Study Title:

Simple Text-Messaging and Social Support to Increase Hypertension Medication Adherence in New Orleans, LA (TEXT MY MEDS NOLA)

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1. Study aim, Background, and Design

Non- adherence to blood pressure medication can significantly predict substandard hypertension (HTN) management and cardiovascular (CVD) control.[1] There are several main identified barriers that contribute to poor hypertension management in AA: low socioeconomic status, dysfunctional health care systems, the presence of comorbid medical conditions, complicated medication regimens, and certain personal patient characteristic.[2] One particular social determinant, the support system of a patient, has been shown to positively contribute to patient adherence to pharmacotherapy.[3,4,5] Telehealth and the utilization of technology have emerged and offered cost-effective health services through various platforms during the pandemic[6,7]; however, despite these benefits, telehealth strategies may not effectively coordinate care for patients with low socioeconomic status and residence in communities with limited access. It is necessary to determine the adequacy of health education learning and assessment for these patients.[8]

The specific aims of this research study are to 1) engage participants with poorly controlled hypertension and medication non-adherence to use simple digital approaches, specifically recurring text-messages to improve medication adherence, 2) promote participant medication adherence and interaction with telehealth platforms with recurring text reminders on medication schedules and refills, science-based hypertension education content, and communication exchange with their health providers to improve blood pressure, and 3) evaluate the role of social support in helping participants manage their hypertension and control of CVD risk factors, including daily blood pressure measurement, changes in participant quality of life, and barriers towards medication adherence, and setting goals for health behaviors.

2. Subject Population

50 adult patients with hypertension will be recruited from the Tulane cardiology clinic and Christian Unity Baptist Church. All participants will need to satisfy the following inclusion criteria to enroll into the study:

- Adults > 18 years of age.
- Speak and read English.
- Diagnosis of stage 1* and 2** HTN, taking at least one antihypertensive medication.
- Internet and mobile phone access with two-way texting capability.
- ≥ 1 on K-Wood-MAS-4 or similar tool.
- Able to download blood pressure tracking App to mobile phone.
  *(*Stage 1 HTN: 130-139 mmHg or 80-89 mmHg[16])*
  *(**Stage 2 HTN: 140 mmHg or higher or >90 mmHg[16])*

The following exclusion criteria will prevent participants from enrolling in the study:

- Having been hospitalized within 6 months of starting the study if you have a diagnosis of heart failure, end-stage kidney disease, acute coronary syndrome, or stroke.
- Plans to cancel mobile phone plan within 3 months.

Participants will be recruited by the academic and community principal investigators and key study personnel. Potential participants from the cardiology clinic will be identified by the study personnel and medical staff prior to cardiology appointment using their clinical knowledge and expertise and the patients' medical history and records; the study team and medical staff will give potential participants the recruitment flyer if they are interested in the study. Interested

patients seen in clinic will be asked to contact the IRB-approved study personnel directly. The research team will screen church participants following their regular Sunday service and distribute recruitment flyers to potential participants. A recruitment script will be read by all study personnel when contacting potential participants by telephone. Eligible participants interested in participating in the study will make appointments with the study team to enroll at the Tulane cardiology clinic.

3. Procedure

All eligible participants will be enrolled into the study at the Tulane cardiology clinic for an 8-week period. Key study personnel will screen patients from the clinic interested in the study during their appointment visit. Identifying information that will be collected from participants will be name, date of birth, and telephone number to send them text messages. Potential participants making study inquiries by email will receive prompt responses. If the participant does not enroll in the study because they are not eligible, we will shred the information. Study personnel will also review medical records of Dr. Keith Ferdinand to identify potential patients and provide the subjects with study information (e.g. flyers, advertisements, recruitment script, etc.) The subjects may then approach the study team about participation. Study personnel will arrange a time and date with the church community site to distribute flyers describing the study to church congregants to seek study interest. Interested persons can be screened on-site for eligibility or at a date to be determined by congregants. Study personnel will use an eligibility checklist to screen participants. Below are procedures performed during the study and the time expected to complete each task:

