MOBILE Intervention in College Students with Elevated Blood Pressure

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Informed Consent Form

INFORMED CONSENT
School of Nursing

TITLE OF STUDY: MOBILE Intervention in College Students with Elevated Blood Pressure: A Pilot Study

INVESTIGATOR(S): Dr. Dieu-My Tran PhD, RN, CNE

For questions or concerns about the study, you may contact Dieu-My Tran at **(702) 895-3371.**

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact **the UNLV Office of Research Integrity – Human Subjects at 702-895-2794, toll free at 888-581-2794 or via email at IRB@unlv.edu.**

It is unknown as to the level of risk of transmission of COVID-19 if you decide to participate in this research study. The research activities will utilize accepted guidance standards for mitigating the risks of COVID-19 transmission: however, the chance of transmission cannot be eliminated.

Purpose of the Study
You are invited to participate in an intervention study. The purpose of this study is to use mHealth technology to increase college students' awareness of elevated blood pressure and undiagnosed hypertension stage 1 through self-measured blood pressure monitoring and motivational level to improve blood pressure.

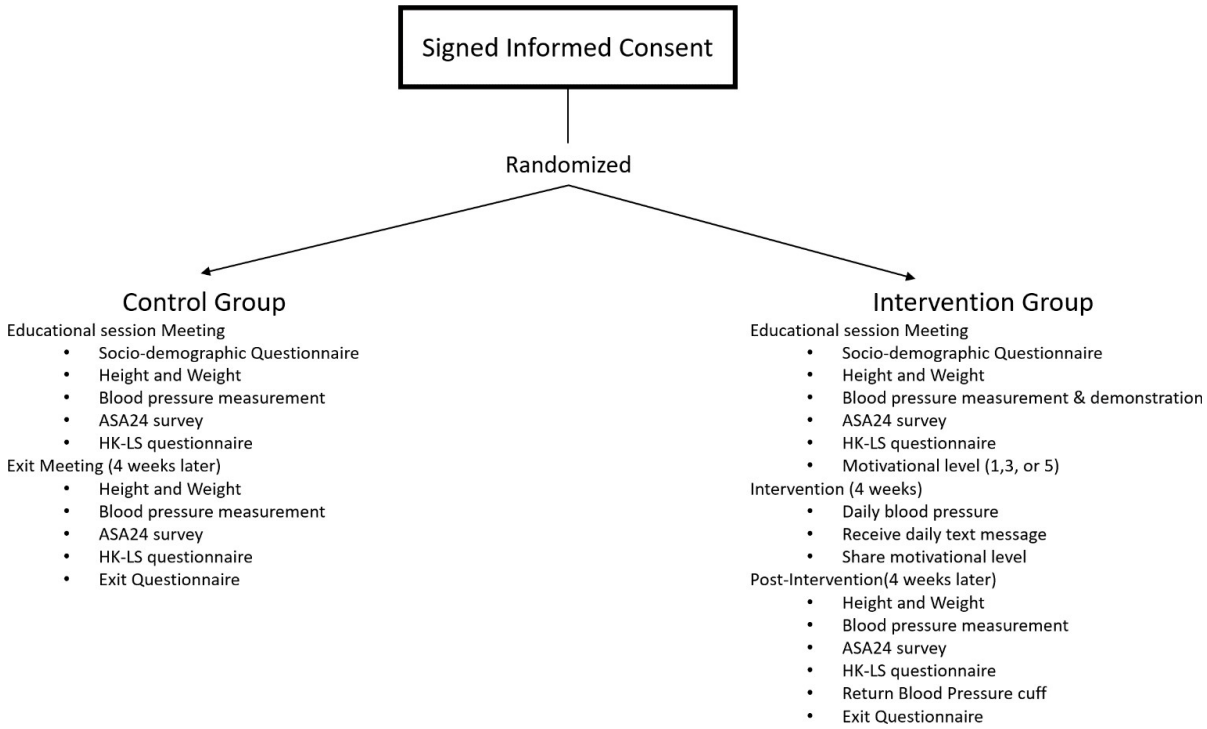
Participants
You are being asked to participate in the study because you fit these criteria: 1) you are a college student, 18-29 years of age, 2) you are enrolled at UNLV full-time (≥ 12 credits for undergraduate and ≥ 9 credits for graduate); 3) you have regular access to a mobile smart-phone with unlimited texting, and 4) have elevated blood pressure (systolic blood pressure [SBP] between 120-129 mm Hg and diastolic blood pressure [DBP] less than 80 mm Hg) or undiagnosed hypertension stage I (SBP 130-139 mm Hg or DBP 80-89 mm Hg). You will not be able to participate if you are: a) taking antihypertensive medication (e.g. angiotensin-converting enzyme [ACE] inhibitors, angiotensin II receptor blockers [ARBs], calcium channel blockers [CCBs], beta-blockers, diuretics, or vasodilators), b) currently pregnant, lactating, plans to become pregnant, or think you might be pregnant during the study duration, or 3) have been diagnosed with a life-threatening illness or condition associated with hypertension.

