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Sponsor: University of Leicester

Centre: [insert site name]

Study title – A Multifactorial Intervention to Improve Cardiovascular Outcomes in Adults with Type 2 Diabetes and Current or Previous Diabetes-related Foot Ulcers - randomised controlled trial (MiFoot RCT)

Chief Investigator: Professor Kamlesh Khunti

Principal Investigator: [insert name]

Participant Information Sheet

>>insert version and date<<

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the study is being done and what it will involve. We want to tell you why we are doing the study and what we would like you to do as someone taking part in it. Please take time to read this information sheet carefully and discuss with others if you wish.

If there is any part of this information sheet that you do not understand, or require further information about, please contact us and we will be happy to answer any questions you have.

WHAT IS THIS STUDY ABOUT?

Type 2 diabetes (T2D) is becoming more common and can lead to diabetes-related foot ulcer disease (DFUD). DFUD is a patch of broken skin on the foot that can be slow to heal and can come back easily. People with DFUD often also experience problems such as heart attacks and strokes. The MiFoot study is a research study that will test a programme designed to improve heart health in people with diabetes and diabetes-related foot ulcers. The MiFoot programme aims to help people to better manage their condition, receive the most up to date care and be more physically active.

In this study we want to see whether the MiFoot programme can improve the health of people with current or previous diabetes-related foot ulcers, and if it is good value for money.

WHY HAVE I BEEN INVITED TO PARTICIPATE?

You have been invited to take part because you are aged between 18 and 100 years old, and have been diagnosed with Type 2 diabetes, and a current or previous (within the last five years) diabetes-related foot ulcer disease.

DO I HAVE TO TAKE PART?

No, taking part is voluntary and will not affect the care you receive in any way. If you decide to take part and then change your mind, please just let us know. You are free to withdraw from the study at any time without giving a reason. If you lose capacity during the duration of the study, you will be withdrawn from any further involvement. However, please note any data collected prior to withdrawal may still be used. If you are happy for us to access your health records for a long term follow up, we will still do this unless you tell us otherwise.

EXPENSES AND REIMBURSEMENTS

Participants will be reimbursed for any travel and parking expenses incurred (original receipts must be provided). Participants randomised to the control arm will receive up to £10 in reimbursement for attendance of the baseline visit. Participants randomised to the intervention arm will be attending approximately 14 face to face visits and will receive up to £140 in reimbursement. The amount will be reviewed on a case-by-case basis, depending upon circumstance.

You may also receive up to £60 in vouchers for your participation in recognition of your time commitment in RCT. At the end of the study those who have taken part in the intervention arm may be invited to take part in a process evaluation. If you take part in this you will be given an additional £20 in vouchers as an acknowledgement of your time commitment.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you meet the study's inclusion criteria, we will arrange a convenient appointment time to talk about the study in more detail with you. You will then be asked to review and sign a consent form to confirm that you wish to take part. Only once you have provided written consent will you be able to start the study. You will also be given the opportunity to consent to the interview or observation parts of the study (explained below), but this is optional. Expressing an interest in these additional parts does not mean that you have committed to them and you can change your mind without this affecting your participation in the main part of the study.

This study is a randomised control trial. This means that you have an equal chance of continuing with your usual care (if randomised to the control arm) or receiving the MiFoot intervention (if randomised to the intervention arm) but neither you, nor the research team can choose this for you. Overall, your involvement in the study will last 24 months (2 years). For both arms, there will be 1 baseline assessment visit and 2 remote follow up visits during this time. The table below gives a summary of the visits, including how long each visit lasts.

Visit Schedule and Assessments	**Timepoint**
Remote, telephone screening (Around 15 minutes via telephone) • Explain study in more detail and answer any questions you have • Check you are suitable for the study (e.g. meet the study's inclusion criteria) • Confirm baseline visit date	Pre visit 0
Visit 0 – Face to face Baseline visit (Around 2-3 hours at [insert site name here]) • Meet with a health care professional, sign your consent form, and have baseline measures taken such as: o Height, o Weight o Blood pressure • You will be randomised to either the control or intervention arm and told which arm you are in and what happens next. • Depending on your randomisation arm you will then; o Have an ECG (Intervention arm only) o Complete physical activity screening (Intervention arm only) o Complete a questionnaire booklet (both arms) o Be shown how to use an activity monitor (wristwatch) which will be posted to your home address to wear for 8 days (both arms) • We will collect routine information from your existing healthcare records held on primary care systems or hospital records (including test results, medication and other factors that may affect your diabetes and DFUD). This does not require a visit or for you to complete any assessments.	Week 0
Visit Schedule and Assessments	**Timepoint**
Usual care or Intervention MiFoot programme If you are allocated to **the control arm**, you will continue to receive your usual diabetes care. If you are allocated to **the intervention arm,** you will continue with your usual care and receive the MiFoot programme.	From week 0 to month 24

The MiFoot programme will include:
• A one-to-one session with a health care professional (**Around 45 minutes** at [insert site name here])
• Group-based education and physical activity sessions (**up to 2 hours each** at [insert site name here] or virtually delivered)
  ○ 7 weekly sessions (occurring after baseline)
  ○ 10 monthly boosters (one per month occurring after completion of weekly sessions-and up to month 12)
  ○ Follow up booster at months 18 and 24
• An online platform designed to support you to live a healthy lifestyle
As a part of the study, we will ask your permission to observe some of the sessions/appointments (optional) and gain your feedback on the MiFoot programme.	

Remote Follow up Visit at month 12 • Questionnaire booklet completed online or posted to home address (both arms) • An activity monitor (wristwatch) posted to your home address to wear for 8 days (both arms)	Month 12
Remote Follow up Visit at month 24 • Questionnaire booklet completed online or posted to home address (both arms) • An activity monitor (wristwatch) posted to your home address to wear for 8 days (both arms)	Month 24

Visit Schedule and Assessments	**Timepoint**
Interview (optional) (intervention arm only) If you consent to this, you might be selected to take part in an interview either face to face (Leicester participants only), over the phone or via video call at a time that is convenient to you. We would like to talk to you about your experience.	Post month 24

WHAT IS INVOLVED AS PART OF THE STUDY VISITS?

<u>Telephone Screening</u>

Once we receive your reply, a member of the study team will contact you. If you reply by post, the study team may contact you by phone or email and ask you some simple questions to check you are eligible to take part in the study, and to carry out COVID screening if applicable. If you reply using the QR code, you will be asked to complete these screening questions online, and we will get in touch if you are eligible. You will have the opportunity to ask any questions you may have. We will then invite you to the baseline visit if you are eligible to participate.

Eligibility confirmation

Prior to attending your baseline visit we will ask for your permission to look at your health records to confirm T2D and DFUD diagnosis. This will help us to see if you are eligible for the study. This is optional and you do not need to agree to it however it may prevent you needing to make a visit to the hospital if your health records show that you are ineligible. If you are not happy for your records to be accessed prior to attending the baseline visit and consenting to take part in the study, this can be checked and confirmed at the baseline visit. Your eligibility will be confirmed by a health care professional. They will look at your health records.

Individuals who are involved in another drug or lifestyle modification study will be unable to take part.

Visit 0 (the baseline visit)

If after reading this Information Sheet, you are interested in taking part in the study we will ask you to provide consent prior to any study procedures being performed.

Data collection

We will ask you directly for some basic information about you (e.g., your age, sex and ethnicity) and medical history, including a review of your current medications. We will also measure your weight and height, your heart rate, and blood pressure. We will ask you about your smoking status and alcohol consumption.

As part of the consent, we will ask your permission to collect some information from your routine existing health records held on primary care systems or hospital records at baseline, month 12 and 24 in the study. This will include recent clinical test results (such as blood pressure, blood sugar and insulin levels, blood fat levels, kidney function), what medications you are being prescribed, how often you have visited the GP, and whether you have had any recent relevant medical events (such as being admitted to hospital for heart disease treatment). At baseline if your most recent

blood test results were completed more than 3 months ago, you will be given a blood request form and we will ask for these blood tests to be completed by your GP.

