# Title: Developing a smart-sensing sock to prevent diabetic foot ulcers: a qualitative study

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## Abstract

**Background:**

Diabetic foot ulcers are common and costly. Most cases are preventable, though few interventions exist to reliably support patients to perform self-care. Emerging technologies are showing promise in this domain, though patient and provider perspectives are rarely incorporated into digital intervention designs.

**Objective:**

This study explores patient and provider feedback on a smart-sensing sock to detect shear strain and alert the wearer to change their behaviour (i.e. pause activity and check their feet); and considers how patient experience and attitudes to self-care are likely to impact uptake and long-term effective engagement with the device in order to curate guiding principles for successful future intervention development.

**Methods:**

This qualitative study combined semi-structured interviews and a focus group alongside a participant advisory group that was consulted throughout the study. Twenty people with diabetic neuropathy (16 with history of diabetic foot ulcer) and two carers were recruited directly from podiatry clinics, as well as via a recruitment network and national health mobile application, for one-to-one interview either in-person, or by landline or video call. Six podiatrists were recruited via professional networks for one virtual focus group. Participants were asked about their experience of diabetic foot health, and for feedback on the proposed device, including how it might work for them in daily life or clinical practice. The data were analysed thematically.

**Results:**

Three main themes were generated each raising a barrier to use of the sock, complemented by potential solutions. 1. Patient buy-in: challenged by lack of awareness of risk, potentially addressed though using the device to collect and record evidence to enhance clinical messaging. 2. Effective engagement: challenged by difficulties accepting and actioning information, requiring simple, specific and supportive instructions in line with podiatrist advice. 3. Sustained use: challenged by difficulties coping, with the possibility to gain control with an early warning system.

**Conclusions:**

While both patients and podiatrists were interested in the concept, it would need to be packaged as part of a wider health intervention to overcome barriers to uptake and longer-term effective engagement. The study recommends specific considerations to the framing of feedback messages and instructions; as well as provision of support for healthcare providers to integrate the use of such smart devices into practice. Guiding principles generated by this study can guide future research and development of smart sensing devices for diabetic foot care, to help optimise patient engagement and improved health outcomes.

**Trial Registration:** International Standard Randomized Controlled Trial Number (ISRCTN) 13991509; https://www.isrctn.com/ISRCTN13991509

**Keywords:** Diabetes; diabetic neuropathy; diabetic foot ulcer; podiatry; prevention; health-technology; behaviour change

## Introduction

Foot ulceration is a common and debilitating problem for people with diabetes, and costly to the healthcare system. Up to one third of individuals with diabetes will develop a foot ulcer in their lifetime [1] and amputation or death is likely in up to half of those individuals within five years [2]. These adverse outcomes understandably impact patient mental health, and it is reported that one third of people experience clinical depression with their first diabetic foot ulcer [3]. In the UK, for the year 2014-15, diabetic foot disease cost the National Health Service (NHS) 1% of its entire budget [4]. Indirect costs include impacts to individual earnings, costs of carers, and absenteeism for employers [5]. Despite many ulcers being preventable [6] only a fraction of healthcare spending is on prevention [7, 8]. It is estimated that preventing one third of ulcers in England, would save the UK’s NHS in excess of £250 million [4].

Digital interventions show promise for supporting foot ulcer prevention. Emerging technologies include wearable devices such as smart insoles or smart socks that can be worn daily to provide constant monitoring of the feet and alert the wearer to at-risk foot loading [9-12]. Tests of these technologies show that regular use could be effective in predicting ulceration [9], and that participants find smart socks comfortable, yielding a good compliance rate [13, 14]. Socks may be preferable to insoles as they can be worn with any type of footwear (or indeed on their own) [15]. Current smart wearable devices (socks and insoles) monitor temperature and plantar pressure, but research suggests that results would be improved by measuring shear strain, which reflects the ‘rubbing’ across the foot [16, 17]. Technology that measures shear strain has only been developed bespoke for research purposes and application to wearables in this population is currently unavailable [18, 19]. Recently, insoles capable of measuring shear safely have been developed and lab tested [20-22], but no studies have yet been found to measure shear strain via socks.

A recent systematic review of smart wearable technology in diabetic foot ulcer prevention highlighted the limited involvement of patient and provider perspectives in device design and evaluation [23]. It is not surprising then, that there is a lack and urgent need of interventions addressing patient barriers to adherence [24], and this requires patients and healthcare providers involved in diabetic foot health care to be consulted throughout the design process [25]. If the aim is to support effective engagement with a device [26] and improve health outcomes, interventions should carefully consider not only usability of features, but whether the technologies are likely to change critical behaviours [27]. For example, it is important that users are supported not only to wear the device, but to respond to it appropriately (i.e. offload the foot or seek medical help if an ulcer has developed). This study uses qualitative data to facilitate the co-design of a novel solution for daily monitoring and prevention of diabetic foot ulcers (a smart-sock to detect shear strain, and an associated feedback system). The aim of this study was to better understand the needs and preferences of those who would use, or support the use of, the technology to inform decisions about what would be needed to make a shear sensing smart sock most likely to be adopted and adhered to in the long term and maximise the potential patient benefit. This includes exploring lived experience of diabetic foot ulcer as well as direct feedback on the proposed technology. This paper summarises our findings thematically and includes a related set of Guiding Principles to guide future research and practice in smart sensing devices for diabetic foot care.

## Methods

### Study design:

Qualitative data were collected via semi-structured interviews and focus groups, in parallel to the technology development, and used to iteratively inform its progress. In addition to participant input, regular patient and public inclusion and engagement (PPIE) opportunities with a patient advisory group of eight people living with diabetes and presenting with a range in severity of diabetic neuropathy (and consequent risk of diabetic foot ulcer) were held at regular intervals throughout the study period.

The role of the PPIE group was to provide lived-experience input and early advice to the research team to help shape the study in the early phases (e.g., codesigning and piloting the interview schedule) and throughout the data collection and analysis phases for credibility checking and feedback, and finally they reviewed and provided input into the authorship of this publicationation. Members were recruited via professional networks and snowballing during the grant and ethics application phases of the study. Their participation was voluntary, with no contractual obligations, and were paid £25 per hour of involvement. The group met 5 times over 12 months.

### Ethics approval:

Ethical approval for this study was obtained from the University of Southampton (ERGO# 78959) and UK Health Research Authority (IRAS# 323631) and local Research Ethics Committee (REC# 23/SC/0098).

