ISRCTN22520786 https://doi.org/10.1186/ISRCTN22520786

Wireless assessment of aEEG Study

Submission date
03/11/2025

Recruitment status
Recruiting

Registration date
18/11/2025

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Pregnancy and Childbirth

[ ] 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
The research team is carrying out a trial using a new compact, non-invasive, wireless, pain-free brain activity monitoring system called Clic EEG. The aim is to see whether Clic EEG would facilitate brain activity monitoring on babies requiring cerebral function monitoring (CFM). CFM is used to monitor the brain activity of babies by acquiring brain signals through fine needles placed on the baby's scalp, transmitted via wires to the monitoring system and converting them to a trace called an amplitude-integrated electroencephalogram (aEEG). Doctors use the aEEG trace to help diagnose seizures and to monitor brain activity. With the Clic EEG, the research team will acquire brain activity signals comparable to the usual CFM monitor.

Clic EEG has previously been studied in volunteers aged above 4 years and brain activity signals have been collected for up to 3 days. Clic EEG did not cause any adverse effects on the participants. The Clic EEG gently sticks to the head using standard medical tape, a material already commonly and safely used in medical practice.

The research team will keep the Clic EEG on the scalp for a minimum of 1 hour and up to 72 hours depending on the duration the CFM is needed for the baby. Once the monitoring is complete, the research team will carefully remove the device and download the data for analysis. They will also download the data from the standard CFM monitor that is being used by the doctor to monitor the baby's brain activity. This is so that they can compare the brain activity traces of the Clic EEG to the traces from the standard CFM monitor and see if they are similar.

In addition, the research team will approach the parents/caregivers of infants enrolled in the study, as well as staff caring for them, and invite them for online interviews to explore their experience of the Clic EEG device.

Who can participate?
As part of this research study, the team will include babies who have been admitted to the neonatal intensive care unit (NICU) as well as babies being cared for on the postnatal ward. In particular, the team would like to find out whether the use of the Clic EEG device enables babies to remain with their caregivers on the postnatal ward, thereby avoiding a potentially unnecessary admission to the NICU and the associated separation of the baby from their caregiver.

What does the study involve?
For babies who have already been admitted to NICU for brain wave monitoring using CFM, the team would also apply the Clic EEG on the baby's scalp to allow collection and review of both sets of data from the CFM and Clic EEG. This will be for a minimum of 1 hour and up to 12 hours depending on the duration of CFM that is needed for the baby.

For babies who are being cared for on central delivery suite or the postnatal ward, the team will apply both the CFM (via three stick-on electrodes to the baby's head) and Clic EEG. This will be for a minimum of 1 hour and a maximum of 6 hours.
Once the monitoring is complete, the research team will carefully remove the device and download the data onto a secure computer for analysis. They will also simultaneously acquire brain activity signals using the standard CFM monitor to check whether the Clic EEG gives brain activity traces similar to the standard CFM monitor.

For the interviews, these will be performed when the caregiver and their baby have been discharged home from hospital. The research team will discuss and arrange a time and date for the interview within three weeks of discharge. This will be held online and should last no longer than one hour. The interview will be recorded and transcribed in real-time.

What are the possible benefits and risks of taking part?
There are no direct benefits to the caregiver or their baby. The team hopes that the information collected from this study will enable improvements to the Clic EEG, so that in the future it can be used for monitoring brain activity remotely in babies who do not need admission to the neonatal unit and can be cared for closer to their mothers.

For babies already admitted to NICU for CFM, the team does not envisage any additional risks or disadvantages to taking part. The baby will already be in the neonatal unit receiving the standard care and monitoring. The CFM aEEG trace will be reviewed by the baby's direct clinical care team and will, as per usual standard clinical care, be used to inform the baby's management /care. The Clic EEG device is being used for purely research purposes; it will not be reviewed in real-time, and no medical management decision will be made based on the Clic EEG trace.

For those babies being cared for on the central delivery suite or the postnatal ward, the baby would need to be connected to extra wires for up to 6 hours. The cables from the CFM may detach or slip during routine activities such as feeding and bonding. The application of standard CFM electrodes may upset the baby during application; however, they do not cause any pain or harm. The baby will have three stick-on electrodes and the stick-on sensor from the Clic EEG. However, the Clic EEG will be wireless.

For both groups, the baby's scalp will be carefully monitored by the nursing and medical team caring for them to ensure no injury occurs as a result of the Clic EEG. If any skin reactions, skin injury or possible discomfort related to the Clic EEG device are noted by staff, the device will be removed, and a member of the medical team will review the baby's skin. Following medical review, a decision will be made by the team regarding re-attachment or discontinuation of monitoring by the Clic EEG device.

The interviews will require individuals to recall memories and experiences during their baby's admission to the neonatal intensive care unit or postnatal ward. This may cause upset or discussion of difficult memories. However, individuals can opt out at any point during the process.

