THE RELIABILITY OF SELF-MONITORED BLOOD PRESSURE

Participant Information Sheet and Consent Form

Title of Study: The reliability of self-monitored blood pressure
Principal Investigator: Jason Au, PhD
Student Investigator: Jessica Jasiak

You are being invited to participate in a research study that is evaluating the reliability of self-monitored blood pressure (BP) measurements using a take-home blood pressure cuff in a healthy, university-aged population. To decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign the form at the end of this information letter if you wish to participate.

WHY IS THIS RESEARCH BEING DONE?

Blood pressure (BP) monitoring is critical for assessing cardiovascular health, diagnosing hypertension, and evaluating treatment efficacy. Traditionally, BP is measured in clinical settings; however, external factors such as stress and the “white coat effect” can influence these readings, leading to potential misclassification of an individual’s BP status. To overcome this limitation, ambulatory blood pressure monitoring (ABPM) has been widely adopted to provide a more accurate representation of an individual’s BP fluctuations over 24 hours. More recently, self-monitored blood pressure (SMBP) using at-home BP devices has gained attention as a cost-effective and convenient alternative to ABPM. SMBP allows individuals to track their BP in their natural environment, potentially improving long-term BP management and adherence to cardiovascular health interventions. However, while SMBP has been shown to correlate with clinic-measured BP, questions remain regarding its reliability when performed independently by individuals without direct supervision. Understanding the reliability of self-monitored BP readings is particularly important as SMBP becomes increasingly integrated into clinical practice and home-based health monitoring.

WHO IS ELIGIBLE FOR THIS STUDY?

We are recruiting healthy male and female participants aged 18-35 who have no history of cardiovascular diseases and are not currently taking medication for blood pressure or heart rate. Participants who have unmanaged cardiovascular conditions or metabolic diseases (such as diabetes or renal disease), are pregnant, or use recreational drugs will be excluded from this study.

WHAT WILL I BE ASKED TO DO IF I DECIDE TO TAKE PART IN THE STUDY?

Interested participants will be asked to meet with the investigators to discuss the details of the study, and what to expect. Any questions or concerns you may have will be addressed prior to providing consent to participate. If you consent to participate, we will ask you to complete a health questionnaire to collect baseline health information. This questionnaire will ask about personal information such as race, education, postal codes, etc., which will allow us to better characterize the study population. Although this information is not a primary outcome of the study, it is required demographic information to contextualize our findings with respect to the general population. The time to complete the questionnaire is estimated to be approximately 5-10 minutes.

During this appointment, an arterial tonometry device will be used to measure the characteristics of your pulse in various locations, including your neck, wrist, arm, and leg. This device has a small pressure sensor smaller than a dime, which will be placed and held over areas where a pulse can be felt, like feeling the pulse on your wrist. All measurements are non-invasive.

After completing the tonometry measure, we will train you to use an at-home blood pressure monitor, which we will send home with you for three days. The following day, we ask that upon waking, you take a blood pressure measurement hourly for 10- 12 hours. This means you will carry the blood pressure monitor with you for 3 days, taking hourly blood pressure measurements wherever you are. Participants will be expected to obtain at least 10 measurements during waking hours, at least one hour apart, with the first measurement being within 1 hour of waking. The self-monitoring will be done every hour during waking hours, to a minimum of 10 measurements and a maximum of 12 measurements. If a participant cannot obtain at least 10 measurements 1 hour apart in a day, they will have the option to keep the device for an additional day of tracking to provide researchers with a full 3-day observance. Participants will be expected to bring the blood pressure monitor if they leave the house, and they will be provided with a carrying bag for the device. A detailed step-by-step guide will be provided to ensure they know how to properly use the cuff and measure their blood pressure correctly. After 3 days have passed, we ask that you return the blood pressure monitor to the lab located in BMH room 2421, or to lead MSc research, Jessica Jasiak, at a predetermined meeting place and time. At this point, participation in the study will be complete. At this point, your participation in the study will be complete.

In preparation for the baseline session, please do not perform any strenuous physical activity for 24 hours before the test and avoid caffeine, alcohol, nicotine, and aspirin on the day of the test. We also ask that you refrain from eating 2 hours before your study visits. If the blood pressure monitor is damaged or lost at any point, please contact the lead researcher as soon as possible.

WHAT IS THE TIME COMMITMENT?

There will be one lab visit, which will last approximately one hour. This visit will occur at a time that is convenient for both the study participant and the researcher. In addition to the lab visit, you will be required to complete hourly blood pressure readings 10- 12 times a day for three days (5-minute readings, total of 50-60 minutes/day, total of 3 hours across 3 days).

WHAT ARE THE ENTRY AND EXIT MEASUREMENTS?

The following measures will be taken during the baseline appointment.

1. *Heart rate*: Your heart rate will be obtained using a 3-lead ECG attached to our tonometry device.
2. *Arm blood pressure*: We will measure the blood pressure in your arm with a cuff that inflates to a high pressure for a few minutes, not unlike what you would have done at your doctor's office. Three blood pressure measures will be acquired.
3. *Applanation tonometry*: We will place small pressure-sensitive wires on your skin over blood vessels found on your neck, wrist, arm and leg to measure the strength of your pulse, similar to if you were to place your fingers over a pulse site to feel your vessels pulse below.
4. *At-home blood pressure*: You will be given instructions on how to use the at-home blood pressure cuff. You will be expected to take your blood pressure once daily for the duration of the study (12 weeks) to track day-to-day changes in arterial health. Each time you take your blood pressure, we will ask you to complete a short 2-minute survey beforehand, which can be accessed via a QR code attached to the machine.