### Participants:

Potential users of the technology were identified to be people with diabetes and neuropathy and therefore, at risk of developing diabetic foot ulcers, who might use the sock and feedback system on a daily basis; their carers who might facilitate this daily use; and podiatrists (although various healthcare providers may be involved in diabetic foot care, podiatrists are most likely to implement the technology in clinical practice and have the most specialised knowledge in the area for device feedback). Recruitment began in May 2023 (month 7 of the study) and completed in December 2023 (month 13 of the study).

#### Patients and carers (for interview):

People with diabetes were recruited via postal mail-out from NHS podiatry clinics. Although the invitations were targeted to patients, carers were also invited to participate. Invitation packages included a cover letter with brief summary of the study and contact information; and a full participant information sheet detailing potential risks and data governance. Patient participants were included if they had diabetes and reported changes in sensation in their feet. Interested participants contacted the research team directly to ask questions, find out more about the study, and provide contact details for participation.

In addition to invitations from the clinic, the study was also posted on the NHS app and an additional recruitment stream was set up using a consent-for-approach recruitment service (National Institute for Health and Care Research (NIHR) Clinical Research Network, Research for the Future).

With an aim to understand barriers to equitable engagement with the technology, and to mitigate against these through its design, participants were selected purposively to include a range of age, gender identity, ethnicity and relative deprivation (based on Index of Multiple Deprivation (IMD) score [28] from address), with an aim to oversample from underserved groups (e.g. lower socioeconomic groups, non-white ethnicity).

Those who were eligible were invited to interview either in-person in their homes, or remotely via teleconferencing software, or by landline telephone. Based on previous similar projects, a sample size of 20-30 patients and carers was estimated to provide sufficient information power [29]. Diversity of perspectives, depth of insight through strong dialogue and rich data collection were prioritised over achieving a specific sample size.

#### Podiatry group (for focus group)

Podiatrists working with people with diabetes were recruited via professional networks. Information about the study was made available via the clinics that were recruiting patients, and emails to colleagues. Interested participants contacted the research team directly to ask questions, express interest, and indicate availability to participate.

### Data collection:

One-to-one interviews were conducted by JC (a qualitative researcher and lead author), in person, in the participants’ homes (n=6), or via teleconferencing (n=11), or by phone where preferred (n=5). Each participant was interviewed once. Prior to recording, the researcher reviewed the purpose of the study. Participants were given the opportunity to ask questions, and then asked to complete the consent form, followed by a demographic questionnaire including questions about their age, gender identity, living arrangements, and medical history (results of this questionnaire inform the participant characteristics shown in Table 1). Participants were advised that specific questions about the technology were asked in terms of co-design, as if they were designing it for their own personal needs, and there were no right or wrong answers. “Shear strain” was described as “rubbing” and the researcher demonstrated this concept by rubbing the back of her hand and showing how the skin “stretches”.

A semi-structured interview guide with main questions and prompts was used and initially piloted and refined with the PPIE group (see Appendix 1). Interviews began by asking about the participants’ experience with their foot care – previous issues, how they manage their foot care, and what they understood about diabetic foot health. The researcher then provided a standardised lay summary of the concept of the sock and feedback system (also developed with the PPIE group) with sock samples where available. The participants were encouraged to ask questions freely during and after the description. Participants were asked about their first impressions, whether the technology might fit into their daily life, how they would respond to alerts, and if there were any concerns they had about the design or elements they would like to change. Interviews lasted an average of 52.5 minutes (SD = 11.0) and were audio-recorded and transcribed verbatim.

One focus group with podiatrists was conducted at month 12 of the study via Microsoft Teams teleconferencing platform and facilitated by JC. Participants were sent four different sock samples and one sample of sensor material in the post prior to the discussion. The discussion began with a review of socks currently marketed for diabetic patients and what the participants thought were important features for a sock designed for high-risk diabetic foot ulcer patients. The concept of the sock and feedback system was presented orally using visual presentation slides. Participants were encouraged to speak freely about their first impressions of the technology in general, specific features, and implications for practice. The focus group lasted 70 minutes, was audio recorded and transcribed verbatim.

Participants were offered a £25 gift voucher as a thank you. Field notes and a reflective diary was kept throughout the data collection period.

### Data analysis:

Data had been collected over five months with positive and negative comments about the socks initially coded for feedback to the PPIE groups and the wider research team including engineers of the sensors and manfacturers of the socks. A brief summary of these findings is presented in Appendix 2, and Figure 1 illustrates the parallel nature of this qualitative data collection and central role of PPIE input alongside the technical development of the sock by the wider research team. This ongoing process allowed for new data to be compared with previously collected data to identify similarities and deviances which were relevant and helpful to consider in the technology development process. Once all data had been collected, an overview and in depth reflexive thematic analysis was conducted by JC, guided by the principles of Braun and Clarke [30].

Since JC collected and transcribed the data, and had reviewed each case for feedback and discussion with the PPIE group, she was already familiar with the data by the stage of full analysis when attentional focus turned to the transcripts and field notes as a corpus. Codes were generated inductively using NVivo software [31]. Since podiatrist data was more technical than the interview data, and focussed more on elements of the technology rather than patient context, these data were assessed in parallel, as a unique perspective, separate from, but related to the patient perspective. Throughout the coding process, the researcher made reflective notes.

Once generated, the codes, and researcher notes were assessed together as a corpus. Throughout the process of data collection, JC had learned about the experience of diabetic foot ulcers and developed an empathy for the participants around the challenges of peripheral neuropathy and self-management of ulcer treatment and prevention. JC drew on the personal impact of these stories while analysing the data to generate themes describing salient aspects of the experience of diabetic foot disease and how a novel technology such as this may work in the everyday lives of people managing it. Initial themes were drafted and presented to the PPIE group and larger research team for discussion, and were reviewed and refined iteratively. PPIE engagement was essential to this refinement process, developing the themes in a way that presents a credible and relevant narrative.

In order to ensure quality of data reporting, the consolidated criteria for reporting qualitative research (COREQ) was followed [32]. A copy of the checklist, including reflexivity statement is included in Appendix 3.

## Results

### Recruitment:

22 participants were recruited for interview including 20 participants with diabetic peripheral neuropathy (13 identified as male, 8 as female, 1 transgender), of whom 5 had type 1 diabetes and 17 had type 2 diabetes. Participants had a mean age of 66.0 (SD 10.5) years and a diabetes duration of 21.6 (SD 12.1) years. Of these, 72.7% had a previous history of ulceration, 27.2% had previous history of amputation, and 13.6% had a diagnosis of Charcot. Participant characteristics are summarised in Table 1.

Table 1: Interview participants

|  |  |  |
| --- | --- | --- |
| Characteristic | | Participants |
| **Participant type, (n)** | |  |
|  | Patient | 20 |
|  | Carer | 2 |
| **Gender identity n (%)** | |  |
|  | Male | 13 (59.1) |
|  | Female | 8 (36.3) |
|  | Transgender | 1 (4.5) |
| **Patient Age (years), n(%)** | |  |
|  | 36-45 | 1 (5) |
|  | 46-55 | 3 (15) |
|  | 56-65 | 2 (10) |
|  | 66-75 | 8 (40) |
|  | 76-85 | 6 (30) |
| **Ethnicity, n(%)** | |  |
|  | White British | 16 (72.7) |
|  | Mixed 2 or more ethnic groups | 1 (4.5) |
|  | Black/African/Caribbean | 2 (9.0) |
|  | Asian (Indian, Pakistani, Bangladeshi, Chinese, any other Asian background) | 3 (13.6) |
| **IMD scorea , n(%)** | |  |
|  | 1 | 3 (13.6) |
|  | 2 | 2 (9) |
|  | 3 | 5 (22.7) |
|  | 4 | 2 (9) |
|  | 5 | 1 (4.5) |
|  | 6 | 1 (4.5) |
|  | 7 | 2 (9) |
|  | 8 | 0 |
|  | 9 | 2 (9) |
|  | 10 | 4 (18) |
| **Housing, n(%)** | |  |
|  | Lives alone | 9 (40.9) |
|  | With at least one other family member | 13 (59.1) |
| **Diabetes, n(%)** | |  |
|  | Type 1 | 5 (22.7) |
|  | Type 2 | 17 (77.2) |
|  | Duration (years) | 21.6 ± 12.1 |
| **Years since diabetes diagnosis, n(%)** | |  |
|  | 1-10 | 3 (15) |
|  | 11-20 | 4 (20) |
|  | 21-30 | 6 (30) |
|  | 31-40 | 7 (35) |
| **Years since neuropathy diagnosis, n(%)** | |  |
|  | 1-10 | 11 (55) |
|  | 11-20 | 4 (20) |
|  | 21-30 | 3 (15) |
|  | Not sure | 2 (10) |
| **Diabetic foot ulcer (DFU):** | |  |
|  | Previous ulcer | 16 (72.7) |
|  | Amputation | 6 (27.2) |
|  | Charcot | 3 (13.6) |
| **Perceived risk vs actual riskc** | |  |
|  | Underestimation | 7 (31.9) |
|  | Accurate estimation | 9 (40.9) |
|  | Overestimation | 3 (13.6) |
|  |  |  |

*Note:* demographics listed include those of the participants (patients and carers) except for the health-related data which include information for the cared-for.

a Index of Multiple Deprivation score: a relative measure of deprivation for a small geographic area (single postcode) in the UK. Scores range between 1 (most deprived) and 10 (least deprived).

bSelf-report of symptoms usually exceeds diagnosis and participants often unsure or in denial. Responses were vague. Where a range was given, an average has been used, where response was “at least x years”, x has been used.

cParticipants were asked if they thought their risk for another ulcer was low, medium or high, and this was compared with the NICE guidelines risk levels informed by their self-reported presence of neuropathy, and history of ulcer.

A total of 6 Health and Care Professions Council registered podiatrists were recruited. All currently worked in England (n=5) or Scotland (n=1), in NHS (n=5) and academia (n=1), participants had previous experience working in public and private healthcare systems as well as working overseas. Participants specialised in wound care (n-5) and musculoskeletal problems (n=1).

### Findings:

This section presents a thematic analysis of participant feedback on the design concept of this device. Three themes were developed: patient buy-in, effective engagement, and sustained use. Each theme is split into two subthemes, the first highlighting a contextual challenge, the second presenting participant preferences for the intervention related to that challenge.

On presentation of the design concept, many participants appeared surprised that such a technology might exist, with comments such as, “it would be a revolution, if it could work” (P17). The subsequent disbelief yielded questions and doubts about the sensitivity of the device.

“you know, a beep every five minutes you’re just gonna get plain fed up with it aren’t you? And then if you don’t find anything, you know your faith in the product is just going to diminish” (P16)

This concern was, understandably a pivotal factor for acceptability. As such, participants were asked to imagine using a device that was perfectly calibrated to them. The remainder of this section describes the themes in detail with quotations from participants.

### Patient buy-in

#### Lack of awareness of risk

Although most participants considered the idea of the sock to be interesting, participants who judged themselves to be lower risk for ulceration, or doubted that rubbing was a cause of foot injury for them, needed more persuading.

“Would I say I would go out and buy a pair of those socks? Not necessarily, because I don't think I need to” (P8)

The device is designed to target loss of sensation caused by diabetic neuropathy, and yet it was particularly challenging symptom for participants to make sense of and describe. Where participants believed they had sensation in their feet, the diagnosis of neuropathy could be more challenging to accept cognitively, while the association with loss or inadequacy could also be difficult to accept emotionally.

“You lose sensitivity in your feet to different degrees, I mean as far as I'm concerned, I fail the medical test where they put a hair across your feet to designate if there's any feeling there, so I fail that, and I failed it for a long time, however in terms of if I stood on something, or if can I feel the pedals in the car, yes, I can.” (P8)

The podiatrist group also noted challenges with limited patient awareness and acceptance of risk, “they’re in denial about a lot of things” (Pod 3) and consequent issues engaging these patients to actively participate in their foot health management “it's a cohort of patients who don't even do the basic kind of self-care stuff” (Pod 1). Despite efforts to educate their patients in clinic, they were aware that many of their patients struggled to perform the self-care instructions at home.

“Essentially we're there to help them heal, but at the end of the day their foot is at the end of their leg and that goes home with them. And what happens in between appointments is obviously based on what they do” (Pod 4)

#### Ability to collect and record evidence

Without the ability to physically perceive shear strain occurring, people with neuropathy would not normally have the information to understand and detect how, when or why damage occurred. This created confusion and doubt in some participants, unsure how to make sense of their ulcers. Participants from both groups (interview and focus group) thought the sock could help elucidate issues around shear strain, thus clarifying misconceptions and reinforcing clinical messaging. The following quote is one participant’s response to being asked why their ulcers may have occurred:

“I haven't got a clue. I feel that there hasn't been a common reason I've had these ulcers… There's no plausible reason for why it's happened. Anything that investigates that would be nice to know the results” (P19)

Podiatrists thought that the sock could be useful in creating awareness and collecting information surrounding the time of alerts that would otherwise not be possible. Importantly, they felt that becoming aware of when the shear strain occurred might help patients (and clinicians) identify factors that could be controlled (e.g. if it only happens at work when wearing steel toed boots) and ultimately help the patient mitigate these risks themselves.

