

APPENDIX A20: Participant Information Sheet

Participant Information Sheet

TITLE: Comparison of transcutaneous oxygen and nerve conduction devices against existing methods to determine neurovascular status in the feet of adult participants with Type 2 Diabetes in the community.

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Ethics Reference: REC 17/LO/2033

You are being invited to take part in a research study which will require you to make two visits. This research study is part of a PhD project, funded by the Wessex Clinical Academic Training Scheme. Please note that we are unable to reimburse your travel expenses after two visits.

Before you decide it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with friends and relatives. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you would like to take part, and if you have any questions or need more information to use the contact details on Page 4 below. Thank you for reading this.

What is the purpose of the study?

This study will use the feet of people with type 2 diabetes to test two machines, that will test:

1. the amount of oxygen reaching the skin (Medicap), and
2. how well a nerve is working (DPN-Check);

and compare them against existing methods.

- 1. The amount of oxygen reaching the skin (Medicap):** This study aims to measure the saturation of oxygen in the skin, compared to other methods of measuring circulation.



Transcutaneous oxygen pressure (TcPO₂) involves measuring the amount of oxygen that leaves the small blood vessels inside the foot and passes through to the skin surface, where it is measured by the machine (Medicap). It is a commonly used method that avoids entering or harming the body, and is therefore safer and quicker than other techniques. It is mainly used in assessing conditions with poor circulation, such as wound healing, determining limb amputation level, and skin survival; and it is hoped it can be useful in testing patients with diabetes to see early circulatory changes. In order to widen the small arteries and for the oxygen to flow to the skin more easily, the machine warms the skin up to 44°C, then measures the amount of oxygen arriving at the skin surface over 15 minutes. This will involve you sitting comfortably in a chair or clinic couch for 30 minutes, and the machine attached to the top of your foot as shown below:



2. How well the nerve is working (DPN –Check). This machine works by measuring how quickly the large nerve near the surface of the skin on the outside of the ankle carries messages. It does this by sending a small electric message from one part of the nerve, and measures how long it takes to arrive at another part. It uses this information to measure the health of the nerve, and can pick up early signs of damage. Nerve conduction studies (NCS) are seen as the reference standard in detecting early nerve damage, but until recently other machines that could measure this were more complicated and took a long time to operate. The DPN-Check is a new device that does not damage the skin, is easier to use and gives more useful information on nerve health. It has potential to find signs of nerve damage earlier than existing methods, but it needs more testing in clinics for patients with diabetes, where it can be compared to other methods normally used. We therefore think it can be useful to find and prove its use in clinics that treat diabetes patients, and compare it to existing methods.

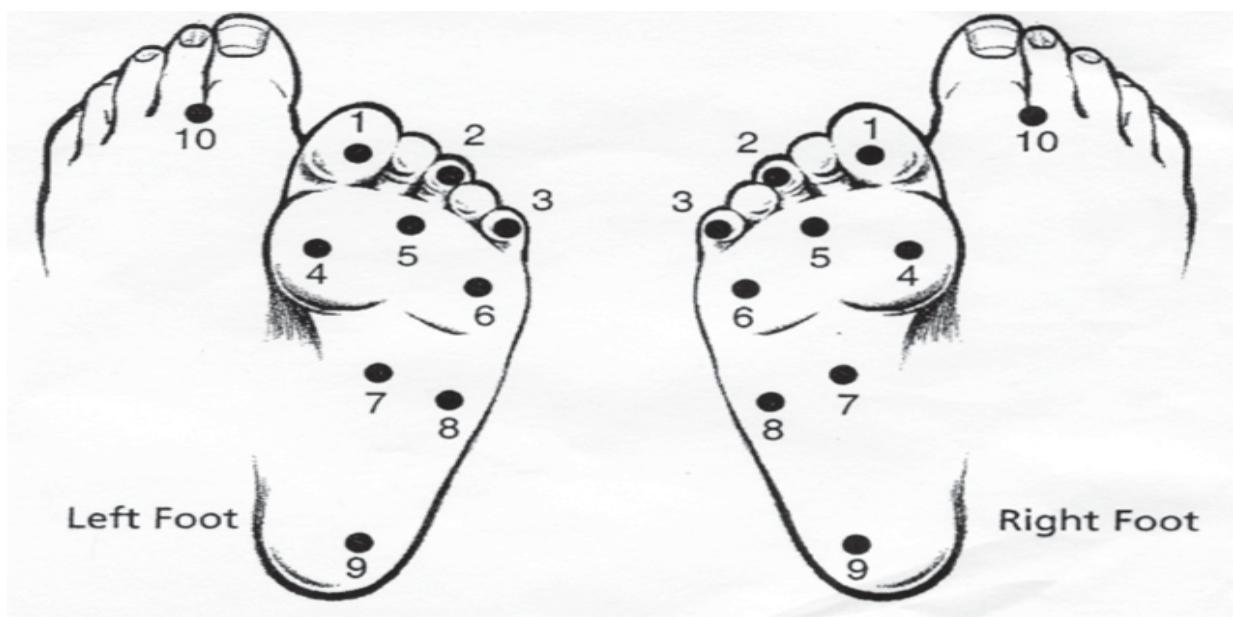


Existing methods

Circulation The pressure of the blood reaching the big toe in your feet will be tested using a Doppler machine as shown below:



Nerve function: a nylon thread will be used to test the feeling in your feet and 10 locations shown below:



What else will you measure?

- **We will also measure:** your ankle size, skin temperature, height and how much you weigh
- **and ask for:** your date of birth, age, if you are male or female; how long you have had diabetes, your if you smoke; your level of diabetes control (HbA1c); any diseases affecting your circulation, liver and kidneys, and any medications you take.

Why have I been chosen?

You have been chosen because you have Type 2 diabetes; and may have responded to a request or to our advertisement, where you can help determine the usefulness of the new machines above when compared to the methods currently used.

Do I have to take part?

It is up to you whether to take part. **Unfortunately, if you have already volunteered for another research project that is still ongoing, then you will not be able to participate in this.** If you do decide to take part, you will be given this information sheet to keep and we will ask for your permission to ask your doctor / GP about your diabetes control levels, and tell them you are taking part in a trial. You will then be asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason and without affecting your usual treatment.

What will happen to me if I take part?

You will be asked to answer a few questions about yourself. If you meet the criteria of the study and agree to take part you will be enrolled to the study. You will be asked to attend the podiatry clinic at the Royal South Hants Hospital, at least once, and may be asked to return 3 months later for a follow-up for the above tests to be repeated. Each time, the visit will last up to 1 hour.

What happens?

1. During the first visit, you will be asked to sign a form confirming your agreement to take part. Measurements will be taken on your weight, height and ankle size, and you will be asked about your age, any medication you take, how long you have had diabetes, your sugar levels and gender. Recording your information can take up to 15 minutes, and if you think of any questions, you can ask them to the assessor at any time.
2. You will be asked to sit in a clinical chair, which will be adjusted to your comfort. Both your feet will be tested for circulation and nerve health according to usual methods (monofilament and Doppler). This part will take less than 15 minutes.

3. The new machines will then be used to repeat the tests on your nerves and circulation. For your circulation; sticky rings will be fixed to the top of your foot between the big and second toes, and the Medicap machine probe will then be attached to the ring. The Medicap machine will be turned on and your skin will experience a warming sensation, and measurement will begin, and will last no more than 15 minutes. During this time the DPN-Check will test the nerve around the outside of both your ankles, by sending a small electric current.
4. Pictures of your feet and ankles may be taken with the machines attached.
5. *How long will it take?* The total time for all the assessments will be about 45 minutes, but allow for your visit to last up to 1 hour so you are not rushing and to allow for any additional questions you may have. You may be asked to return after 3 months to have the above measurements repeated.

Are there any risks involved?

It is most unlikely that you will suffer any discomfort or adverse effects from this study, although some may experience a mild, painless, short-lasting skin irritation following the skin warming. The nerve conduction device sends a small charge around the ankle, which may result in slight "buzzing" or "tingling" sensation which may make you feel uncomfortable for about 5 - 10 seconds. Both these methods for measuring the amount of skin oxygen and nerve function do not involve entering the body.

Are there any benefits in my taking part?

You would not receive any benefits directly. However, this study will increase our understanding of how a new device compares to another when measuring skin oxygenation. It will also help us to find a way to find changes earlier in the feet of people with diabetes, that may lead to ulcers.

What happens if something goes wrong?

If you have any complaints or concerns during this study you should immediately inform the investigator. In the unlikely event that something goes wrong during the study indemnity insurance has been provided. If you have a concern or a complaint about this study you should contact Trudi Bartlett, Research Governance Officer, at the University of Southampton (Address: Research Integrity & Governance Office, Building 37, Room 4079, University of Southampton, Highfield, Southampton SO17 1BJ. Email: rgoinfo@soton.ac.uk; Tel: 023 8059 5058). If you remain unhappy and wish to complain formally the Research Integrity & Governance Office can provide you with details of the University of Southampton Complaints Procedure.

Would my taking part in this study be kept confidential? Your GP will be informed by letter that you are taking part in this study. All data will be treated in compliance with the Data Protection Act and the University of Southampton policy for the storage of data (<http://library.soton.ac.uk/researchdata/retention>). Results will be recorded on paper, and images taken by an unlinked digital camera. This refers to a camera that has no other external connectivity apart from a storage card and USB cable for image transfer. Your details will be anonymised by a study number and date of birth, and will be transferred to a University of Southampton encrypted computer, and the papers and images then securely destroyed immediately on transfer to the computer. The research data will be stored with the University of Southampton, and your details will be securely stored for up to 10 years from completion of the study, in a secure computer archive. After this period, to enable the secure disposal of electronically held data, the data will be overwritten multiple times and the physical disk destroyed in line with the university of Southampton policy on the destruction of research data (<http://library.soton.ac.uk/researchdata/destruction>).

What will happen to the results of the research? It is hoped that the findings from this study will be published in suitable professional and scientific journals. It will not be possible to identify any individuals from any of the data presented. You will be asked whether you wish to be personally informed of the results of this study at the end.

What happens if I change my mind?

You have the right to withdraw from this study at any time, without giving a reason. This will not affect the level of care you receive or your usual treatment.

Who has reviewed the study?

This study has been reviewed by the Faculty of Health Sciences research ethics committee.

Contacts for further information:

Simbarashe Tanyanyiwa – email: srt1e14@soton.ac.uk

Keith McCormick – email: K.G.McCormick@soton.ac.uk

Prof. Catherine Bowen- email: C.Bowen@soton.ac.uk

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

Thank you for taking the time to read this information.