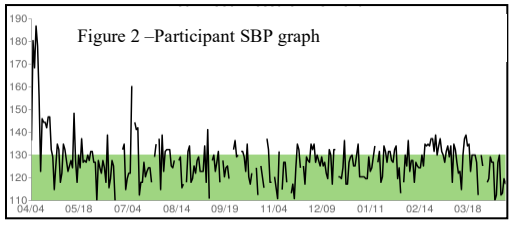


Figure 2 –Participant SBP graph

Facilitated PCP appointments and transportation

For participants without a PCP our research team will assist in establishing medical care at Hamilton Community Health Network. Our research team will inquire through text message(s) of participants if they would like assistance scheduling PCP appointments. Our research team will identify available appointment times with the participant's provider or with Hamilton, for those without a provider, that will be texted to the participant. If a participant's provider requires additional permissions for scheduling, we will complete and provide the provider's officer with an authorization form (Appendix E). If a provider's office requires their own specific authorization form, we will work with them and the participant to have that completed, these specific forms will not be uploaded to the IRB. Participants will communicate their desired time and the research staff will complete the appointment scheduling. Preceding the appointment, automated text reminder messages may be sent to the participant and/or partner. Prior to the appointment, a transportation ride or voucher may be sent to the participant and/or partner (to assist participant). Participant who have declined or are unresponsive to PCP appointment scheduling may still be offered a transportation ride or voucher. These may be implemented through Rides to Wellness, Uber, Uber Health, Lyft, Taxi services, or any similar available transportation company. Participants may decline this particular aspect of the intervention , and still be considered a part of the interventional group.

Extended observational cohort of prompted SMBP monitoring

After the 6-month intervention, participants in the intervention group will have to option to enter a longitudinal cohort. They may be asked at the outcome assessment or via text message. Participants opting to continue will receive weekly prompted SMBP monitoring and tailored feedback for up to 3 years, based on when they enrolled in the trial. Partner messages may also continue. When the longitudinal cohort is ending, all will receive a text message indicating text messages will end.

Participant Retention

We will maintain contact with participants throughout the trial and will include phone calls and/or texts at about 1, 3, 6 months post-enrollment to update contact information and schedule outcome visits, and various other informational updates such as a welcome card, seasonal greetings, quarterly newsletters and a study website. These materials are available in Appendix F and G. We may also contact participants through phone call, text message, or letters, to assess any perceived technological difficulties or troubleshooting, as needed or requested.

A sample contact guide and material outline can be seen in Table 2.

Table 2

	Timepoint						
(Months)	**0** **Enrollment**	**1**	**2**	**3**	**5**	**6**	**Other time-points**
Materials							
Participant	• OMRON Cuff • Welcome card • Newsletter • Study website • BP instructions • Texting instructions	• Comic book	• Newsletter	• Mailed outcome reminder	• Newsletter	• Mailed outcome reminder	• Seasonal greetings • Technology assistance • Newsletter
Partner	• Welcome card		• Newsletter	• Mailed outcome reminder	• Newsletter	• Mailed outcome reminder	• Seasonal greetings

Criteria for discontinuing or modifying allocated interventions {11b}

Participants may withdraw from the study by any means (for example, phone call, text message). If a participant withdraws from the study, the partner's text messages will be stopped. Additionally, if any requests are sent in by the participant to modulate, pause, or stop their text messages or any other intervention components, we will still contact the participant for outcome assessments or appropriate other intervention components. Partners are not research subjects, and thus are not considered with withdrawals. They may stop their messages about participants by any means (for example, phone call, text message).

Outcomes {12}

Data will be collected in several ways. Prior to outcomes, we will attempt to schedule and remind participants of outcomes assessments, this may include letters, text messages and/or phone calls. Reminder messages may be sent the few days before and the day of the outcome assessment. Outcomes may be built into REDCap or similar secure platform. Outcomes may be visually modified, questions removed, rearranged, or re-worded as resources become available, but the messaging, and content will remain consistent. To increase retention for outcomes, we may also be mailing outcome reminders (Appendix H), and/or newsletters (Appendix G) periodically. Some aspects of the outcomes may be tailored. For example, some specific questions may be asked to participants who are unresponsive, and others to participants who are responsive to better understand each individual's experience. 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, 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.

In-person outcome assessments will occur at 3- and 6-months. These assessments will occur at a provider office to coincide with a scheduled provider appointment, in the ED research space, at a convenient location or home visit. BP will be measured by the research team with the same devices and technique as at enrollment in accordance with national standards for measurement. Participants will also complete brief research assistant administered surveys (Table 3). Medications will be collected via interview, with the possibility of a home phone call or text message for participants to read their pill bottles to the research assistant if needed at 3- and 6-months. To understand PCP establishment and utilization we may utilize study team provided transportation and vouchers as confirmation of PCP attendance, and may utilize records from Hamilton Community Health Network EMR for patient provider appointments. Transportation with voucher, ride share, public transit, or parking vouchers will be provided as previously described and/or needed. Participants will be compensated with cash or gift card equivalent of $25 for the 3-month assessment and $50 for the 6-month assessment.