Physical activity monitor (both control and intervention arms)

We will show you how to use a physical activity monitor. This is a small device a bit like a wrist watch which you will be asked to wear on your wrist for 8 days in a row. This measures how much time you spend sleeping, sitting and moving. It can be worn all day and night and you can sleep and shower in it.

The study team will demonstrate how to wear the device and will ask for your permission to store your contact details so that we can post the device to you at various time points during the study. The monitor is set to record during set dates (8 days at a time), we will inform you of these dates and will ask you to wear the monitor during the recording period. After the 8 days we will ask you to return the monitor to the research team. You will be provided with a pre-paid envelope.

Questionnaire booklet (both control and intervention arms)

We will ask you to complete several questionnaires. These will help us to find out:

- If you are distressed by your diabetes
- How confident you are in looking after your diabetes
- Your quality of life
- How you are feeling
- How many times you have recently visited your GP or local hospital
- Whether or not you are able to take your medications regularly as prescribed
- What your diet is like, including what types of foods you eat most often, and portion sizes.

Altogether, this visit will take around 2 to 3 hours. It will be shorter if you choose to complete the questionnaires online later that day at your convenience, if you prefer. If you prefer to take home paper copies to complete, we will give you a pre-paid envelope to return the questionnaire booklet to us once you complete them.

If you are randomised to the control arm, there are no other face to face study visits or assessments required. If you are randomised to the intervention arm (MiFoot

programme) you will be offered a one-to-one session with a healthcare professional and group sessions with other people in the MiFoot programme. These will be face to face appointments as described in the table above and in the MiFoot programme later in this Information Sheet. Follow up assessments are completed remotely (online or via post) and so this means you will complete these from the comfort of your home.

Treatment Allocation

At the baseline visit, we will put you into one of two treatment arms, one that continues to receive their usual care only (control arm) or one that continues to receive their usual care and receives the MiFoot programme (intervention arm). Your treatment arm is decided randomly, which means by chance (like flipping a coin) and cannot be changed. Whatever treatment arm you are in, your involvement in the study follow ups (for data collection) will be the same.

1) Intervention arm – MiFoot programme plus usual care

or

2) Control arm - Usual care with no additional treatment.

Physical activity screening and ECG (Intervention arm only)

If you are randomised to the intervention arm, at the baseline visit a physical activity screening process will be completed to make sure that you are safe to participate in the physical activity sessions. We will measure your heart's rhythm and electrical activity using an ECG (electrocardiogram). Sensors will be attached to the skin and these are used to detect the electrical signals produced by your heart each time it beats. If this test produces any unusual results, you may not be able to take part in the physical activity part of the intervention, but you will still be able to take part in the rest of the programme.

Randomisation arms:

1) **Intervention – MiFoot programme plus usual care**

For the MiFoot programme you will receive your usual care plus there will be additional visits or appointments with a range of trained healthcare professionals:

- A one-to-one session with a health care professional (Lasting around 45 minutes at [insert site name here])

- Group-based education and exercise sessions with other participants in the study (up to 2 hours at a time at [insert site name here])
    - Weekly sessions up to 2 months
    - Monthly boosters up to month 12
    - Follow up booster month 18-24
- An online platform designed to support patients to live a healthy lifestyle

If you are not able to participate in any specific element of the intervention (the MiFoot programme) this will not prevent you from participating in the study or the other elements of the intervention.

The aim of the MiFoot programme is to help you to:

- Increase your knowledge about diabetes and diabetes-related foot ulcers, how this might affect heart health and how to better take care of yourself with these conditions
- Improve your ability to control things that might increase health risk (such as smoking, cholesterol levels, blood pressure and weight)
- Manage your blood sugar levels
- Look after your heart
- Improve your diet and help with weight management
- Improve your knowledge about the benefits of physical activity and provide guidance on home-based exercises to help you to increase your physical activity levels
- Better manage your emotions, through techniques such as mindfulness
- Set goals in order to improve your overall health
- Get the most from your medications, including exploring whether newer medications might be beneficial for you

As a part of the study, and if you are in the arm that receives the MiFoot intervention, we will ask for your feedback on the MiFoot programme and your permission for a researcher to observe some of your sessions/appointments. This is so we can see if the healthcare professionals are delivering the intervention in the way they are supposed to. This part of the study is **optional**, and no confidential information about you will be assessed.

