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INFORMATION SHEET FOR: SENSE project
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SENSE Project - Information Sheet for Parents/Caregivers

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. A member of the research team can be contacted if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

This research project looks at sensory processing in full-term and pre-term infants and children. It will take place at the BabyLab at Birkbeck, University of London, and will be completed by 31st August 2028.

You have been chosen to participate in this study because you either have previously participated in the neonatal study at UCL/UCLH, or because you have indicated you have a child between 6 and 18 months old.

What is the study about?

Sensory experiences play a crucial role in your child's learning and development. A significant part of their learning comes from using their senses to gather and retain information. The brain undergoes significant changes during early life, especially in how it processes sensory information at different stages of development. The data we collect will be analysed to better understand how children respond to different sensory experiences, and how sensory processing develops over the early years of life.

What is involved in the study and how long will this take

If your child is between 6 and 12 months old, we will ask you to complete some online questionnaires at 6 and/or 12 months (subset of children, depending on age). This will take around 30 minutes. We will then invite you to the lab at 18 and 30 months.

At 18 and 30 months, we invite all families for an in-person visit, which will take around 3-4 hours (18 months) or 4-5 hours (30 months). During these visits, we will ask your child to watch some videos and play some games to assess your child's responses to touch and sound. We will use child-friendly techniques to measure brain activity (i.e. using EEG), physiological responses (i.e. heart rate, skin conductance ('sweat'), body movement and muscle movement), attention (i.e. using eye-tracking) and behaviour (i.e. using video recordings). We will also ask you some questions and give you some questionnaires to complete online or on paper. We may also ask you if you would be happy for your child to wear a wearable device at home during the week prior to or after your visit.

We understand the assessment is quite lengthy. We will accommodate your needs during in-person visits, by ensuring you and your child have sufficient breaks, and refreshments and snacks will be provided. Additionally, there will be time for a lunch break, and we can work around your child's nap time. We understand that flexibility is important, so if you would prefer to divide the assessments into two half-day sessions. We are happy to adjust based on what works best for your child.

We also understand that young children can be unpredictable. If your child is not in the mood to participate in some assessments, for whatever reason, that's completely fine. We never force participation. You can stop any assessment, skip any questions or withdraw from the study at any time, without needing to provide a reason.

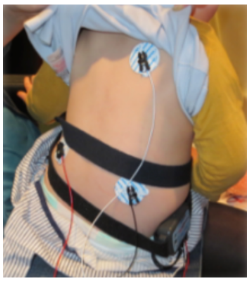
To reduce any stress on your child, we will regularly remind you that breaks are available during tasks. Our assessments are designed to be enjoyable, and we want to ensure that your child remains comfortable throughout the process.

Descriptions of each measurement

Brain activity: EEG
Electroencephalography (EEG) is a safe and non-invasive technique to record brain responses to stimulation or brain activity at rest. A cap will be fitted in the child's head. Your child will be sitting on a chair while watching images, listening to sounds and receiving some gentle taps to their hand.

Eye-tracking (ET)
During the EEG, we will also collect eye-tracking data. This will allow us to monitor your child's visual attention and tells us where your child is attending on the screen. The eye-tracker looks like a normal computer screen with the difference that it has incorporated a few light-emitting diodes. These emit light in a similar way to the light emitted by a camera in order to prevent the "red eyes", when using flash. The intensity of the light used is very small and is therefore harmless.

Physiology (Heart rate, skin conductance, movement)
We will measure your child's heart rate, skin conductance ('sweat'), body movement and muscle movement. The child will be able to move around freely whilst wearing this equipment.



To measure heart rate and skin conductance, we will put sensors ('stickers') on the child's chest or back. To measures muscle movement, two sensors are placed on the child's lower arm. To these sensors we will connect some leads and a little transmitter which we will attach to your child using an elastic belt.

An accelerometer will be placed around your child's ankle to measure their movement.

Tactile and auditory stimuli
We want to record your child's brain activity in response to touch and sound.

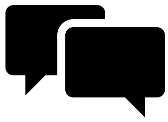
To measure their response to touch, we will attach a round stimulator to the back of your child's hand with some stretchy self-adhesive bandage. A little tap or vibration will be delivered at pre-set intervals and intensities. These taps won't be painful and will feel like a gentle touch.