SMBP data will be captured in REDCap (or similar) and Mosio. All participant BPs texted through the Mosio text messaging system flow to the Reach Out database via API integration. Key participant variables will also be outgoing to Mosio (such as phone number, participant ID, tailoring variables). SMBP, updated tailoring variables and phone numbers will also be available within the participant text history and profile in Mosio to facilitate text messaging. If at any point the API integration is not functional between Mosio and REDCap, we will facilitate this connection through direct secure upload and/or download of variables.

The primary endpoint is the systolic BP at 6 months. We will adjust for baseline systolic BP and compare these systolic BPs at 6 months to the control group. Using the 6-month systolic BP (with adjustment for

baseline), as opposed to change, is preferred in clinical trials. Of note, the baseline BP is the median value of the research assistant measured BPs as previously described.

Here we describe secondary and exploratory outcome examples, these may not fully encompass all outcomes and endpoints that will be analysed.

Secondary Outcomes

- Diastolic BP at 6 months
- Proportion of participants with controlled BP at 6-months

Exploratory Outcomes and Processes

- BP control defined as BP less than 140/90 mmHg
- Collect additional BP measurements both from surveys and via the EHR
- Initiation of antihypertensive medication
- Change in antihypertensive medication
- Establishment of primary care
- Hypertension awareness, diagnosis, treatment of hypertension
- BP medication adherence
- Health care utilization at other health care sources (urgent care, outside clinics, outside EDs)
- Continued engagement with and impact of SMBP monitoring
- Engagement- Proportion of participants who continue SMBP monitoring after 6-months (threshold for success is greater than 50%).
- Impact- Proportion of SMBP monitoring responses that are controlled (threshold for success is 80%).
- Adherence with SMBP monitoring- Proportion of BPs received after a BP prompt
- Self-reported use of ‘GRAPH’ link
- Completed facilitated provider appointments
- Rides to medical appointments
- Satisfaction and perceptions of the acceptability and appropriateness of Reach Out 2
- Open-ended questions of participants’ experience

To assess participant and/or partner feedback and satisfaction with the Reach Out intervention and messaging, we will conduct interviews and/or focus groups of up to 40 participants and partners. We will choose the best format (individual or group) for our study population. We anticipate the interviews or groups will last about 30-60 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). The interview or groups will be based on a semi-structured interview guide. Given this is minimal risk, and conversational, this will be submitted to the IRB as a guide. During this team members will assist in taking structured notes and may be recorded. This will be consented for during the initial consent process, and the up to 40 participants will be contacted after completion of the Reach Out Intervention. We will have a conversation to ensure continued interest and consent to participate. Participants will be given $25 in appreciation of their time.

Table 3									
		Baseline	Control Assessment	Control Assessment	3-Month Outcome Assessment	Control Assessment	Control Assessment	6-Month Outcome Assessment	Extended Observation
Time point	**Weeks**	0	4	8	12	16	20	24	6-months to 36 months
	Range				(+/- 30 days)			(+/- 30 days)	
Measures to be collected									
Enrollment:									
Contact Information		X	x		x			x	
Motivational Text Message Creation		X							
Questions/ Assessments:									
Demographics		X							
Medical History		x							
Physical Activity		X							
Diet		X							
Study taken BP measurement		x			x			x	
Self-rated Health Evaluation		x							
HTN Awareness		x			x			x	
HTN Treatment		x			x			x	
BP Medication Adherence		x			x			x	
Medical Literacy		x							
Health-Related Social Needs		x							
Healthcare Utilization		x			x			x	
Establishment of PCP		x			x			x	
Assessment of SMBP			x	x	x	x	x	x	
Medications:									
Medications		X							
Changes in anti-hypertensive treatment		x			x			x	
Medication Review		x			x			x	
Antihypertensives		x			x			x	
Process Measures:									
Sustained engagements with SMBP monitoring									x
SMBP monitoring adherence					x			x	
Pcpt 'GRAPH' link utilization								x	
Transportation vouchers used					X			x	
PCP Utilization								x	
Intervention Feedback								x	

Qualitative interviews Acceptability Outcome							x	x

Participant timeline {13}

Table 4									
		Baseline			3-Month Outcome Assessment			6-Month Outcome Assessment	Extended Observation
Time point	**Weeks**	0	4	8	12	16	20	24	6-months to 36 months
	Range				(+/- 30 days)			(+/- 30 days)	
Informed consent		x							
Randomization		x							
Contact Information		x	x		x			x	
Participants randomized to intervention									
Training with BP cuff		x							
Training with Text Messages		x							
Optional Partner		X							
SMBP Control Assessment			X	X	X	X	X		
SMBP graph			X	X	X	X	X	X	
Intervention dependent on SMBP uncontrolled									
PCP Appointment Scheduling		X	X	X	X	X	X		
PCP Transportation		X	X	X	X	X	X		

Sample size {14}

A total sample size of 500 (assuming 25% loss to follow up from recruitment of 670 participants) is needed to find a comparison of group means of 134 and 130mmHg, assuming a SD of 15, 84.6% power, and alpha of 0.05. Due to the pandemic, in Reach Out 1, outcome BP data were often based on home monitoring readings, which were substantially more variable compared to the more precise measurements we currently propose. Furthermore, attrition was 50% in Reach Out 1 mostly due to the COVID-19 pandemic which caused major disruption in the Flint community, as with most communities around the world. We estimate attrition in Reach Out 2 to be 25%.

Assignment of interventions: allocation

Sequence generation {16a}

We will use three baseline factors for stratification: 1) race (Black vs. other); 2) sex; 3) taking an antihypertensive medication within the last 6 months (yes vs. no). Within each of these eight baseline characteristic strata, we will create randomization sequences in randomly permuted blocks of two, four, and six, balanced to the two arms. Some strata may be less common than others; however, this strategy should limit imbalance of potentially important prognostic factors. We successfully employed a similar procedure in Reach Out 1.

Implementation {16c}

The statistician will generate the randomization sequences. These allocation sequences will be uploaded to a secure web-based randomizer like CSCAR's randomization application (https://trial-randomize.appspot.com/), or similar. The project manager will then input stratification variables and generate a randomization assignment. This randomization assignment will be assigned to pre-populated participant forms into REDCap or similar. From here, research assistants will utilize these in sequence as they recruit participants from the ED. This or a similar implementation method will be utilized.

Assignment of interventions: Blinding

Procedure for unblinding if needed {17b}

Unblinding may occur under specific circumstances, and approved and overseen by the Independent Medical Monitor. To request unblinding, the principal investigators and medical monitor, must provide a clear and compelling justification for the unblinding request to the statistician. Reasoning will be based on potential medical management or safety of a participant. Upon approval, the statistician will disclose the relevant information while maintaining confidentiality.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The primary analysis will be intent-to-treat where BP measured at the 6-month visit is the outcome variable and baseline BP is a covariate. The analytic plan for the differences between arms will use a linear regression model (transformation of outcome if needed) with an indicator variable for the treatment arm controlling for age, and stratification variables of sex, race, and being on antihypertensive medication in the 6 months prior to baseline.

Demographic and clinical characteristics of participants with and without missing data will be compared for any missingness patterns. Multiple imputation will be conducted under missing at random assumptions. If we observe statistical evidence that the data are not missing at random, we will stratify the participants into

subgroups that share the same missing data pattern and estimate the statistical model separately for each missing data pattern. The results of all missing data analyses will be presented, and the sensitivity of our inference to the assumptions and approaches will be included in the interpretation of results.

Hypothesis 1b: Participants randomized to the mHealth intervention will have a lower diastolic BP and will be more likely to have BP control (<130/80) at 6 months than participants who receive usual care (secondary).

Across the 8 groups from Reach Out 1, we observed a mean change in diastolic BP of -3.7 mmHg (95% CI, -5.7 to – 1.7 mmHg) with SD ranging from 9 to 15 mmHg. We have 79.7% power with a total sample size of 500 and alpha of 0.05 to find a difference in group means of 90 and 87 mmHg, assuming a SD of 12.
The model for this analysis mirrors that for the primary analysis but with diastolic BP measured at the 6-month visit as the outcome and baseline diastolic BP as a covariate.

Our main secondary analysis of efficacy will evaluate a 2-arm comparison of the proportion of participants whose BPs are controlled (i.e., < 130/80). From Reach Out 1, the proportion of controlled BPs across the 8 treatment groups ranged from 6-31% at 6 months. Assuming a baseline rate of 15% control of BP in our usual care group, we will have approximately 91% power (alpha = 0.05) to detect an absolute difference in proportion of controlled BPs between the two groups of 12%, assuming 500 observations. This difference represents approximately the difference between the median group and the arm with the best control in Reach Out 1. We provide power under alternative scenarios in our statistical design and power plan. The analysis will employ a logistic regression model for control vs. no control adjusting for the covariates mentioned in above analyses plus baseline diastolic BP.

Hypothesis 1c: Participants randomized to the mHealth intervention will be more likely to initiate an antihypertensive medication and establish primary care than participants who receive usual care (exploratory).

Our exploratory analyses will examine between group differences in initiation of antihypertensive medication among participants who did not initially take antihypertensive medication and establishment of primary care among participants without a PCP at baseline. We will fit a logistic regression model exploring the association of initiation of antihypertensive medication with an indicator for the treatment group and adjust for race and sex. We will fit another logistic regression model exploring establishing primary care with an indicator for treatment group and adjust for race and sex.

Aim 2: To assess the long-term engagement with prompted SMBP monitoring and the effect on BP control

Baseline demographics and 3-and 6-month BP outcomes will be compared between participants randomized to the intervention group who continue vs. those who do not continue with SMBP monitoring. Propensity scores will be developed via logistic regression to account for selection bias in models of long-term BP control. Joint longitudinal survival models will estimate the association between BP measurements over time

and time to discontinuation of SMBP responses. We expect 80% of self-reported BPs among participants continuing past 6 months to be controlled and that 50% of participants will continue prompted SMBP monitoring to the end of the study period (6 months – 3 years depending on initial enrollment date). We will calculate 95% CIs for these proportions. We will declare this exploratory aim promising if the confidence intervals for the proportions include those stated performance criteria (80% BP control, 50% continuing monitoring). Additional details are in statistical design and power plan.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

We will complete intention to treat and per protocol analyses. We will also conduct a sensitivity analysis with multiple imputation to handle missing data.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

We will have frequent steering committee meetings and input from community advisor board.

