Participant Information Sheet

MeasureBP Study

Dr Dean Picone (Responsible Researcher)
School of Health Sciences, Faculty of Medicine and Health
Phone: 02 9351 9952 | Email: measure.bp@sydney.edu.au

1. What is this study about?

We are conducting a research study to test different ways to measure blood pressure outside of medical centres. Hypertension (high blood pressure) is a leading cause of cardiovascular diseases like stroke, heart attack and heart failure that can often lead to disability or death. Accurate measurements are required to diagnose and manage high blood pressure.

The *Measure BP Study* aims to compare the blood pressure measurements taken using home blood pressure devices with 24-hour ambulatory blood pressure measurement and wearable blood pressure measurement. 24-hour ambulatory blood pressure testing is considered the gold standard for blood pressure measurement out of a clinical setting. Researchers will also provide and test a new wearable device for 24-hour monitoring and compare these results to the 24-hour ambulatory measures. All these different measures will be compared against each other and against a reference device normally used in the doctor's medical clinic.

Please read this sheet and ask questions about anything you don't understand or want to know more about. Following this information we will check your eligibility.

2. Who is running the study?

The study is being carried out by the following researchers:

- Dr Dean Picone, Senior Research Fellow, School of Health Sciences, Faculty of Medicine and Health, The University of Sydney
- Dr Ritu Trivedi, Postdoctoral Research Fellow, School of Health Sciences, Faculty of Medicine and Health, The University of Sydney
- Isabelle Granville Smith, Project Officer, School of Health Sciences, Faculty of Medicine and Health, The University of Sydney
- Dr Niamh Chapman, Senior Research Fellow, School of Health Sciences, Faculty of Medicine and Health, The University of Sydney
- Dr Kaylee Slater, School of Health Sciences, Faculty of Medicine and Health, The University of Sydney

This study is supported primarily through a NSW Health Elite Postdoctoral Grant.

3. Who can take part in the study?

We are seeking people that measure their blood pressure at home using an automated device (with an upper-arm cuff or wrist cuff). See below inclusion and exclusion criteria.

To be eligible you must:	You are ineligible if you:
• be 18 years of age or older • use and record your blood pressure at home using an upper arm or wrist cuff automated device • be able to have blood pressure measured on both arms	• have an acute condition that may affect your blood pressure (e.g., infection, renal failure) • have had a myocardial infarction or stoke in the last 6 months • have atrial fibrillation that is uncontrolled

4. What will the study involve for me?

If you decide to participate in this study, you will be asked to come to the Susan Wakil Health Building, University of Sydney campus, Western Ave, Camperdown, 2050 on two separate occasions.

First visit:

Your first visit will be approximately 1 hour. This visit will be booked at a time convenient for you with a researcher. Free parking is available on site. For out-of-pocket public transport costs, taxis or rideshare, we provide a gift voucher to the value of your transport costs or a maximum of $50 per visit (whichever is lower). This gift voucher will be provided when receipts for transport are provided and upon completion of the study.

You will be asked to undertake the following health and blood pressure-related questions and measures:

- *Body measurements:* We will take basic measurements such as height, weight, arm length, upper arm circumference, hip and waist circumferences.
- *Blood pressure measurements*: We will take blood pressure measurements using your own device and a reference device. For us to take accurate measurements, we ask that the cuff/s measures against the bare skin of your upper arm.
- *Questionnaires:* You will be asked to complete some questionnaires that include demographics, medical history, general health, medications and blood pressure measurement-related questions.

We request that you please refrain from caffeine, smoking, tobacco, alcohol (or any other stimulants) or any type of exercise (except walking) 3 hours prior to the visit. There should be no heavy meals 3 hours before (a snack is fine) and we also request no strenuous exercise 24 hours before the visit.

Testing your home blood pressure device:

You will be asked to bring your home blood pressure device and a record of the previous weeks' readings to you first visit. We will ask you to leave your home blood pressure device (and any cuffs you use) with us so we can test it for accuracy and quality.

24-hour blood pressure measurements (at home):

You will be fitted with two blood pressure measurement devices (a cuff and a finger ring) during your first visit. These devices will measure your blood pressure at home while you do your daily activities for 24-hours. You will be asked to keep a diary of your activities, including sleep-, wake- and meal- times in this 24-hour period. We request you do not undertake vigorous physical activity or shower during the 24-hour period. You will be given instructions on how to operate and troubleshoot the devices and be provided a number to call if you require assistance.

Second visit:

The second visit will take about 15 minutes and will take place after you complete the 24-hour blood pressure measurements. During this visit, we request that you return the 24-hour and wearable blood pressure devices, and we will return your home blood pressure device. Researchers will provide you with a report about its accuracy and quality and give recommendations to improve device performance (if required). You may wish to complete an optional feedback survey.

Blood pressure results:

Your blood pressure results will be sent to you via email or post within three working days of the second visit and be available to discuss with your GP.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part. If you do consent to participate, you may withdraw at any time and request collected data about you be destroyed. You do not have to give a reason for withdrawing from the study.

6. Are there any risks or costs?

We do not anticipate many risks associated with taking part in this study.

- Some people may feel uncomfortable during the time of the 24-hour monitoring, due to repeated cuff inflation
- Blood pressure monitoring overnight may interfere with your sleep
- There is a possibility of skin irritation from the three-lead attachment to your body for the 24-hour period.
- Part of the research rates and provides a report for you about the accuracy and quality of your device. You may feel mild distress if your report notes an issue with your device. Research staff have been trained to discuss participants' options regarding home blood pressure device accuracy and quality.

7. Are there any benefits?

Benefits to participating in the study include:

- Results from 24-hour blood pressure monitoring at no cost – available for you to discuss with your GP, which may assist with your blood pressure management.
- Report tailored for you, regarding the accuracy and quality of your home blood pressure measuring device.

Results from this study will benefit the wider community by adding new knowledge about blood pressure measurement that may lead to recommendations to improve methods of blood pressure management and cardiovascular disease prevention.

8. What will happen to information that is collected?

By providing your consent, you are agreeing to us to collect information from or about you for the purposes of this study and other ethically approved blood pressure research in the future.

Any identifiable information you provide us will be stored securely. No identifiable information will be used in data analyses or in research publications.

These data will be stored on secure University of Sydney servers after study completion.

These data will be retained for a period of 5 years post publication of results.

Sharing research data is important for advancing knowledge and innovation. A de-identified set of the data collected in this study may be made available for use by other investigators in future research.

9. Will I be told the results of the study?

You can request feedback about the overall results of this study. You can indicate your interest when completing the consent form.

10. What if I would like further information?

When you have read this information, the Chief Investigator Dr Dean Picone will be available to discuss it with you further and answer any questions you may have:
Email: measure.bp@sydney.edu.au
Phone: 02 9351 9952

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [ethics reference: *2024/HE001019*] according to the National Statement on Ethical Conduct in Human Research.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
+61 2 8627 8176

Please select to download and retain a copy of this sheet for your reference.