For all measurements, please wear a comfortable short-sleeve shirt that allows researchers to access your arms.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

All procedures are non-invasive and offer minimal risk to you. During study visits researchers will use electrodes to obtain your heart rate through an electrocardiogram (ECG). The adhesive of the ECG electrodes may cause a skin rash in a small group of individuals.

Assessment of blood pressure can cause a brief tingling or pins and needles sensation in your arm, which will go away in a few minutes. There is also a risk of anxiety when taking blood pressure measurements at home, where the act of taking blood pressure causes anxiety in some people; you will be familiarized with the procedures during your lab visit where we will explain what to expect at home and in ambulatory conditions.

The blood pressure monitoring may be intrusive on everyday life for 10-12 hours per day. The device is not expected to be more intrusive than carrying a tote bag.

Any of these procedures may cause general anxiety due to unfamiliarity or close contact with the researchers applying blood pressure cuffs and tonometry equipment. To minimize this general anxiety, a familiarization period will be used to explain the procedure, including the equipment used during the assessment, and you will be given time to ask questions prior to undergoing procedures.

At any point, you are able to request that the visit be stopped, or you may take a break.

WILL I RECEIVE ANYTHING FOR PARTICIPATING IN THE STUDY?

Your participation is entirely voluntary and without any expectations of reward.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY FOR ME AND/OR SOCIETY?

We cannot promise any personal benefits to you from your participation in this study. Anticipated benefits of this research include advancing our understanding of SMBP's accuracy and consistency over extended periods. This study could improve blood pressure monitoring practices, enhancing early detection and management of hypertension, particularly in identifying non-dipper hypertensives. By assessing SMBP's reliability, the research may lead to better self-monitoring guidelines, contributing to more effective hypertension management and preventative care. Additionally, it will offer valuable insights into statistical methods for evaluating continuous physiological data collected outside clinical settings, benefiting future research and public health initiatives aimed at improving cardiovascular health through self-monitoring practices.

WILL I FIND OUT ABOUT THE STUDY RESULTS?

All participants will be given the opportunity to contact the student investigator at the end of the study to receive a summary of their results.

WHAT IF I CHANGE MY MIND ABOUT PARTICIPATING IN THE STUDY?

Your participation in this study is voluntary. If you volunteer to be in this study, you may withdraw at any time, even after signing the consent form or part-way through the study, including during any of the tests. If you choose to withdraw, paper and electronic data will be erased/destroyed and/or returned to you, where applicable. You may choose to have your data removed from the study database up to 12 months after the completion of your study visit, after which point data will be analyzed and anonymized.

WHAT IF I DISCONTINUE MY PARTICIPATION IN THE START-FIT PROGRAM?

If you decide to discontinue from participating in the START-FIT program for any reason, you will be asked if you wish for the collected data thus far to be included in our study. We will ask you to return all study equipment that may be in your possession. At this point, data collection will be stopped, and your data collection will be used as an incomplete set, with your status changed from 'enrolled in study' to 'withdrawn from study'.

HOW WILL MY DATA REMAIN SECURE AND MY CONFIDENTIALITY BE MAINTAINED?

Your personal identified data will not be shared with anyone except with your consent. All personal information will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure place, separate from your file. The data will be securely stored in a locked office. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure. You will be completing a health questionnaire through an online platform operated by Qualtrics. Qualtrics has implemented technical,

administrative, and physical safeguards to protect the information provided via the Services from loss, misuse, and unauthorized access, disclosure, alteration, or destruction. However, no Internet transmission is ever fully secure or error free.

FUTURE RESEARCH

There will be future opportunities to participate in studies in our lab. If you are interested in being contacted about participants in future studies, please indicate so on the final page of this informational letter. Agreement for subsequent contact does not oblige you to participate in future studies, which can be decided at the time of contact.

ADDITIONAL INFORMATION

- This study is a Master's thesis level research project with intent to publish the findings
- The data collected during this research may be deposited in an online public repository or database with participant permission. Prior to submission, all data will undergo a rigorous de-identification process, ensuring that personally identifiable information such as names, student numbers, and specific demographic details are removed. Data will then be presented in aggregate form in online publications, safeguarding participant privacy. This deposition process is essential as it facilitates transparency and reproducibility in research by enabling other investigators to verify findings and prevent unnecessary duplication of studies.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?

If you have any questions about the research now or later, if you wish to withdraw from the study at any time, or if you think you have a research-related injury, please contact one of the study investigators:

Jason Au
jason.au@uwaterloo.ca
519-888-4567 x40522

Jessica Jasiak
jessica.jasiak@uwaterloo.ca

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB#47327). If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca

THE RELIABILITY OF SELF-MONITORED BLOOD PRESSURE

CONSENT STATEMENT

SIGNATURE OF PARTICICIPANT

I have read the preceding information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study involving the treatment and procedures described above, with an understanding of the known possible risks that might occur. By providing my consent, I am not waiving my legal rights or releasing the investigators or involved institutions from their legal and professional responsibilities. I understand that I will receive a signed copy of this form via secured email.

_____
Name of Participant

_____ _____
Signature of Participant Date

Consent form administered and explained in person by:

I confirm that I have explained the nature and purpose of the study to the participant's name above. I have answered all questions.

_____
Name and title

_____ _____
Signature Date

THE RELIABILITY OF SELF-MONITORED BLOOD PRESSURE

CONSENT TO SHARE DATA IN OTHER SCIENCE DATABASES AND PUBLICATIONS

Are you willing to share the data from this study on an online public repository/database? Sharing this data will mean that researchers and organizations outside this study can gain access to data that has been stripped of information that can identify you.

☐ Yes ☐ No

THE RELIABILITY OF SELF-MONITORED BLOOD PRESSURE

FUTURE RESEARCH

Are you willing to be contacted about future studies in our laboratory for which you are eligible?

☐ Yes ☐ No