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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

Registration date
24/04/2023

Overall study status
Completed

Last Edited
19/03/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 (EPSCR) (UK)

Who is the main contact?
Jenny Corser, j.c.corser@soton.ac.uk (UK)

Study website
https://gtr.ukri.org/projects?ref=EP%2FX001059%2F1

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
323631

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers

IRAS 323631, 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

Study design
Observational qualitative study design

Primary study design
Observational

Secondary study design
Qualitative

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

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 measure
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).

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

Overall study start date
18/01/2023

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

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
50

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
England

United Kingdom

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
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NW1 5JD

Study participating centre
West London NHS Trust
1 Armstrong Way
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United Kingdom
UB2 4SD

Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.southampton.ac.uk/

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, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/02/2025

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?
Protocol file	version 2	13/03/2023	24/04/2023	No	No
HRA research summary			26/07/2023	No	No
Results article		14/02/2025	19/03/2025	Yes	No