“I would be thinking straight away what activity are they doing? Are they stationary? Are they, you know, walking along somewhere? Are they pottering around indoors? Because when is it rubbing? That's because that's the type of thing that I would ask in clinic, you know, with footwear. What were you doing?” (Pod 6)

Lack of sensation not only limits the ability of patients to know what is happening with their feet in real-time, but also how they can communicate issues to others. Consequently, information that patients report in clinic is often not complete or reliable for the podiatrists, or at home for the carer, to know how and when to proceed with treatment. Participants saw the sock as a tool that might improve (self-) care by providing objective, real-time information for feedback and reassurance to the wearer and/or care provider. In this way it could be used to raise awareness of safety as well as risk. At home, it could help choosing new footwear or checking that they have effectively resolved a previous alert, and likewise, in clinical practice, it could be potentially useful when prescribing custom footwear or other offloading devices.

“For me, I think it would be useful as an early warning and actually checking is my [clinical offloading] device doing what I think it's doing” (Pod 4)

### Effective engagement

#### Challenges accepting and actioning information

While the idea of a smart-sensing sock was generally accessible and acceptable to participants, when questioned further about how they would use the sock, more practical questions arose, particularly about how to respond to the alert, what to look for on the affected foot, and how to find and correct the cause of the shear strain.

“What can you do? You're getting this information that's telling you there is rubbing taking place, and is likely to cause you a problem. So, guidance or suggestions is what has to come.” (P20, carer)

This reaction was fuelled by limited understanding about foot ulcers, associated risk factors, or what could be done to prevent them. Even when there was adequate understanding, many participants faced multiple competing demands of family, community or employment responsibilities and reflected how this deprioritised their self-care.

“It’s difficult to prioritise yourself when you’ve got two children, you’re working, you’re trying to keep all the balls in the air. I don’t think I prioritised my health enough” (P7)

Sometimes this competition for attention was exacerbated by the sheer amount of information that needed to be absorbed after their diabetes diagnosis. The seriousness of diabetic foot ulcers, and their own risk of getting them might only have come to light at the time of a foot emergency, resulting in a steep learning curve and information overload.

“It was a period in our lives where I'd got so much information. Trying to compartmentalise it all”. (P20, carer)

Participants noted that information about foot ulcer, and especially associated risk of amputation and threat to life, could be frightening. While some participants actively sought information, and felt it reinforced the importance and practice of self-care, others appeared to be more vulnerable to the information and preferred not to know “don’t read up on it because it’ll scare you to death” (P4). These participants recalled the loss of close family members because of foot problems; or reflected that it was information that they could not identify with, assuming it was something that happened to other people and would not affect them. Whether it was trauma, naivety, bravado, or turning a blind eye, the reality of their own susceptibility was difficult for them to accept.

“It was the worst time of my life. It took me 18 months to go to hospital to get it done in the first place. I was an ex-footballer. I was a man who was proud, if you know what I mean. I shouldn't be losing my toe, even though what had happened. I just couldn't get it in my head” (P17)

#### Simple, specific, and supportive guides

Given the importance of underestimation of risk, lack of information, and social and emotional distractions to carrying out instructions, podiatrists recommended a clear and simple decision-making tool to accompany the device. They suggested step-by-step prompts to guide the patient to safely respond to an alert, assess damage, and critically, to know when to contact their foot health team.

“It sounds like you're spoon feeding them, but sometimes it ends up being the case that you have to do that to prevent this… The time between a problem arising and how long something is done about it, within hours, diabetic feet can deteriorate, you can get a foot attack. So if that prompt is there like, “you need to check it right now” that would be really useful.” (Pod 4)

In addition, lack of sensory information should also be addressed and supported. Both interview and focus group participants called for information in the feedback system to indicate the location of shear strain, as well as instructions on how to respond to rubbing in different areas.

“You have to put yourself in their shoes. They don't actually feel, so if you or I were to get a bit of rubbing, we'd stop what we're doing and alternate our foot, or fix our shoe, tie our lace, because they can't feel they haven't a clue” (Pod 3)

### Sustained use

#### Difficulties coping

While some were comfortable with monitoring their own health, and reassured by taking measurements or recording data, others preferred to wait until clinic appointments, feeling that constant management created more, not less, anxiety. One participant, who was sceptical about using the sock, referred to health-monitoring devices as “worry-meters” (P5). This was a concern for the podiatrist group also, who worried that challenges with patient engagement could be due to overwhelm and were hesitant to add additional burden.

“You just know there'll be patients that probably wouldn’t want to have another thing to check – got to check the blood sugars, insulin like everything else. This is just another tool, but it's another thing to do as well, and sometimes people get kind of overwhelmed” (Pod 1)

As we can see from the previous subthemes, participants could start their diabetic neuropathy journey without awareness, acceptance or understanding of their foot health risk. When they experienced foot ulcer, they were understandably unprepared, challenging their ability to cope. Narratives ranged from hopeless, including misusing their insulin in attempts to die, to emphasising their luck in life and downplaying the misfortune of their experiences. While the fortunate few who were happy with their medical care, confident in their own abilities to self-manage their conditions, and supported by family felt that their symptoms did not dominate their lives, other participants felt they had less control.

“it's [my foot health] totally entwined with the diabetes that really controls me, controls my feet, my eyes, all the other diabetic symptoms” (P3)

Diabetic foot ulcers can escalate rapidly, and participants reported that the progression of their wounds was shocking. One participant did not even know he had diabetes until five days after he noticed a “small sore” when he was admitted to hospital for emergency amputation.

“I was whisked up to some theatre or other, fully conscious - because I'd eaten. I couldn't have an epidural, so they put a needle down my leg. I was lying there, conscious - compos mentis. There was a screen up, so I couldn't see what he was doing, but I could hear it. He took four toes off, and a little bit of the foot. I signed up to the knee, because they keep going until they run out of the bad” (P12)

Where there was pain associated with the ulcer, and more obvious threat to life, amputation appeared easier to understand and accept, there could even be a sense of relief after treatment. Conversely, where neuropathy masked any pain, it was more difficult to perceive the severity of the wound, and consequently amputation could be harder to cope with. Participants described having part of the body taken away with a sense of loss, and grief.