Where is the study being run from?
This study is being run from a single hospital site: St Michael's Hospital, Bristol. Babies who take part in the study will be cared for on one of the central delivery suites, postnatal wards or the neonatal intensive care unit.

When is the study starting and how long is it expected to run for?
September 2025 to February 2026.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) via the 'Invention for Innovation (i4i)' programme, UK.

Who is the main study contact
Dr Ela Chakkarapani, Ela.Chakkarapani@bristol.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Ela Chakkarapani

Contact details
University of Bristol, 3.08, Canynge Hall, 39 Whatley Road
Bristol
United Kingdom
BS8 2PS
+44 0117 342 5325
Ela.Chakkarapani@bristol.ac.uk

Additional identifiers

NIHR Invention for Innovation (i4i) programme grant reference number
44164

Central Portfolio Management System (CPMS)
68720

National Institute for Health and Care Research (NIHR)
209026

Integrated Research Application System (IRAS)
358058

Study information

Scientific Title
Optimising remote aEEG monitoring in newborns with acquired brain injuries

Acronym
BabyWAvES

Study objectives
Primary objective:
1. To explore the feasibility of acquiring EEG data using Clic EEG on newborn babies in the NICU environment and to evaluate the comparability of data between Clic EEG and standard CFM.

Secondary objectives:
1. To explore the feasibility of acquiring EEG data using Clic EEG on newborn babies when they stay with their parents in the delivery room or postnatal ward.
2. To compare the quality of aEEG data acquired by Clic EEG to standard CFM in a neonatal patient population who require CFM as part of standard care on the NICU.
3. To compare the quality of aEEG or EEG data acquired by Clic EEG with standard CFM on a healthy neonatal patient population on the delivery suite or postnatal ward.
4. To establish the acceptability of using Clic EEG through qualitative interviews with staff and parents of enrolled infants

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/09/2025, West Midlands- South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 02071048115; southbirmingham.rec@hra.nhs.uk), ref: 25/WM/0161

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Specialty: Children, Primary sub-specialty: Neonatal; Health Category: Neurological

Interventions

This is a feasibility and pilot study with qualitative interviews.

This is a single-centre clinical investigation of a medical device trial. Following informed consent, participants will be enrolled from the NICU, delivery suite, and postnatal wards. We aim to recruit up to 15 babies who are already receiving aEEG monitoring via CFM from the neonatal intensive care unit and up to 15 healthy babies being cared for in the delivery suite or postnatal wards. Recruitment of both groups will occur concurrently.

All babies admitted to the NICU for CFM, and without significant scalp swelling or injuries to the scalp, are eligible for inclusion. Parents will be approached for written informed consent by members of the research team and the direct clinical care team on the delegation log. After consenting, the baby will have the Clic EEG placed on their scalp close to the standard CFM electrodes. Recording will be for a minimum of 1 hour and for a maximum of 12 hours.

The Clic EEG has two EEG electrodes on its interface, and the interface sticks on to the scalp, similar to the stick-on hydrogel electrodes used in clinical practice. We will use the Clic EEG, alongside the standard needle electrodes used for CFM in routine clinical practice, on newborn infants requiring brain activity monitoring in the NICU. Needle electrodes are used routinely with CFM in the NICU to obtain high quality EEG data and eliminate the risk of high impedance due to reduced contact between the sensors and the scalp, introducing noise into the EEG data. As in usual practice with stick-on electrodes, any changes on the scalp surface around the Clic EEG site will be monitored regularly. For infants receiving single-channel CFM monitoring, we will place the Clic EEG sensor between the needle electrodes. For infants receiving two-channel aEEG recording using the CFM monitoring, one Clic EEG interface will be placed alongside the two needle electrodes on each side of the head.

In the healthy baby cohort, to test the feasibility of remote monitoring using Clic EEG, we will acquire a single-channel aEEG recording using the Clic EEG and standard CFM simultaneously. We will use stick-on or cup electrodes with the standard CFM. Data acquisition will last for a minimum of 1 hour and up to 6 hours.

The two aEEG signal traces, from Clic EEG and CFM, will then be compared in several domains as described below. Study investigators will be able to score the traces from both devices visually and score objectively the minimum and maximum amplitude of the trace. Further, we will use the open access computational analysis server, Babcloud, to objectively score up to 60 minutes duration of aEEG traces from both monitors and check the comparability of scores from both monitors.

Data analysis:

A previously developed algorithm that converts EEG data collected by Clic EEG into aEEG data will be used.

'Noisy signal' quantification: study investigators will review and compare signal quality of EEG and aEEG from Clic EEG and CFM. Determination of signal quality will be based on the degree of signal impedance, with high impedance being >10 kilohms. The proportion of recordings with high impedance will be quantified as a noisy signal.

