

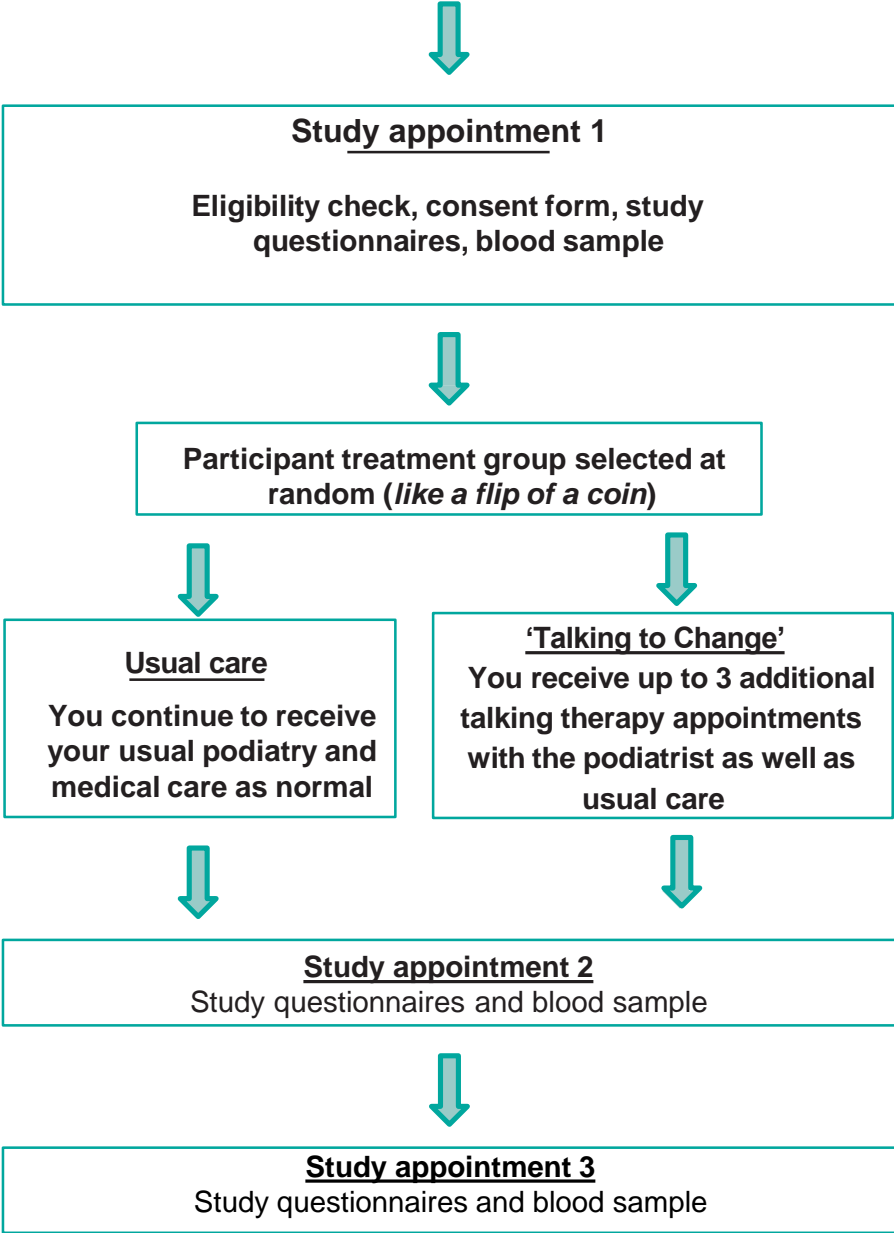


A study to assess if a talking therapy helps people with Diabetes make positive changes to stop foot ulcers

Participant Information Leaflet

A pilot trial of motivational interviewing for the prevention of diabetes-related foot ulceration

Participant Pathway Diagram



Can I contact a member of the research team for further information?

If you have received this information leaflet you will be offered an opportunity to speak with a researcher when you attend for your appointment. They will be able to provide further information on this study, answer any of your questions and tell you about the next steps should you wish to continue with being part of this study.

