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

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Data Analysis Plan

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A pilot version of a parallel-group 6-month randomized controlled trial (RCT) will be utilized to this study. 30 participants will be randomly assigned either to standard care and treatment (the standard follow up group) or to the mobile intervention group (the mHealth group). For the standard follow up group, participants' BP will be measured in an upright seated position with feet flat on the floor while being at rest for at least 5 minutes (1). During each visit, participants will be measured twice or more, separated by two minutes in each arm. The Welch Allyn Spot Vital Signs LXi electronic blood pressure monitor will be utilized for this group. Participants' systolic blood pressure (SBP), diastolic blood pressure (DBP) and pulse will be measured and recorded by the J&HCHC nurses. For the mHealth group participants' BP data will be collected in two ways: iHealth's MyVitals and office visit BP records. The office visit BP will be measured in a manner identical to the standard follow up group. iHealth's MyVitals BP data were collected by a project research assistant every week. Data were aggregated, and an average of the BP readings recorded at baseline (beginning of the study), at three months and six months will be used for data analysis.

BP monitoring adherence for the standard follow-up group will be calculated by dividing the total number of office visits to measure BP by the total number of expected visits (one office BP measurement every week for 6 months). BP monitoring adherence for the mHealth group will be calculated by dividing the total number of times iHealth BP-7 was used to measure BP by the total number of expected times it should have been used (one BP measurement performed every day for 6 months).

Improved health related quality of life, patient self-efficacy, and reduced hospital utilization will be measured. Medical Outcomes Study 36-Item Short- Form Health Survey (SF-36) will be utilized to measure the health-related quality of life. Patient self-efficacy and treatment adherence will be measured by the Medication Adherence Self-Efficacy Scale (MASES). Self-reported hospital utilization rate will be used to measure reduced hospital utilization. Participants hospital utilization data will be retrieved from their electronic medical record.

Data analysis will be performed by using Statistical Package for the Social Sciences, Version 24.0 software (SPSS Inc., Chicago, IL, USA). All statistical analysis will be two-sided. A p-value of ≤ 0.05 will considered as statistically significant. Two by three repeated measures ANOVA test will be used to assess the effect of time (baseline, 3-month, and 6-month) on the difference of SBP and DBP between the standard follow-up group and the mHealth group. For this analysis, the between groups factor will be the standard follow-up group vs. the mHealth group. The within subject factor will be time, baseline, 3-month and 6-month. Simple contrasts will be used in case the interaction terms were significant to determine differences in SBP and DBP between groups. The nonparametric, Mann-Whitney U test will be used to compare the values of SF-36 scores, MASE scores, hospital utilization between the baseline and 6 month later.

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Reference:
1. Perloff, D., Grim, C., Flack, J., Frohlich, E. D., Hill, M., McDonald, M., & Morgenstern, B. Z. (1993). Human blood pressure determination by sphygmomanometry. *Circulation*, *88*(5), 2460-2470.