Qualitative scoring: 30 to 60 minutes of comparable time-locked noise-free segments of aEEG trace from both Clic EEG and CFM will be scored. The pattern will be scored based on voltage criteria and pattern criteria. Voltage criteria for aEEG assessment are as per published thresholds as below:

1) Normal aEEG trace: lower margin of trace > 5microvolts and upper margin of trace > 10 microvolts

2) Moderately abnormal aEEG trace: lower margin of trace ≤ 5microvolts and upper margin of trace > 10 microvolts

3) Severely abnormal aEEG trace: lower margin of trace < 5 microvolts and upper margin of trace < 10 microvolts

aEEG pattern classification is as per published patterns and will include 'continuous normal voltage'; 'discontinuous voltage'; 'burst suppression'; 'low voltage', and 'flat trace'.

Quantitative scoring: an automated and algorithmic review of aEEG signals from Clic EEG and CFM will be performed using the 'brain state of the newborn' (BSN). Anonymised aEEG data will be fed into the open-source machine learning software, BabaCloud. This will provide an objective score of the captured signals and delete the data after analysis. Scores from Clic EEG and CFM will then be compared.

Qualitative interviews: staff and parents will be asked to participate in qualitative interviews, performed online, to assess the acceptability of the Clic EEG system in clinical practice, provide feedback on device usability, and evaluate the impact of remote monitoring on parents, clinical services, and health care staff.

Intervention Type
Drug/Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Clic EEG

Primary outcome(s)
1. Amplitude-integrated encephalogram pattern measured using comparison of patterns recorded by Clic EEG and standard CFM at up to 72 hours (normal duration of standard CFM) for participants in NICU, and up to 6 hours for healthy participants in delivery suite or the postnatal ward

-

Key secondary outcome(s))
1. Noisy signal quantification is measured by review and comparison of EEG and aEEG signal quality from Clic EEG and CFM, with determination based on impedance greater than 10 kilohms and proportion of recordings with high impedance quantified at one time point
2. Qualitative scoring of aEEG trace is measured by scoring 30 to 60 minutes of comparable time-locked noise-free segments from Clic EEG and CFM based on voltage and pattern criteria at one time point
3. Quantitative scoring of aEEG signals is measured by automated algorithmic review using ‘brain state of the newborn’ (BSN) via BabaCloud9, providing objective score comparison between Clic EEG and CFM at one time point
4. Acceptability of the Clic EEG system is measured by online or in-person qualitative interviews

with staff and parents to assess usability and impact of remote monitoring at one time point, up to 8 weeks after giving birth or looking after the participants

Completion date
16/02/2027

Eligibility

Key inclusion criteria
Clic EEG:
1. Infants with gestational age >= 25 weeks undergoing aEEG monitoring using standard CFM for clinical reasons, or
2. Healthy term or near-term born infants with gestational age >= 36 weeks being cared for in the delivery suite or postnatal ward

Qualitative interviews
1. Parents of infants enrolled in the study
2. Staff member (midwife or neonatal staff) looking after infants enrolled in the study

Participant type(s)
Patient

Healthy volunteers allowed
Yes

Age group
Neonate

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Infants who have significant scalp swelling (e.g. subgaleal haemorrhage) or scalp injury (e.g. cuts or breaks in the skin).
2. known skin allergies to adhesives
3. open wounds, skin infections, burns or any other skin conditions at the application sites
4. Infants taking part in other research studies where it is felt that taking part in more than one study could affect the study results.

Date of first enrolment
15/09/2025

Date of final enrolment
16/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Michael's Hospital
Southwell Street
Bristol
England
BS2 8EG

Sponsor information

Organisation
University Hospitals Bristol and Weston NHS Foundation Trust

ROR
https://ror.org/03jzzxg14

Funder(s)

Funder type
Government

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

The database system will be designed, and the data will be collected and retained, in accordance with the UK Data Protection Act 2018 and UK General Data Protection Regulation (GDPR) 2016. Study staff will ensure that the participants' anonymity is maintained through the protective and secure handling and storage of patient information in accordance with ethics approval. All documents will be stored securely and only accessible by study staff and authorised personnel.

All quantitative and qualitative data will be stored in a secure University of Bristol server. The CFM data will be downloaded using the NHS pathway and will be stored on an encrypted hard drive. The Clic EEG data will be downloaded using a docking station and stored in the secure University of Bristol server. Access to the server is only available to the research group. Any anonymised data fed into the Babacloud will be deleted by the Babacloud after producing the BSN score.

The chief investigator, investigators from the University of Exeter, and the researchers working on the project will access the final dataset. We will deposit anonymised data on the University of Bristol data repository. This will generate an openly accessible DOI link, which will be published in the publications and the NIHR report, that can be accessed by other researchers.

Study documents (paper and electronic) will be retained in a secure location during and after the study has finished. All essential documents, including patient records and other source documents, will be retained for a period of 25 years following the end of the study. Where study-related information is documented in the hard copy medical records, those records will be identified by a 'Do not destroy before dd/mm/yyyy' label where the date is 25 years after the last patient last visit. Where electronic records are in use, the trust policy will be followed.

IPD sharing plan summary

Stored in publicly available repository

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