Composition of the data monitoring committee, its role and reporting structure {21a}

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 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.

Adverse event reporting and harms {22}

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

All of these recorded AEs and SAEs will be reported to both the University of Michigan and Hurley Medical Center.

All AEs reported to the research team and all serious adverse events (SAEs) occurring until participation in the study has ended are recorded. 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 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 fully resolves and then recurs later, the second occurrence is considered a new AE. 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.

Funding {4}

National Institute on Minority Health and Health Disparities: 1R01MD019124-01

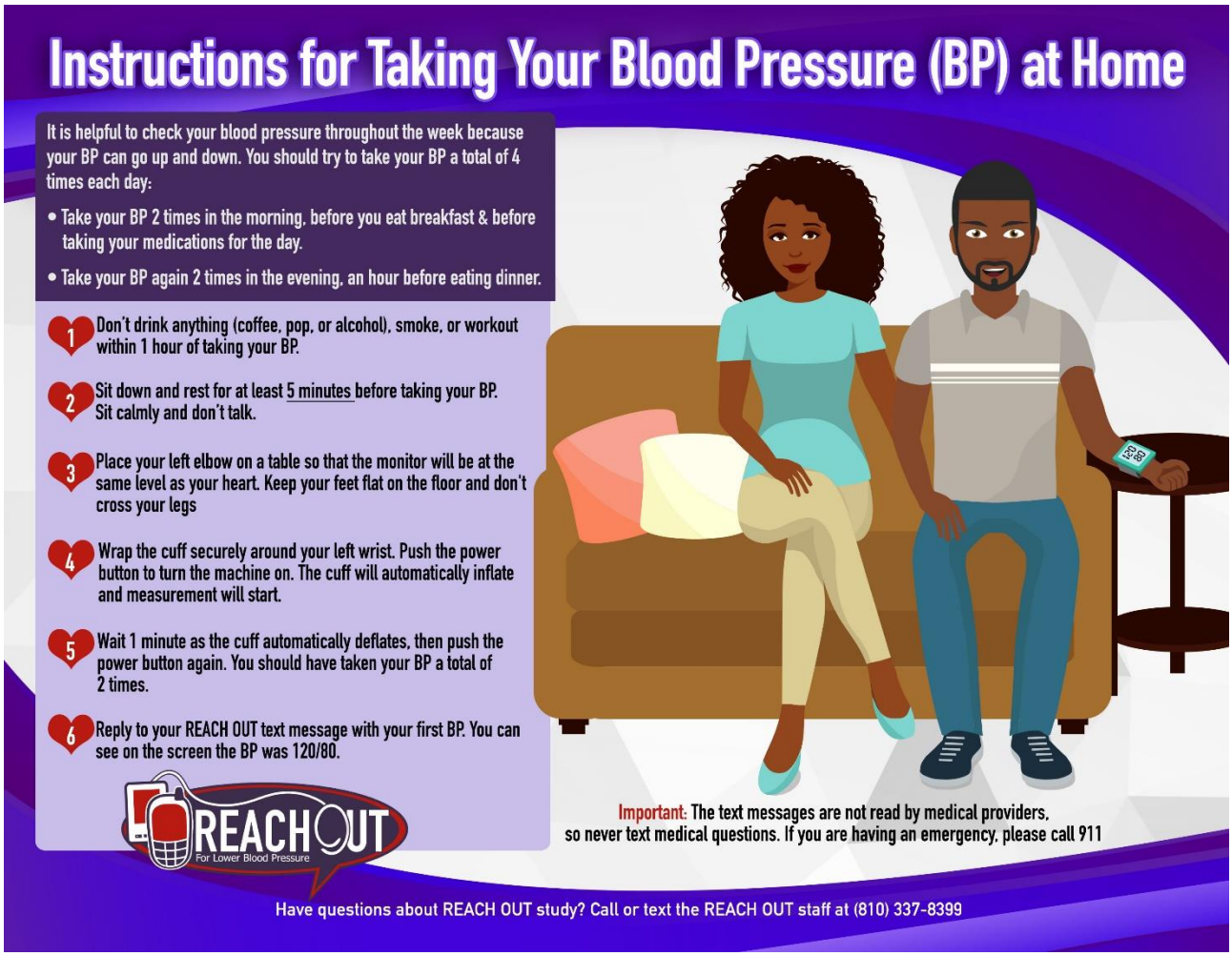
Availability of data and materials {29}

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 participant 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.