“The first one I was in pain and I wanted to get rid of it. The second one, I was in no pain, and it was unexpected. It’s like someone dropping down dead; or someone dying slowly of cancer or something. That’s the difference. That one was painful, and I wanted to get rid of it. I know it was for the better. That one, I was in no pain, and it was unexpected” (P1)

Participants reported lasting emotional impacts after ulceration. This could be paranoia or hypervigilance, checking their feet multiple times a day. There could be feelings of guilt or regret for not taking better care beforehand. Where there was deformity or amputation, some participants noted shame in the appearance of their feet, or in being classified as disabled. One of the hardest things to deal with for participants was a lack of independence.

“I’m aware people make concessions for me… and psychologically that’s horrible… I don’t like it. I don’t like being needy really.” (P16)

Participants reported doing what they could to manage their foot health, based on their understanding and acceptance of risk factors and preventative measures. Even then, some still experienced repeated wounds and infections, often from what they considered an innocent cause, such as a small cut, a new shoe, or getting sand in between their toes on holiday. For some there was a feeling of frustration that whatever they tried, they could not stop it happening.

“You get to the end of your tether and you think, “what? what? what can I do?” (P4)

#### Gaining control with an early warning system

When speaking to participants, concerns about calibration and sensitivity were undermined by the positive possibilities of the sock. For those who recognised the risk of shear strain for themselves, if the sock was easy to use and provided reliable information, participants felt it would be more of a support than a burden, one participant said it could be “another best friend” (p6), in the same way that she described other valued tools in her life like her mobile phone and well-fitted walking shoes.

Participants who reported using health devices such as continuous glucose monitors, were already used to responding to alerts, and appreciated the real-time feedback and prompt to take corrective action in the moment. They felt the devices gave them more control over their health, and related the sock to this same concept.

“I guess I'm used to sort of reacting to information that I've received on, on the sort of shape of things during the course of the day. So this would just be another thing” (P16)

One participant referred to the idea of an early warning system as providing, “a level playing field” (P23) by compensating for lost sensation. Others felt it could help in social situations, empowering them to speak up for themselves and take the breaks they needed rather than pushing on to keep up with others.

“Especially being on your feet all day and you get busy, you get distracted. They would be great because then it would give me a bit of an alarm, so to speak, to say something’s not right, and then I need to sit out” (P4)

If these benefits outweighed the burden of using the sock, as well as the burden of not using it, then it would help patients manage their foot health more easily.

“Well, I think it's a good positive idea, but I don't think it's a game changer for diabetes. I think it's a useful addition, like fingerprinting is a useful addition. It doesn't make me better. It doesn't change my life. It just helps me manage the situation better … if they were available and they work and I’m not sending them off for dry cleaning every day or, you know, that sort of thing, if the process was hard in living terms, then that would put you off. I'm sorry to give you the extra problem, but they need to fit into an ordinary sort of life, you know” (P16)

## Discussion

### Summary and comparison with other work

This is the first qualitative study to explore patient and podiatrist perceptions of a smart-sensing device to measure shear strain for the prevention of diabetic foot ulcers. Findings suggest that potential users welcome the idea of such a device, but that the experience of living with diabetic neuropathy presents several barriers to uptake and sustained effective engagement, namely: limited awareness of risk among patients and family caregivers; psychosocial challenges accepting health information and actioning health behaviours; and emotional burdens of living with diabetic neuropathy. These barriers suggest that for the device to be effective in improving health outcomes for this population, it should be implemented alongside a behavioural intervention.

There is limited research in this area, and our findings confirm those of the few other qualitative studies looking at patient experience of diabetic foot ulcer [33]; treatment burden in long-term conditions [34]; patient and podiatrist perspectives of other smart-sensing wearable devices for diabetic foot ulcer [35-37]; and behavioural understandings of the impacts of emotional burden on self-care behaviours [38, 39]. A key novel finding in this study was that, unlike plantar pressure, often caused by inactivity (e.g., the foot being in a single loading position for an extended period), participants considered alerts for shear strain to be associated with a different type of cause (i.e., from a certain activity or incorrectly fitting footwear), and consequently that alerts would signal the need to assess and address the cause, rather than simply to offload. It was not always obvious to patients how to appropriately respond to an alert for shear strain and therefore any future device would need to clarify responses required. Research into smart-sensing wearables for plantar pressure has found that a minimum number of alerts (one every two hours) is required for optimum response [40], whereas this paper suggests that for shear strain, if the alerts were perceived as too frequent, and there was no clear resolvable issue in the footwear or visible indication of rubbing on their foot (e.g., redness), there is a risk that participants would assume the device to be faulty.

In addition to identifying barriers to uptake and engagement of a smart sensing device, findings also present potential solutions to these barriers through participant-identified adaptations to the device and its implementation. These highlight novel patient and podiatrist priorities and include: using the sock to collect evidence to support clinical messaging and patient understanding of shear strain and ulceration; provision of a simple decision-making tool to guide safe self-care and response to alerts; and supporting the normalisation of health monitoring behaviours to increase self-efficacy and self-advocacy regarding foot health. To further these learnings, we have curated a set of Guiding Principles [27] derived from the outcomes of the present study to support future development of smart-sensing devices for diabetic foot ulcer (see Table 2). These guiding principles draw on data-driven findings, supported by evidence from the wider literature about this patient population and similar devices, to identify key intervention features to address identified psychosocial barriers to uptake and engagement. This provision of principles addresses an urgent need to provide behaviourally informed guidance to this emerging field of smart-sensing technology for diabetic foot ulcer [24]. These findings may apply to beyond devices that measure shear strain and be relevant to smart-sensing devices for diabetic foot health more generally, and it is hoped that publishing these principles will help guide further optimisation of diabetic foot health devices and implementation of devices into standard care.

Table 2: Guiding Principles

|  |  |  |
| --- | --- | --- |
| **User Context** | **Key design objective** | **Intervention design features** |
| **Risk appraisal:** | | |
| From the data:   * Many participants had difficulty accepting their diagnosis of neuropathy which reduced their motivation to perform self-care. It appeared to be contrary to their personal experience as they felt they did have at least some feeling in their feet. In contrast, those who accepted their diagnosis were more motivated to perform self-care. * Some participants did not accept that shear pressure could be causing their ulcers. Participants who were aware that shear pressure could cause issues were more careful with their footwear. * Participants believed that shear pressure must have an external cause such as a rolled sock and were unaware of issues with changes in gait from neuropathy. * Almost half of the participants underestimated their risk of ulceration. * Podiatry participants thought the real-time feedback could help their patients become more aware of footwear or activities that are causing risky levels of shear strain and may help to reinforce their clinical messaging.   From the literature:   * People at high risk of diabetic foot ulcer have changes in gait and exhibit greater levels of shear strain than their lower-risk counterparts [16], so their exposure to risk is higher, but patients with lower acceptance of their illness show less self-care behaviour and poorer foot health [41, 42]. * Neuropathy-related illness beliefs are little understood, but one study has shown them to directly influence foot care behaviour and foot health outcome [43]. * International Working Group on the Diabetic Foot guidelines highlight the need for continuous assessment of risk and need for frequent screening [6] | * Highlight personal risks of diabetic foot disease and how this is associated with neuropathy and shear pressure. * Personalise health information to specifically target beliefs about personal risk factors [44, 45]. * Reinforce self-efficacy in order to reduce emotional burden as well as risk of (re)ulceration [38, 39] | * Provide an informational resource illustrating diabetic neuropathy and the associated risk of ulcer in simple lay language. This should include information about gait changes as well as information about variations in neuropathy (e.g. fine touch versus pressure) to address potential issues of conflict between personal experience and clinical messaging leading to confusion in perception and acceptance of the diagnosis; as well as frequently asked questions, and signposting to further information where relevant. * Provide an informational resource that demonstrates causes of shear pressure in feet including potential corrective actions (e.g., safe footwear guidelines, care when walking on an incline). * Provide an informational resource that demonstrates how the sock sensors can compensate for neuropathy and help prevent foot ulcers. * Illustrate different uses of the sock to facilitate evidence collection to improve risk acceptance for patient buy-in, and support ongoing effective engagement.   E.g. 1: instructions for podiatrists to use the sock as an educational tool to demonstrate that the sock can detect and alert to shear in a safe setting (in clinic).  E.g. 2: instructions for patients/carers/podiatrists on how to use the sock to evaluate new footwear/offloading device, or for reassurance that an issue has been solved.  E.g. 3: provide an additional resource that can support the sock user to record key information about when the alert occurred (checkbox: shoes, activity, time of day) for personal record, and facility to share with podiatrists. |
| **Health literacy and behaviour change:** | | |
| From the data:   * None of the participants had a clear and comprehensive understanding of what diabetic foot ulcers are, how they are caused, or how to prevent them. This was influenced by cognitive burden (information overload), and emotional overwhelm (difficulty absorbing information). * Better understanding of foot health was associated with more informed preventative behaviours * Participants who reported better understanding as well as good relationships with healthcare providers, and family support appeared more confident in their self-management * Podiatrists reported attempts to educate their patients in clinic about self-care practices, but struggled to motivate them to carry them out at home. * Some participants did understand about ulcers and self-care but reported challenges performing health behaviours e.g., competing social demands, conflicts with identity.   From the literature:   * Lack of understanding about the connections between diabetes and foot ulceration is critical to address to improve both preventative and treatment-seeking behaviours [8, 33, 46-49] * It is well established that in addition to competence, other factors such as opportunity and motivation are critical to behaviour change, so the provision of information alone is inadequate [50, 51] * Patient education needs to include support that is in line with their individual lifestyle, needs and values [8, 52-54] * An alert-based insole system for plantar pressure included offloading advice and was shown to improve adherence to alerts and modify behaviour (pre-emptively offloading) [40] * 4 week feasibility study of a podiatrist-led health coaching intervention to facilitate smart shoe insole adoption showed improved adherence during the intervention, [35] but declined afterwards [37] * International Working Group on the Diabetic Foot guidelines highlight the impact of health literacy and adherence to recommendations calling for improvements in patient education [6] | * Support users to improve general foot health awareness and confidence in their own self-management * Support users to respond safely to an alert * Support healthcare providers to use the device as an educational tool for collaborative engagement with patients towards ongoing improvements to long-term self-management of foot health | * Provide an informational resource to illustrate what ulcers are including what patients should be aware of (e.g., changes in skin quality, or sensation, loss of hair on the legs) * Provide a tool to clarify self-care behaviours and best practice advice for patient self-management of foot health (e.g., how to perform daily foot checks) and support habit formation and positive feedback (e.g., self-monitoring of behaviour, buddy systems) * Provide a decision-making tool that guides a user through steps to respond to an alert, including when to seek medical attention * Pilot test all educational resources on diverse groups of people to ensure that the messaging is as inclusive and acceptable as possible, and iterate to address any barriers to understanding and acceptance * Device development needs to continue into implementation phases to allow for further iterations to support normalisation of use in clinical practice |
| **Health inequalities:** | | |
| From the data:   * Podiatrists identified that their patients were either pro-active and engaged with their health or reactive and less engaged with their health. They assumed that the device would only be acceptable or used properly by those already engaged (possibly based on demographic factors) * Our stakeholder groups (including PPIE) were engaged from the planning phase of the project and acted as inequality champions actively scrutinising research processes for potential discrimination * Knowledge and experience of ulceration was often associated with trauma, for example emergency amputation, stigma, family bereavement. High fear and low efficacy was associated with frustration and hopelessness. * Digital literacy varied across participants   From the literature:   * Multidisciplinary co-design is essential for device development and implementation to facilitate the device to function as a clinically integrated self-care tool for prevention of diabetic foot ulcer [55]. * International Working Group on the Diabetic Foot guidelines highlight interpersonal differences in foot health progression and outcomes and highlight the need for personalised care [6] | * Support healthcare providers to facilitate behaviour change in their most vulnerable (unengaged) patients * Ensure that all universal elements of the intervention are targeted towards disadvantaged or unengaged groups. | * Provide an informational resource for podiatrists to highlight common barriers to adherence and provide strategies to improve behaviour change * Co-design intervention from the outset with diverse stakeholders to ensure good representation and mitigate against inequalities. E.g: ensure that all supplementary education material is simple (grade 6 reading level), inclusive (available in multiple languages/pictures), and strength-based (positively framed) * Allow for personalisation of settings * Provide non digital as well as digital options for resource materials to address issues of digital exclusion, and provide other accessibility options (e.g., translations to different languages, options to increase font size or text-to-speech) |
| **Managing expectations:** | | |
| From the data:   * Participants were concerned about false alarms. * Others thought that the sock would keep their feet safe   From the literature:   * performance expectancy moderates behavioural intentions of both patients and healthcare providers to adopt or use such a device [35-37] | * To provide information about device calibration, sensitivity and robustness. * To manage expectations for the scope of the device | * Provide clear information about what the sock can and cannot do * Provide clear instructions on washability and care, and quality testing. |

### Strengths and limitations

Impacts of social determinants of health on individuals with diabetic neuropathy are acknowledged, but not well understood [56, 57], and should be considered from the outset of the research process to maximise inclusivity [58]. Strengths of the study include that people with diabetes were involved in all stages of the study; recruitment of patient and podiatrist participants were purposively sampled to ensure heterogeneity of perspective (good representation was achieved in terms of gender identity, race, age, professional experience, and patient risk factors); data collection explored feedback on the technology in the context of lived experience of diabetic foot health; and analysis was led by a multidisciplinary team of researchers. This approach, using multidisciplinary co-design for device development and implementation, and acknowledgement of contextual influences, is critical to facilitate a device to function as a clinically integrated self-care tool for prevention of diabetic foot ulcer [55]. Future research can build on the findings and guiding principles presented in this study to develop a prototype for the device, and wider intervention, including supportive materials for patients, carers and healthcare professionals. These supportive materials can be tested, iterated and optimised alongside the development of the device itself. It is critical that this process continues with a focus on diversity and inclusion.