We may also ask you to take part in an **optional,** one off, interview with a trained researcher to find out about your experiences of the MiFoot programme. The interviews would take place either face-to-face (available to Leicester participants only) or remotely (telephone or online). They will take no longer than an hour and would be arranged in a private location. The interviews would be audio-recorded on a secure device and then typed up. At this point, any information that could be used

to identify you (such as your name or date of birth) would be removed. The recording would then be destroyed. Some of your quotes may be used in future reports; however, this will be completely anonymous. Your participation would also help us to understand how we can improve the MiFoot programme and deliver it to other people as part of everyday healthcare.

2) Control Arm – usual care

- You will receive your usual diabetes care.
- After month 24 we will offer you access to an online diabetes self-management programme to help you to become more physically active if you would like and to thank you for taking part. The study contact details on the final page of this document will remain available to you if you have any questions after the study.

Month 12 and 24 Follow-up visits

At each of these visits we will ask you to complete the same questionnaire booklet that you completed during the baseline visit, and to wear the activity monitor for 8 days in a row to monitor your physical activity. We will give you a pre-paid envelope to return the activity monitor to us after you have worn it.

If you choose to complete the questionnaire booklet online, we will send you the details to complete these. If you prefer to have paper copies to complete, we will post these to you along with a pre-paid envelope so that you can complete them at home and send them back to us.

With your permission we will also collect data from your health records (including test results, medication and other factors that may affect your diabetes and DFUD) at months 12 and 24. You will not be required to visit the clinic or complete any other assessments for this.

WHAT WILL HAPPEN TO ANY STUDY DATA COLLECTED FROM ME?

We will analyse your results throughout the study. This will mainly happen at the University Hospitals of Leicester NHS Trust or the University of Leicester by the main research team. We will also ask for your permission to keep the data collected for future ethically approved research; this is optional.

Research data may also be shared with other academic, industry and commercial partners or organisations (we will make sure that there are appropriate agreements in place). These may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your research data will be shared in a coded format (e.g. you name will be replaced with a unique study number), so

that these individuals or organisations cannot identify you. Any information collected 'after' verbal agreement but prior to written consent (i.e., information used to help us determine whether you are eligible), will be destroyed if you then do not consent to take part.

The database containing identifiable information for the purpose of contacting participants will be held on the host NHS organisation servers, and access will be limited to delegated members of the research team only.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Taking part in this research study could potentially benefit other people with diabetes and diabetes-related foot ulcers by providing information on how best to organise and deliver care in order to improve heart health and reduce the risk of future heart problems. This is important as there has not been much research in this area. The results could lead to improved medical treatments and care in the future.

If you are in the intervention arm, the MiFoot programme could potentially benefit you in several ways:

- Physical activity, including exercise, improves fitness. It also helps to control blood sugars. Exercise training also lowers blood pressure, the amount of harmful fat in the blood and may improve the blood supply to the heart. These changes may have long-term health benefits, including reducing the risk of future heart problems such as heart attacks or strokes.
- The dietary support may help you lose weight and feel healthier. There are often long-term health benefits from maintaining weight loss.
- You may have earlier access to medications that may be beneficial. These will be medications that are licensed for use in the UK for diabetes management, but which you may not receive as part of your usual care. They may help improve your glucose levels and may have benefits for heart health and kidney function and may help to reduce weight.
- You may benefit from psychosocial support to help you to manage the stress, anxiety and distress that can be a part of living with the challenges of managing a long-term condition like T2D and DFUD.
- You may benefit from a better understanding of what causes diabetes and diabetes-related foot ulcers and what you can do to control your blood sugar and manage your overall health in the longer-term.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There will be an additional time commitment for people in the intervention arm, as this arm will complete assessments which will be used to personalise and tailor their treatment.

Although there are many benefits of physical activity, it can pose some risks, however it is anticipated that these will be minimal. For example, you may experience delayed onset muscle soreness. Physical activity carried out as part of the MiFoot programme will be light-moderate, which can equate to walking upstairs or completing housework; therefore, your risk would not be increased over and above their usual day to day activities.

