

MOBILE Intervention in College Students with Elevated Blood Pressure

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Statistical Analysis Plan

Statistical Design and Power

Sample size. We will recruit 32 subjects to be randomized to an intervention and control arm with a ratio of 1:1 ($n = 16$ per study group), using a random number generator. A sample size comparable to a prior study of cellular phone and internet-based intervention on BP reduction that showed medium to high effect sizes (ES $f = 0.395$) on BP reduction.⁴⁹ Using an estimated ES of $f = 0.39$ for the within-subject effect (Time), we conducted a power analysis for a mixed design ANCOVA with 2 groups, 2 measurements per subject, and $r = .5$ for the bivariate correlation between two measures tested at $\alpha = 0.05$. To achieve 70% power for the significance test of the within-between interaction effect, a sample of $N = 28$ will be needed. Anticipating a 7-11% attrition rate⁴⁹ based on the previous study,⁴⁹ an initial $N = 32$ will be needed to achieve 70% power to test preliminary impact. We acknowledge that the low power level is a limitation in our pilot study; therefore, we will attempt to recruit more within the timeframe to reach a higher power level.

Data Analysis. Aim 2: We will perform preliminary descriptive analyses on all variables, use Pearson's correlation (r) to assess relationships between primary and secondary outcome variables at each data collection point, and calculate Pearson's r to assess the stability of each outcome variable pre- and post-intervention. To evaluate feasibility and acceptability, we will use content analytic methods to identify students' likes and dislikes and suggestions for future app improvement.⁶⁵ Thematic analysis of interviews will be conducted to describe the elements of feasibility and acceptability as perceived by subjects. Participation rate will be calculated as the percentage of students enrolled out of all eligible students who are invited to participate in the study; engagement will be calculated as a percentage of students' available data out of all the intended data points. **Exploratory Aim.** "The intervention group will have a significantly greater reduction in BP and sodium intake and greater increase in HTN knowledge from baseline to completion, compared to control group." A 2x2x2 mixed design ANCOVA will be performed for each of the above primary and secondary outcomes, with Study Group (Intervention vs. Control) as the between-subject factors, years of age as the covariate. A Time effect on an outcome variable would indicate the impact of the **MOBILE** intervention on the outcome measure in college students with elevated BP.