

A user survey of an early prototype handheld novel pain measurement device

Submission date 11/10/2026	Recruitment status Not yet recruiting	☒ Prospectively registered ☐ Protocol
Registration date 13/10/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 12/10/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

The purpose of this research project is to improve the measurement of pain in healthcare. If pain can be measured better, it may help improve the management of pain.

Who can participate?

Health professionals working in the Rosie Hospital, Cambridge. Healthy antenatal or postnatal women who are inpatients in the Rosie antenatal or postnatal wards and not receiving active care or therapy.

What does the study involve?

An interview survey of opinion of volunteer participants of the value, function and form of a prototype pain measurement device which participants will be encouraged to handle and use.

What are the possible benefits and risks of participating?

There are no direct personal benefits of participating. There should be no expected risks from participation.

Where is the study run from?

Cambridge University Hospitals (Rosie Hospital)

When is the study starting and how long is it expected to run for?

October 2026 to March 2027.

Who is funding the study?

Obstetric Anaesthetists' Association

Who is the main contact?

Dr Jim Bamber, Consultant anaesthetist, james.bamber1@nhs.net

Contact information

Type(s)

Principal investigator, Public, Scientific

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Integrated Research Application System (IRAS)

363382

Study information

Scientific Title

A user survey of an early prototype handheld novel pain measurement device

Study objectives

A non-clinical user evaluation survey of an early prototype of a handheld novel pain measurement device for patient use. The information obtained from this survey will be used to guide prototype development and provide non-clinical information for a future application for approval for an early feasibility study of the prototype.

Ethics approval required

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Ethics approval(s)

Approved 03/09/2026, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8241; cambridgesouth.rec@hra.nhs.uk), ref: 26/EE/0192

Primary study design

Observational

Secondary study design

A qualitative user survey to understand the opinions of health professionals and patients about the design and function of an early prototype device for pain measurement

Study type(s)**Health condition(s) or problem(s) studied**

Opinions of health professionals and patients about the design and function of an early prototype device for pain measurement

Interventions

A qualitative study involving an interview survey of opinion of volunteer participants of a prototype pain measurement device . All survey interactions will be one-to-one conducted by the study investigator.

The participants will be recruited in the Rosie Hospital from health professionals and from healthy inpatients on antenatal and postnatal wards who are not receiving active care or treatment.

The sampling strategy will be combination of purposive and convenience sampling with a intended sample size of 15 in each group (health professionals and patients).

All participants will be given a prototype device to handle and use. The purpose of the device and its function will be explained by the investigator. The participants will be encouraged to use the device but without causing any self-discomfort.

The survey about the device will involve a structured questionnaire using paper and pen completed by the participant supervised by the investigator. It is expected that completion of the questionnaire by the participant will require less than 30 minutes. There will be some differences between in the structure of the questionnaire used for the survey of the opinion of health professional volunteers and the questionnaire used to survey the opinion of patient volunteers with regards to questions about the participants. To ensure uniformity of the questions about usability of the device, the other questions are similar for both groups.

No identifying data will be collected from either group.

Participants will be able to complete the questionnaires anonymously without direct observation and in confidence.

Intervention Type

Other

Primary outcome(s)

1. Completion of questionnaire measured using a questionnaire at a single time point

Key secondary outcome(s)

Completion date

31/03/2027

Eligibility

Key inclusion criteria

1. Any health professional who is working in the local centre and whose job role is likely to involve pain assessment of patients as judged by the investigator will be invited to participate in the survey
2. Healthy women who are inpatient in the local centre on the antenatal and postnatal wards and who are not receiving active care or therapy at the time of the invitation for inclusion
3. English speaking

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 Years

Upper age limit

120 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Health professionals whose work would not be expected to involve patient pain assessment and those to decline the invitation to participate
2. Patients who are unwell or receiving active ongoing treatment
3. Patients who have a disability or condition that will preclude or inhibit their ability or to cause any discomfort to use the prototype device
4. Women who cannot understand, read or speak English
5. Women who are in distress of any kind or who are in pain
6. Women who are not inpatients on the antenatal or postnatal ward

Date of first enrolment

26/10/2026

Date of final enrolment

31/03/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus

Hills Road

Cambridge

England

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

ROR

<https://ror.org/04v54gj93>

Funder(s)**Funder type****Funder Name**

Obstetric Anaesthetists' Association

Alternative Name(s)

The Obstetric Anaesthetists' Association (OAA), The OAA, The Obstetric Anaesthetists' Association, OAA

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available