MOBILE **Intervention in College Students with Elevated Blood Pressure**

Version Date: 05/19/2021

Protocol and Procedures

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Aim 1 Formative research design. We will recruit two student panels (4-5 students each) to further refine the **MOBI**LE intervention and assist in developing measures used in the study. We will recruit one set of student panel at a time. This 4-month phase will enable the team to design an extensive list of SMS messages tailored to different levels of motivation. In a 4-week intervention, enough messages are needed to ensure no message will be sent more than twice. Given 3 levels of motivation (1-low, 2-moderate, and 3-high), each level requiring different prompting messages, at least 42 (28 days x 3 levels = 84/2 = 42) messages need to be created across the 3 levels. The team will draft an initial set of messages, drawing content from the American Heart Association high BP recommendations;[60] each message's behavioral suggestions will correspond to each of the 3 motivation levels. Students will be surveyed to rank the effectiveness of each message; they will be asked to assess how clear, compelling, engaging, and motivating each message is in itself and how effective each message might be in propelling them to action. The investigative team will identify strong and weak messages, characterizing what makes strong messages strong. The team will then build a revised list of messages, discarding the weakest, or use what we have learned to strengthen the weaker messages. We will repeat this process with the second group of students using the revised list of messages and use those results to build a stronger final set of messages to be used in the implementation phase of the study. This iterative approach will also refine the study's motivational scale and self-report survey. This phase will be held via zoom with no in-person contact.

Aim 2 and Exploratory Aim Research Design. The proposed pilot study will use a randomized two-arm intervention and control group design to test the preliminary impact of the **MOBI**LE intervention. The PI will be involved in all aspects of study and will train a research assistant (RA) to provide the educational session, monitor subjects, and address technology challenges.

Aim 2 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 α = 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 rate[49] based on the previous study,[49] an initial N = 32 will be needed to achieve 70% power to test preliminary impact. The low power is a limitation; we will attempt to recruit more within the timeframe to reach a higher power level.

Aims 1 and 2 Site for subject enrollment. UNLV is the largest university in Nevada with over 30,000 undergraduate and graduate students, and it is most diverse university in the nation. This increases the potential for inclusive recruitment of different race/ethnicities that reflect the changing demographics of the state and nation.

Aim 2 Enrollment and recruitment. We will use recruitment strategies that have been successful in the PI's previous studies, including posting research flyers around campus, UNLV Rebel Announcements, UNLV Today (monthly), Student E-Newsletters from Department (SEND), and UNLV Graduate & Professional Student Association. Recruitment will occur face-to-face with students at sites around campus (once campus is opened). Subjects will be screened privately for inclusion (1. During the initial zoom meeting going over the informed consent in addition to 2. Having high blood pressure, meet via face-to-face following CDC guidelines for 5-10 minutes).

Aim 2 and Exploratory Aim Study Procedures - MOBILE **Intervention**

Baseline data collection. Baseline data collection (using Qualitrics) will occur before the start of the educational session, described below. Subjects with blood pressure value less than 120/80 mm Hg during this visit (second blood pressure reading) will no longer qualify for this study. The gold standard BP measurement using a sphygmomanometer through auscultation will be taken twice, five minutes apart to be averaged. Other baseline data include: anthropometry (height and weight), Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24) focusing on sodium intake, pre-test Hypertension Knowledge-Level Scale (HK-LS), and initial motivational level assess (using Qualitrics) using the study's iPads. We have two research iPads that are only designated for this project. The subjects will not use their own devices and the link are not send to subjects. It is already set up to collect data from the subjects. We locked the screen on the iPads so only the questionnaires can be accessed.

Aim 2 Educational session, all subjects. The PI or RA will provide a brief one-on-one or group educational talk (no more than 2 subjects, to separate intervention and control group subjects) before the 4-week trial on the importance of SMBP, elevated BP regarding CVD risk, the role of motivation in adopting lifestyle behavior, and specific behaviors to reduce BP. This is akin to HTN risk reduction advice received in an office visit.

Aim 2 MOBILE **Intervention Group.** Following the educational session, intervention subjects will receive a Withings BP cuff and Health Mate app will be installed on their smartphone. *The research team will create a username (subject's ID for the study to maintain confidentially) for each subject.* By consenting, subjects will grant us access to their recordings and direct access to app manufacturer data on them. As a second layer, we will also ask the subjects to send the research team their daily blood pressure value to ensure we have the data and continual daily communication. We will show them how to use the Health Mate app, upload Withings BP cuff readings, upload historical data to the cloud, read trend lines in their record, rank their daily motivational level, and answer a brief SMS question about whether they completed the behavioral change task encouraged by the daily message. A one-page instruction sheet with the research team's contact information will be provided. In addition to addressing questions, the session will offer the opportunity to practice using and entering data on the app. Subjects' use of the app will be assessed and followed-up within 72 hours by the RA to ensure subjects' comfort level using the instruments and app. Subjects will be instructed to take their BP daily, before their first meal and encouraged to avoid prior alcohol and caffeine intake as well as physical activity. They will be instructed to rate their motivational level as low, moderate, or high via SMS when transmitting their BP value. Their level will trigger the appropriate behavioral change SMS prompt. Thus, a subject at a high motivational level – because they feel good about having their BP in the normal range – will receive an encouraging text message ("keep up the good work") along with a prompt to complete a difficult task (e.g. do some form of physical activity for 30 minutes). On a low motivation day, a subject might be encouraged to look up low-salt salad dressing recipes online. Subjects will receive a reminder SMS if they have not provided their daily BP. *This is not a physical activity or dietary intervention; therefore, specifically physical activity or dietary education will not be provided, rather this is a behavioral intervention that encourages the subjects to engage in healthy behaviors that they have previous experience to draw from, with additional information provided during the educational session, to reduce their blood pressure value.*

If we haven't heard from the subject for more than 7 days, we will invite the subject to a meeting to explore why the subject hasn't been participating. Such meetings will give us an opportunity to identify barriers and challenges subjects are experiencing and to remind them why they enrolled in the first place. An RA will contact each subject two times during the 4-week intervention to (a)

explore the acceptability of and engagement with the intervention and (b) reinforce study participation. Subjects can always withdraw from the study if they wish to do so.

Aim 2 Control Group. Following the educational session, the control group subjects' BP, ASA24 (sodium intake), and pre-test knowledge on HTN will be obtained (using Qualitrics). Four weeks later, the subject will be scheduled for a follow-up meeting to collect each subject's BP, ASA24, and post-test knowledge on HTN (using Qualitrics).

Aim 2 Post-intervention data collection and intervention engagement. We will schedule a post-intervention meeting with each subject for data collection (gold standard BP) and return of the Withings BP cuff (intervention group only). We operationalize acceptability, the key Aim 2 outcome, as the subject's favorable perception of the **MOBI**LE intervention as being appropriate and reasonable in addressing their elevated BP, convenient to use, easy to apply to their daily lives, and effective in addressing their elevated BP both currently and long-term. Data on acceptability and other study variables will be gathered using questionnaires and open-ended questions in a semi-structured exit interview (using Qualitrics). The research team will monitor the intervention for subject acceptability operationalized as active and continual participation in the intervention (receiving the subject's daily BP value), and favorable responses to the tailored change behavior SMS. The team will also measure engagement with the intervention, operationalized as the extent to which the subject followed the self-monitoring protocol. The self-report survey and semi-structured interview script will be created and implemented by the research team during the formative phase. The intervention subjects will be informed that they may delete the Health Mate app at any time once their participation is completed. The research team will no longer have access to their BP data once they completed the study.