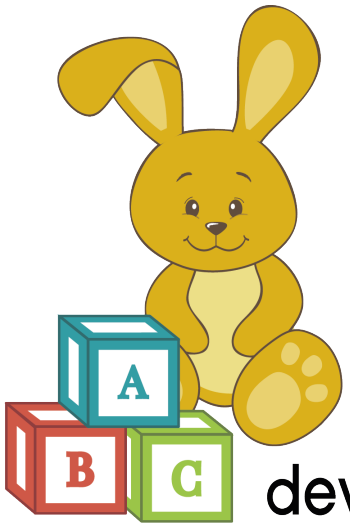

Breathing and brain development

Breathing and brain development in premature infants

Parent Information Leaflet

UNIVERSITY OF OXFORD

DEPARTMENT OF PAEDIATRICS
Medical Sciences Division

Oxford University Hospitals NHS
NHS Foundation Trust

We would like to invite you and your child to take part in a research study. Please ask us if anything is unclear. We welcome the opportunity to meet with you to discuss the study further.

What is the purpose of this study?
Pauses in breathing, known as apnoea, regularly occur in babies who are born prematurely. We want to understand the relationship between apnoea and brain development in premature infants and investigate whether apnoea effects premature-born infants' development at two years of age. We will also explore how other factors, such as gestational age at birth and certain medical conditions, may affect brain development.

We will assess brain development by looking at your baby's brain activity at rest and in response to light, sound and touch once a week while they are in the Newborn Care Unit. We will measure their development at two years of age using a standard assessment.

You are being asked if you would like to take part because your baby was born between 28 – 32 weeks' gestation. If you take part in this study, you will be asked to sign a consent form.

This study is voluntary. Your decision whether or not to take part will not affect the care and treatment of your baby. If you would like to take part, you can also change your mind and withdraw your baby from the study at any time by telling the research team. You do not have to give a reason. You will be asked if we can use the data that has already been collected.

What is involved in the study?
Recording vital signs
Your baby's 'vital signs' (which include breathing rate, heart rate and oxygen saturation levels) are routinely monitored continuously as part of their clinical care. We will electronically record this data from the point your baby is enrolled in the study, up until when your baby is discharged.

Measuring brain activity and responses to stimuli
Once a week up until your baby is discharged, we will record your baby's:
- brain activity using a technique called **Electroencephalography (EEG)**, which involves gently placing sensors (small metal discs) on the head using a paste. This is a safe technique routinely used in the neonatal unit for clinical reasons.
- muscle activity using a technique called **Electromyography (EMG)** where small slightly sticky sensors are placed on the skin.

Each recording session will last approximately 3 hours, including set-up. During this time, we will record responses to **sensory stimuli** (visual, auditory and touch). If your baby needs a blood test, we will also record how they respond to this test. This will only be done if your baby needs a blood test clinically; no clinical procedures will be carried out solely for research purposes. We will also record the response to a control procedure at the same time as the blood test (this does not pierce the skin). We will **video** your baby's face during this blood test and the control procedure. You are welcome to stay with your baby throughout the recording and the recording can be paused or stopped at any point if required for your baby's comfort.

Two-year follow-up

- At about 2 years of age we would like to assess your child's development using the **Bayley Scale of Infant Development (BSID)**.
- This is a standardised measure to assess cognitive, language and motor development.
- Your child may have this assessment as part of their standard clinical follow-up. If this is the case, we will find this score from their medical notes. If not, we will contact you to find a suitable time to carry out this assessment, which takes about 90 minutes to complete.

Participation in future research

We may wish to follow-up your child for longer than 2 years, as part of a separate study. We will ask you if you are happy to provide consent specifically for us to contact you in the future about other studies. This is completely optional. If you agree to this you may be contacted by our research team about other research studies you may be interested in which are directly linked to this study. Your contact details will be stored in a locked filing cabinet up until your child is approximately 16 years old. You can remove your contact details from this register at any time by contacting us (contact details are on the last page of this leaflet).

What other information will be collected about my baby?

We will collect clinical information from your baby's medical notes. This will include details about your baby's delivery, diagnoses, medical treatment and progress while they are in the Newborn Care Unit and up until their two-year follow-up appointment.

What are the known risks of the study?

All the techniques, including EEG and EMG, do not present a risk to your child.

What are the possible benefits of taking part?

There are no direct benefits for your baby in taking part; this study will help us improve the quality of care for premature babies in the future by improving our understanding of breathing patterns and their effect on brain development. Data collected are for research, not medical diagnosis, and are not routinely looked at by a doctor.

What will happen to the results?

The results will be analysed and published in a journal. All publications of the results will be made available on our website: https://neuroimaging.paediatrics.ox.ac.uk/. The findings may also be used for teaching or academic research presentations.

Thank you for reading this information leaflet. We really appreciate you taking the time to consider this research study. Further information can be found overleaf.

Photo shows example of an EEG recording

Further information

Who has reviewed the study?

All research that involves NHS patients has to be approved by a Research Ethics Committee. Approval means that the Committee is satisfied that yours and your child's rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision about whether to take part. The London - Riverside Research Ethics Committee has approved this study.

What will happen with the data?

All information and videos that are collected about/of your baby during the course of the research will be kept strictly confidential. Each baby will be allocated a study number so that all information is de-identified. De-identified data may be shared with other researchers to address other research questions. We may ask you if you are happy for us to use images recorded by video and/or photograph, for teaching, publicity and/or scientific journals, but this is optional.

Data protection regulation requires that we state the legal basis for processing information. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will keep identifiable information about you and your infant for at least 5 years after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for a minimum of 21 years after the end of the study. If you have provided additional consent for your details to be held regarding future research studies, we will retain your contact details (and a copy of your consent form) until your child has reached approximately 16 years of age.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to this information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to this personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/. You can find out more about how we use this information using the contact details at the end of this leaflet.

Responsible members of the University of Oxford or the Oxford University Hospitals NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations.

Who is funding the research?

This study has been funded by The Wellcome Trust and The Royal Society through a Sir Henry Dale Fellowship awarded to the Chief Investigator (Dr Caroline Hartley).

Comments or concerns during the study

The University of Oxford has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which your child is provided. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Caroline Hartley (caroline.hartley@paediatrics.ox.ac.uk, 01865 234537) or the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or ctrg@admin.ox.ac.uk.

Contact for further information

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