Participant Information Sheet
Version: 4.0, Date: 01/11/2022

IRAS Project ID: 291141

Title of Study: Monitoring wound status using multi-parameter optical fibre sensors

Name of Chief Investigator: Professor Frances Game
Local Researcher(s): Professor Frances Game, Ms Katie Gray

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives. In general, only half of all foot ulcers in patients with diabetes will heal in 6 months. At the moment, the assessment of possible ulcer infection and checking the ulcer is healing properly can only be assessed at a clinical appointment with a health care professional.

If, however, we could easily monitor an ulcer away from a clinic setting it could notify the patient and clinician that either the ulcer is not healing or has become infected between clinical appointments. This alert could mean that clinicians could intervene earlier with treatment of infection. But equally if the ulcer is healing well, means that routine clinic appointments just for checking could be reduced.

This study is a preliminary study to see if a new type of ulcer sensor, which is made of very fine fibres (Optical Fibre Sensors) and built into a standard dressing, can measure chemicals and gases that we think may be associated with ulcer healing and infection. Although the ultimate aim will be to monitor ulcers at home, in this first stage we need to see whether these fibres do

in fact measure what we think they should whilst on an ulcer. So, this study will take place in the diabetic foot clinic and you will not be expected to wear this new "sensing" dressing at home.

Why have I been invited?

You have been invited because you have diabetes and have an ulcer on one (or both) of your feet. We are planning to include about 10 patients with diabetes and foot ulcers from the University Hospitals of Derby and Burton NHS Foundation Trust Diabetic Foot Clinic.

Do I have to take part?

No, it is up to you to decide whether or not to take part. Even if you decide to take part, but change your mind at a later date, you will be free to withdraw at any time and without giving a reason. Your usual care will not be affected in any way whether or not you take part, or even if you take part and then decide to withdraw at a later stage. If you do withdraw from the study, we will keep any information relating to the study which has been collected about you up until to that point. This information will, however, be coded so that you will not be identifiable from it in any way.

If you do decide to take part you will be given this information sheet to keep and be asked to sign consent.

If you wish some independent advice on taking part in research then you can contact:
Patient Advice and Liaison Service (PALS) on:
Freephone: 0800 783 7691 or
Office: 01332 785156 or
Email: dhft.contactpals@nhs.net or
Text: 07799 337 500.

What will happen to me if I take part?

If after reading this information sheet you are interested in taking part one of our research team will arrange to meet you at your subsequent clinic visit or a time convenient for you. A member of the clinical team will try to book a research visit to coincide with a routine clinic appointment. You will have an opportunity during this initial meeting to discuss any questions or worries you may have. After this, if you agree, you will be asked to sign a form to say you consent to be part of the study.

To discover if the Optical Fibre Sensors (research device see diagram 1) can detect whether an ulcer is healing or infected we will compare readings from this sensor to a set of readings taken at the same time with a conventional measurement device (comparator see diagram 2) which is already used in other conditions.

The study will take place over an eight week period. During this time you will have fortnightly visits until week 8, unless your ulcer heals before that. All study visits will take place at your routine diabetic foot clinic, and we will do any of the usual care you would expect at a routine foot clinic at the same time. Once you have had your routine Podiatry treatment your research visits will last around approximately 2 hours, for a total of 4 study visits.

At your first visit the following will be done:

- We will ask some brief questions about your medical history and current medication.

- Assessment of the appearance of your ulcer, including whether it's infected, the size and depth of it, and take a picture of it with the Silhouette wound imaging camera (this uses a photo taken of the wound to measure wound area), as we usually do in foot clinic.

- Treatment of foot ulcer as per usual care – nail care, debridement of hard skin, wound care.

- Assessment of your foot pulses by feeling them.

- Assessment of neuropathy using a 10g monofilament (thin nylon filament which is standard care for detection of feeling in feet).

- Ankle brachial pressure index (ABPI) measurement (measuring the blood pressure in your arms and leg with a cuff which blows up).

- We will look at your medical records to see if blood tests have been taken for eGFR and HbA1c in the last 12 months, if no results are found a blood test for eGFR and HbA1c will be taken.

- We will ask you to complete a scale of the pain (from 0 to 100) you may be experiencing from your ulcer.

- The dressing which was on your ulcer will be removed by the podiatrist and, with your permission we will send this away to researchers in Brunel University, who will be measuring the tiny amounts of gases given off the dressing.

- We will take a swab from your ulcer to test for the degree of acidity (pH). Once measured the swab will be destroyed as clinical waste.

- Whilst you are lying on a couch the dressing of the research device (diagram 1) will be placed over your ulcer. This could be left in place for up to 1 hour.

- A video camera (for research purposes) will be used to record the wound/foot during the time the measurements are being taken. We will only record your feet not any other part of you and this is just so that if the sensor stops reading we can see whether it is because of movement on the sensor location. If you have any distinguishing marks on your feet (e.g. a tattoo) which could potentially identify you on the video recording we will ensure that these identifying features will be removed from the video recordings using appropriate software.

- Whilst you are lying on a couch another measurement device (diagram 2) will be placed on the wound to compare the measurements taken with the new research device. This may take up to 30 minutes.

- We will also collect some gases in a container and, with your permission, we will send these for later analysis at the Open University. They will measure the tiny amounts of gases given off by your ulcer. This may take up to 10 minutes.

- Whilst you are lying on a couch the measurement device (diagram 2) will be placed on the intact foot skin to compare with measurements using the new research device. We will also collect some gases in a container and, with your permission, we will send these for later analysis at the Open University. They will measure the tiny amounts of gases given off by the intact foot skin. This may take up to 10 minutes.

At each fortnightly visit the following will be done:

- We will check that you are still happy to be in the study.

- The research podiatrist will then remove the usual dressing you have on your ulcer and, with your permission, we will send this away to researchers in Brunel University, who will be measuring the tiny amounts of gases given off the dressing.

- Assessment of the appearance of your ulcer, including whether it's infected, the size and depth of it.

- We will take a swab from your ulcer to test its degree of acidity (pH). Once measured the swab will be destroyed as clinical waste.

- Whilst you are lying on a couch the dressing of the research device (diagram 1) will be placed over your ulcer. This could be left in place for up to 1 hour.

- A video camera (for research purposes) will be used to record the wound/foot during the time the measurements are being taken. We will only record your feet not any other part of you and this is just so that if the sensor stops reading we can see whether it is because of movement on the sensor location. If you have any distinguishing marks on your feet (e.g. a tattoo) which could potentially identify you on the video recording we will ensure that these identifying features will be removed from the video recordings using appropriate software.

- Whilst you are lying on a couch another measurement device (diagram 2) will be placed on the wound to compare with measurements using the new research device. We will also collect some gases in a container and, with your permission, we will send these for later analysis at the Open University. They will measure the tiny amounts of gases given off by your wound. This may take up to 10 minutes.

- Whilst you are lying on a couch the measurement device (diagram 2) will be placed on the intact foot skin to compare with measurements using the new research device. We will also collect some gases in a container and, with your permission, we will send these for later analysis at the Open University. They will measure the tiny amounts of gases given off by the intact foot skin. This may take up to 10 minutes.

If your foot ulcer heals during the study, you will have completed the study and your participation will end.

Diagram 1: Optical Fibre Sensing System for Wound Monitoring overview (research device)

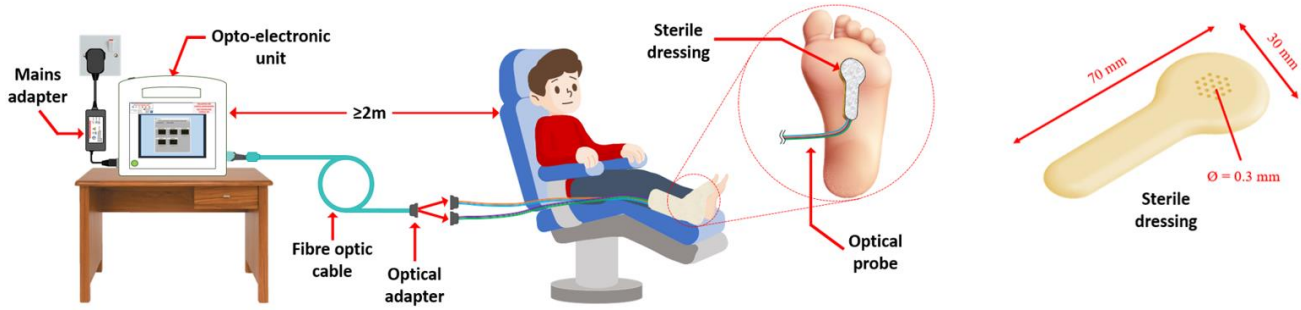
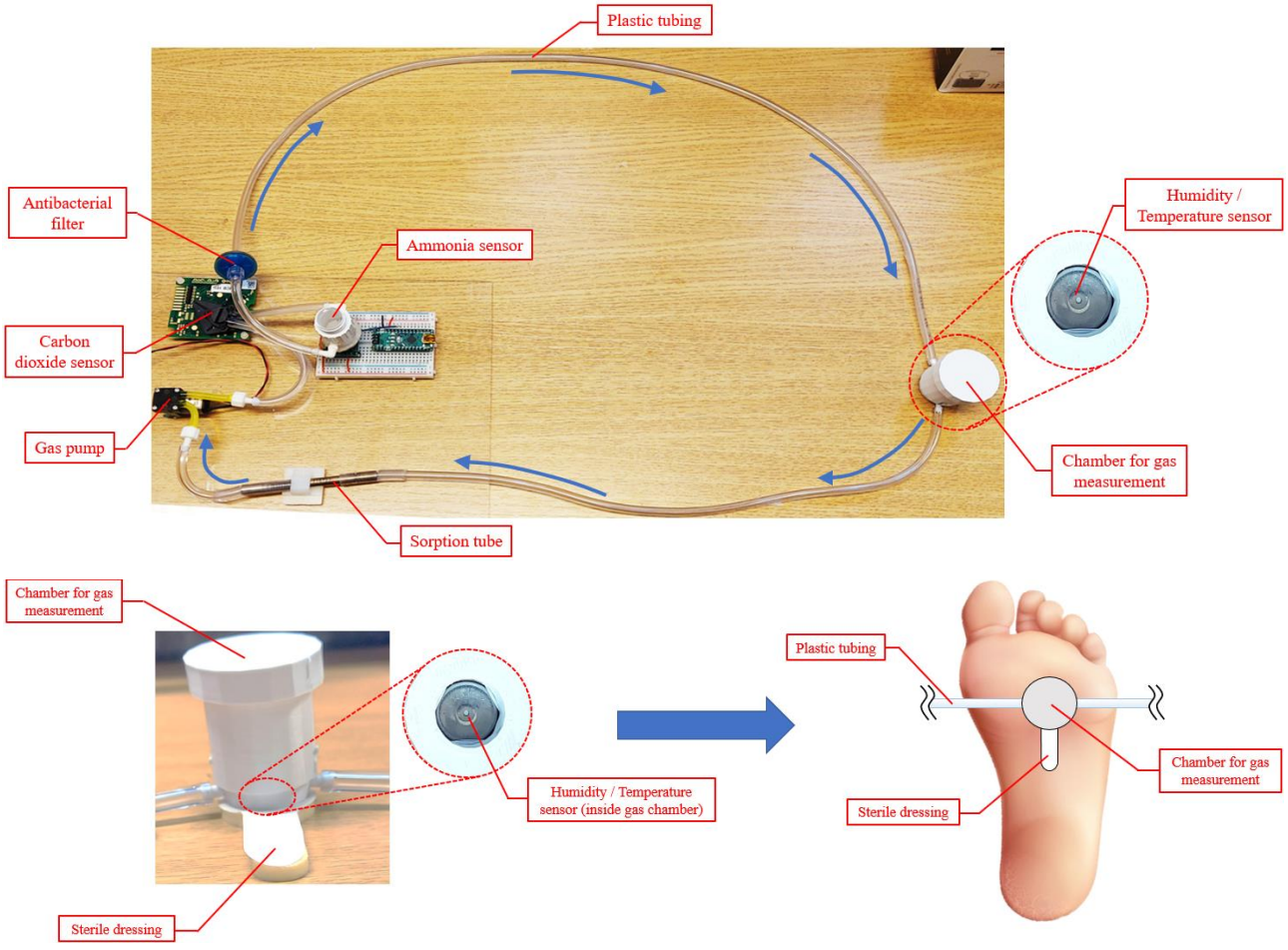


