

Participant Information Sheet | Screened Women

A feasibility study to evaluate acceptability, uptake and effect of combined peripheral arterial disease, high blood pressure and abdominal aortic aneurysm screening - PHAST-F

Chief Investigator: Professor Matthew Bown

Introduction

We are inviting you to join a research study looking at ways to improve NHS screening programmes.

Why have we asked you to take part in this research?

We are asking you to participate in this research because you are attending for your peripheral arterial disease (PAD – furred up arteries in the legs) and high blood pressure screening today. This screening is part of a pilot screening programme to see if women will attend for this screening and how many of them might benefit from such screening.

What will be involved if you take part in this research?

If you decide to participate in this research we will ask you to complete a questionnaire now and then repeat this again at regular intervals over the next few years. We will also collect information about what happens at your screening appointment and afterwards.

Do I have to take part in the research?

No - participation in this research is entirely voluntary. Your decision will not affect the care you receive from the NHS today or at any time in the future.

How will my personal data be used?

- In this research study, we will use information from you, your medical records and/or GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
- Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
- At the end of the study we will save some of the data in case we need to check it and/or for future research.
- We will make sure no-one can work out who you are from the reports we write.

This information pack tells you more about this

Deciding whether or not to take part in the research study

- It is important for you to understand why the research is being done and what your participation would involve, so please take your time to read this information sheet.
- A member of the research team will go through this with you and answer any questions you may have.
- If you decide you do not want to take part, you will receive the PAD and blood pressure screen today as planned without any involvement in the research. This is because the PAD and blood pressure screening is not research. Please refer to your clinical information sheet for information on your PAD and blood pressure screening.

What is the purpose of this study?

The research is being done because we don't know if finding PAD and high blood pressure early through screening is beneficial or not for women. These screening tests may improve cardiovascular health, but they may also have no benefit or even unexpected problems. To find this out, we need to collect information from women attending for screening in this pilot programme. Information collected from you as part of this study will be used to work out the best way to run a screening programme for women. If it looks like women will benefit from this type of screening, additional research funding will then be applied for to test this screening for women on a larger scale.

If I do decide to take part in the research, what will I have to do?

- At your screening appointment, we would like to collect some information from you by asking you to fill in some questionnaires. (Approx. 15 minutes).
- After this, we will contact you again by post at three months, six months, one year, and once a year after this for up to five years. We will send you a follow-up questionnaire (via post) for you to complete and send back to us each time. We will provide a pre-paid envelope for this. (Approx. 15 minutes for each).
- We may ask you whether you are happy for us to collect information about your activity levels using a watch-like device called a GENEActiv. (Wearing for 7 days initially and then again for another 7 days, 6 months later).
- We will ask if you would like to be part of an interview to take place as soon as possible after your screening appointment (Max. 60 minutes).
- If you screen positive for PAD and/or high blood pressure, as part of your clinical care, we will phone you regardless at ~ 5 weeks as a reminder, to see if you have booked an appointment with your GP, but if you take part in the research we will ask you a few more follow-up questions at this stage. (Approx. 5-10 minutes).
- We may ask if you would like to be part of another interview 6 months later. (Max. 60 minutes).
- Please note:
 - ⇒ the postal follow-up questionnaire may change format (e.g. move to an electronic questionnaire or be done via the phone) as the study continues. If this happens we will contact you to let you know.
 - ⇒ You will not be paid or reimbursed for any part of the research unless you specifically request to attend an interview face-to-face (where circumstances

allow), you will be reimbursed for any reasonable transport/parking costs. You will be asked to provide original receipts for our records.

What will happen as part of:

... the questionnaires?

- We will ask for your name, date of birth NHS/CHI number, and contact details such as your postal address, email address, and phone landline/mobile number.
- We will ask you your sex, height and weight, as well as your date of birth, ethnicity, and most recent occupational status.
- We will also ask you to provide a brief medical history and ask questions about smoking habits, alcohol use, quality of life, and psychological wellbeing.
- Later in the research study, we will ask you for an update on your health and in addition, ask you about any use of health services.

...assessing physical activity?

Whether we ask you to wear a GENEActiv device will depend on your screening result and device availability. GENEActiv is a lightweight, waterproof, wrist-worn device, designed for 24-hour wear. You will be shown how to use this device and first asked to wear it for 7 days. After this, it will then need to be returned using the pre-paid envelope provided. We recommend that you obtain a certificate of posting. After approximately 6 months, you may receive the device again to measure any change in your activity. We may need to contact you to arrange delivery.

... the interview(s)?

- We will ask you if you would be interested and willing to be contacted for an interview to take place as soon as possible after screening (Max. 60 minutes).
- If you are interested and willing to take part, and provide consent for this, please note, as we only need to speak to a small number for this part of the study, whether we contact you depends on this, but also availability of the research team.
- If selected, the interviews will take place over the telephone/online (e.g. Microsoft Teams or similar). If requested and circumstances allow, it may be possible for the interviews to take place face-to-face.
- The person conducting the interview will not follow a strict list of questions, but will ask open-ended questions so the experience is more like a discussion, without being tied to a yes or no response.
- The questions will seek to find out:
 - ⇒ your experience and how acceptable you found the different parts of the screening process;
 - ⇒ the psychosocial impact of screening (i.e. the relationship between social factors and your thoughts and behaviours);
 - ⇒ your thoughts and actions following a positive screening result for PAD and/or high BP (where relevant) and the likelihood that you think you will engage with cardiovascular risk management strategies.
- You will be able to ask the interviewer to pause the recording at any time during the interview. You are also free to stop the interview should you wish to do so.

- Should you be selected and you screened positive for PAD and/or high BP, we would also like to conduct an interview 6-months later. The 6-month interview will be conducted in the same way, but will explore the extent to which you engaged with cardiovascular risk management strategies.
- Interviews will be audio-recorded using an approved encrypted recording device and the recording saved on a secure network file store. The recording will then be transcribed (written up) word-for-word by a third-party company. All transcribers will have signed confidentiality agreements. All information that could potentially identify you will be removed so no one will be able to identify you. After, the recording will be deleted and your transcript will be given a code number.

Will any of my electronic health records be used as part of the study?

Yes... and all participants in the study will be followed up for up to five years.

- The PHAST-F research team (including the University of Leicester, study investigators, and the central coordinating centre) are therefore asking for your permission to use your personal information to obtain information about you from the electronic medical records held by central NHS and UK Government organisations [(NHS Digital (England and Wales), NHS National Services Scotland or the NHS Central Register (Scotland))] or your GP.
- Your personal information (name, date of birth, and NHS or CHI number) and a code number will be securely provided to these NHS organisations. These groups will then use this personal information to extract information about you from their databases (e.g. visits to your GP, visits or admissions to hospital, etc.). Using the same secure process, these organisations will send this information (your electronic health records linked to your code number) back to the research team.
- If we need to obtain this information via your GP instead, we will need to first contact your GP to notify them about your participation in the study.

How will we use information about you?

- The University of Leicester, the research team, and the central coordinating centre will need to use information from you, your medical records and/or your GP for this research project.
- This information will include your: name/initials, date of birth, contact details, GP records, NHS number (in England), CHI number (Scotland), AAA screening programme ID, signed consent forms, and recordings/written transcripts of interviews (where relevant). People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- We will keep all information about you safe and secure.
- Once we have finished the study, we will keep some of the data so we can check the results.
- We will write our reports in a way that no-one can work out that you took part in the study.
- The data collected as part of this study may be used for the writing of educational projects such as a Master's degree or a PhD. If you would like to know more about

this, please contact the PHAST central coordinating team via phast@leicester.ac.uk

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health via routinely collected health data or contacting your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can I find out more about how my information is used?

- at <https://www.hra.nhs.uk/information-about-patients/>
- by reading the 'Patient Data and Research leaflet' available at: <https://www.hra.nhs.uk/patientdataandresearch>
- by asking one of the research team
- by sending an email to dpo@le.ac.uk
- by visiting the following website: <https://www2.le.ac.uk/offices/ias>
- by ringing us on 0116 229 7945
- Sponsor's Data Protection Officer: <<Insert details>>

What are the possible disadvantages/advantages of taking part?

You will need to give up some of your time to complete the questionnaires and interviews (where relevant). You may find discussing your thoughts and feelings as part of the interview distressing. We cannot guarantee any direct benefit from participating, but you will be helping to make a significant contribution into the research of new NHS screening programmes.

Who is organising and coordinating the research?

- The study is led by the Chief Investigator, Professor Matthew Bown, a Professor of Vascular Surgery. Professor Bown is part of the University of Leicester, Department of Cardiovascular Sciences. More information about the department and Professor Bown can be found here: <https://www2.le.ac.uk/departments/cardiovascular-sciences/people/bown>
- This study is organised by the Department of Cardiovascular Sciences, University of Leicester and sponsored by the University of Leicester.
- The central coordinating team is the Leicester Clinical Trials Unit. They are overseeing the organisation and management of the study together with clinical and academic investigators and collaborators (some from other universities) who are experienced in the delivery of clinical research.
- Patients and members of the public have also been involved in the design of this study from the very beginning and will be involved until the study is complete.

- Please note: none of the research team receive financial reward if you decide to participate.

Contacting the research team

Local site team: <<Insert Principal Investigator name>>; <<Insert local site contact details>>; <<(including emergency contact number)>>

PHAST central co-ordinating team: phast@leicester.ac.uk

What will happen to the results of the research study?

The information collected during the study will be entered into a computer database, analysed, and interpreted. The results of the research study will be presented to medical researchers at scientific meetings and published in medical journals. Once the study has finished, we can provide you with the research highlights detailing what we have learned, as well as direct you towards the full results of the study.

Who is funding the research?

The study is funded by a grant from the National Institute for Health Research Programme Grants for Applied Research (NIHR PGfAR): <https://fundingawards.nihr.ac.uk/award/NIHR200601>.

What if I am harmed or wish to complain about the study?

It is very unlikely that you will be harmed in this type of research study, but should you wish to complain, you can first ask to speak to the local site team (see page 6). If you wish to further address your concerns on a formal basis, you should contact the Patient Information and Liaison Service or local complaints service via <<Insert local details>>. If you are harmed during the research due to someone's negligence, then you may have grounds for legal action against the University of Leicester, but you may have to pay your own legal costs. The normal NHS complaints service will still be available to you.

Who has reviewed the study?

All research that involves NHS patients or staff is reviewed by an independent group of people called a Research Ethics Committee (REC) to protect your safety, rights, wellbeing and dignity. This study has been reviewed by North of Scotland (2) Research Ethics Committee and has received a favourable ethical opinion.

I've read this information sheet, asked the research team my questions, and have decided I want to take part in the research, what now?

You will be given this information sheet to keep and be asked to sign a consent form. You will be given a copy of your signed consent form to keep.

Thank you for reading this information pack