This study will follow an 8-week interventional cohort design using a series of questionnaires to collect data pre-post study procedures from two sites: Tulane cardiology clinic and Christian Unity Baptist Church. Participants will be screened for eligibility at both sites by in-person interviews, telephone using an IRB-approved recruitment script, and/or clinic medical records. After screening, eligible participants will be enrolled into the study at Tulane cardiology clinic by study personnel. Blood pressure and weight will be measured by study personnel on the first and the last day of the study, in addition to calculating their risk for heart attack and stroke using the ASCVD Risk Estimator Plus.[9] Study personnel will calculate participant's ASCVD risk by downloading the app on their mobile device. No patient information is collected and stored in the app. Anonymous user behavior (e.g., number of people who downloaded the app, how many times a day the app was used) will be gathered through Google Analytics. All data collected in the app is anonymous and cannot be traced back to an individual user.

Age, gender, race, medication, smoking behavior, and laboratory information from the clinic medical record will be inserted into the app to calculate ASCVD risk. Calculations from the church site will be performed if participants have their laboratory values (e.x. total cholesterol, HDH cholesterol, and LDL cholesterol) to insert into the app. ASCVD risk will not be measured if participants do not have their laboratory values.

Participants will be enrolled in a bidirectional text messaging system from Tulane University Medical Group where they will receive and send text from their mobile phones to monitor their antihypertension medication regimen. Text messages will be sent: daily for medication and refill reminders; weekly for hypertension education messages and asking if a support person helped them with medication reminders. Study personnel will educate participants on proper blood

pressure technique to conduct self-measured blood pressure (SMBP) at home. These blood pressure values will be automatically uploaded twice daily from a Bluetooth device to a phone application to allow the participant and healthcare team track their blood pressure. Participants will receive the Bluetooth blood pressure device to perform SMBP at enrollment.

Participants will schedule their second and final in person appointment at the end of the 8-week period. Participants will be asked to complete the HRQOL-14 and K-Wood-Mas-4 adherence to medication scale, as well as have their blood pressure and weight measured.

After the study team has coded the data, a statistician from Tulane University School of Public Heath will analyze and clean data for missing values using standard statistical software. Descriptive statistics will be measured for all variables to evaluate the range, mean, standard deviations, frequencies, variance and normality of the data. Pearson correlational statistic will determine the association or relationship between hypertension medication adherence and text messaging, BP, and calculated ASCVD (atherosclerotic cardiovascular disease) Estimated 10-year and Lifetime Risk and social support.

Screening procedures:

1. ***≥ 1 on K-Wood-MAS-4 adherence to medication scale***
2. ***Diagnosis of Stage 1 and Stage 2 hypertension (see above #2 Subject Population)***
3. ***Taking at least one antihypertensive medication.***

First day for enrollment procedures at the Tulane cardiology clinic:

1. ***Sign informed consent***
2. ***Completion of questionnaires (demographic/medical history; HRQOL-14)***
3. ***Blood pressure and weight measurements***
4. ***Instructions on home blood pressure measurement with Bluetooth blood pressure device and download of Sphygmo app on participant mobile phone***
5. ***Instruction on receiving and responding to text messages on mobile phone***

Last day of study procedures at the Tulane cardiology clinic:

1. ***Completion of HRQOL-14 and K-Wood-Mas-4 adherence to medication scale***
2. ***Blood pressure and weight measurements***

Study Procedures	Time to Complete
Sign informed consent	10 minutes
≥ 1 on K-Wood-MAS-4 adherence to medication scale	2 minutes
Demographic and medical history form	3 minutes
HRQOL-14	5 minutes
Blood pressure education using Bluetooth blood pressure device to learn how to: Take proper self-measurement technique every day in the morning and evening Download Sphygmo app to monitor blood pressure	10 minutes
Instruction on receiving and responding to text messages on mobile phone	10 minutes

Measure clinic blood pressure and weight	5 minutes

Participants enrolled into the study will be identified by site (TCC for the cardiology clinic and CUBC for the church) and number beginning with 01 for each site. Participants will receive their standard medication regimen for the management of their hypertension from their primary provider.

4. Risks

Participation in this study involves minimal risk exposure. Participants may experience inconvenience in taking time to complete the questionnaires and forms. The blood pressure cuff may feel uncomfortable after inflation while taking self-measurements. Participants may feel the number of text messages received to be overwhelming. Although participants will have the option to opt-out of receiving text messages it will involve discontinuing the study. There is the potential for loss of confidentiality by participating in the study. However, appropriate efforts will be made to protect the confidentiality of identifiable information. All data will be stored and scanned on an external hard drive and in a locked file cabinet in Dr. Keith C. Ferdinand's office accessible only by co-investigators for the duration of the study. All identifiers will be removed and the data will be kept for a number of years in a safe place, or archived in the safe place.

Standards of identifying, organizing, and assignment of data will be determined by investigators. Participants will be identified by assigned successive numbers beginning with 01 on study documents and by site, clinic or church**.** All study documents will be organized in a file folder per participant. The texting messaging system operated by The Tulane Medical Group will store messages on a HIPPA compliant secured cloud server. The Sphygmo remote blood pressure monitoring system also uses HIPAA compliant data security procedures throughout the clinical workflow process from data collection to a cloud server storage center. Data collected from the Tulane Medical Group text messaging system and Sphygmo will be identified by participant number and site. This data will be organized in a report format by assigned identifying numbers and site.

5. Benefits

There will be no direct benefits to subjects for participating in this research, but the knowledge gained from the study may benefit society in general. Anticipated benefits might include a participant's greater understanding of different methods to increase adherence with hypertension medication to improve blood pressure. Participants will have use of a Bluetooth blood pressure device during the study, which will be significantly discounted for purchase if desired upon study completion.

6. Remuneration

Participants will receive a $20 gift card on the enrollment day, which is the first study visit, and a $30 gift card on the last study visit for travel to Tulane cardiology clinic and/or inconvenience. They will receive the compensation even if they did not complete study procedures.

7. Academic or Extra Credit

NA

8. Costs

There will be no costs for participating in this research study.

9. Alternatives

You do not have to participate in the research study.

10. Consent Process and Documentation

Approval of the study will be obtained from Tulane University IRB. Following official IRB approval, the participants will be recruited and given a full description of the research purpose, personnel, procedures, risks, and benefits of the study. They will be told that their participation is voluntary and have the right to discontinue at any time. They will be asked to read the informed consent where the research team will answer any questions regarding the study. If participants agree to participate in the study, they will be asked to sign the informed consent. The research team will keep these consents for at least 3 years.

11. Qualifications of the Investigators

Keith C Ferdinand, MD is academic co-investigator, clinical cardiologist, and professor of medicine at Tulane University School of Medicine. He has a clinical investigator and board certified in internal medicine and cardiovascular disease. His research is primarily focused on cardiometabolic risk and control, exploring differences across sex groups and racial/ethnic minorities in addition to the role of adherence in supporting better outcomes. Over the course of his career, he published 200 peer-reviewed articles, reviews, and book chapters and served on 5 advisory boards, 2 of which I chaired. His clinical, administrative, and research experience supports his role as co-investigator for the proposed study.

Daphne Ferdinand, PhD, RN is community co-investigator/project director, registered nurse, and executive director of the Healthy Heart Community Prevention Project. She has 22 years of experience in administration and management at Heartbeats Life Center, formerly a cardiovascular diagnostic testing center and clinical cardiology consultation practice. She was a clinical trials coordinator over hypertension and cholesterol research studies. She developed and implemented a BP education and training program for neighborhood hair salons and barbershops; CVD prevention Sunday for church pastors. She co-authored publications on hypertension prevention and management, cardiometabolic risk, and community-based approaches to cardiovascular disease. She is well qualified as a co-investigator and project director given her work and experience with community health programs.

12. Statistical Analysis

Age is summarized with means and standard deviations. All categorical participant characteristics are summarized with counts and percentages. Baseline, follow-up and differences in outcome variables are summarized with means and standard deviations. In addition, differences in outcome variables from baseline to follow-up are summarized with medians and interquartile range. Statistically significant differences from baseline to follow up were assessed using the Wilcoxon Signed Rank Test at the 5% significance level. P-values are reported for each comparison. Statistical analyses were performed using SAS9.4.

12. References

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