Procedures
If you volunteer to participate in this study, you will be asked to do the following located at the School of Nursing, following the CDC guidelines to mitigate COVID-19:

1. Schedule a meeting via zoom to go over the study. If you are eligible and still want to participate, schedule the **first in-person meeting** to have your blood pressure taken as an initial screening. This will take 5-10 minutes.
2. If you met all inclusion criteria, sign this informed consent, and you will be randomized into one of two groups, intervention or control. If your blood pressure level is as followed: SBP >140 mm Hg or DBP >90 mm Hg, you will need clearance (a letter or note) from your primary health care provider to participate in the study. If you have elevated blood pressure or undiagnosed hypertension stage 1, we strongly recommended and encourage you to go see your primary health care provider. If you are diagnosed without being on antihypertensive medication, you are still eligible to participate in the study with clearance from your primary health care provider. If you are being treated and are on antihypertension medication, then you are no longer qualify to participate in this study. If you do not have a health care provider, we strongly encourage you to go to the university health care center. *At any time during the study, if you have a blood pressure reading of >140/90 mm Hg, we will refer you back to your health care provider and clearance is needed for you to continue with the study.*
3. If you are in the control group, you will participate only in the educational session (**second in-person meeting**) and

post-intervention (**third/last in-person meeting**) to share your experience. During the educational session, you will have your blood pressure taken again (if your blood pressure level is less than 120/80, you are no longer qualify to participate), complete a 24-hour dietary (ASA24) questionnaire electronically, a socio-demographic questionnaire, and Hypertension Knowledge-Level Scale (HK-LS) questionnaire in addition to your height and weight using Qualtrics software. *We will use our research-designated iPad with the Qualtrics link for you to complete the questionnaires; therefore, IP address will not be collected.*

4. If you are in the intervention group, you will participate in an educational session (**second in-person meeting**) before beginning the 4-week intervention on the importance of high blood pressure regarding cardiovascular disease risk. During this meeting, complete surveys via Qualtrics (a socio-demographic, ASA24, HK-LS, and height and weight), have your baseline blood pressure taken again prior to the educational session (if your blood pressure level is less than 120/80, you are no longer qualify to participate), and you will be shown how to use a blood pressure cuff and a phone application that will be used by you during the study. This will take approximately 1 to 1.5 hours.
    a. Participate in a 4-week intervention consists of using the blood pressure cuff and providing your motivational level daily (1, 3, and 5). You will be sharing data via the app and text messages with the research assistant.
    b. Agree to receive text messages from one of the research assistant every time you take your blood pressure with different encouraging messages depending on your blood pressure levels. For example, if your blood pressure level was within the normal range, you can receive "keep up the good work" or if your level is elevated and you are highly motivated, you can receive "do some form of physical activity for 30 minutes." Please note that this is not a physical activity or dietary intervention; therefore, you will not receive specific instructions or education on this topic. This behavioral intervention encourages you to engage in healthy behaviors that you have previous experience to draw from to reduce your blood pressure.
    c. Meet with the research assistant after completion of the 4-week intervention to return the blood pressure cuff (**third/last in-person meeting**) and participate in the post-intervention questionnaire via Qualtrics regarding your experience with the intervention. This will take approximately 30 minutes or less.



Benefits of Participation

The potential benefits to you for participating in the study include being able to self-monitor your blood pressure level with your motivational level to assess your current state of health related to your blood pressure and receive feedback daily on your blood pressure levels with the potential to change your behavior to improve your heart health.

Risks of Participation

There are minimal risks involved in this research study. The baseline assessment and self-measured blood pressure

monitoring are considered routine medical care for preventive services during health visits. The blood pressure cuff and input of your data on your phone applications are regular tasks that are meant to be used by individual outside of the medical facilities. The minimal possible risks identified in this study included: psychological risks, loss of confidentiality, and social risks. If your blood pressure level remains high, we will refer you to your primary health care provider or the university health center provider for treatment.

The following measures are put in place to mitigate the COVID-19:

- Social distancing when possible
- Researchers will be wearing the appropriate personal protective equipment (face-coverings and gloves)
- Face mask will be available for potential participants upon contact
- Hand sanitizer will be readily available for researchers and participants
- Researchers will clean and disinfect between participants' visit
- To avoid share objects, a new pen will be given to each participant

During the three in-person visits, the School of Nursing meeting room will be used. You will be distant 6 feet or more and no more than three people in a room. The research assistant will be seated on one side of the room and you and potentially one more subject are distant in the middle and the other side of the room. The room can hold up to 50 people; therefore, social distance is not a problem. Everyone is required to wear a mask. All the CDC guidelines are implemented as described above.

Cost /Compensation

There is no financial cost to you to participate in this study. The equipment (blood pressure cuff) and app will be provided to you at no cost. The study will take 5 weeks to participate; however, not all your time during the week will be involved in participating, only when you take your blood pressure. At the start of the study, after the educational session, you will receive $25 VISA credit card for agreeing to participate, and after completion of the intervention, during the final meeting, another $75 VISA credit card will be given to you as compensation for your time.

Confidentiality

All information gathered in this study will be kept as confidential as possible. A unique subject identifying number will be used to protect the confidentiality of the data. Only the PI and research team will have access to the master list that contains the identifying subject data. Your name will not appear on the questionnaires or any data in this study; the data will instead be collected and tracked with a unique identifier. No reference will be made in written or oral materials that could link you to this study. All records will be stored in a locked facility at UNLV for a minimum of 3 years after the completion of the study. After the storage time, the information gathered will be permanently deleted and/or shredded. You may delete the Health mate app at any time once your participation is completed. The research team will no longer have access to your blood pressure data once you have completed the study.

Voluntary Participation

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with UNLV. You are encouraged to ask questions about this study at the beginning or any time during the research study.

Participant Consent:

I have read the above information and agree to participate in this study. I have been able to ask questions about the research study. I am at least 18 years of age. A copy of this form has been given to me.

_____ _____

Signature of Participant Date

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Participant Name (Please Print)

Dieu-My T. Tran, Ph.D. RN, CNE (PI)
Assistant Professor
UNLV School of Nursing
Dieu-my.tran@unlv.edu
(702) 895-3371