Participant Information Sheet for
AI-guided point-of-care ultrasound to diagnose deep vein thrombosis in primary care

Participant Information Sheet for the IRAS Project ID: 332800

You are cordially invited to participate in our research study. Your participation in the study is completely voluntary. Prior to making a decision, we would like to ensure that you have a clear understanding of the reasons behind conducting this research and its implications for you. A member of our team will personally guide you through an information sheet that will provide you with the necessary insights to determine whether or not you would like to be a part of this study. They will also be available to address any inquiries you may have. If you wish, please feel free to discuss the study with others.

Part 1: Tells you the purpose of this study and what will happen if you decide to take part.

Part 2: This section presents additional information regarding the implementation and procedures of the study**.**

Why have you been asked to take part?

You have come to the GP Care DVT clinic because you are experiencing symptoms that indicate a possible deep vein thrombosis (DVT). To confirm or rule out a thrombosis, your doctor has requested an ultrasound scan. The GP Care patient support team has provided you with information about the study, and sent you links to documents such as the consent form, the patient information sheet and the patient satisfaction survey which is to provide feedback on your satisfaction with the app guided ultrasound scan after your 2 scans.

You will be given as much time as you need to read the participant information sheet, consider participating in the study, and ask the research team any questions you may have. If you agree to participate, you will be asked to sign a consent form. Once the GP Care Healthcare Assistant (HCA) has confirmed that consent has been obtained, the GP Care Healthcare Assistant (HCA) will conduct an ultrasound scan (USS) of your upper leg with a handheld ultrasound probe.

Following the first scan, you will remain on the treatment table, and the sonographer will conduct the standard DVT diagnostic scan. After both scans are completed, you will be asked to complete a patient satisfaction survey.

What is the purpose of the study?

This pilot study is being conducted as part of a research project leading to a PhD degree at the University of Bristol. AutoDVT is a smartphone app which could enable non-specialists to perform a DVT scan of the upper leg. This tool could offer faster, more convenient diagnoses, potentially leading to better patient outcomes and cost savings. These quick, app guided scans can be done in community settings like GP offices, homes, or nursing homes.

What will happen if I take part?

If you choose to participate, we will request your agreement by signing the consent form and providing some information such as height, weight, gender, age, and your postal code. This information will help us determine the area of the BNSSG (Bristol, North Somerset, and South Gloucestershire) where you reside. The app guided scan will be conducted during your scheduled appointment at the GP Care DVT clinic and will typically last approximately 3-5 minutes.

After you have undergone both the app guided scan and standard ultrasound scans, you will be asked to complete the patient satisfaction survey. If you wish to receive a £10 voucher as a thank you for giving up your time, you will be prompted to provide your email address.

Furthermore, within the survey, kindly specify whether you would be open to participating in the second phase of our research. This phase will entail a 30-45-minute semi-structured interview aimed at delving into your perspectives and opinions regarding app-guided DVT diagnostics. Participants in this second phase will also receive voucher as a thank you for giving up your time and contribution.

Do I have to take part?

Participation is completely voluntary. If you choose to participate, you will be required to sign a consent form indicating your agreement to join the study. However, you have the freedom to withdraw from the study at any time. Your decision to withdraw or not participate will have no impact on the quality of care you receive.

In the event that you become incapable of providing consent, or you have loss of capacity during the course of the study, or you voluntary withdraw from the study, your participation will be discontinued, and any identifiable data collected up until that point will be deleted.

What are the possible benefits of taking part?

While there are no immediate direct benefits to participants, the study holds potential future benefits for patients with symptoms of DVT.

What are the possible disadvantages and risks of taking part?

The intervention carries minimal potential risks. Ultrasound, which utilises sound waves instead of radiation (like X-ray), is considered safe, and no known risks are associated with it. Compression ultrasound is a safe way to diagnose DVT, but there's a small chance of dislodging a clot if compression is done incorrectly, especially by non-specialists. To prevent this, proper training is given by an expert to ensure the right pressure is applied.

