Neuropathy evaluation using the vibration function of a mobile phone.

Chief Investigator: Dr Tamas Hickish, University Hospitals Dorset NHS Foundation Trust

Principal Investigator: Debbie Sharman, Consultant Podiatrist, Dorset HealthCare University NHS Trust

What is the purpose of the study?

Summary

We have developed a new device using a smart phone to help detect peripheral neuropathy (weakness, numbness and/or pain in the hands or feet) in people with diabetes. This brings some of the benefits of current hospital diagnostic equipment to everyday use by GP surgeries or even patients and could replace the 'monofilament' test you may have had at your annual diabetes review.

We have developed a prototype and would like your help in comparing this to the expensive hospital equipment, seeing how closely the readings match and how reliable they are.

You won't feel anything more than a mild tingling in your foot at any stage and all you have to do is say if you can feel it or not. By helping us develop this new technology you could be helping improve the diabetes care for generations to come.

Background

Diabetes can affect the functioning of the nerves, particularly in your hands and feet. This can mean that you do not feel rubbing and pressure, which can cause ulcers to develop.

To try to prevent this happening, the majority of people living with diabetes in the UK will have an annual foot check for early signs of a loss of sensitivity. Currently this is done using a device called a 'monofilament'. A healthcare professional will touch this to various points on your feet and ask whether you can feel it or not, and calculate a score based on your responses. Together with other assessments this is used to determine your 'foot risk', and if above a certain level you may be referred for additional care.

The monofilament has been shown to be good at predicting the risk of developing an ulcer, however, there are things that could be better:

- The assessment takes quite a long time.
- Whether or not you can feel the touch can possibly be affected by the healthcare professional performing the test.
- The test needs to be performed by a healthcare professional – many patients have not had their checks over the last couple of years due to the pandemic.

Our proposed solution, the patented NERVE (**Ne**u**r**opathy evaluation using the **v**ibration function of a mobile phon**e**) device has been developed as part of a collaboration between University Hospitals Dorset NHS Foundation Trust and Bournemouth University.

This uses 'Vibration Perception Threshold' testing, where a vibration source is applied to the foot, and the vibration intensity is varied to find the point at which the person starts/stops feeling it. There is some evidence that this could be more accurate than the monofilament test. However existing devices are large and expensive, so they are generally only used in specialist clinics.

As most people own a mobile phone, the NERVE device is intended as a low-cost and easy to use alternative.

This study aims to answer three key questions:

- Does the device work as well as the monofilament machine?
- Can patients test themselves using the device and are the results the same as when this is done by a healthcare professional?
- How easy is the device to use?

Why have I been invited?

Anyone living with diabetes, and who can get to University Hospitals Dorset NHS Foundation Trust, is welcomed to participate in this study.

Do I have to take part?

No, it is up to you to decide.

If you would like to, please click 'I want to take part' and complete the form. One of the team will then get in touch to let you know if you are able to take part and if, so arrange your visit.

You are free to change your mind at any point. Please let us know by contacting the Dorset Clinical Research Centre on 0300 019 6686. If you are at all unsure, a team member will be happy to discuss your concerns when they contact you, or at any other time.

What will happen to me if I take part?