If you have any further questions about the study at any stage, please feel free to contact:

Dr Ruth Barn

Chief Investigator MIDI Trial

Glasgow Caledonian University

0141 331 3869

ruth.barn@gcu.ac.uk OR

midi@gcu.ac.uk

If you would like information about research more generally please contact:

Dr David Hamilton,

Glasgow Caledonian University

0141 331 8328,

david.hamilton@gcu.ac.uk

Information about the study is available on the following website: www.miditrial.com

Thank you for reading this and considering taking part in this study.

Introduction

You are being invited to take part in a research study. Before you decide, it's important to know why we're doing this research and what it means. Please read this info carefully, talk to others if you want. We'll explain it to you and answer any questions. If you're unsure about anything or want more info, just ask. Take your time to decide if you want to join in.

What is the purpose of the study?

Motivational interviewing is a special talking therapy that helps people improve their habits and behaviours that might improve their health. We're not sure if our talking therapy called 'Talking to Change' helps people with diabetes foot ulcers. We need to do more research. This study wants to see if using our talking therapy, along with your usual care, is better than just usual care for preventing diabetes foot ulcers.

Why have I been asked to take part?

You have been asked to take part because you are a person with Diabetes who has had or currently has a foot ulcer living in an area with greatest need. We want to recruit 60 people like you to take part in the study. We will check your postcode to see if you are exposed to more deprivation. It's important to stress that this score isn't about labelling individuals or communities negatively. Instead, it's about recognising where additional resources might be needed to address inequalities.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do, you will be asked to sign a consent form. If you change your mind, you can withdraw at any time. You don't need to explain why, but it would help us if you could let us know you would like to withdraw. This will not affect the care you receive. Travel expenses will be provided for all study appointments. As a thank you for participation, we will provide you with a £20 voucher for completing each study visit at 6 months and 12 months.

What will happen to me if I take part?

If you are interested, you will be asked to attend a study appointment to check if you are eligible. At this appointment, you will be asked questions about your diabetes. If you are eligible and interested in taking part, you will be asked to sign a consent form. Next you will have your feet checked, we will ask you to complete some short questionnaires about your general and mental health. If you feel uncomfortable answering any of the questions, you can pause at any time, you can also decline to participate. We will then collect 2 small blood samples, these will be used to measure your blood sugar and how well your kidneys are working. You may have already had these blood tests recently, and if so, we will collect these results from your medical notes with your permission. You will then be randomly selected (using a computer) to receive either standard care, or our new talking therapy (Talking to Change).

Follow up visits

You will be asked to attend study appointments 6 and 12 months after your first appointment. You will be asked to complete some questionnaires and have blood samples taken (or we will collect the results from your recent blood tests with your permission). If you develop a foot ulcer during your time in the study, we will ask you to report it (instructions will be provided).

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. In the first instance contact Ruth Barn ruth.barn@gcu.ac.uk, telephone -0141 331 3869.

The sponsor of this study's research has taken out insurance that covers its civil responsibility for any possible harm and injury from taking part in the study . If you remain unhappy and wish to complain formally, you can do this by accessing the NHS complaints website;

<https://www.nhsinform.scot/care-support-and-rights/health-rights/feedback-and-complaints/making-a-complaint-about-your-nhs-care-or-treatment/>

What will happen to the results of the study?

The results will help us to understand which treatments may help people with Diabetes and foot ulcers and how effective it is. We hope that the results will be published in a number of journals so that others can read and learn from the results of the study. If you wish, when the study is complete we will send you a summary of the findings.

Will the information I provide be kept confidential?

