

Socksess - understanding the needs and preferences of people with diabetes to help co-design a smart sock and feedback system for prevention of diabetic foot ulcers

Submission date 17/04/2023	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 24/04/2023	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/03/2025	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The 'Socksess' project aims to create new technology to help make people with diabetes aware of how much pressure they put on their feet and prevent ulcers. We will develop and test a new 'smart-sensing sock' that will 'reconnect people with their feet' and help prevent ulcers and amputations. Diabetes damages nerves in the feet, known as 'neuropathy', affecting 1 in every 2 people with diabetes. This can cause people to lose all sensation and feeling in their feet which means that people with diabetes and neuropathy put excessive pressure on their feet without knowing. With nerves that are damaged, people do not have any natural way of knowing how much pressure they put on their feet and can literally wear a hole in the bottom of their foot, known as a diabetic foot ulcer. Although they can start off as a small hole in the foot, a diabetic foot ulcer can become infected and someone may need to have part of their foot or leg removed (amputated) to stop the infection and save their life. In the UK, there are over 120 amputations every week because of a diabetic foot ulcer. In recent work using insoles named Orphyx, the study team showed proof-of-concept that providing pressure feedback to people using insoles can reduce diabetic foot ulcers. The study found that additional measurement of shear pressure (rubbing) would improve the prediction and prevention of diabetic foot ulcer formation. There are limitations in the ability of insoles to measure rubbing, so we are looking to adapt available technologies to develop a smart-sensing sock and feedback system that may provide a novel solution for the daily monitoring and prevention of diabetic foot ulcers. The present study will aim to do this through 'co-design' - working closely with people who have experience living with diabetes, their families and healthcare professionals, to develop the technology, make design choices and publicise the work. The study team will conduct interviews and focus groups with these people, to make sure that we understand their views, needs and preferences and can include these in the design of the smart-sensing sock. The study will also be supported by a panel of international experts in diabetic foot care and industry partners who will help guide long-term development, clinical evaluation and commercialisation.

Who can participate?

Adults with diabetes, their carers, or healthcare professionals who work with people with diabetes and diabetic foot ulcer.

What does the study involve?

After consenting to participate, people with diabetes and their carers will be interviewed about their needs and preferences with regard to the proposed design of the smart sock and feedback system. Healthcare professionals will discuss their needs and preferences in a focus group discussion.

What are the possible benefits and risks of participating?

There is no direct benefit to taking part in the interview. The process might help participants focus on the best ways to look after their own feet. Healthcare professionals may enjoy the opportunity to learn more about the technology and connect with other healthcare professionals. A certificate of participation is available for those who wish to use this for CPD /professional development. Participants will be compensated for their time. The only known 'con' of taking part is the time required to participate.

Where is the study run from?

The University of Southampton (UK)

When is the study starting and how long is it expected to run for?

January 2023 to February 2024

Who is funding the study?

Engineering and Physical Sciences Research Council (EPSRC) (UK)

Who is the main contact?

Jenny Corser, j.c.corser@soton.ac.uk (UK)

Contact information

Type(s)

Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)

323631

Central Portfolio Management System (CPMS)

55647

Study information

Scientific Title

Socksess - Co-designing a digital health intervention: smart sensing socks for monitoring diabetic feet and preventing ulceration

Acronym

SOCKSESS

Study objectives

In order to develop a technology that will be inclusive, accessible, useable, and promote effective engagement by people with and at risk of diabetic foot ulcer, their carers and healthcare providers, their needs and preferences need to be qualitatively explored and applied to the design and optimization of the technology.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/03/2023, South Central - Hampshire B Research Ethics Committee (2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)207 104 8088, (0)20 7104 8289, (0)20 7104 8289; hampshireb.rec@hra.nhs.uk), ref: 23/SC/0098

Primary study design

Observational

Study design

Observational qualitative study design

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of diabetic foot ulcer

Interventions

This study will be using a person-based approach (a combination of user-centred design and behavioural science) to codesign a smart-sensing sock and an associated feedback system to alert the user of high pressure and shear stress that may lead to developing a foot ulcer. The person-based approach enables a detailed understanding of target user needs and preferences in order to facilitate high-quality codesign that will lead to a digital intervention that is not just acceptable and feasible, but also appealing, persuasive, motivating and highly accessible, so that it is widely adopted and engaged with by users long-term. This involves conducting qualitative work with key stakeholders to explore their views of the new technology and what it needs to include to work for them personally. The study will run for 1 year.

Qualitative interviews (approx 1hr) will be undertaken with people with diabetes and their carers, and a focus group (approx 90 mins) with healthcare professionals working in diabetes collecting information regarding the needs and preferences of these user groups to help co-design the smart sock and feedback system.

Intervention Type

Other

Primary outcome(s)

Qualitative data describing user needs and preferences of people with diabetes, their carers, and healthcare professionals. These data will be measured using individual bespoke qualitative interviews (for people with diabetes and their carers), and a focus group (for healthcare

professionals) across the study period in order to iteratively guide the technology design process (occurring in a parallel study).

Key secondary outcome(s)

Brief demographic descriptives of the participant groups will be measured using a questionnaire conducted during the interview and prior to the focus group.

Completion date

29/02/2024

Eligibility

Key inclusion criteria

1. Age over 18 years
- 2.1. Patients: Diagnosed with diabetes with/without a history of diabetic foot ulcer
- 2.2 Carers: Carer of a person with diabetes with/without diabetic foot ulcer
- 2.3 Clinicians: Healthcare professionals regularly managing people with diabetes and/or diabetic foot ulcers

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

28

Key exclusion criteria

1. Unable to understand and communicate in English
2. Severe mental illness that would interfere with their capacity to consent (e.g., dementia)
3. Diagnosed with terminal illness

Date of first enrolment

18/04/2023

Date of final enrolment

25/10/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Solent NHS Trust

Solent NHS Trust Headquarters

Highpoint Venue

Bursledon Road

Southampton

United Kingdom

SO19 8BR

Study participating centre

Kent Community Health NHS Foundation Trust

Unit D

The Oast

Hermitage Lane

Maidstone

United Kingdom

ME16 9NT

Study participating centre

Central London Community Healthcare NHS Trust

Ground Floor

15 Marylebone Road

London

United Kingdom

NW1 5JD

Study participating centre

West London NHS Trust

1 Armstrong Way

Southall

United Kingdom

UB2 4SD

Sponsor information

Organisation

University of Southampton

ROR

<https://ror.org/01ryk1543>

Funder(s)**Funder type**

Research council

Funder Name

Engineering and Physical Sciences Research Council

Alternative Name(s)

UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository at the University of Southampton

- The type of data stored: we will collect personal contact information for the purposes of payment and arranging interviews etc, This will be kept for 3 years and then destroyed. The raw data will include interview and focus group transcripts and answers to the demographic questionnaire. This will be kept in the University of Southampton data storage facility for 10 years. There is a question on the consent forms (attached) to consent to the anonymised data being accessible to other researchers. For the interview participants, this is optional and so only interview transcripts of those who consent will be available.
- The process for requesting access: via the University of Southampton <https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>
- Timing for availability: data will be made available via the University of Southampton data repository after publication of our data analysis
- Whether consent from participants was required and obtained: consent will be obtained

- Comments on data anonymization: all transcripts will be anonymised (names and places removed) and any statements that could indicate the identity of the participant (e.g job description, timing of events) will be redacted. Personal information will be kept separately from the qualitative data. Pseudonyms and/or anonymous ID codes will be used to identify results in place of the participant names.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/02/2025	19/03/2025	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 2	13/03/2023	24/04/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes