

Neuropathy evaluation using the vibration function of a mobile phone.

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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 patients may have had at their 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.

Background

Diabetes can affect the functioning of the nerves, particularly in the hands and feet. This can mean that people 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 the feet and ask whether the patient can feel it or not, and calculate a score based on the responses. Together with other assessments this is used to determine the 'foot risk', and if above a certain level patients 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 patients 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 (**Neuropathy evaluation using the vibration function of a mobile phone**) 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 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?

You have been invited to participate because you have attended the study visit with a person taking part in the study.

Do I have to take part?

No, it is up to you to decide.

What will happen to me if I take part?

If you decide to take part you will be provided with the opportunity to learn how to use the NERVE device. You will be asked to complete the vibration perception threshold testing with the NERVE device on the person you attended the visit with twice and asked to complete a simple questionnaire after each test to help us understand how user friendly the device is.

Expenses and payments

If you drive to the 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.

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 (TheNerveStudy@uhd.nhs.uk) 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
- Email address or phone number (if you wish to be informed when the study results become available).

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.

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.

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 the 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.

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. 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 the 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.

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.

We will share the results on University Hospitals Dorset NHS Foundation Trusts 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.

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.