SOCKSESS

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

PROTOCOL

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KEY STUDY CONTACTS

Principle Investigator	Professor Neil Reeves
Co-investigators	Dr Katherine Bradbury Miss Irantzu Yoldi Dr Peter Culmer
Sponsor for this study	University of Southampton
Chief Investigator for this study	Dr Katherine Bradbury
Funder	Engineering and Physical Sciences Research Council (EPSRC)
Key Protocol Contributors	Professor Neil Reeves School of Healthcare Science Manchester Metropolitan University N.Reeves@mmu.ac.uk Dr Katherine Bradbury, Centre for Applications of Health Psychology University of Southampton Kjb1e08@soton.ac.uk Miss Irantzu Yoldi Health, Sport and Biosciences University of East London i.yoldi@uel.ac.uk Dr Peter Culmer Mechanical Engineering University of Leeds P.R.Culmer@leeds.ac.uk Miss Jenny Corser Centre for Applications of Health Psychology University of Southampton j.c.corser@soton.ac.uk Mr Benjamin Jones Faculty of Environment and Life Sciences University of Southampton B.Jones@soton.ac.uk
Expert Contributors	Dr Prabhuraj Venkatraman Mr David Russell Professor Andrew Boulton Professor Frank Bowling
Programme Steering Committee	Dr Andrew Weightman Dr Katherine Grady Professor Andrew Boulton Arjun Sikand Dr David Russell EPSRC representative PPIE representative

ROLES OF INVESTIGATORS

Principle Investigator:
Dr Katherine Bradbury, Southampton University
Katherine is a behavioural scientist with expertise in developing highly accessible, engaging, and effective digital interventions. She will lead this study overseeing all data collection, analysis, and dissemination of findings.

Co-Investigators:
All co-investigators will provide input into study design, interpretation of findings and dissemination of results.

Ms Irantzu Yoldi, University of East London
Irantzu is a is a podiatrist, clinical academic and former Minor Surgery & Physical Therapies Lead in NHS. She will leverage her expertise by ensuring that clinical perspectives are embedded across the project.

Mr Benjamin Jones, University of Southampton
Benjamin is a Senior Teaching Fellow at the University of Southampton, his research focuses on genomics and diabetic foot complications. His previous clinical experience was in NHS as a specialist podiatrist. Benjamin will ensure clinical perspectives are embedded across the project.

Ms Jennifer Corser, University of Southampton
Jennifer is qualitative researcher with a focus on health behaviours and disease self-management. She will be collecting, analysing and writing up the data.

Professor Neil Reeves, Manchester Metropolitan University
Neil will be involved in an advisory capacity

Dr Peter Culmer, Leeds University
Peter will be involved in an advisory capacity

ROLE OF STUDY SPONSOR

The University of Southampton will act as the sponsor and sees its responsibilities as follows:

The University of Southampton as research sponsor will:

1. Assess the adequateness of any independent expert review.
2. Ensure that the chief investigators have the necessary expertise, experience and qualifications to conduct the study.
3. Provide a formal written agreement of the sponsorship conditions and formal notification of sponsorship.
4. Provide the necessary insurance to cover the chief investigator and research team.
5. Determine the arrangements for monitoring research studies.
6. Provide advice and guidance on study management, conduct and applicable legislation, guidelines and policies.
7. Determine the acceptability of the archive arrangements proposed by the chief investigator.

ROLES AND RESPONSIBILITIES OF PROGRAMME STEERING COMMITTEE

The role of the steering committee is to provide oversight of the conduct of the programme. This includes oversight of the practical aspects of the study as well as ensuring that the study continues to be run in a way which is both safe for the patients and provides appropriate safety and efficacy data to the sponsor and investigators.

Specific responsibilities of the steering committee include, but are not limited to, the following:

- to provide overall supervision of the studies within the grant
- to take steps to reduce deviations from the protocol to a minimum
- periodic review of the progress of the study
- to resolve any differences within the research team or between research team and sponsor on the data management and monitoring procedures in the study or any recommendations for modifications to the protocol.

KEY WORDS Diabetes, foot ulcers, digital intervention, self-care, prevention, adults, wearable technology, innovation, neuropathy, amputation, qualitative, patient and public involvement, PPIE

FUNDING

Funder	Engineering and Physical Sciences Research Council
Grant Amount	£436,919.24 (for whole project, of which this is part)

STUDY SUMMARY

Study Title	Digital Health: 'Socksess' - Co-designing a digital health intervention: smart sensing socks for monitoring diabetic feet and preventing ulceration
Short Title	SOCKSESS
Study Design	Patient and public involvement and engagement via stakeholder group Qualitative interviews with adults with diabetes and their carers Focus group with healthcare professionals involved in the treatment of diabetes and diabetic foot ulcers
Study Participants	20-30 adults with diabetes 10 carers of adults with diabetes 10 healthcare professionals involved in the treatment of diabetes and/or diabetic foot ulcers
Planned Size of Sample (if applicable)	Approx. 30 patients Approx. 10 carers Approx. 10 healthcare professionals
Planned Study Period	1 January 2023-1 January 2024
Research Question/Aim(s)	To understand the needs and preferences of people at risk of diabetic foot ulcers, their carers and healthcare professionals, in order to codesign the smart-sensing sock and its feedback system that can alert them to offload their foot during periods of at-risk foot loading.

GANTT CHART

Months	1-3	4-6	7-9	10-12	13-15	16-18
Assemble stakeholder group						
Recruit participants						
Qualitative interviews with adults with diabetes and their carers						
Focus group with healthcare professionals involved in the treatment of diabetes and diabetic foot ulcers						
Stakeholder meetings						
Modify design based on feedback						

LAY SUMMARY

Aim

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.

Background

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 and 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 our recent work using insoles named Orphyx, we showed proof-of-concept that providing pressure feedback to people using insoles can reduce diabetic foot ulcers. We found that additional measurement of shear pressure (rubbing) would improve 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 daily monitoring and prevention of diabetic foot ulcers.

In the present study, we will do this through 'co-design' - working closely with people who have experience of living with diabetes, their families and healthcare professionals, to develop the technology, make design choices and publicise the work. We 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. We 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.

BACKGROUND

The need for innovative digital health systems to help prevent diabetic foot ulcers
The loss of protective sensation in the foot that comes with diabetic neuropathy (nerve damage) is one of the major risk factors for diabetic foot ulcers and removes the possibility for people to 'naturally' self-regulate their foot pressures. Over time, these high foot pressures lead to tissue breakdown and ulceration, with limb amputation, or death as the ultimate consequence, with NHS costs >1billion annually [1,2]. The loss of protective sensation with diabetic peripheral neuropathy therefore presents the ideal opportunity for healthcare technology to support people in having more control over their foot health and providing a sense of empowerment.

We recently showed proof-of-concept that providing pressure feedback to people using insoles (Orpyx) can reduce diabetic foot ulcers [3], providing the evidence-base and innovation gaps (see below) for our smart-sensing socks technology. However, we have highlighted the need for measurement of shear loading on the foot, in addition to pressure, to better predict, and prevent, diabetic foot ulcer formation [4], measurement capability/functionality, which is unfortunately lacking in current insole technology [5].

Knowledge and innovation gaps include that insoles are constrained by their requirement for footwear, i.e., calibration to a specific pair of shoes, their inability to accommodate indoor footwear - limiting wear to predominantly outdoor activity and missing large parts of daily activity and foot loading. Indeed, our experience from recent smart insole research is that these aspects are barriers to adoption and optimal adherence [3,6]. Furthermore, insoles are limited to measurement of the foot's plantar aspect (foot sole), thus neglecting other key regions at risk of ulceration (e.g. the heel) and limiting wider application to other areas of clinical need including the development of pressure ulcers/sores due to prolonged bed rest. A crucial engineering-based innovation gap is that daily monitoring smart insole systems are only capable of measuring vertical pressure and although this is known to be important in diabetic foot ulcer development, shear stress is becoming increasingly recognised as an important contributory factor in diabetic foot ulcer development [7,8].

Recent works in textile-based sensing technology highlight the potential to improve measurement and monitoring of foot loading through instrumented 'smart-socks' [9]. Lin et al., embedded piezo-resistive sensing elements in the sock for pressure [10], Carbonaro et al., used a similar approach to investigate different pathologies linked to gait change [11]. Triboelectric Nanogenerators (TENGs) are an emergent technology with promise for healthcare monitoring within textiles which have been embedded into sock fabrics for energy harvesting and gait characterization [12,13]. These systems serve to highlight the potential for embedding textile-based sensors within socks, and for exploiting the novel self-powered functionality of TENGs, but none are capable of measuring shear stress, and none provide full coverage of the foot.

Current systems are also limited by their reliance on smartphones for patient feedback, limiting access based on socio-economic status and digital literacy [14]. Our work indicates using smartphones for patient feedback is unlikely to reach >30% of this cohort, who do not use smartphones and have low digital literacy (KB: REDUCE trial, NR: Orpyx trial).

A recent systematic review of patient and provider perspectives on smart socks and insoles for diabetic foot ulcers showed a limited number of studies of varied quality, a lack of user involvement in study design, and conflicting results [15].

The ‘Socksess’ project will develop ‘smart-sensing socks’: a novel solution for daily monitoring and prevention of diabetic foot ulcers, building on the team’s work with smart insoles (Orpyx, FeetMe, Walk With Path and SLIPS) and addressing innovation gaps in this healthcare technology area, delivering novelty in:

- self-powered sensing technology for measurement of pressure and shear stress
- integration of sensing into a smart-sock garment for full-foot load measurement
- new data from clinical validation showing pressure and shear stress measures in the high-risk foot
- Inclusive feedback mechanism co-designed with stakeholders

AIMS AND OBJECTIVES

Aim

The aim of this current study is to seek the views of patients, care givers and healthcare professionals, in order to co-design an ambitious new smart sensing sock focused on preventing diabetic foot ulcers.

After this study we will build the smart sensing sock and will conduct further studies with patients who use the smart sensing sock in lab conditions to test its acceptability, feasibility, safety and efficacy, we will seek further ethical approvals for this work later on. For now, the current study is **only** focused on the qualitative co-design work of understanding people’s needs and preferences to allow us to design a product that will be maximally beneficial to those who it.

Objectives

1. To understand the needs and preferences of people with diabetes, their carers and healthcare professionals, in order to co-design a smart-sensing sock that will be engaged with by users long-term.
2. To co-design, together with all relevant stakeholders, a highly accessible feedback system that can alert the user when they are at risk of foot ulceration due to excessive pressure and shear and need to take action to offload the foot.
3. To understand how best to process and ‘repackage’ data back to the user to inform and alert during periods of at-risk foot loading

STUDY DESIGN

We will take a person-based approach (a combination of user-centred design and behavioural science) to codesigning the 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 co-design 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 a new technology and what it needs to include to work for them personally.

Patient and public involvement and engagement

Our stakeholder group (n=6) includes PPIE representatives living with diabetes (ranging in their level of diabetic foot ulcer risk, enabling us to capture the full range of perspectives and keep this technology open to not only those at the highest risk level for foot ulceration), and healthcare professionals.

The function of the stakeholder group is to provide user input into all aspects of the project, including the design of this study protocol. The stakeholder group meet once a month, discussing the overall study and patient and clinical needs for the smart-sensing sock. Once interviews with participants begin, the findings will be discussed regularly with the stakeholder group to enable a lay and clinical perspective to be incorporated into the data analysis, product design, and eventual dissemination of the findings.

Patient members of the stakeholder group are offered £25/hr for their time via shopping vouchers (as recommended by INCLUDE guidance).

DATA COLLECTION

Patients and carers

People with diabetes (with/without a history of diabetic foot ulcer) will be recruited via postal mail-out from specialist diabetes and foot clinics. Though mail-out will be targeted to patients, the invitation letter will note that any full-time carers of participants are also invited to interview. The mail-out will include an invitation letter briefly describing the inclusion criteria (over 18 with diabetes, or their carer), involvement (30-60 minute face-to-face interview) and information on how to contact the research team via phone or email for more information or to express an interest in participating, and a participant information sheet. Potential participants will contact the study team directly using their contact details provided in the letter.