Ethics approval and consent to participate {24}

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

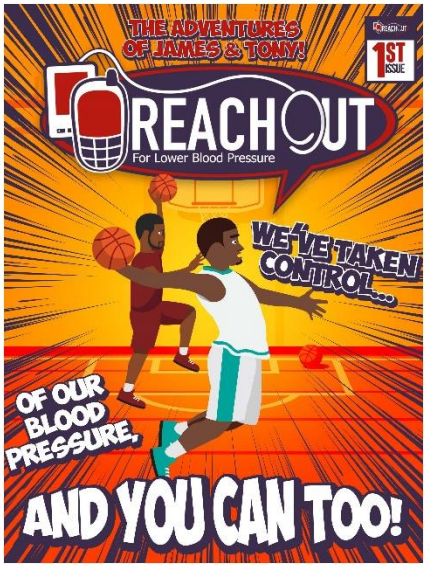
Appendix A :


Instructions for Taking Your Blood Pressure (BP) at Home
It is helpful to check your blood pressure throughout the week because your BP can go up and down. You should try to take your BP a total of 4 times each day:
• Take your BP 2 times in the morning, before you eat breakfast & before taking your medications for the day.
• Take your BP again 2 times in the evening, an hour before eating dinner.
1 Don't drink anything (coffee, pop, or alcohol), smoke, or workout within 1 hour of taking your BP.
2 Sit down and rest for at least 5 minutes before taking your BP. Sit calmly and don't talk.
3 Place your left elbow on a table so that the monitor will be at the same level as your heart. Keep your feet flat on the floor and don't cross your legs
4 Wrap the cuff securely around your left wrist. Push the power button to turn the machine on. The cuff will automatically inflate and measurement will start.
5 Wait 1 minute as the cuff automatically deflates, then push the power button again. You should have taken your BP a total of 2 times.
6 Reply to your REACH OUT text message with your first BP. You can see on the screen the BP was 120/80.
REACH OUT
For Lower Blood Pressure
Important: The text messages are not read by medical providers, so never text medical questions. If you are having an emergency, please call 911
Have questions about REACH OUT study? Call or text the REACH OUT staff at (810) 337-8399

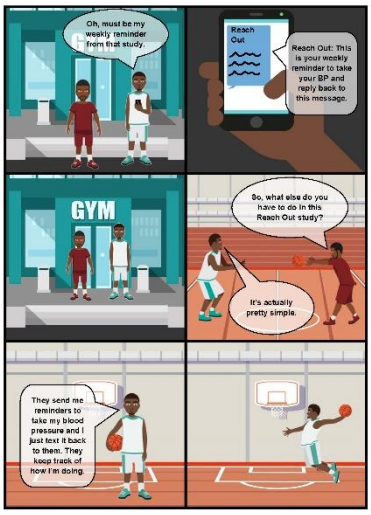
Appendix B :


Instructions for Text Messages
You will be getting text message reminders to take your blood pressure (BP).
To make sure you are able to receive and send messages:
1 When you get the text from REACH OUT to take your BP, follow the instruction sheet for taking your BP at home
2 Text your BP to "REACH OUT" as xxx/xxx (for example: 135/80)
If you want to know all the changes you can make to your text messages, just text 'HELP'
You can take a break from getting text messages. Just text 'SNOOZE'
• After a 2-week break, you will start getting text messages again.
You can change how often you get text messages to remind you to take your BP.
• Text 'DAILY' to get text message reminders every day.
• Text 'WEEKLY' to get text message reminders once a week.
If you would like us to send a graph that tracks your BP readings, text 'GRAPH'
You can stop participating in the REACH OUT project at any time. Just text 'END'
Things to know before you decide to 'END':
• You won't receive any more text message reminders to take your blood pressure.
• We'll only contact you for follow-up at 6 months and 12 months.
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.
135/80
Your BP is 135/80. Your top number is above the normal range but your bottom number is normal. Meds, eating healthy and exercise can lower that top number!
Important: The text messages are not read by medical providers, so never text medical questions.
If you are having an emergency, please call 911
Abbreviations we may use:
BP = Blood Pressure
ED = Emergency Department
Dr = Doctor
Meds = medications
REACH OUT
For Lower Blood Pressure
Have questions about REACH OUT study? Call or text the REACH OUT staff at (810) 337-8399

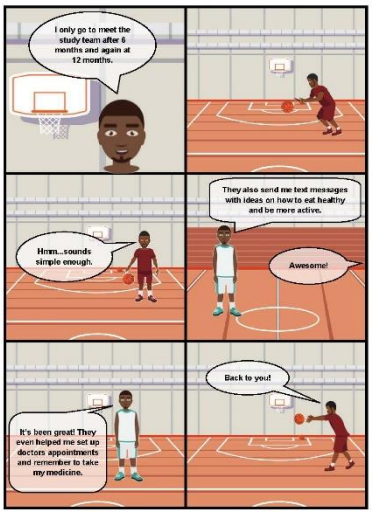
Appendix C :

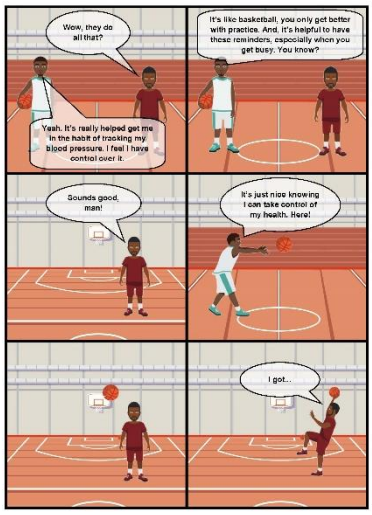

THE ADVENTURES OF JAMES & TONY!
1ST ISSUE
REACH OUT
For Lower Blood Pressure
WE'VE TAKEN CONTROL...
OF OUR BLOOD PRESSURE,
AND YOU CAN TOO!

