Protocol Document

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Title: mHealth to Address Uncontrolled Hypertension Among Hypertensive Homeless Adults

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STUDY PROTOCOL

Project Summary

Annually, millions of Americans experience homelessness. Hypertension (HTN) is one of the most common conditions among persons experiencing homelessness (PEH) but is often uncontrolled; 40.1% of hypertensive PEH have uncontrolled blood pressure (BP) compared to 24.8% of hypertensive adults in the general population. PEH face multiple barriers to therapeutic lifestyle changes that complicate their HTN management. Strategies targeting self-management behaviors and counseling to support adherence to medications and lifestyle changes contribute to better BP control and significant cardiovascular risk reduction. However, these strategies are not available or accessible to the PEH. At the patient level, educational interventions with behavioral support through continued patient contact over months are effective in the treatment of chronic diseases including HTN. The mHealth strategies including short messaging service (SMS) texting have been shown to improve adherence to BP medications and BP control and were feasible and acceptable among hypertensive adults. Majority of the PEH have access to mobile phones that can receive and send SMS texts. Considering mobility of the PEH, we propose that an mHealth strategy using SMS texting could be used as a platform for better communication and information management for BP control, facilitate coordination of care, support behavior changes, and improve targeted outreach. The mHealth strategies for HTN have never been evaluated in the PEH despite the growing evidence of their effectiveness and the accessibility of mobile phones among PEH. This study will test this strategy and pave the way for its utilizations in the health settings where the PEH seek care and has potentials for adaptation for control of other chronic diseases among PEH. This study will be implemented in shelter-clinics in New York City (NYC) and in collaboration with community organizations making sustainability of the intervention effects and its scalability feasible. We propose a mixed methods study: AIM1: To evaluate the efficacy of a 6-month SMS texting targeted on HTN management (INT) versus an attention control (CL) on changes in systolic BP (SBP) and diastolic BP (DBP) and adherence to BP medications and appointments at 6 months in hypertensive PEH with uncontrolled BP age 21 or older (n=120). *H1)* Those randomized to the INT (n=60) will exhibit at least 8 mmHg reduction in either SBP or DBP compared to those randomized to the CL (n=60) at 6 months. *H2)* The INT group will exhibit better adherence to BP medications and appointments compared to those in the CL at 6 months. BP readings and adherence to appointments and medications will be measured at regular clinic visits. Randomization will be at the individual level in the shelter-clinics. AIM2: To assess patients' and providers' attitudes, acceptability, and experience of a 6-month mHealth SMS texting for HTN management in hypertensive PEH age 21 or older with uncontrolled BP in NYC's shelter-clinics. We will use semi-structured interviews using random and criteria sampling of the PEH and providers.

APPROACH

Overview of study design and intervention: Participants will be recruited directly in the clinics, via medical record reviews, and through the outreach team. Individual participants will be assigned to treatment groups by a computer-assisted permuted randomization schedule using of a block size of four, stratified by clinic site (n=2) a. Inclusion criteria: patient PEH age 21 or older already diagnosed with HTN whose SBP or DBP at the most recent clinic visit were >140 or >90 mmHg, respectively (see Clinic Visits) (54); English or Spanish speaking; currently presenting to the PR shelter-clinics for medical care; connected to multidisciplinary social and health services in the PR. Exclusion criteria: pregnant or within three months postpartum (55); recent heart attack or stroke (in the previous 6 months); aortic aneurysm, end stage renal disease or on dialysis; inability to read and respond to SMS texts; severe mental illness; current severe or uncontrolled substance abuse or any condition preventing participants to provide informed consent. Patients with a SBP >175 mmHg or DBP >105 are eligible only if they have no symptoms suggesting a hypertensive emergency or urgency evaluated by a medical provider (55). In these cases, providers will be given notification of intent to enroll the patient in this study and have 48 hours to opt them out of the study for any reason including mental and physical health issues. Provider participants are PR's physicians, NPs, social workers, counselors working at the sites not involved in study design or implementation. The intervention will include 6 months of mHealth HTN management support via SMS texts including reminders for medication adherence, appointment attendance, and HTN specific health education and support. The control group will receive 6