Based on previous experience, we will aim to invite at least 200 people to participate, expecting a 10% uptake.

Participants will be sampled purposively to include a range of age, gender, ethnicity and relative deprivation (based on IMD code from address) as well as a range of diabetic foot ulcer risk. We will aim for a sample with 50% of people with a history of diabetic foot ulcer. We will oversample from underserved groups (e.g. lower

socioeconomic groups, non-white ethnicity) to fully understand barriers to equitable engagement and mitigate against these through design of the smart sensing sock.

Those who express interest in the study, and are eligible, will be invited to interview which will take place in-person or remotely via teleconferencing or telephone. Face-to-face interviews will be held in participants' homes, but if they would prefer to meet elsewhere, alternative arrangements may be made for the meeting to be held on University Premises. We aim to interview a total of 20-30 people with diabetes, and any carers involved with that sample (up to 10).

Semi-structured interviews will last approximately 30 minutes, but up to 1 hour (depending on how much they have to say). Participants may be invited to up to 2 additional interviews to gain information on emerging questions that arise throughout the study, participation is entirely optional.

Informed participant consent will be sought prior to the start of all interviews. If the interview is taking place by telephone or by videoconferencing then they will be asked to provide verbal consent at the start of the interview, if in-person they will sign a consent form. They will then be briefed on the proposed technology.

During the interview, open-ended questions will be used to explore perceptions of the potential to use a smart-sensing sock, and any potential barriers or facilitators to its use. Questions will explore immediate thoughts, preferences, possible benefits/concerns, ideas for things that may need to change. Interviews will be conducted by a member of staff trained in qualitative research methods.

As thanks, all participants will be offered a £25 shopping voucher on completion of interview.

Healthcare Professionals

Healthcare professionals working with people with or at risk of diabetic foot ulcers (i.e., specialists, general practitioners, diabetes nurses, podiatrists) will be recruited via email. We will work with the CRN to identify possible diabetes/foot clinics through which to recruit staff. The email will briefly describe the study, inclusion criteria, and involvement (60-90 minute online focus group), and information on how to contact the research team via phone or email for more information or to express an interest in participating. A focus group participant information sheet will be attached for more information. Potential participants will contact the study team directly using their contact details provided in the email.

We aim to recruit approximately 10 healthcare professionals. Based on availability of maximum potential participants, a date and time will be selected for the focus group. Another email will be sent out to interested participants to confirm their availability and attendance. Those who confirm attendance will be sent an online information sheet and consent form for completion prior to attendance.

The focus group will be carried out via teleconferencing (using Microsoft Teams) and moderated by a member of the research team. The session will last approximately 60-90 minutes. Discussions will be facilitated by a member of staff trained in qualitative methods and will aim to explore views on the technology and potential barriers/facilitators to implementation in the NHS, at scale.

All participants will be paid a reimbursement at their hourly rate up to £85/hr for their time. A certificate of attendance will also be offered for their professional development portfolio if desired, to show their contribution to research and design.

Eligibility

Patient/carer inclusion criteria	- Over 18 years of age - Read, speak and understand English - Diagnosed with diabetes with/without a history of diabetic foot ulcer, or involved in their daily care
Healthcare professional inclusion criteria	- Registered medical professional in the UK - Involved in the care of people with or at risk of diabetic foot ulcer

Consent

Consent from participants will be sought only after a full explanation of the study has been given, a participant information sheet offered, and time allowed for consideration. For interviews in-person, they will be asked to read and sign a consent form. For remote interviews, the questions will be asked aloud and they will provide verbal consent, this will be recorded separately from the interview. Focus group participants (healthcare professionals) will be asked to complete and return a consent form prior to receiving the link for attendance, or to complete one online (as in the RECUR/CLASP/RECON studies).

DATA ANALYSIS

Each interview will be recorded using University-provided equipment. The focus group will be recorded using the recording function of the call platform (Microsoft Teams). Audio recordings will be professionally transcribed, anonymised and checked. Transcripts will be assigned anonymised identifiers and imported into NVivo for data handling.

