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A study of Sensore: continuous pressure monitoring for wheelchair users

Submission date
22/01/2026

Recruitment status
Recruiting

Registration date
23/01/2026

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pressure ulcers can develop when people sit in the same position for long periods, which is a particular risk for wheelchair users. Sensore is a pressure monitoring system designed to help people understand when pressure is building up and when it may be helpful to change position. The aim of this study is to see whether people can use the Sensore system easily, safely and as intended in everyday situations. The study focuses on usability and acceptability, not on testing health benefits or clinical outcomes.

Who can participate?
Adults aged 18 or over who are wheelchair users, carers of wheelchair users, or healthcare professionals involved in pressure care may be invited to take part. Participants must be able to give informed consent and use a smartphone or tablet.

What does the study involve?
Participants will attend a small number of sessions at a specialist NHS rehabilitation centre. They will be shown how to use the Sensore system and asked to use it while researchers observe. Participants will complete short questionnaires and may take part in interviews or group discussions. Wheelchair users may also use the system at home for a period of time as part of their normal routine. The study does not involve medical treatment or changes to usual care.

What are the possible benefits and risks of participating?
There may be no direct benefit from taking part, but feedback will help improve the design of the Sensore system for future users. Risks are expected to be low and may include mild inconvenience, tiredness, or discomfort from sitting. Participants can stop at any time and can withdraw without giving a reason.

Where is the study run from?
The study is run from the Rehabilitation Engineering Unit at Cardiff and Vale University Health Board (UK).

When is the study starting and how long is it expected to run for?
The study will start on 1st April 2026. Recruitment will take place over several months, and each

participant will be involved for up to a few months. The study is expected to run until October 2026.

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR) and Graphene Trace Ltd.

Who is the main contact?
The main contact is Stephanie Wentworth, Study Chief Investigator and Principal Clinical Engineer at Cardiff and Vale University Health Board. Contact details will be provided to anyone interested in taking part.

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Stephanie Wentworth

ORCID ID
https://orcid.org/0000-0002-9648-1763

Contact details
Rehabilitation Engineering Unit, ALAS Posture & Mobility Centre
Unit A Taffs Fall Road
Treforest
Pontypridd
United Kingdom
CF37 5TF
+44 2921833931
stephanie.wentworth@wales.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
365158

National Institute for Health and Care Research (NIHR)
510280

Study information

Scientific Title
A summative usability study of Sensore: continuous pressure monitoring for wheelchair users

Study objectives
The objective of this study is to evaluate whether intended users can use the Sensore continuous pressure monitoring system safely and effectively under realistic conditions of use. The study aims to assess usability, acceptability, and perceived workload; to identify use-related

errors, difficulties and residual risks; and to gather qualitative feedback from wheelchair users, carers and healthcare professionals to inform design refinement, instructions for use and labelling. The study does not assess clinical effectiveness, safety outcomes or changes to usual care and is conducted as a non-interventional summative usability evaluation.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Observational

Secondary study design
Non-interventional summative usability study (human factors evaluation)

Study type(s)

Health condition(s) or problem(s) studied
Usability and acceptability of a continuous pressure monitoring system for pressure ulcer risk management in adult wheelchair users and their carers and healthcare professionals.

Interventions
This is a single-arm, non-interventional observational study conducted at a single NHS site. Adult wheelchair users, carers and healthcare professionals will participate in clinic-based usability sessions and periods of routine at-home device use. Participants will receive supervised training in device operation and will interact with the Sensore system under realistic conditions of use.

Data will be collected through structured observation of critical tasks, validated usability and workload questionnaires, in-depth interviews, focus groups and automatically recorded device telemetry. Data will be analysed descriptively to characterise usability, acceptability, workload and use-related risks. No randomisation, blinding or control group is used, and the study does not alter participants' usual care.

Intervention Type
Other

Primary outcome(s)
1. Overall usability of the Sensore system measured using System Usability Scale (SUS) at End of Study

Key secondary outcome(s))
1. Perceived workload associated with device use measured using NASA Task Load Index (NASA-TLX) at Visit 1 (Workshop), Visit 2 (Mid-Study), Visit 3 (End of Study)

2. Identification of use-related errors and difficulties measured using Structured observation of critical tasks at Visit 1 (Workshop), Visit 2 (Mid-Study), Visit 3 (End of Study)

3. User acceptability and qualitative feedback measured using Structured interviews and focus groups at Visit 1 (Workshop), Visit 2 (Mid-Study), Visit 3 (End of Study)

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or older.
2. Able and willing to provide informed consent.
3. Adult wheelchair user, carer of a wheelchair user, or healthcare professional involved in pressure care or pressure ulcer prevention.
4. Able to use a smartphone or tablet compatible with the Sensore user interface.
5. Sufficient cognitive and language ability (English or Welsh) to understand study instructions and questionnaires.
6. Willing to participate in clinic-based usability sessions and periods of at-home device use.

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. Presence of an active pressure ulcer in areas where the sensor would be placed.
2. Prior involvement in the design or development of the Sensore system.
3. Use of bespoke or specialist seating systems incompatible with the Sensore mat.
4. Presence of an implanted or non-removable medical device that may interfere with sensor function.
5. Inability to understand study procedures or instructions for use.
6. Participation in Patient and Public Involvement and Engagement groups associated with this study.

Date of first enrolment
01/04/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Rehabilitation Engineering Unit, Cardiff & Vale University Health Board
Unit A Taffs Fall Road
Treforest
Pontypridd
Wales
CF37 5TF

Sponsor information

Organisation
Graphene Trace Ltd

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date