Glasgow Caledonian University is the sponsor for 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. All information which is collected about you during the study will be kept strictly confidential. Your name and address will be removed from any information which leaves the hospital so that you cannot be identified. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Your identity will remain confidential at all times and all of your personal information will be processed in accordance with the EU General Data Protection Regulation (GDPR) (2018). You will be given a unique study number. We ask permission however to retain your contact details so as to contact you during the study period. This information will only be available to the study team who are all bound by NHS rules on confidentiality. All the study data collected will be anonymised. The majority of the study related data will be held within Glasgow Caledonian University and the Robertson Centre for Biostatistics at the University of Glasgow. Your electronic data will be stored securely at the Glasgow Caledonian University and the Robertson Centre for Biostatistics at the University of Glasgow for 5 years before being destroyed. If you wish to enquire about any of your rights concerning use of your data, please contact our Data Protection Officer at dataprotection@gcu.ac.uk. Your GP will be informed of your participation in this study. By signing the consent form you will be agreeing that your GP can be notified.

If you are selected for Usual Group

Your clinical care team will be informed that you are to continue with your current standard care.

If you are selected for the 'Talking to Change' Group

We will organise your first appointment with the podiatrist for the 'Talking to Change' therapy which involves a technique called motivational interviewing. The podiatrist will be trained specially in motivational interviewing and may not be the usual podiatrist you see for your foot problems. Motivational interviewing is a way for you and your podiatrist to work together to explore your feelings and motivations regarding making changes to improve your health and wellbeing. This will involve 2 sessions lasting around 60 minutes each, over 3 months. You may be invited for a 3rd appointment if your podiatrist feels you might benefit from an additional session. The treatment will involve conversations with the podiatrist about any changes you have made, or have considered, since having a foot ulcer. Conversations will be based on topics you would like to discuss and the podiatrist will ask you questions and offer you support to help you achieve any goals you set yourself.

The idea is to help you find your own reasons and strategies for making the changes you want in your life. You may also be referred for additional support for any issues raised in these sessions such as for help to stop smoking. All "Talking to Change" sessions will be audio-recorded with your permission to help us write up our notes for analysis later. You will not be identifiable and only the research team will have access to these recordings.

Please note that carers are not usually present for your 'Talking to Change' sessions. At the end of the 3 months treatment period, you may be invited to participate in an additional telephone interview study with one of our researchers. If you are willing to be contacted about this study and receive an information sheet, please indicate your willingness to be contacted on your consent form

How long will I be involved in the study ?

You will be involved in the study for 1 year.

What are the possible disadvantages or risks of taking part?

The main disadvantage is that you will be asked to attend some additional appointments. Appointments will be held in a consulting room at clinic or hospital within your local NHS area which may be different to where you normally receive your podiatry care. However, we will work with you to find a location which is suitable to you. We will provide expenses so you are not out of pocket for any additional travel. If for any reason there are limited travel options available to you, we can offer you a taxi free of charge to take to you to your appointment and take you home afterwards. Our study staff will ask you about your travel options and will book and pay for your taxi as required. We do not anticipate any risks to you from being involved in the study but we are aware that talking about your experience of foot ulcers and completing the questionnaires may be upsetting. If you wish to pause the discussion or completion of questionnaires at any time you can.

What are the possible benefits of taking part?

The Talking to Change therapy may help to identify positive lifestyle changes you wish to make and how to make them. The information we get from this study may help improve the treatment of people with Diabetes who are at risk of developing foot ulcers..

As a token of our appreciation for your participation, we would like to say thank you by offering you a £20 voucher for completion of each follow up visit at 6 and 12 months after your baseline appointment.

Who is doing this study?

The research is being carried out by a group of experienced Podiatrists and researchers from a number of different organisations:

- Glasgow Caledonian University
- NHS Lanarkshire
- NHS Ayrshire and Arran
- NHS Tayside
- NHS Fife
- Robertson Centre for Biostatistics, University of Glasgow

The study is funded by the Chief Scientist Office

Who has reviewed this study?

The following groups have reviewed this study and given their approval for it to be carried out:

- Glasgow Caledonian University School of Health and Life Sciences ethics committee (AHP/A23/010)
- West of Scotland Research Ethics Committee 5 (24/WS/0044 IRAS 335427)
- Each local NHS Board Research & Development department.
- Consent to take part in the study will be obtained. You will receive a copy of all signed consent materials.