For familiarity and verification, the interviews will first be listened to, and transcripts read in full by the research team. An inductive thematic analysis will be applied to ensure findings are data-driven. Rigour will be facilitated through the creation of a coding manual and subsequent team discussion of emergent themes. Additionally, a clear audit trail will be maintained, and deviant cases analysed to ensure minority views are not overlooked. Finally, credibility will be enhanced by reviewing the analysis with the stakeholder group on a regular basis.

DATA MANAGEMENT

Data will be managed per University of Southampton Research Data Management Policy.

Participant data will be pseudo anonymised by assigning each participant a code. All pseudo and fully anonymised data used for this study will be retained for 10 years after study end and permanently deleted/destroyed thereafter.

Data with personal information such as contact details, will be stored on a secure University network, and deleted once study write-up is complete (maximum of 3 years after study end).

Access to data will be granted to relevant members of the research team and authorised representatives from the sponsor for monitoring and/or audit purposes.

Recordings

The full focus group recording will be completed using a web call platform (i.e. Microsoft Teams). Full interview recordings will be completed using University approved recording equipment.

The original recordings will be identified via a unique study identifier and will be moved and deleted from the web call server to a secure University network.

A confidentiality agreement will be signed by those analysing the interviews, and correspondence to and from the externally approved transcription service or supervised students will occur via secure email (e.g. safesend).

Original transcripts will be saved onto the secure University network and the anonymised copy saved onto the network and/or cloud storage for collaborative access during analysis.

ETHICAL AND REGULATORY CONSIDERATIONS

Assessment and management of risk

There is low anticipated risk associated with this study. All participants will be made aware that participation is voluntary and that they can withdraw from the study at any time. It is not expected that the topic being discussed will cause them any undue stress.

All participants will be fully debriefed and given details of support resources. The interviewer will be aware and sensitive in case the participant becomes upset. If participants do experience distress during the study, the interviewer will reiterate that the participant can stop at any time, and will signpost to sources of support such as their GP and online NHS and Diabetes UK resources, or MIND mental health support charity.

Approvals

The protocol, invitation letters, social media post, participant information sheets, informed consent form, debrief sheet, and the interview/focus group guides will be submitted to appropriate Research Ethics Committees (REC), and host institution for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Regulatory review and compliance

Recruitment will not begin until full ethical approval has been received from all appropriate committees.

Accidental protocol deviations can happen at any time. They will be adequately documented on the relevant forms and reported to the chief investigator and sponsor immediately.

Deviations from the protocol that are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Reporting

The Chief Investigator shall submit an end of the study report to the funder, host organisations and sponsor.

Participant Confidentiality

The study will comply with General Data Protection Regulation (GDPR) and the Data Protection Act 2018 with regards to collection, storage, processing and disclosure of personal information.

Qualitative data will be anonymised and identified only by a study generated participant ID number as soon as possible. Descriptive demographic data will be stored separately to personal information and will be identifiable by participant ID. All documents will be stored securely and only accessible by study staff and authorised personnel.

Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time and request that any data collected be deleted. It will not be possible for the participant to withdraw their data once the analysis has started because the data collected will already be pseudonymised and have been used.

Participants can withdraw from the study without giving a reason by contacting the research team.

Indemnity

The University has a specialist insurance policy in place which would operate in the event of any persons suffering harm as a result of their involvement in the research. Of course, risk of harm is incredibly low in a qualitative study of this kind.

Access to the final study dataset

The qualitative work is aimed at developing an intervention therefore it is not intended that the dataset will be used for secondary analysis but the anonymised dataset will be made available upon reasonable request as required, and if ethical approval is granted to conduct secondary analysis.

DISSEMINATION POLICY

On completion of the study, the data will be analysed and tabulated for publication and for a Final Study Report submitted to the funder, which will be publicly available.

Any commercially exploitable results, and ownership of any IP generated, will be split equally among the academic institutions involved in the study.

The Engineering and Physical Sciences Research Council will be acknowledged in any publications and informed in advance of any planned publications. Authorship will be determined per the ICMJE guidelines and other contributors will be acknowledged.

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