Any adverse events will be captured and monitored within the data. Risks will be managed with face-to-face assessments; support, observation and monitoring during the activity sessions; and reduced intensity of exercise, with appropriate adaptations suggested. You will also be screened briefly prior to commencing the weekly group sessions, and will be monitored throughout the session and for a period of 15 mins afterwards, by trained facilitators using a combination of heart rate, observation, Rating of Perceived Exertion and any reported symptoms from the participant. Your overall care and comfort will be considered paramount at all times during the study.

WILL MY PARTICIPATION BE KEPT CONFIDENTIAL?

We will need to use information from you for this study. When you consent to take part in the study we will ask for your permission to link your electronic records from your GP to the electronic patient record system held by your NHS trust, and to use this information for the purposes of the research. This helps us to:

- personalise your care
- look at information already collected so that we are not duplicating information
- keep in contact with you
- make returning some of the assessment measures easier for you.

You will need to agree to this linkage to take part in the study. Once your data up to month 24 is extracted from GP and hospital records, we will not extract or access your GP and hospital records beyond that point. The study is designed so those extracting and analysing your data will not know who it belongs to.

The information will be held securely on paper and electronically under the provisions of the 1998 Data Protection Act.

While you are taking part in the study, your contact details along with the information provided on a reply slip will be made available to the researchers so that they can

contact you to arrange the details of your study appointments, and specific elements of your care which will be undertaken by the team at Leicester Diabetes Centre (including physical activity consultations, psychosocial care and the interviews for the process evaluation).

Audio-recordings from semi-structured interviews will be typed out word-for-word using a professional service with which University of Leicester has a service agreement in place with. The transcribers are bound by a confidentiality agreement.

On the consent form, you can also choose to be informed about the results of the study. If you consent for this to happen, we will store your contact details securely, separately from your other clinical information, and we will only use them for the purposes you have chosen. Your contact details will be destroyed once they have been used for the purpose that you have agreed to.

We take confidentiality very seriously. As we will be using information from you to undertake this study, the University of Leicester will act as the data controller for this study and is responsible for looking after your information. Access to your medical records and research data will be granted to the regulatory authorities, the sponsor (University of Leicester), universities, NHS organisations or companies involved in health and care research for monitoring and auditing purposes.

Your medical records may also be reviewed by a member of the research team associated with the study. This is to make sure that you are eligible and can safely participate. The results of some of the assessments will also be shared with your GP. 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.

We would also like to use your central NHS records, health records and your GP to follow-up on your health status in the future (for up to 10 years). You will not be required to attend any additional visits if you chose to participate in this aspect of the study. This would help us to understand the longer-term effects of the study. This is optional and does not affect your participation in the study.

WILL YOU LET MY GENERAL PRACTITIONER/FAMILY DOCTOR (GP) KNOW ABOUT MY INVOLVEMENT IN THE STUDY?

We will tell your GP that you are taking part in the study. Any other medical practitioners who treat you (e.g., if you are admitted to hospital for any reason) will also be informed. If we find anything during the baseline or intervention visits that needs the attention of your GP or a healthcare professional, we will let both you, and them know.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you, your medical records including GP records for this research project.

This information will include your:

- Initials
- Name
- Date of Birth
- Sex
- Ethnic Group
- NHS number
- Contact details including address, post code, email address and phone numbers
- Medical records
- Vehicle identifiers to reimburse parking costs

The above bullet list of identifiers will be held by University Hospitals of Leicester NHS Trust (UHL) and University of Leicester (UoL) for the study. People will use this information to do the research or to check your records to make sure that the research is being done properly.

Your initials, sex and date of birth will be supplied to >> randomisation system name i.e., Sealed Envelope Ltd<< for their explicit use to randomise you into one of the treatment groups for the study.

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 instead meaning any information that could identify you (such as your name) will be removed and replaced with a code number. We will keep all information about you safe and secure.

