ISRCTN11335900 https://doi.org/10.1186/ISRCTN11335900

# Understanding pain and discomfort in preterm babies using artificial intelligence

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| **Submission date**<br>20/06/2022 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>19/07/2022 | **Overall study status**<br>Completed | |
| **Last Edited**<br>24/08/2022 | **Condition category**<br>Neonatal Diseases | |

## Plain English summary of protocol

Background and study aims
This study aims to explore whether a machine learning tool can better identfy whether babies born before their due date (preterm) who are being looked after in neonatal intensive care units are comfortable or not.

Who can participate?
Babies born at least 4 weeks before their due date (born before 36 weeks gestation) and who are medically stable with consent from their parents.

What does the study involve?
No changes to routine care are involved. Participating babies will undergo video and sound recordings during their normal neonatal care, and computer ratings are compared to the clinical team's assessment of whether the baby was comfortable or not. Machine learning will be used to develop the best algorithm to identify baby discomfort that could be used in the future to alert staff and parents that the baby is uncomfortable.

What are the possible benefits and risks of participating?
Participants will not gain from taking part. There are no risks expected as the researchers are only video recording infants during standard care.

Where is the study run from
Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2021 to August 2023

Who is funding the study?
The Lerverhulme Trust as part of the Newcastle University doctoral training programme in behaviour informatics (UK)

Who is the main contact?
Dr Janet Berrington, janet.berrington1@nhs.net

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Janet Berrington

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
299441

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IRAS 299441, CPMS 53578

# Study information

### Scientific Title
Preterm Enhanced Automated Capture Of Comfort Knowledge: the Peacock study

### Acronym
PEACOCK

### Study objectives
Current observational informatics using state-of-the-art machine learning can better understand whether a newborn baby in an intensive care setting is comfortable or not.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Observational case series

## Primary study design
Observational

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Preterm infant discomfort during intensive care

## Interventions
The study uses computer learning to evaluate a video of the baby during routine procedures and learns as more cases are observed.

No changes to routine care are involved. Participating babies will have video and sound recordings during their normal neonatal care, and computer ratings are compared to the clinical teams' assessment of whether the baby was comfortable or not. Machine learning will be used to develop the best algorithm to identify baby discomfort that could be used in the future to alert staff and parents that the baby is uncomfortable.

## Intervention Type
Other

## Primary outcome(s)
How well the final learning model performs, assessed using machine learning metrics (confusion matrix, accuracy, precision, recall/sensitivity, F1 score, specificity and area under the curve) at the time of the video recording

## Key secondary outcome(s))
1. What signal or mixture of signals is most informative of preterm babies' state (face, body, sound and physiological data) at the time of the video
2. What algorithms are best suited for each data stream and why
3. Which methods are best for combining different data streams to make the most accurate estimation of preterm babies' comfort levels
4. Are any of these factors different for some babies e.g. the most immature, those with ventilator devices on their faces
5. Can these models detect prolonged pain (e.g., chronic pain post-surgery), can they distinguish this from acute procedural pain
6. What medical and contextual factors affect behavioural responses to pain
7. How many recordings are required to achieve the best model performance

All will be measured at the time of the video recording and assessed using performance metrics for machine learning outlined in the primary outcome measure

## Completion date
01/08/2023

# Eligibility

### Key inclusion criteria
1. Born at <36 weeks gestation
2. Medically stable
3. Signed parental consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex
All

### Key exclusion criteria
1. Infants with significant brain, spine or facial congenital abnormality
2. Parents unwilling to provide consent
3. Infants with postmenstrual age >36 weeks

### Date of first enrolment
01/08/2022

### Date of final enrolment
31/07/2023

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**The Royal Victoria Infirmary**
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

# Sponsor information

**Organisation**
Newcastle upon Tyne Hospitals NHS Foundation Trust

**ROR**
https://ror.org/05p40t847

# Funder(s)

**Funder type**
Charity

**Funder Name**
Leverhulme Trust

**Alternative Name(s)**
The Leverhulme Trust

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The researchers do not anticipate making data available routinely as it is complex video and audio and would breach patient confidentiality.

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |