Study Title: **Improving DFU Outcomes: Early Detection of Foot Ulcers Using Novel Technology**

ID (Einstein IRB#): **2023-14915**
NCT05968924
IRB Approval Date (ICF): **12/18/2024**

KEY INFORMATION FOR IMPROVING DFU OUTCOMES: EARLY DETECTION OF FOOT ULCERS USING NOVEL TECHNOLOGY

We are asking you to choose whether or not to volunteer for a research study about the use of a foot monitoring mat to detect early diabetic foot ulcers. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Briefly *describe the purpose of the study and the procedures to be followed in lay terms. For detailed descriptions, use the Consent Document.*

By doing this study, we hope to learn if patients use this mat and if it reduces complications of diabetic foot ulcers. Your participation in this research will last about six months

The purpose of this research is to gather information on adherence and effectiveness of a FDA cleared Podimetrics Foot Monitoring Mat to predict the development of diabetic foot ulcers.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

This device has already been shown to decrease severe diabetic foot ulcers and need for health care services regarding foot health. A possible benefit is early detection of an ulcer during the 6 month study period. This study will also help us to know whether this device should be used in our patients and is acceptable for daily use. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This study requires that you step on the mat each day for less then a minute. We will call you once a month and ask you questions regarding your foot health. You many not want to participate in these tasks and thus this study is not for you. *For a complete description of risks, refer to the Consent Document below.* There is no alternative to this study.
. For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Johanna P Daily, M.D., P.I. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: jdaily@montefiore.org or office number 718-678-1176.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Improving DFU outcomes: early detection of foot ulcers using novel technology.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Dr. Johanna P. Daily You can reach Dr. Daily at:
AECOM
Price Center
1301 Morris Park Avenue, rm 508
Bronx, NY 10461
Telephone #: 718 678 1176
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

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American Diabetic Association

Why is this study being done?

Diabetic foot ulcers (DFU) remain a prevalent and highly morbid complication of diabetes. The effects of DFU and amputation on the individual are substantial with declines in well-being, economic instability, and depression. The impact of DFU's on U.S. health care costs is large and have been estimated to be 9-13 billion dollars annually. A foot mat that detects changes in foot temperature and has been shown to reduce severe DFUs has been developed. The purpose of this study will determine if this mat can be used daily by our Bronx population and whether it will decrease the need for health care interventions. If this mat has a positive effect to prevent DFU it will be studied more widely.

Why am I being asked to participate?

You are being asked to participate in this study because you are an adult who has been hospitalized for a diabetic foot ulcer and therefore at risk for a recurrent diabetic foot ulcer. Enrollment criteria include that you are ambulatory, have not undergone a foot amputation and are able to provide informed consent. We will enroll up to forty patients from MMC health care system with a goal of twenty patients completing the study.

What will happen if I participate in the study?

The goal is to identify the development of a future foot ulcer, to intervene before you develop the ulcer.
If you participate in the study, you will be asked to
1) present to a study clinic visit, and if you fulfill the study enrollment criteria, receive a foot mat
2) receive training on setting up the mat and learn how to use it (step on the mat)
3) step on the mat every day (less then one minute a day)
4) receive monthly phone calls where we will ask you questions regarding your foot health.

If the mat detects changes in temperature that may predict a foot ulcer, the nursing team at Podimetrics, who manages the mat information will call you to help manage this, to help return your foot to health. They will also alert the study team (Dr Daily).

If there are signs of infection, they will advise you to see your foot doctor. If there are no signs of infection, they will advise you to off load the foot. This means to stay off your feet until the temperature normalizes. This simple off-loading technique results in recovery 50% of the time in other studies.

The duration of the study is six months.

As part of this study we will review your medical records and put the information we collect in our research records.

How many people will take part in the research study?

You will be one of about **25** people who will be participating in this study.

How long will I take part in this research?

It will take you about six months to complete this research study. During this time, we will ask you to make one study visit to [**Montefiore Medical Center Study Clinic.**

Information Banking (Future Use and Storage)

No Data is Stored

Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will receive 60$ payment for travel costs for the enrollment visit. There are no other additional payments or other compensation for taking part in this study.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Albert Einstein College of Medicine and Montefiore Medical Center are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to the Study PI: Dr. Johanna Daily 718 678 1176.

What else do I have to do?

- You may carry out all your normal daily activities.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, medical record numbers, etc. In addition, the researchers wish to review information pertaining to your diabetes and history of diabetic foot ulcers. By law, you must specifically authorize access to these records:

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable-Podimetrics will have your protected health information related to your history of Diabetic foot ulcer
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Are there any risks to me?

We do not think there are any physical risks related to participating in this research study.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include identification of early signs of diabetic foot ulcer that we can manage to prevent ulcers.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if you stop using the device, become non ambulatory or withdraw your consent. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of the person conducting the consent process	Signature	Date