



Utilizing a mobile health (mHealth) application to improve hypertension monitoring and self-management in an underserved community: A pilot study

Research Protocol

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Abstract

Monitoring and self-management are important components of effective chronic disease care and improved patient outcomes. With the rapid development of integration of mobile health technology (mHealth) into health care delivery services, mHealth intervention provides a great opportunity to improve the efficiency of chronic disease management. However, little is known about whether mHealth interventions can effectively impact the health and health care outcomes in underserved populations. This pilot study will assess the preliminary effectiveness of a mobile-based health intervention in an urban underserved community with a high incidence of hypertension. It is hypothesized that patients with hypertension will experience improved outcomes due to the use of a mHealth application compared with patients who are not using the application. The findings from this study will advance our understanding of the utility of mHealth interventions among underserved populations and generate evidence to support this new health care delivery approach in underserved urban communities.

Key words: mHealth, hypertension, monitoring, self-management, underserved community

Specific Aims

This study will examine the effectiveness of a mHealth application to enhance hypertension monitoring and self-management at an urban nurse-managed community health center. The specific aims are to determine 1) whether hypertensive patients who are randomized to receive either the standard care plus the mHealth intervention or standard care will show differences in blood pressure (BP) control, 2) whether hypertensive patients who receive the standard care plus the mHealth intervention will show differences in patient-centered outcomes as compared to those receiving existing standard care only. Accordingly, the follow hypotheses will be evaluated:

1. Hypertension patients using the mHealth application exhibit a greater decrease in blood pressure and better maintenance over a 6-month period compared to those who receive standard care.
2. Hypertension patients using the mHealth application will exhibit more effective self-management as compared to those who receive standard care.

Patients receiving the intervention are expected to show greater BP decrease over 6 months, greater maintenance of BP at 6 months, reduced hospital utilization, greater BP monitoring adherence, and are expected to improve health behaviors associated with better patient-centered outcomes such as better health-related quality of life, greater self-efficacy and optimism about BP control, as compared to those receiving standard care only.

Background and Significance

Hypertension is the leading risk factor for cardiovascular disease and stroke, impacting more than 348,000 Americans in 2009 (CDC, 2012) and causing nearly 1000 deaths each day (Go et al. 2013). Approximately 31% (75 million) of American adults have high blood pressure, but only about half of these individuals have their condition under effective control (CDC, 2012). In addition, significant ethnic/racial and socioeconomic disparities persist in hypertension patients. The prevalence of hypertension in African Americans is among the highest in the U.S.; African Americans also have the highest rates of uncontrolled essential hypertension in this country. It has also been reported that African-Americans from lower socioeconomic classes are more likely to develop hypertension than other groups (Cooper, et al. 2000). The New Jersey Department of Health and Senior Service (2010) estimated that 29% (53,286) of the Newark adult population has high blood pressure. Unlike acute diseases that may be amenable to short-term interventions, hypertension requires long-term monitoring, self-management, behavior changes, and adherence to a medication regimen. The ability to help high-risk populations to constantly monitor, self-manage, control, and improve their condition plays a crucial role in successfully managing and preventing this particular chronic disease. Mobile Health technology (mHealth) has the potential to contribute significantly to hypertension management by enhancing monitoring and self-management among hypertension patients.

mHealth is defined by the World Health Organization (WHO) as “medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDA), and other wireless devices” (WHO, 2011, p.6). Naturally, people use mobile devices to communicate, but technologies like this have powerful unintended outcomes (Morten, 1936). In the case of mobile devices, health monitoring practices can be recorded in real-time and then self-reported. Depending on when, where, why and how people use their mobile devices, self-reported, real-time health data can become a valuable unintended outcome of mobile device. Through this technology, individuals within geographically-specified target groups may voluntarily reveal information that is otherwise incredibly challenging to gather. For example, in a 2012 Harvard study, cell phone data from 15 million cell phone users was gathered and used to identify and predict new patterns of malaria spread in Kenya. With the mHealth platform, patients can provide close to real-time feedback to their health providers. Based on such self-reported data, health providers could proactively predict patterns of the disease, and provide improved and timely educational programs to the targeted populations, thereby promoting more efficacious prevention and treatment strategies. Other research evidence also suggests that mHealth may be beneficial in weight loss treatment (Duncan et al, 2011; Spring et al. 2013), physical activity involvement (Hurling et al, 2007; Consolve et al, 2006), asthma control (Anhoj et al, 2004; Britto et al, 2012; Massoudi & Rothemich 2012) and diabetes management (Faridi et al, 2008; Vahatalo et al, 2004).

Furthermore, Smith (2014) reports that more African Americans in this country use mobile phones than do Caucasians: 92% of African Americans own a cell phone, of which 56% own a smartphone. Additionally, text message use is common among people of varying health insurance statuses (PricewaterhouseCooper’s Health Research Institute, 2010). Together, these facts provide enough evidence to suggest that the mHealth platform may be able to penetrate the urban underserved community in which this study will be conducted.

Existing Gaps between mHealth Applications and Underserved Populations

Contextual gap: underuse of mHealth in underserved populations

According to the NIH’s Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7, 2004), life style modification and monitoring for blood pressure are among the necessary steps in hypertension therapy. At that time, electronically based support systems, such as computer-based and PDA based technologies, were believed to be potential tools for hypertension treatment. The prevalence of mHealth in the past decade has realized some of this potential. Even though mHealth has been promoted by many for its utility in increasing wellness and changing life styles, the study of mHealth in clinical contexts targeting underserved populations has not been widely reported. To begin addressing this gap, the Robert Wood Johnson Foundation funded a \$500,000 project in November of 2013 to educate entrepreneurs in bridging technical aspects of this gap. The proposed study is an attempt to bridge the gap in a clinical setting.

Measurement gap: AMBP vs. self-measurement in hypertension treatment

The JNC 7 specifically pointed out that two types of measurement, the Ambulatory Blood Pressure (AMBP), and self-measurement, are important components for accurately measuring blood pressure. The characteristics of mHealth provide meaningful clinical measurement to address both a 24 - hour automatic measurement for AMBP and an easy access measurement by patients. The effectiveness of mHealth to fulfill these measurements is yet to be determined.

Behavioral gap: mHealth and patients' motivation in hypertension treatment

Hypertension treatment is effective only when the patient is motivated (JCN7, 2004). A motivated patient is willing to monitor his or her blood pressure, change his or her life style, and take necessary medications. How the use of mHealth motivates patients' active participation remains unknown and needs to be explored. The provision of accessible feedback to patients coupled with support for behavioral change should, in theory, both motivate and support improved patient outcomes.

Possible outcomes and implications for future research

The integration of mobile technology and self-management of chronic diseases such as hypertension and diabetes presents the perfect opportunity for innovations in health care delivery. However, it has proved challenging to integrate underserved populations into emerging healthcare strategies. This study will demonstrate that the mHealth intervention can provide a fast, reliable and inexpensive communication mechanism between health care providers and their underserved patients, which will help to integrate them into emerging innovations in health care delivery and reduce health and health care disparities. Specifically, this mHealth application study will not only make real-time patient monitoring feasible in underserved communities, but it can also help optimize the use of limited medical resources in these settings, adding to the promise of the nurse-managed community healthcare model by allowing nurses to proactively identify patients with worsening disease conditions in order to offer timely medical intervention. The results of this study will provide the initial data required to apply for future research funds from the National Institutes of Health (NIH), which has announced funding opportunities in developing and using mobile technologies to improve the health of underserved populations.