months of mHealth including basic healthcare and general health promotion via SMS texts. Both groups undergo BP measurements and adherence assessment at regular clinic visits. Participants will have a follow-up appointment scheduled at 2 months by the research associate at the baseline visit. Data obtained from patients via SMS texts is reviewed by the system and study team members. During the study, feedback to SMS texts, including automated and reciprocal feedback responding to patient-specific input, will be directly provided to the patients within the same day to enhance education and behavioral changes in a protocolized fashion. We will recruit a total of PEH (n=120) with uncontrolled HTN and a range of providers from the PR in NYC. The timeline will consist of socio-demographics and baseline data collected at the enrollment followed by a 6-month mHealth for each participant until the last enrolled participant completes the study. Primary outcomes of BP readings, medication adherence (Voils DOSE-nonadherence (68,69)), and appointment attendance will be measured at regular clinic visits. Other outcomes include phone retention rates; utilization of phones and SMS texts (# of texts read and responded by subjects). PEH with HTN and providers will be interviewed. Research assistants (RA), fluent in Spanish, will perform semi-structured interviews and collect data. Interim analysis will be performed; the final analysis of quantitative and qualitative data will ensue after the completion of data collection.

Study Procedures: Hypertensive PEH with uncontrolled BP will be identified and enrolled from the proposed site during weekdays via both electronic medical records and during their clinic visit on the day of enrollment and will be approached in the waiting rooms and offered to participate in the study. Potential unsheltered participants' eligibility will be assessed at the two predetermined clinic sites.. Uncontrolled BP is measured by the BP readings from the most recent visit (*Clinic Visit below*) and defined based on the current updated guideline and diagnoses of HTN. (54) Patient's other co-morbidities (CAD, stroke, MI, DM or chronic kidney disease) will be collected but will not be factored into eligibility assessment. The study is described to potential participants as "a study to evaluate the effect of mobile technology/SMS texts on improving HTN control for persons experiencing homelessness". If accepted, participants will be consented in a private area/room. Participants with severe mental illness or current severe or uncontrolled substance abuse will be excluded. Socio-demographics and baseline data will be collected including BP measurements by clinic nurses, and behavioral surveys, medication adherence measurements, and other data by RA. RA will offer health education on HTN for 20 minutes to all participants; provide them with free single type of cell phones (with calendar and WiFi access) with unlimited minutes and text plans for the study period; train them how to charge and maintain phones and use SMS texts; and provide ongoing help and follow-ups to assure proper understanding and usage of the phones. Lost/broken phones are replaced free of charge. At enrollment, participants will be randomly assigned to either the INT or CL group described above. Study coordinator will oversee randomization and supervise the application and implementation of the mHealth.

Brief description of mHealth/SMS texting, technology requirement, and communication venues: In initial phase of this study, to better develop and adapt the intervention, we will use a community-based participatory approach to incorporate views from a group of hypertensive PEH, shelter case workers, counselors, and providers. Using focus groups, we will explore literacy factors, HTN health literacy, and mobile technology literacy to adapt SMS platform, the intervention and its components, and evaluation tools. This process will also help further understand and address chronic diseases among other priorities. The study's AIM 1 will also help understand challenges and opportunities and refine the intervention for subsequent studies. In the INT group, participants will receive SMS texts every other day (58) to reinforce medication and appointment adherence, lifestyle changes, and health promotions related to HTN control and CVD risks. For appointment adherence, they will receive reminder SMS texts, 3 and 1 days before each appointment, with a follow up text if missed the appointment. SMS text queries will also be sent about PB medications' side effects. Texts are interactive and reciprocal; for example, if patients send texts (helping in refill medications, answering specific medication, nutrition or other questions) they will be responded within the same day by the system, or directed to an NP and or referred to the PI if need further help. For urgent matters, RA and study coordinator will direct patients to clinic providers or emergency room. If there is no response from participants after one week/three texts, the study coordinator will call to help troubleshoot or address potential reasons for dropouts. We have already identified technology companies to provide the SMS platform (English & Spanish) and IT development services for this study; evaluated their HTN management SMS platforms; and will further adapt and modify them for the intervention and attention control arms. Participants in both groups will receive welcome texts

(Thank you for participating. We will never ask for personal/banking details. Participation is voluntary etc.) and Birthday SMS-texts. Tables 1 presents brief constructs and examples of SMS texts in the INT group (29,55,59).