Before your involvement in the study, participants will receive comprehensive information regarding both the potential risks and the expected duration of the study scan. The HCA responsible for conducting the additional scan will be extensively trained to minimise any delay for the participants. If you have any questions or concerns, the scanning staff will make every effort to provide the best possible answers during or after the scan.

What happens when the research study stops?

The study will be conducted as part of your regular clinical appointment at the GP Care DVT Clinic. In the event that the study is discontinued, it will have no impact on your treatment plan or follow-up assessment. Your clinical care and any necessary future assessments will proceed as originally planned, regardless of the study's status.

What if there is a problem?

If there is any issue concerning your treatment or potential harm while participating in the study, please be assured that steps will be taken to address it promptly.

Contact details for the GP Care DVT Clinic Service:
Jackie Adams, Clinical Matron
Phone: 07885 459 636
Email: Jackie.Adams@gpcare.org.uk

GP Care UK Ltd, 160 Aztec West, Bristol BS32 4TU
Phone: 0333 332 2100
Email: Complaints@gpcare.org.uk

The primary supervisor is Dr. Jessica Watson. You can reach her at:

Phone: 01174551012
Email: Jessica.Watson@bristol.ac.uk

Alternatively, if you prefer to contact Research Governance at the University of Bristol, you can do so by email at research-governance@bristol.ac.uk or by post at Research Governance, 2nd Floor, St Augustine's Courtyard, Bristol, BS1 5DS.

Regarding insurance coverage, both GP Care and the University of Bristol hold policies that pertain to this study. Should you experience harm or injury while participating, you are eligible to claim compensation through these policies. This in no way affects your legal rights to seek compensation. If you believe your harm is due to negligence, you may have grounds for legal action. If you have any complaints or concerns about your treatment during the study, please inform the Investigator immediately. You can contact Mrs. Kerstin Nothnagel at 01174559936 or via email at Kerstin.Nothnagel@bristol.ac.uk. Additionally, standard National Health Service mechanisms are available to address your concerns.

Will my participation in the study be kept confidential?

Yes, all the information about your participation in this study will be kept confidential.

Contact details

If you have any further queries about this study, please contact:
Chief Investigator
Mrs Kerstin Nothnagel
Centre for Primary Care Research at Canynge Hall
Clifton Bristol, BS8 2PS
Kerstin.Nothnagel@bristol.ac.uk
01174559936

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you want to participate, please read the additional information in Part 2.

Part 2

How will we use information about you?

We will need to use information from you and from your medical records from your GP for this research project. This information will include your name/ postcode/ age/ gender/ site of the affected leg (left or right)/ the diagnosis of the scan/ your BMI and ultrasound images of your blood vessels. 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.
Some of your information will be uploaded to a cloud dashboard which is managed by the manufacture of the AI app, the German company ThinkSono Ltd. This information will be anonymous, you will not be identifiable.
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.

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 from 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 that 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, your data saved from this study may be used for future research.

Where can you find out more about how your information is used?
You can find out more about how we use your information:
at http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
by asking one of the research team
by sending an email to data-protection@bristol.ac.uk , or
by calling the University's Data Protection Officer on (0117) 3941824.

Primary research data: Retained for 10 years after the study is completed.

Anonymised ultrasound images of your blood vessels will be shared with ThinkSono to assist them in optimising the app. ThinkSono is bound by our regulations to maintain the confidentiality of your information. When presenting our report, we will ensure that no one can identify your participation in the study.

What will happen to the results of the research study?

The outcomes of this study will not directly benefit you personally. You will not have access to view your individual results; however, a summary of the overall findings will be made available to you when it is ready.

The results will be compiled in a student research project and shared with colleagues at conferences. There is also a possibility that the findings may be published in medical journals. Rest assured, your identity will remain anonymous in any publications or presentations.

Who is organising and funding the research?

This research is supported by the National Institute for Health Research. The researchers are currently employed as postgraduate researcher by the University of Bristol.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the Research Ethics Committee and the University of Bristol Research & Development Department.

Contact for further information

You can contact chief Investigator, Mrs Kerstin Nothnagel:

Email: Kerstin.Nothnagel@bristol.ac.uk
Phone number: 01174559936

Thank you for considering taking part in this study and taking time to read this sheet!