Research Design and Methods

Study Design

This study will have two phases. In Phase 1, a pilot version of a randomized controlled trial (RCT) will be utilized to examine BP decline and BP maintenance with 30 participants assigned either to standard care and treatment (a control group) or to the standard care plus mHealth (the intervention group). In Phase 2, improved quality of life, patient self-efficacy, greater treatment adherence, reduced hospital utilization.

Setting and Sample

The proposed study will take place at the Jordan and Harris Community Health Center (J&HCHC) in Newark, NJ. The J&HCHC is a nurse-managed, community-directed health center providing health services for a vulnerable, underserved population in the city of Newark. This center is utilized by the residents of three public housing developments in the East Ward of Newark. The great majority of these residents are low-income African Americans.

The proposed pilot study sample of 30 patients (15 in the standard care group and 15 in the standard care plus mHealth intervention group) is approximately 10% of the approximate sample size we hope to incorporate into future mHealth studies (TCD Guidelines, 2010).

Eligible study participants will be defined as 1) 18-64 year-old residents of one of the three housing developments, and 2) subjects who have been documented with uncontrolled ambulatory blood pressure (BP), and whose 24-hour ambulatory BP measures 140/90 mm Hg or higher for either of the two numbers. Eligible nurses will be defined as nurses who are currently working at J&HCHC. Patients will be recruited from J&HCHC via Community Health Workers (CHWs). Children (under age 18) and pregnant woman are excluded in this study.

Study Procedures

Based on the J&HCHC's current practices, all hypertensive patients are required to visit the nurse for their regular hypertension monitoring every week. Therefore, all participants in this study will be asked to visit J&HCHC once a week for the 6-month period as usual. The standard follow-up group will receive the typical regular hypertension care, which consisted of nursing assessment, medication management, patient education, follow up and continuing care. While the mHealth group will be asked to use iHealth BP7-Wireless Blood Pressure Wrist Monitor on a daily basis at home, while also visiting the J&HCHC once a week to receive regular hypertension care for the 6-month period. Furthermore, all study participants will be asked to complete the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) and Medication Adherence Self-Efficacy Scale (MASES) in-person at the beginning and the end of the study.

In this study, a FDA 510K approved device, iHealth BP7-Wireless Blood Pressure Wrist Monitor (iHealth Lab Inc.) will be utilized for the mHealth group. This is a fully automatic wrist-cuff blood pressure monitor that uses the oscillometric principle to measure blood pressure and pulse rate. The monitor works with a mobile app to test, track, and share vital blood pressure data. There are no physical risks associated with using the device to monitor blood pressure at home. Besides the FDA 510K approval, iHealth BP7-Wireless Blood Pressure Wrist Monitor has also CE medical certification (Europe) and ESH Certification (European Society of Hypertension). iHealth BP7-Wireless Blood Pressure Wrist Monitor works with both Apple and Android devices. iHealth MyVitals is an



application that is downloadable for free at both the Apple Store and Google Play. It automatically tracks and analyzes key health vitals all in one place. The measurements taken by iHealth BP7-Wireless Blood Pressure Wrist Monitor are automatically stored in an easy to read format. It also provides instant access to patient measurements and allows patients to see how they are doing and even set optimal goals.

Each iHealth BP7-Wireless Blood Pressure Wrist Monitor user receives a free cloud service account. When patients measure their BP, the BP vital data is then stored and backed up securely into the iHealth cloud through their account. The patient and/or healthcare provider can log into the cloud account from any device and access the data, regardless of where the measurement was taken. Healthcare providers can also create master accounts through which they can access all users' data held under their care. This allows healthcare providers to monitor their patients' blood pressure remotely and intervene in a timely fashion.

The research team will hold three training sections prior to the start of the study in order to train all the mHealth group participants how to appropriately use the device and monitor their BP. Two nurses and six CHWs will also receive training on how to access the mHealth group participants' data in the iHealth cloud account. In addition, the research team will do home visits or telephone calls for both group participants each week during the study period to assure the study participants followed the study protocol.

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