Future research can also learn from the limitations of this study. As is typical of qualitative research, participants were self-selected, and therefore represent a portion of the population who, by their interest in taking part in research, may be be more engaged in healthcare than those who did not respond to the invitation. Several of these patients did reflect that they had not always been so engaged, and thus provided insight into issues that might otherwise not have been included. Participants recruited through NHS clinics were pre-screened as high-risk for diabetic foot ulcer, while another recruitment stream used could only pre-screen by diagnosis of diabetes. All interested participants were further screened by a non-clinical research member using questions guided by author IY who is a podiatrist. Inclusion to the study was therefore ultimately based on their self-report of diabetic neuropathy, which is likely less reliable than clinical screening, but their diagnosis was confirmed through clinically informed screening and the narratives of their interviews, and using different recruitment streams actually helped to achieve the broad sample of patients with a range of ulcer histories and experiences.

### Conclusion:

This qualitative study explored patient and provider feedback on a novel smart-sensing wearable technology (a sock and feedback system to detect and alert to shear strain) for the prevention of diabetic foot ulcers. Findings suggest that potential users welcome the idea of such a device, but that the experience of living with diabetic neuropathy presents several barriers to uptake and sustained effective engagement, namely: limited awareness of risk among patients and family caregivers; psychosocial challenges accepting health information and actioning health behaviours; and emotional burdens of living with diabetic neuropathy. The study also identified potential solutions to these barriers to improve device uptake, engagement and sustained use. These include using the sock to collect evidence to support clinical messaging and patient understanding of shear strain and ulceration; provision of a simple decision-making tool to guide safe self-care and response to alerts; and supporting the normalisation of health monitoring behaviours to increase self-efficacy and self-advocacy regarding foot health. These suggest that the device should be considered as a tool within a wider behavioural intervention designed to support self-management behaviours, for example, by specific framing of feedback messages and instructions to improve risk appraisal and build self efficacy, and by supporting healthcare professionals to introduce and utlize the device as part of their practice. A set of guiding principles is presented to support future research towards device design that addresses contextual barriers for successful uptake and long term effective engagement identified in this study.

### Acknowledgments

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Technology development: The device described in this study is being developed collaboratively by the author affiliated institutions with no industry partners involved.

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### Authors’ contributions

**Conceptualization** – NDR (lead), KB (equal), PC (supporting), IY (supporting)

**Data curation** – JC

**Formal analysis** – JC (lead), KB (supporting), IY (supporting)

**Funding acquisition** ​- NDR (lead), KB (equal), PC (equal), IY (equal)

**Investigation** – ​JC

**Methodology** – JC (lead), KB (supporting)

**Project administration** – JC (lead), KB (supporting), IY (supporting)

**Supervision** – KB (lead), IY (supporting)

**Validation** – PB (equal), EW (equal), RL (equal), GP (equal)

**Visualization** – JC (lead), KB (supporting), IY (supporting)

**Writing – original draft** – ​JC

**Writing – review & editing** – KB (lead), IY (supporting), NDR (supporting), PC (supporting), PV (supporting), GO (supporting), RT (supporting), PB (supporting), EW (supporting), RL (supporting), GP (supporting),

### Data Availability

This study was registerd under the UK’s clinical study registry (ISRCTN). The protocol and other study information can be found at <https://www.isrctn.com/ISRCTN13991509>. Transcripts of the qualitative data is not publically available, however, relevant exerpts have been shared in this paper as per participant consent.

### Conflicts of Interest

None declared.

### Abbreviations

IMD: Index of Multiple Deprivation

NIHR: National Institue for Health and Care Research

NHS : National Health Service (UK)

P#: participant identification (interview participant)

Pod #: participant identification (podiatrist focus group participant)

PPIE: patient and public inclusion and engagement

### Appendix 1: Semi-structued interview guide

**About the participant and their foot care:**

* **Can you tell me if foot ulcers are a concern for you?**
  + Do you do anything in your daily routine to manage or prevent foot ulcers?
  + How often do you do this?
  + How confident are you in your ability to manage the health of your feet?
* **Does anyone help you with your foot care?**
  + Who would be your go-to person for foot care questions/support?
  + How often do you contact them for help with your foot care?

**About the sock:**

* **Thinking about the sock itself, can you tell me your first impressions?**
* **Can you tell me if you can see yourself using this sock in your daily life?**
  + How often do you think you might use it?
  + In what situations do you think you might use it?
* **Can you tell me about any features that appeal to you?**
  + What is it about this feature that you like?
* **Can you tell me any specific features that might be a concern?** 
  + How concerned are you about this feature?
  + Would this be a barrier to your using the sock at all?/ long-term?
* **Is there anything about the sock that you would like to change?**

**About the feedback system:**

* **Thinking about the feedback system, can you tell me your first impressions?**
* **Can you tell me if this feedback system would work for you in your daily life?**
* **Can you tell me about any features that appeal to you?**
  + What is it about this feature that you like?
* **Can you tell me any specific features that might be a concern?** 
  + How concerned are you about this feature?
  + Would this be a barrier to your using the feedback system at all?/ long-term?
* **Is there anything about the feedback system that you would like to change?**

**General prompt examples**

* **How does/did that make you feel?**
* **Can you tell me a little bit more about that?**
* **That’s really interesting – please can you explain a bit more?**
* **That sounds really difficult – do you feel able to tell me a bit more about that?**