Diagram 2: Measurement device (comparator)



What will happen to my samples?

- Your discarded wound dressing will be transported via tracked courier delivery to researchers at Brunel University. They will only be measuring gases given off by the dressing. You will not

be able to be identified by these researchers as the dressing will be labelled only with a research number. The dressing will be destroyed after use in accordance with the Human Tissue Act.

- The gases collected directly from your ulcer or skin will be transported via tracked courier to researchers at the Open University. You will not be able to be identified by these researchers as the gas sample will be labelled only with a research number.

Expenses and payments

You will not be paid to participate in the study; however we will reimburse you for travel expenses for any extra clinic visits. Unfortunately, we will not be able to reimburse any other expenses.

What are the possible disadvantages and risks of taking part?

Although this is the first time sensors have been applied to diabetic foot ulcers, we think that any risk to you from the monitoring equipment is very low as the equipment has all had an independent safety review and been passed as safe.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help to better understand ulcer healing and monitoring for future patients.

What happens when the research study stops?

The routine clinical care of both you and other people will not be affected once you have taken part in this study. The results from this study will be used to design a larger study. If you wish to receive a summary of the findings of this study we will, with your permission, keep your contact details and will send you a newsletter once the results have been analysed.

What if there is a problem?

We do not expect anything to go wrong. If you have any concerns or queries about any aspect of this study, you should ask to speak to one of the research team who will be undertaking the day to day running of the study and who will do their best to answer your questions.

If you wish to complain about the conduct of the research, you should contact the Chief Investigator Professor Frances Game, Dept. Diabetes and Endocrinology, University Hospitals of Derby and Burton NHS Foundation Trust, Derby, DE22 3NE. Telephone 01332783283.

Alternatively, if you wish to speak with someone not involved in the study, you could contact the Patient Advice and Liaison Service (PALS) on:

Freephone: 0800 783 7691
Office: 01332 785156
Email: dhft.contactpals@nhs.net
Text: 07799 337 500.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. It is necessary to record in your hospital notes that you are participating in this study, for your benefit and protection.

If you join the study, we will use information collected from you and your medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Any information about you which leaves the hospital will have your name and address removed and a unique code (which will consist of your study number and date of birth only) will be used so that you cannot be recognised from it. By signing the consent form you agree to the above.

If you advise us that you wish to be contacted about the findings of the study and possible follow-up studies, and you give us specific consent to do this, your contact information will be kept by the University of Nottingham for 7 years after the end of the study. This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may

have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be formally informed of your participation in this study as there will be no change to your usual care.

What will happen to the results of the research study?

The results of the research will be used to inform future studies. The results will be published in medical journals, you will not be identified in any report/publication.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by The Medical Research Council: Developmental Pathway Funding Scheme.

Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by South East Scotland Research Ethics Committee.

Further information and contact details

For further information please contact the diabetic foot research team on Tel: 07384871088 or email dhft.footres@nhs.net.