ISRCTN51549193 https://doi.org/10.1186/ISRCTN51549193

Can a smart insole fit into standard treatment pathways?

Submission date 06/01/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/01/2026	**Overall study status** Completed	
Last Edited 08/01/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study is about new “smart” textiles that have electronics built into them, (an emerging field know as e-textiles) such as smart clothing and wearable health devices. Although these products can work well as early prototypes, it can be difficult to make them reliably at larger scale and to make sure they keep working properly in everyday life outside the lab. Most existing research is based on small studies or controlled tests, which often have only a few samples, so we need more information about how these technologies perform in the real world.
To address this, this study will collect feedback and practical data from a range of people using the Smart Insoles in their normal daily routines. What we learn will help improve future smart textile products and guide future research

Who can participate?
Adults aged 18 years or over who have full physical capability and do not have any documented health conditions or physical impairments.

What does the study involve?
Participants will be provided with a pair of Southampton Smart Insoles that contain miniature electronics. They will be asked to wear the insoles as you would any normal insole, as part of their usual daily routines, for up to 5 weeks. The insoles will be provided with minimal instructions to encourage natural, real-world use. During the wear period, they will complete a simple wear diary. They may be asked to take a straightforward sensor reading at the start and end of the wear period using a standard smartphone. These readings are non-invasive and do not include identifiable information. After the wear period, they will return the insoles to the investigator for analysis. They will be invited to a short Microsoft Teams call (around 15–20 minutes) to share feedback via a questionnaire. We will also collect basic demographic information (such as age range, gender, and occupation) to help interpret the findings.

What are the possible benefits and risks of participating?
Their participation is vital in helping improve the understanding of how smart insoles, and E-textiles as a whole, perform in real-world conditions. Their feedback will help improve future smart insole and E-textile designs and support research at Southampton. There are no foreseeable disadvantages of taking part in this study - the usual 'easing in' period of using an

orthotic will apply, but no additional risks will be introduced. Participants are free to stop wearing them at any time if they experience discomfort, or for any other reason. Data privacy risks are minimised by secure handling of study information. The electronics in the insoles are designed to be lightweight and do not come into direct contact with the skin. The sensor data collected by the insoles is non-identifiable and is limited to temperature and basic magnetic (magnetometer) readings.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
November 2025 to March 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Michael John Lynch, m.j.lynch@soton.ac.uk
Full contact details will be provided in the Participant Information Sheet

Contact information

Type(s)
Principal investigator, Public

Contact name
Mr Michael John Lynch

ORCID ID
https://orcid.org/0009-0009-7248-2874

Contact details
9 Hadfield Grove
Leigh
United Kingdom
WN7 2ET
+44 (0)7511479495
mjl2g23@soton.ac.uk

Type(s)
Scientific

Contact name
Mrs Kate Lynch

ORCID ID
https://orcid.org/0009-0009-8804-051X

Contact details
Warrington and Halton Teaching
Hospitals

NHS Foundation Trust
Warrington
United Kingdom
WA5 1QG
+44 (0)7436872425
kate.lynch4@nhs.net

Additional identifiers

Study information

Scientific Title
Scalable manufacturing processes for fully integrated e-textiles: smart insole

Study objectives
The objectives of this study are centred on obtaining real-world feedback from participants engaged in wearing a prototype E-textile, specifically focusing on a Southampton-developed Smart Insole. This information aims to investigate the non-inferiority of comfort of smart insoles when compared with standard practice.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/10/2025, University of Southampton Research Ethics and Governance Office (University of Southampton University Road, Southampton, SO17 1BJ, United Kingdom; N/A; risethic@soton.ac.uk), ref: 104938.A1

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Factorial

Purpose
Device feasibility, Health services research, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Patient compliance to orthotic intervention

Interventions
All possible interventions were entered into an online randomisation tool, which generated a random combination of interventions:
1. Standard simple insoles
2. Simple insoles with flexible circuit board, but no componentry
3. Simple insoles with flexible circuit board and added componentry

Each participant will be asked to wear their randomly assigned insoles for a period of 4 weeks. They will be provided with a wear diary for this time period and asked to wear the insoles for as much as is reasonable.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Smart simple insoles

Primary outcome(s)
1. Comfort measured using numeric comfort score rating at 4 weeks

Key secondary outcome(s))

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Over the age of 18 years
2. Can walk 20 metres unaided
3. Functional sensation of foot and ankle
4. No current foot ulceration

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Diabetic population
2. People with vascular neuropathy
3. Active foot ulceration
4. Pregnant women
5. Vulnerable groups
6. Those under the age of 18 years

Date of first enrolment
24/11/2025

Date of final enrolment
27/02/2026

Locations

Countries of recruitment
Ireland

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available