### Appendix 2: Sock design features

|  |  |  |
| --- | --- | --- |
| Component | Detail | Comment |
| Sock |  |  |
|  | Tightness | Consider oedema, ease of putting on and off. Should be supportive, but not tight. Wider fit on legs as well as toe area if bandages are being worn |
|  | Seams | Completely seamless especially at the heel and toe, but also careful that the welt stitching is not too sharp especially when stretched. |
|  | Welt | Important area for tightness consideration – wider welt area less likely to impede circulation |
|  | Toes | Covered or padded toes are good for protection and warmth, but toeless option is good for people with burning sensation, or nail issues. Also concerns about discomfort in the toes and needing to feel “free” rather than rubbing together |
|  | Fabric | Breathable/absorbing excessive moisture is an infection risk, anti-odour |
|  | Additional | Right and left labels, grip pads – to reduce sliding |
| Sensors |  |  |
|  | Location | Ball of foot, heel, met heads, side of big toe |
|  | Practical | Washable, durable |
| Terminal |  |  |
|  | Concerns | Ease of removal and reattachment, charging |
| Feedback |  |  |
|  | Key elements | Haptic feedback or app were acceptable;  Indication of specific area of rubbing was preferable;  Prompts to accompany the alert to facilitate decision making (what to do, when, how urgently);  Simple clear instructions (multi-language, pictures best);  Advice about regular self-care, foot emergency, footwear fitting, when to seek medical attention |

Four different sock samples were produced at Manchester Fashion Institute, Manchester Metropolitan University using a Santoni sock knitting machine after carefully reviewing a wide range of commercially available diabetic socks. The design of the sock was also based on the discussions and initial feedback from the patient groups. During the design stage, various factors, such as the thickness of the socks, ease of wear, ability to stretch easily, and seamless toe, were considered. Socks were composed of recycled Nylon, combed cotton, lycra and elastic. All the socks have a double welt at the top of the sock and a seamless toe design that offers comfort in the toe region. Except for design number 3, all the remaining socks have terry heel and toe, which provide softness and added comfort to the heel and toes. Socks with three zones allow the sock to be designed with additional lycra. This feature lets the sock stay on the leg and feet without gathering or sliding when donning and doffing.

A pair of socks on a mannequin

Description automatically generated

### Appendix 3: COREQ checklist

#### Reflexivity:

Reflexive thematic analysis explicitly recognises researcher input into the analysis. As such, it is important to declare researcher positioning. Author JC collected the data, conducted the analysis and write-up. She is an experienced qualitative researcher with a background in health psychology and approached the data from a constructivist standpoint [59]. She does not have lived experience of diabetes and had no previous relationship with any of the participants. Supervising the study and providing input to the analysis, was KB, an experienced qualitative researcher, Health Psychologist and expert in the Person-Based Approach with over 15 years in the field of health intervention design; IY, a Podiatrist specialising in diabetic foot care and clinical academic; and the engineering team including experts in digital diabetic foot care interventions development. To ensure credibility, all stages of the research were reviewed with the PPIE group for feedback.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | Item | Guide questions/description | Manuscript section where information can be found |
| **Domain 1: Research team and reflexivity** | | | | |
| Personal Characteristics | 1 | Interviewer/facilitator | Which author/s conducted the interview or focus group? | Method- data collection |
| 2 | Credentials | What was their occupation at the time of the study? | Method- data collection  Supplementary material - Reflexivity |
| 3 | Occupation | What was their occupation at the time of the study? | Method- data collection Supplementary material - Reflexivity |
| 4 | Gender | Was the researcher male or female? | Supplementary material - Reflexivity |
| 5 | Experience and training | What experience or training did the researcher have? | Supplementary material - Reflexivity |
| Relationship with participants | 6 | Relationship established | Was a relationship established prior to study commencement? | Method – participants Supplementary material - Reflexivity |
| 7 | Participant knowledge of the interviewer | What did the participants know about the researcher? e*.g. personal goals, reasons for doing the research* | Method – data collection |
| 8 | Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* | Supplementary material - Reflexivity |
| **Domain 2: study design** | | | | |
| Theoretical framework | 9 | Methodological orientation and Theory | What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* | Introduction Method – data analysis |
| Participant selection | 10 | Sampling | How were participants selected? *e.g. purposive, convenience, consecutive, snowball* | Method- participants |
| 11 | Method of approach | How were participants approached? e*.g. face-to-face, telephone, mail, email* | Method- participants |
| 12 | Sample size | How many participants were in the study? | Findings- participants |
| 13 | Non-participation | How many people refused to participate or dropped out? Reasons? | Our recruitment method does not allow us to know why participants did not respond to our invitation to participate. |
| 14. | Setting of data collection | Where was the data collected? e*.g. home, clinic, workplace* | Method- data collection |
| 15. | Presence of non-participants | Was anyone else present besides the participants and researchers? | Method- data collection |
| 16. | Description of sample | What are the important characteristics of the sample? *e.g. demographic data, date* | Method - participants  Table 1 |
| Data collection | 17. | Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Method- data collection |
| 18. | Repeat interviews | Were repeat interviews carried out? If yes, how many? | Method – data collection |
| 19. | Audio/visual recording | Did the research use audio or visual recording to collect the data? | Method- data collection |
| 20 | Field notes | Were field notes made during and/or after the interview or focus group? | Methods- data collection |
| 21. | Duration | What was the duration of the interviews or focus group? | Methods- data collection |
| 22. | Data saturation | Was data saturation discussed? | The authors are very cautious about claims of data saturation in thematic analysis (see, for example, arguments in Braun and Clarke [60]) Data saturation for the current analysis was not aimed for, instead, authors prefer the concept of information power [61] and n>20 was considered a good sample size to aim for based on our experience in previous projects. |
| 23. | Transcripts returned | Were transcripts returned to participants for comment and/or correction? | n/a  (member checks with participants were not conducted, professional transcribers transcribed the interviews and researchers checked for accuracy, and the PPIE group was consulted regularly for credibility checking) |
| **Domain 3: analysis and findings** | | | | |
| Data analysis | 24. | Number of data coders | How many data coders coded the data? | Method- data analysis |
| 25. | Description of the coding tree | Did authors provide a description of the coding tree? | Method- data analysis.  A coding tree was not used and analysis followed reflexive thematic analysis approach and discussion with peers. |
| 26. | Derivation of themes | Were themes identified in advance or derived from the data? | Method- data analysis |
| 27. | Software | What software, if applicable, was used to manage the data? | Method- data analysis |
| 28. | Participant checking | Did participants provide feedback on the findings? | n/a  (participants did not provide feedback, but ongoing analysis and reflections were discussed with the PPIE group (of people living with diabetes, at risk of diabetic foot ulcers) throughout the study period as stated in Method – study design section) |
| Reporting | 29. | Quotations presented | Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e*.g. participant number* | Results |
| 30. | Data and findings consistent | Was there consistency between the data presented and the findings? | Results |
| 31. | Clarity of major themes | Were major themes clearly presented in the findings? | Results  Discussion |
| 32. | Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Results |

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