# Statistical Design and Power

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Title: mHealth to Address Uncontrolled Hypertension Among Hypertensive Homeless Adults

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## STATISTICAL DESIGN AND POWER

**Sample size and statistical power**:
The study is powered for the outcomes of AIM 2 and based on the comparison of mean BP between the CL and INT groups at 6 months. Given the data scarcity on the effect of mHealth strategy on HTN in the PEH, there is not sufficient data for power estimation. A decrease in SBP of 5 mmHg is associated with clinically important reduction in the relative risk of stroke/CAD events (66). Based on our recent study (14), we used the standard deviation of SBP (15 mmHg) and DBP (13 mmHg) to calculate sample size. Assuming a two-sample *t*-test, we calculated that a total of 120 (60 per each group) is sufficient to achieve a power of 80% to detect a difference of 8 mmHg assuming the SD for both groups is at 15 at the 0.05 significance level (two-sided). Based on data from our site, this is a conservative power estimate for either outcome of SBP or DBP. Up to 27% of PEH have HTN (6); 40% uncontrolled (14). In 2019, the PR served at least 1000 unique PEH with HTN (53). Using medical record reviews and outreach, with a conservative 50% response rate, we will be able to enroll 120 participants within 4-6 months. Risk of contamination will be low as weekly enrollment in each clinic is low and PEH are from different shelters (each 100-300 PEH) in and outside PR or on streets.

**Data Analysis, Outcomes and Measurements:**
**AIM 1:** The primary outcomes are changes in SBP and DBP and the percentage/degree of adherence to BP medications and appointment attendance.
Blood pressure will be measured by clinic nurses at the initial enrollment and at each follow ups to the end of study follow-up period for each participant. BPs will be measured with the patient seated in an upright position with right arm resting on a table at the level of heart and a proper cuff size is fitted, after 5 min rest (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) and considering other co-morbidity including CAD, stroke, MI, DM or chronic kidney disease (54). When no co-morbidity, we define Stage 2/Uncontrolled HTN as ≥140/90<160/100, and "Stage 3/Very uncontrolled ≥160/100".
Adherence to medication for each participant will be measured by Voils DOSE-nonadherence tool (68,69). Appointment attendance is collected via medical records and as ratio and number of kept appointments to all appointments scheduled (0-100%) (58). Other outcomes will include utilization and frequency of phone and SMS text use/message exchanges for the level of engagement (number of texts read and responded by participants) (58); phone retention rates; changes in adherence to other CVD medications (statin, anti-platelets) and risk factors (non-HDL or LDL, smoking cessation); (56,57). Interim analysis will be performed. Final analysis will be performed after the completion of data collection. Main predictor is the HTN specific mHealth intervention. Independent variables including self-reported sociodemographic and clinical data/indicators (including age, race/ethnicity, gender, years and episodes of homelessness, BMI, health insurance status, and history of chronic disease such as diabetes, renal insufficiency, hyperlipidemia, asthma, COPD and CAD/MI, tobacco, alcohol or substance abuse, or mental illness), will be analyzed for the association with the outcomes.

**AIM 2**: Attitudes, acceptance and experience of mHealth will be assessed from qualitative individual audio-taped interviews with hypertensive patients and providers using 8-10 open-ended questions with probes. Primary discussions with key informants in the shelters for discourse will help bring up issues to be explored by questions during interviews.

**Analytic Plan and Statistical Analysis:**
**AIM 1:** The primary statistical analysis will be on an intention-to-treat basis. The trial results will be reported as comparative summary statistics (difference in response rate or means) with 95% confidence intervals and in accordance with the CONSORT. All statistical tests will use a 0.05 two-sided significance level. We will test the difference of outcomes (change in SBP and DBP from baseline) between the groups after 6 months using a two-sample t-test. We will examine the outcomes using a mixed-effects model on data collected at 6 months to calculate the outcome of change from baseline. An interaction between time and randomized group will be fitted

to allow estimation of treatment effects (INT vs. CL) at each time point. Analysis of covariance will be used in place of a t-test, if covariates needed. A regression analysis will be performed using the final assessment of adherence as a response and randomization group as a predictor. Other variables that may potentially have effects on adherence such as age, gender, education and comorbidity will also be included if they are not balanced between groups by the randomization or if determined by univariate analysis to be significantly predictive of adherence. The medication adherence will be calculated for 6 months and compared between two groups using the generalized estimation equation (GEE) method (or multivariate ANOVA). Message exchanges in two groups will be analyzed for the engagement level to explain outcomes. Numbers and percentages of appointment attendance and all secondary outcomes will be compared between groups. We will report missing data and explore patterns and mechanism, though a mixed-effects model does implicitly account for data missing at random. We will report all results in total numbers and percentages.

**AIM 2:** Interviews will be transcribed coded and analyzed using an inductive grounded theory analysis. Content analysis will be done by two research team members to identify core perceptions regarding mHealth strategy for HTN management. During content analysis, we will develop preliminary coding based on priority codes derived from the theoretical framework and conceptual model guiding the study. We will perform critical deliberation about initial coding and review coding for similarities and variations among coders' output to achieve a high level of agreement and assure that the coding scheme is appropriate. Reviewers will independently review codes, meet and discuss them, identify concepts and categories, and describe major important themes.

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