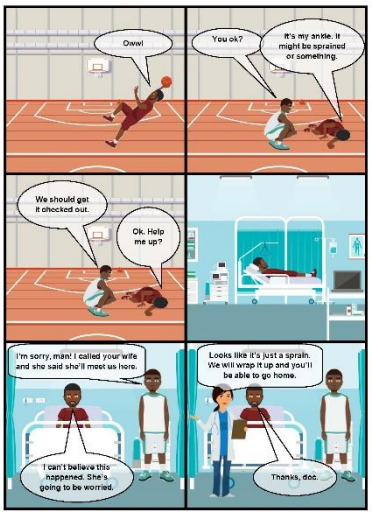

Mind if we swing by the pharmacy?
Yeah, sure. Everything alright?
Yeah, I just need to pick up my blood pressure meds.
What?! You're taking blood pressure meds? You're only 45!
Yeah, man. I've been on them a few months now, and they seem to be helping keep my blood pressure down.


Oh, must be my weekly reminder from that study.
Reach Out
Reach Out: This is your weekly reminder to take your BP and reply back to this message.
GYM
So, what else do you have to do in this Reach Out study?
It's actually pretty simple.
They send me reminders to take my blood pressure and I just text it back to them. They keep track of how I'm doing.


How'd you even know you had high blood pressure? Seems way too early to worry about that.
That's what I thought too. But, when I was in the ER for the flu, they told me I had high blood pressure.
The doctor said that most people don't even know they have high blood pressure since they may not have signs or symptoms.
They also said that if someone has symptoms, it's likely from the high blood pressure harming different parts of the body, not from the high blood pressure itself.
So, he gave you medication?
Yeah, we decided it was best. He also told me about this study called Reach Out. It helps me manage my blood pressure in some really cool ways.
GYM
Beep Beep (Phone rings)
What's that?


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

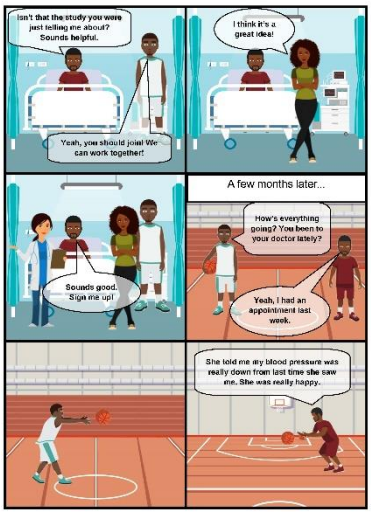

Wow, they do all that?
It's like basketball, you only get better with practice. And, it's helpful to have these reminders, especially when you get busy. You know?
Yeah. It's really helped get me in the habit of tracking my blood pressure. I feel I have control over it.
Sounds good, man!
It's just nice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

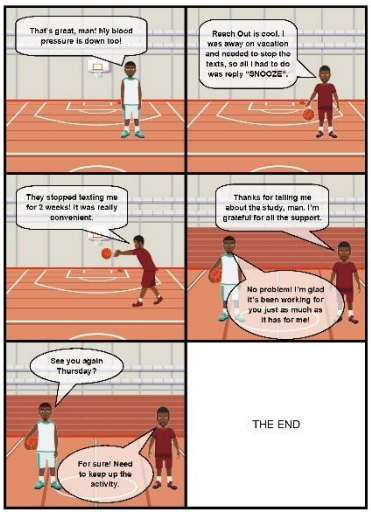

Oww!
You ok?
It's my ankle. It might be sprained or something.
We should get it checked out.
Ok. Help me up?
I'm sorry, man! I called your wife and she said she'll meet us here.
Looks like it's just a sprain. We will wrap it up and you'll be able to go home.
I can't believe this happened. She's going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


Tony, you ok!?
Is that true, doctor?
I'm fine, Mary...it's just a sprain
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.
I guess I can try to work out more often.
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.


If you smoke, quitting is a way to improve your health.
Another thing you could do is eat a healthy diet with more fruits and vegetables, less salt, and less foods high in fat.
I'd also like to talk to you about this research study that's looking for participants.
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.
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!
A few months later...
How's everything going? You been to your doctor lately?
Sounds good. Sign me up!
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 D :