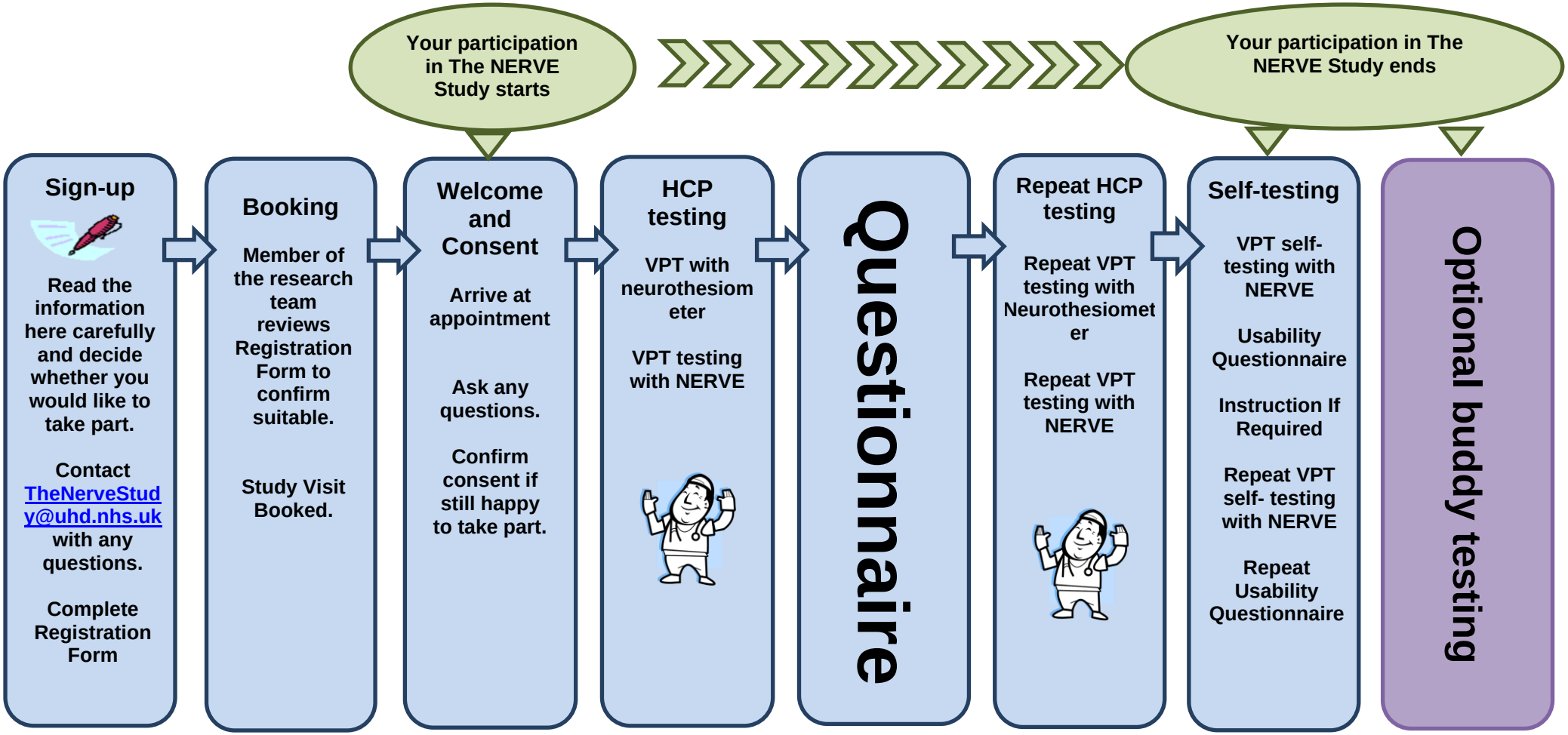
If you are suitable for the study and choose to take part, you will be invited to attend a single clinic visit that will last approximately one hour. You will be given the chance to ask any questions you may have, and we will ask you to confirm consent to participate in the study.

A healthcare professional will then test your foot using the Neurothesiometer and the NERVE devices. Both devices work by gradually increasing and decreasing vibration levels to find the point at which you just start or stop feeling them. You will then be asked to complete a brief questionnaire about how you might use your mobile phone

to manage your health to help us further develop the device. The healthcare professional will then repeat the vibration threshold testing with the Neurothesiometer and the NERVE device.

You will then be offered the opportunity to try using the NERVE device to test yourself. We will ask you to complete this test twice, and to complete a simple questionnaire after each test to help us understand how user friendly the device is.

Some people may find it hard to self-test or prefer to have someone else do it for them, such as a family member or friend. If you have someone with you and are both happy we will ask them to try testing the device and to complete the usability questionnaire.



Glossary
HCP: Health Care Professional
VPT: Vibration Perception Threshold

Figure 1: Your journey through the NERVE STUDY.

What are the possible disadvantages and risks of taking part?

There is no risk above that of the normal 'monofilament' test you would have at your annual foot check.

All equipment will be disinfected according to Infection Control guidance between uses.

If you have any areas of painful or broken skin (including ulcers) these will be avoided, and should this be present on both feet you will unfortunately not be able to participate in the trial.

Both devices produce vibrations that are applied to your big toe. You may experience slight discomfort at higher intensities, however as the test is stopped once you can feel the vibrations this will only last for a couple of seconds or so.

The questionnaire does not involve any particularly sensitive topics. The questions do however include asking about your history of ulceration, and recollecting these events may be distressing to some people.

What are the possible benefits of taking part?

We cannot promise the study will help you personally, but the information we get from the study will help with development of the NERVE device that may be offered either to yourself or other patients in the future.

We will try to provide early access to the device to those who have participated in the study.

You may not have received an annual diabetic foot check within the last year. Should the research team have any concerns regarding your feet, with your permission, they will escalate these to the study podiatrist. Please note this is not a replacement for your annual check and will not affect your ability to receive one.

Expenses and payments

If you drive to your appointment we can provide you with a free hospital parking pass. Just provide a member of the team at your appointment with the ticket issued by the machine to exchange this for an exit ticket. Alternatively we are able to provide reimbursement for bus travel within the BCP area of up to £5, to claim this please ensure you hold onto your ticket and show this to a member of the team at your clinic appointment who will take a copy. Unfortunately we are unable to provide reimbursement without a copy of the ticket.

You will be offered a £10 voucher to thank you for your time.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the lead researcher (Dr Tamas Hickish) or Principal Investigator (Mrs Debbie Sharman) who will do their best to answer your questions. Please use the main study email

address in the first instance to ensure your message is dealt with promptly. Their contact details are also available at the bottom of this page.

If you remain unhappy and wish to make a formal complaint, you can contact the concerns team for University Hospitals Dorset NHS Foundation Trust on 0300 019 4886 or alternatively email them on pals@uhd.nhs.uk.

You can also write to them at the following address:

Patient Advice and Liaison Services (PALS)
Royal Bournemouth Hospital
Castle Lane East
Bournemouth
Dorset
BH7 7DW

Alternatively you can contact the Research and Development Department at ResearchOffice@uhd.nhs.uk or 0300 019 6686.

We value your feedback - if you have any suggestions as to how the study could be improved, please get in touch using the details below.

Harm

In the event that something does go wrong and you are harmed during the study and this harm is due to someone's negligence, then you may have grounds for legal action for compensation. The normal National Health Service complaints mechanisms will be available to you (if appropriate).

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name and/or initials
- Contact details (including email address)
- Date of Birth

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 (study ID) 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.

University Hospitals Dorset NHS Foundation Trust is the Sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study, and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Certain individuals from University Hospitals Dorset NHS Foundation Trust Sponsor Team and regulatory organisations may look at your research records to check the accuracy of the research study. These individuals work in accordance with strict regulations and guidelines.

The research team at Dorset Clinical Research Centre will collect information from you for this research study in accordance with our instructions. Pseudonymised data (i.e. using your study ID) will be shared with the collaborators involved in this project.

It is a regulatory requirement that any unexpected serious complications should be reported to the Sponsor and other authorities throughout the duration of the trial. Therefore if such an event were to occur your medical records will be utilised for this purpose regardless.

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.
- 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.

Will my taking part in the study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and any other personal identifiers removed, so that you cannot be recognised.

The only personally identifiable information collected will be from the registration form. This will only be accessible to members of the research team at UHD who have been granted permission to do so because they need this to contact you, via password protected accounts.

Will my General Practitioner/family doctor (GP) be informed of my participation?

No, as this study does not involve any treatment or other procedures that may affect your health or put your wellbeing at risk it is not necessary to inform your GP of your participation in this research study.

Due to their experimental nature, the measurements collected during the visit will not be used to inform your ongoing care, and therefore will not be shared with your GP either.

If any incidental issues are noted during your visit, we will signpost you to the relevant services as appropriate.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- on our research website https://www.uhd.nhs.uk/services/research-and-innovation/rbch/for-public-and-patients/protecting-your-data-in-research
- by asking one of the research team at your hospital
- by sending an email to Information.Governance@uhd.nhs.uk,
- or by ringing the R&D team on 0300 019 8500.

University Hospitals Dorset NHS Foundation Trust will keep identifiable information about you from this study for no longer than required and a maximum of approximately 2 years after the study has finished. Should an 'early access programme' be planned we will contact you before the end of this period to confirm whether you would like your details to remain on file for this purpose.

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

You are free to withdraw at any time before or during your research visit. This will have no impact on the on-going care that you receive. You are not required to give a reason for withdrawal; however we would be grateful for any feedback, as this may help us to improve the study in the future.

If you choose to withdraw, we will use the information collected up to that point. So once you have completed your visit you will not be able to withdraw from involvement in the study. As described in 'How will we use information about you?' your study ID will be used in the database, and therefore it will not be possible to identify you in the study dataset.

If you no longer wish to receive results of the study, please let a member of the team know using the contact details on this page.

What will happen to the results of the research study?

The results of this study will help with the ongoing development of the 'NERVE' device and mobile app, and therefore will be shared with the organisations collaborating on the project including Bournemouth University.
It is likely the results will also be shared with potential commercial partners (under strict confidentiality arrangements) and submitted to regulatory authorities as part of the Medical Device approval process.

They will also be published in academic journals and presented at conferences.

No personal identifiable data will be shared with any external organisation/partner, nor in any publication.

If you would like to be informed of the results of the study, please indicate this on the registration form (including how). We will also share these on this website and social media accounts for the study and organisations involved in the project.

Who is organising and funding the study?

This research is a collaboration between University Hospitals Dorset NHS Foundation Trust, Dorset HealthCare University NHS Foundation Trust and Bournemouth University. As 'Sponsor' University Hospitals Dorset NHS Foundation Trust takes overall responsibility for managing the study. Funding has been provided by the Department of Health and Social Care through the National Institute of Health and Care Research's 'i4i' programme.

Conflicts of Interest

The Chief Investigator (Dr Tamas Hickish) is a founder of a company called iQHealth Tech whose core product is iQemo. This is an Electronic Prescribing and Medicines Administration system. iQHealth Tech are also developing an app to be used by patients to allow them to report side effects of medicines they are taking. iQHealth has no involvement in this project. This has been considered by the Sponsor, Funder and the Research Steering Group and it has been determined that this is not in conflict with the development of the NERVE device or this study.

Who has reviewed the study?

A 'Patient Advisory Group' has been established for the project, comprised of individuals with diabetes or peripheral neuropathy, or involved in the care of those living with these conditions. The Group provided suggestions for and feedback on prototype designs of the NERVE device during development. Furthermore, they have reviewed the study design and documents, including this information page.

All research is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by South Central – Hampshire B Research Ethics Committee and approval by the Health Research Authority.

Further information and contact details:
If you have any questions, you can speak to one of the research team:

Tel: 0300 019 6686
Email: TheNerveStudy@uhd.nhs.uk

Thank you for taking the time to read this information.