THE HEARTGUIDE BLOOD PRESSURE LVMI STUDY

PARTICIPANT INFORMATION SHEET

Thank you for your interest in this study. This information sheet describes the research project and what taking part will involve.
Please take time to read it through and understand there is no obligation to take part.

If you have any questions, the study team would be delighted to discuss any aspect of the study with you. Our contact details are given at the end of this document.

What is this study about?

Accurate measurement of blood pressure (BP) is important in managing risk for cardiovascular disease such as heart attack and stroke. BP has been routinely measured at a Doctor's surgery for many years, but increasingly patients are measuring their own BP at home or at work. There is evidence that this may provide a better measurement of the patient's true BP. In this study we plan to evaluate a wrist watch-like BP monitor to see whether it is a convenient way for patients to measure their own BP and whether it provides reliable information about the effects of BP on the structure of their heart.

High blood pressure affects the structure of the heart. Specifically, there is a thickening of the muscular wall of the heart when it has to pump against a high pressure. This thickening of the heart muscle is a good predictor of the BP load on the heart and a good predictor of future risk of heart disease and stroke. We will measure the structure of the heart muscle using cardiac MRI (cMRI), which is the most accurate way of quantifying the thickness of the heart muscle. We will relate the BP measurements using the wrist-type monitor to the thickness of heart muscle in different patients with high BP to define whether this wrist-type BP monitor is a good predictor of the effects of BP on the heart. We will also see whether it is a better predictor than the usual ways we measure BP in routine clinical practice.

The results of this study will tell us whether this new wrist-type BP monitor might provide a more convenient way for patients to monitor their BP.

Why have I been asked to take part?

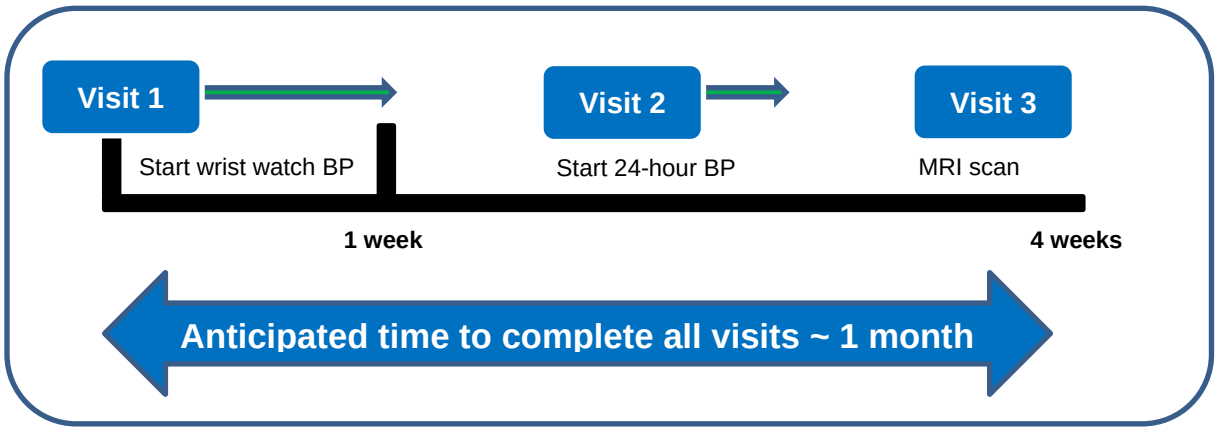
We are recruiting men or women aged ≥ 35 years with raised blood pressure. You may or may not be on medication for your blood pressure. This would not exclude you from participation.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you would like to participate, a member of the research team will discuss your participation with you and answer any questions you might have. If you are happy to proceed you will be asked to provide written consent to take part.

What is involved if I take part?

You will be asked to attend a minimum of 3 visits over the course of one month at our research facility located at the University College London, Roger Williams Building, 65-79 Chenies Mews, London, WC1E 6HX.



A proposed timeline of events is detailed below.

Visit 1 ***Screening visit and wrist watch blood pressure monitor fit***

At this visit we will measure your blood pressure using a standard arm cuff to confirm your eligibility for the study. If your blood pressure is in the range required for participation your height and weight will be recorded and we will ask questions about your medical history. An ECG (electrocardiogram), which is a recording of the electrical activity of your heart, will be made at this visit as well as a CAVI (cardio ankle vascular index) - a non-invasive measurement of arterial stiffness. It is anticipated that this visit will take 60-90 minutes. At the end of this visit you will be provided with and be shown how to use the HeartGuide wrist BP monitor. You will be asked to complete a minimum of 3 consecutive week-days of measurements taking measurements with the watch both in the morning and evening and at hourly intervals during the daytime.

Visit 2 ***Wrist watch returned and ambulatory blood pressure monitor fit***

At this visit you will return the HeartGuide wrist BP monitor. We will review the data and provide you with feedback about your BP. If you wish, we will provide you with a copy of your BP measurements. We will then ask you to wear a standard 24-hour

ambulatory BP monitor. The monitor will be programmed to take blood pressure measurements over a continuous 24-hour period, recording your BP every 30 minutes during the daytime and every 60 minutes at night. During the period of monitoring you will be able to complete your everyday activities, however, we would advise against engaging in prolonged vigorous exercise. It is anticipated this visit will take up to 30 minutes.