Table 1. Examples of intervention group's SMS texts for medication adherence in English for each construct **(**29,55,59)

Self-efficacy	*"Have you taken all your medications in the past? Write down what helped you be successful"*
Motivation	*"Set a short-term goal, and achieve it! "You will do whatever it takes to take your medications as prescribed"*
Social Support	*"Ask someone you trust to help you remember to take your medicine as directed"*
Importance	*"Blood pressure can't be cured. To keep healthy, keep on with your pills" " What would you say to your loved ones if they were not taking their medications? Say it to yourself"*
Knowledge, attitude, barriers	*"Use a pillbox to organize your medications" "Talking to your doctor or pharmacist about your medications helps you understand why you are taking them" " Leave yourself a note, voice or email to take medications"*
Implementation, Intention	*"Make taking your pills part of your daily routine, like brushing teeth. It helps take them regularly" "If I have 5 pills left in my bottle, I will call the pharmacy for a refill" "Going on a trip, I will pack my medicine first!"*

The CL arm will receive SMS texts regarding basic general health and health promotions such as the importance of hydration (58), and safety and protection that do not overlap with HTN specific management. The INT arm also receives the same basic general health texts. Both groups will receive routine robocalls regarding their appointments and if they missed them. IT company services will be free of charge for subjects.

Clinic Visits: After enrollment, participants will be scheduled for assessment visits in the shelter-clinics to measure and record their BP readings and medication adherence at regular clinic visits. They will continue to have regular care with their respective providers at their clinics. Blood pressure is measured by clinic nurses at the initial enrollment and at each follow-ups to the end of study follow-up period for each participant. Measurements will be taken per clinic protocols for proper blood pressure measurements (60). Since patients are already diagnosed with HTN, BP readings from the most recent visit will be used to determine uncontrolled vs controlled HTN. Uncontrolled BP is defined based on the current updated guideline (SBP>140 or DPB>90 mmHg) (54). If BP readings indicate critical values, a clinic medical provider will evaluate the patient as an urgent visit and offer the appropriate care. For medication adherence, at each assessment visits, Volis DOSe-nonadherence will be used. Since this population has unstable housing, unannounced pill counts are not feasible. Appointment attendance will be measured by accessing medical records. At enrollment, we will collect socio-demographics and clinical data including age, race/ethnicity, gender, years and episodes of homelessness, BMI, health insurance status, and history of chronic disease (diabetes, renal insufficiency, hyperlipidemia, asthma, COPD and CAD/MI, tobacco, alcohol or substance abuse, or mental illness).

Attrition/Retention: Clients at PR on average stay 1 year within the system which will decrease the attrition rate as they will be reachable in shelters; many patients continue to see their providers afterward. If no responses to texts in one week/three texts, the study coordinator will contact patients by phone and seek support from shelters case workers to connect and identify and address issues related to drop out. Multidisciplinary teams in the shelters to address social barriers and improve social services will help decrease drop-outs.

Data Management: All data received via SMS texting will be captured through the SMS texting interface developed for this project. Each enrolled participant will have a unique identifying ID that will capture their baseline and ongoing outcome data as entered by the RA. All data will be collected and sent electronically in password-encrypted files via an electronic cloud-based system to the GWU data management team that maintain and managed them. The data will be reviewed on a bimonthly basis and issues will be communicated to the contact PI to be addressed during the coordinator's periodic visits to the sites. Outlying, inconsistent data, and missing data will be the targets of the data quality review.

Timeline: Coordination of research & IRB (Mon 1-3); mHealth development and implementation (Mon 1-5); Recruitment and ongoing enrollment, data collection and patient interviews (Mon 6-18); Providers' qualitative interviews (Mon 18-20); Data cleaning and analyses, manuscripts preparation for dissemination (Mon 7-24).

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