We will be using information collected from you and the records obtained through surveys or interviews (written notes, audio recordings and written transcripts) in order to undertake this study. All study information collected from you will be recorded. This data will be entered into a secure electronic database held by Derby Clinical Trials Support Unit on University Hospitals of Derby and Burton NHS Trust computer. The electronic databases will be password protected and will be accessed by study specific personnel on encrypted hospital computers. Your data will be sent to the University of Leicester and University of Sheffield teams for processing. To make sure this data is not identifiable to you the study team will use a series of letters and numbers as unique study identifiers. All paper documents will contain the same unique study identifiers.

Some of your information will be sent to Australia. They must follow our rules about keeping your information safe.

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. The UHL or UoL will keep identifiable information about you from this study for 6 years after the study has finished.

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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your health records, your hospital and your GP. If you do not want this to happen, tell us and we will stop. If you choose to stop taking part in the study, the data collected up to the point of the withdrawal will be retained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

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.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. With your permission, we would like to retain your contact details and some basic information about you on our Leicester Diabetes Centre Research Volunteer's database for the purpose of being able to contact you in the future about our other research studies that you might be eligible for and interested in participating in. This database is held on University Hospitals of Leicester NHS Trust computer servers and can only be accessed by researchers at the Leicester Diabetes Centre and your information will not be shared with anyone else.

Direct quotes from the interview or feedback survey may be used in the study report, research publications, conference proceedings and other academic outputs and you will not be identifiable in any way.

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/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the study team
- You can also contact the University's Data Protection Officer by email dpo@le.ac.uk

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Once completed, the findings of this study will be published in a written report for the National Institute for Health Research (NIHR). You will be offered a copy of the results, if you would like to receive it but this is optional, and you don't need to agree to that. Findings will also be used in scientific journals and conference presentations. We will also share the results with the public through press releases, TV and radio interviews, social media, public lectures and the internet. All information about participants will be pseudonymised (given a code in place of your name) and you will not be able to be recognised from any report or publication.

WHO IS ORGANISING AND FUNDING THE STUDY?

The person in overall charge of this study is Professor Kamlesh Khunti. This study has been organised by the University of Leicester and the Leicester Diabetes Centre at the University Hospitals of Leicester. This study is co-funded by the National Institute for Health Research and Diabetes UK under Programme Grants for Applied Research (NIHR202021) and sponsored by the University of Leicester. The funders are not directly involved in running the study or analysing the results.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed and approved by a group of independent people called a NHS Research Ethics Committee and by University of Leicester as Sponsor. The NHS Research Ethics Committee has reviewed and granted our research a favourable ethical opinion. This opinion cannot guarantee that no harm will come to the participants. However, it means that the committee members are satisfied that the study will respect your rights. It also means that all risks are as reduced as they can be. They are also satisfied that you have been given enough information to make an informed decision.

WHAT IF SOMETHING GOES WRONG?

If you have a concern about any aspect of this study, you should ask to speak with a member of the study team who will do their best to answer your questions. If you have concerns about any aspect of the way you have been approached or treated during the study, you may wish to contact the hospital's Patient Information and Liaison Service (PILS) <insert local NHS PILS information>. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the PILS office or from the hospital.

In the unlikely event that something does go wrong, and you are harmed during the study and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Leicester. However, you may have

to pay your legal costs as there are no special compensation arrangements for this study. The normal National Health Service complains mechanism will still be available to you.

I AM INTERESTED IN TAKING PART, WHAT DO I DO NEXT?

If you are interested in taking part in the study, please reply using the QR code or the 'Reply slip' making sure you provide us with your contact details. Please return the Reply slip to the study team in the pre-paid envelope provided or by email. You can also contact us by phone to express your interest. Even if you are not sure if you would like to take part at this stage, we will be very pleased to answer any questions you may have.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION AND CONSIDER TAKING PART IN THIS STUDY

CONTACT FOR FURTHER INFORMATION

If you would like any further information or have any questions, please contact the MiFoot study team [site contact name here] on [site telephone here], [site name here] (available times and days here) or by email: [site email contact here].

[insert QR code]

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DIABETES UK
KNOW DIABETES. FIGHT DIABETES.