Visit 3 ***Ambulatory monitor return and MRI scan***

We will ask you to return the 24-hour ambulatory BP monitor to us at this visit. Data from the monitor will be downloaded and we will provide you with feedback about the results. You will then be asked to undergo a magnetic resonance imaging (MRI) scan of your heart in the scanning facility which is located on the ground floor, of the research clinic. We anticipate this visit to take around 60 minutes.

What does having an MRI scan involve?

Images of your heart will be taken using a large magnet, radio waves and a computer. The scan does not hurt and does not use X-rays or radioactivity. The MRI machine is shaped like a short, open-ended tunnel. You will be asked to lie down on a flat scanning bed that slides into the tunnel. Although some people may feel uncomfortable in the enclosed space of the scanner, this usually resolves quickly.

The magnetic field of the scanner is harmless to humans but it can move some metals. Rarely, people have metal objects in their bodies, usually due to operations or accidents. This can prevent them from having an MRI scan safely. We will ask you a series of questions first to make sure it is safe for you. During the scan, you will be asked to lie still on your back for up to one hour.

During the scan you will be exposed to loud noises which are normal. You will be asked to wear headphones to protect your ears from these noises and to allow the person operating the scanner to communicate with you. During the scan, you may be asked to hold your breath for short periods of time.

What are the potential disadvantages or risks of taking part?

There are few risks involved in taking part in this study. Some people find 24-hour BP monitoring uncomfortable and inconvenient to wear, however, our previous studies indicate that it is generally well tolerated.

The MRI scan requires you to lie still in an enclosed space for up to one hour, which some people find claustrophobic.

If at any stage during the scanning process you find this experience intolerable, you can either tell the radiographers (who will be able to hear you) or press the panic button that you will be provided with in order to stop the scan.

What are the potential benefits of taking part?

Whilst there is no direct benefit of taking part, we hope you will find the study interesting and that your participation helps you gain or improve your understanding about your BP. We can provide you with copies of your BP measurements and other tests for your records.
Furthermore, you will be informed about any potentially abnormal results or previously undiagnosed conditions and referred via your GP, to the appropriate medical service if necessary.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving a reason and this will not affect your on-going clinical care or your legal rights. If you wish to withdraw, please inform one of the study team (contact details at the end of this information sheet). Once the team knows, there will be no more tests performed and you do not need to do anything further. All data that has been collected up until your withdrawal will be retained as part of an anonymised dataset.

Will I be compensated for taking part?

There is no monetary compensation for your time, however study participants may claim travel cost of up to £15 per visit. The HeartGuide wrist BP monitor and 24-hour ambulatory BP monitor required for this study will be on loan to you only for study purposes and are not available for purchase through the study team.

Will my data from this study be kept confidential?

Yes, it will. All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. Only people who need to know who you are for study purposes or your clinical care will be able to see your name or contact details. Some of your information will be combined with anonymised data from other participants and shared as a study summary with collaborators working on a similar study, at the Jichi Medical University in Japan. We will write our reports in a way that no-one can work out that you took part in the study.

How will we use information about you?

All data and documents will be labelled using an anonymised code. Study data will be stored on password-protected computers. Only staff working on the study, authorised personnel from University College London and University College Hospital Trust and regulatory authorities will have access to it. It may be accessed for auditing and monitoring purposes to ensure that the study is being carried out properly. If you agree,

we will contact your GP to let them know you have taken part in this study. If you withdraw from the study before it has completed, your data will remain on file and will be included in the final study analysis, unless you object. At the end of the study, your data will be securely archived for a minimum of 20 years prior to confidential destruction.

You can find out more about how we use your information at https://www.ucl.ac.uk/legal-services/data-protection-overview or email the University Data Protection officer at data-protection@ucl.ac.uk

What will happen to the results of the study?

At study completion the results will be published in a medical journal or presented at a scientific conference. The data will be anonymous and participants will not be identified. We should also be pleased to make a summary of the study results available to you.

Who is funding the research?

Study funding is provided by a grant in Aid of Research to the Chief Investigator, Professor Williams, by the Omron Healthcare Co. Ltd.

Who is sponsoring the study?

The study has been sponsored by University College London.

Who has reviewed the study?

An independent Research Ethics Committee (REC) has reviewed this study to protect the interests of the participants and ensure that the research is ethical. The REC assigned to this study is:

London – Fulham Research Ethics Committee

This study was also reviewed by independent scientists, working in the area of blood pressure measurement research, to ensure the validity of the scientific content of the study protocol.

UCL Hospitals Biomedical Research Centre (BRC) patient and public involvement (PPI) panels will be involved in the dissemination and presentation of study results and their implications to clinical practice. A lay format of the results may be made available to all participants once findings are published. Personal data will not be included in any study report.

What if there is a problem or I have a complaint?

If there is any sort of problem, you are unhappy during the study or have questions as a result of your participation in this study, please feel free to discuss with a member of the research team. Our contact details are given below.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Patient Advice Liaison Service (PALS) at UCLH:

PALS
University College Hospital
235 Euston Road
London
NW1 2BU
Email: uclh.pals@nhs.net
Tel: 0203 447 3042

Further information and contact details:

If at any time you would like more information about this study or have questions related to your participation please contact our principal investigator or research team:

Chief Investigator:	Professor Bryan Williams Tel: 0203 108 7907
Research Assistants:	Ewan McFarlane or Dawid Jedrzejewski Tel: 0207 679 9425
Research Administrator:	Donna Moskal-Fitzpatrick Email: donna.moskalfitzpatrick@nhs.net

Thank you for taking the time to read this information sheet.