Triggers	Participant Action	Category	Proposed Message
Open/Closing	Initial message	WELCOME	Welcome to REACH OUT! Save this number to your contacts so you can text in your blood pressure once a week and get feedback/tips on how to better manage your BP!
	Final Message	6 MONTH END	Thank you for being a part of REACH OUT this past year! Healthy BP is very important for your brain health. If you have questions please reach out to our team :)
	Continuance	6 MONTH END	As we reach the end of REACH OUT, you could continue receiving texts from REACH OUT. Its your choice! Reply YES to continue or NO to end as anticipated. Thank you for being a part of REACH OUT!
	Final Message	CONT END	Thank you for being a part of REACH OUT! This is your final message. Healthy BP is very important for your brain health. If you have questions please reach out to our team :)
UMreachweeklyBPsurvey	Initial message	Weekly BP Survey	Today is the day to check your blood pressure. Reply to this text with your blood pressure.
	NL feedback response	Weekly BP Response	One of your recent blood pressures was %recent_bp% and in a healthy range. Great job! Keep up the great work :)
	SBP too high feedback response	Weekly BP Response	One of your recent BP's was %recent_bp%. Your top BP # is high but your bottom # is OK. Meds, eating healthy and physical activity can lower that top #!
	DBP too high feedback response	Weekly BP Response	One of your recent BP's was %recent_bp%. The bottom BP # is high but the top # is OK. Meds, eating healthy and physical activity can help lower the bottom #!
	SBP and DBP too high	Weekly BP Response	One of your recent BP's was %recent_bp%. Both the top and bottom #s are high. Keep working to lower your BP with meds, eating healthy and physical activity 😊
Monthly	Graph Out Survey	Normal Range	Your most recent blood pressure is in a healthy range! You are doing an awesome job!
	Graph Out Survey	High BP	Your most recent BP is high meaning that you have high blood pressure. Talk to a doctor about meds. Physical activity and eating healthy can help lower your BP!
	Graph Out Survey	Emergency BP	Your blood pressure is very high. If you have symptoms like chest pain, call 911. See a Dr. soon to get your blood pressure down!
PCP Scheduling	Controlled BP Monthly	Passive Reminder	This is a reminder to make an appointment with your doctor to talk about your blood pressure. Call Hamilton if you need to find a doctor (810) 406-4246
	Uncontrolled BP Monthly	PCP Schedule	REACH OUT can help schedule appts with your Dr. If you would like, reply YES! Reach Out will also provide free rides to one of your primary care Dr. appts this month! Please let us know by texting, or call (810)-337-8399
	Uncontrolled BP Monthly	PCP Schedule	OK, thanks for letting us know! If you would like to schedule appts with your Dr, or rides to your PCP appointment in the future please let us know by texting, or call (XXX)-XXX-XXXX.
	Uncontrolled BP Monthly	PCP Schedule	Your Dr. has an opening at XX:XX XXXXX. Please reply YES within 24 hours if you would like this appt. If reply NO, we will send you another appt option. If you have questions call REACH OUT at (810)- 337-8399.
	Uncontrolled BP Monthly	PCP Schedule	Your Dr. has an opening at XX:XX XXXXX. Please reply YES within 24 hours if you would like this appt. If reply NO, we will send you another appt option. If you have questions call REACH OUT at (810)- 337-8399.
	Uncontrolled BP Monthly	PCP Schedule	Your Dr. has an opening at XX:XX XXXXX. Please reply YES within 24 hours if you would like this appt. If reply NO, we will call you to see what options may generally work for you. If you have questions call REACH OUT at (810)- 337-8399.
Blood Pressure Response/ Errors	Not real BP number- an unrealistic number was sent in		The BP you sent in does not seem to be right. Your BP should setup like xxx/xxx. Look at your BP cuff instructions and the home BP measurement handout.
	Reminder: Did not text in BP reading (After waiting 3 hours)		Remember to text in your blood pressure reading so you can know how you are doing!
	Follow-up message x2		This is a reminder to take control of your health and reply to this text with your blood pressure. Keeping track of your blood pressure helps keep you healthy!
	Text the following day if still no response (THURSDAY)		Don't forget to text in your blood pressure this week. Questions about taking your BP? Look at your BP cuff guide and the REACH OUT handout for help!
	Text something other than BP		Remember: this is an automated system. For questions about REACH, call the study team. For questions about your BP, ask your Dr. If this is an emergency, call 911.
	Safety Measures - BP too high		You recently sent a BP where one or both of your numbers were greater than 180/110, which is very high. If you have symptoms like chest pain, call 911. See a Dr. soon to get your BP down!
	Safety Measures - BP too low		You recently reported a BP where one or both of your numbers were less than 90/60 which is low. If you have symptoms like dizziness call 911 or go to the hospital. See a Dr. soon for your BP health!
	If not a biological BP		The BP you sent in does not seem to be right. Your BP should be like xxx/xxx. Look at your BP cuff instructions and the BP handout. Reply with your new BP.

Appendix E :

Version 1.0 911.27.2023

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 F :

v1, 11.27.2023

Thank you for taking part in Reach Out!

This year you have done a great job focusing on your blood pressure and making healthy choices!

Wishing you a Happy New Year
From the Reach Out Study Group!

Appendix G :

November 2024 Volume 1, Issue 1 HUM00XXX/XXX

REACH OUT
For Lower Blood Pressure

Dear Reach Out Participant,

We want to update you on the progress of the Reach Out study. You continue to be a part of Reach Out, and we thank you from the bottom of our hearts for your continued participation!

- 6 month outcomes are underway!
- Continue sending in your blood pressures!

6 Month Outcomes: Call us!

Please remember that we would love to meet with you at 6 months to have a 30 minute check-in. In appreciation, you will get $50 for completing the outcome.

It doesn't matter if you have been texting your blood pressures to Reach Out regularly or not, we'd still love to connect with you! These visits are important for our study, so that we can know how you are doing.

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

Blood Pressures

If you are able, please continue to text your blood pressures to Reach Out. Monitoring your blood pressure is one way to help lower your blood pressure.

When you get a text from Reach Out to take your BP, just text your BP as XXX/XXX (for example: 135/80). If you need a new blood pressure cuff, just let us know! Call or text 1-810-337-8399.

Staff Spotlight: Abby!

As I approach my 1-year anniversary working with The Reach Out team, I not only reflect on my growth as a researcher, but my growth as a person, inspired by you- our participants! The heartwarming testimonials you have all shared with us during your outcomes have motivated me have a healthier lifestyle and to never give up.

Within this last year we have been able to launch our tele-outcomes and a new study, all while staying safe at home. Even though we were able to touch base with you during these hard times, we can't wait to be able to meet everyone in person again, when the time is right.
Thank you all for a wonderful year, and stay safe!

How do you cut a cake into eight equal pieces with only three cuts?

the cake in the puzzle is not necessarily the one pictured below

Answer: Use two cuts to cut the cake into four equal pieces. Stack the four pieces vertically, and use your third cut to cut the four pieces in half horizontally.

Appendix H :

Version 1.0 11.27.2023 HUM00xxx/xxxx

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 3-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 30 minutes, and you will be given $25 for your time. Please drop in anytime:

Flint Farmer's Market 11AM-1PM
Saturday x/xx/xxxx.

If you are unable to meet on xx/xx/xxxx, 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, Abby, Nishat

Version 1.0 11.27.2023 HUM00xxx/xxxx

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 30 minutes, and you will be given $50 for your time. Please drop in anytime:

Flint Farmer's Market 11AM-1PM
Saturday x/xx/xxxx.

If you are unable to meet on xx/xx/xxxx, 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, Abby, Nishat

Appendix I :

Screening Phone Recruitment Script:

Hello, my name is _____ from 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 may be asked to take your own blood pressure throughout the study while receiving text messages. You will be randomized (like the flip of a coin) to receive text messages, or not.

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]
Critical Illness
[If no, continue with script. If yes, 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]

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

[If yes, continue to consent. If no, thank the patient and code him/her as a screen refusal]

Appendix J :

Version 1.0 11.9.2023

Dear _____,

You are invited to participate in a new study called REACH OUT 2. REACH OUT 2 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 (XXX) XXX-XXXX.

To participate in the REACH OUT 2 project, you will need to…

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

After calling **(XXX) XXX-XXXX**, 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 6 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 3 months and 6 months
- Be willing to receive and send text messages
- Take your blood pressure and text it to REACH OUT 2

Will I be paid for my time?

- When you sign up, you will be given $25
- You will be randomized (like the flip of a coin), and some people will receive a free blood pressure cuff.
- $25 at the 3-month follow-up
- $50 at the 6-month follow-up

You may also be able to include a friend or family member with you, if you want! If you have any questions about the study or are interested in enrolling, please call/text us at **XXX) XXX-XXXX**!

Sincerely,
[Staff Member's Name and Job Title]
Phone: **XXX) XXX-XXXX**

Appendix K : Alternative Implementation Plans

We intend for these alternative implementation strategies to not be utilized as primary means of enrolment, and instead be utilized as exceptions. We anticipate, if utilized, we may include statistical strategies to account and acknowledge participant difference. We anticipate instancing of utilizing may include in the case of a public health emergency, large electronic system down ages, etc.

Virtual recruitment

If in-person recruitment is not feasible, virtual recruitment may also be utilized. We may screen ER patients that meet age range and blood pressure inclusion criteria via EMR, and then call the patient to complete eligibility screening. The research staff will follow a phone screening and recruitment script for virtual recruitment (Appendix I). We may also mail letters to these patients, letting them know of their potential eligibility (Appendix J). 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).

Virtual Consent procedures

As stated, if in-person recruitment is not feasible, virtual recruitment may also be utilized. If patients are found to be eligible by virtual recruitment, we will proceed to a virtual consent process utilizing the informed consent document, this may be done with whatever means best possible for patient (telephone, zoom, etc). This will not be recorded.

The research staff will ask for the last name, and month and year of birth as confirmation that we are speaking to expected patient (information will be known through EMR screening). Only once confirmed, will the research staff begin the process of consent. Interested patients will be enrolled in the study after providing consent. The research staff will discuss questions with the individual, and research would only begin after informed consent is obtained. The study team will have a conversation with the participant regarding informed consent. Verbal consent will be received and will be documented by the study team.

We will attempt to provide a copy of the consent to potential participants prior to obtaining consent. This will be done in whatever way best preferred by potential participant such as via email, text message to download, or texted link. If requested, we will give the participant a copy of the informed consent document via postal mail. Following consent, patients will be asked to complete a baseline assessment. The research staff will postal mail a validated, automated, oscillometric BP monitor, and will teach the participant how to use the BP cuff (Appendix A) and text the readings to the study team (Appendix B), including the timing of BP self-monitoring, body position, and resting prior to testing. 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, and provided a link to the reach out website (reachouted.com) which has these materials along with

videos of blood pressure monitoring.

All enrollment training discussed would be done over the phone or through video services, and materials (blood pressure cuff, instructions sheet(s)) would be either presented through reachouted.com, emailed, texted, or postal mailed to participant. The $25 incentive will be cash or gift card equivalent. It will either be mailed, emailed, or texted, depending on participant preference. We will ensure the preference of the participant.