To measure their response to sound, we use a speaker placed near your child. It will play different tones at specific intervals. These will occur either alone or in combination with the taps. All sound levels will be within safe limits for toddlers.

We will also use this to measure your child's palmer grasp by putting a little handle/ball in front of the child and encouraging them to grab the object, which has a pressure sensor inside.

Observations
Your child will be involved in various play tasks. Sometimes this may be a bit more structured, where we give your child little tasks or ask them some questions. Sometimes it may be more explorative. We ask you to be there and encourage your child to interact, but not to interfere. There is no right or wrong and we simply want to understand how your child responds or how they solve a problem. Some of these tasks will involve toys or a tablet.

Questionnaires and Interviews
We will ask you to complete questionnaires about your child's behaviour when they are 18 and 30 months old (and at 6 and/or 12 months for some participants). This will help us understand how your child is developing and how they respond/behave outside of the lab. You can complete these questionaries online on a phone, tablet or computer. If you rather receive paper questionnaires, please ask and we can provide these for you.



We also may do some interviews with you to get more detailed insight into your child's development. We try to fit these interviews in whilst your child is playing some games with another researcher and you can remain in the same room.

Actigraph
We will ask you if you are happy to have your child wear an actigraph at home the week before or after your visit to the lab. An actigraph is a small wearable device that measures activity patterns. It is often used in sleep research to understand sleep patterns better, which is what we are interested in.

We would like your child to wear the actigraph for a full week, taking it off during periods of bathing/washing/etc. You can fit the actigraph using the soft Velcro strap that you can close and adjust yourself and have it as tight as you/your child feels comfortable with. It is very lightweight and your child will likely forget they are wearing it. We will send it to you and you can bring it back when visiting us or we provide you with an envelope to return it.

Despite numerous quality assurance and device safety approvals, because a child's skin is sensitive it could be that their skin becomes irritated or a rash develops. The device can be worn over some clothes, e.g. socks, to reduce any irritation. Should you notice any irritation or discomfort, remove the activity monitor immediately and contact us researchers (see our contact details at the end of the information sheet).

What about expenses?

We will reimburse you for travel costs and lunch where applicable. We will also provide you with snacks during your visits and you will receive a t-shirt for your child as a thank you for your participation. You will also receive a £10 voucher at the end of the 18 month visit, and £20 at the end of the 30 month visit.

What are the possible benefits of taking part?

There are no direct benefits for your child as a result of taking part in this study. This study is designed to gather information that will help to develop better care for children in the future. Our goal is to make this study a positive and enjoyable experience for both you and your child. Based on feedback from past participants, we expect you will find it engaging and rewarding.

Are there possible side effects?

We do not expect any risks or side effects to arise from participation in this experiment. The testing procedures we employ are widely used with infants and children and are completely non-invasive. However, if you or your child want to stop at any time or not take part in certain aspects of the study, for any reason, just let us know.

Does my child have to take part?

No, it is up to you to decide whether or not your child will take part. If you do decide to allow your child to take part, you will be asked to sign a consent form. If you decide you do not want to take part in the study, we fully understand and assure you that this will have no effect on your child's normal care. Signing the consent form does not mean you have to take part in every part of the study and you can ask us to stop a task or the whole assessment at any time, for any reason.

How will the data be used and stored?

At the start of the study, your child will be assigned a unique ID number, which will securely link them to any personal or identifying information (e.g., name, email address, video material). Only the research team directly involved in the study will have access to personal information. Confidentiality will only be breached in the unlikely event that serious concerns about child protection arise.

Anonymised data from this study may also be (i) used to answer other scientific questions which arise in the future; (ii) shared with our collaborators and other researchers. We have a collaboration and data sharing agreement in place with our collaborators at UCL (Prof. Fabrizi) and UCLH (Dr. Meek). Any data transfers are conducted securely via encrypted USB memory stick or sftp.

All our staff has received GDPR training on keeping data safe. Any reports based on the collected data are always written in a way that no-one can identify you or your child.

In this study, we will be collecting what is known as 'special category data.' This refers to certain types of personal information that are considered more sensitive under data protection law. In this study, we will collect data on participants' ethnicity and health (e.g. details on pregnancy, birth, hospitalisation and interventions/support received by the child). This information is used to understand whether our sample is representative of the broader population. Also, it will help us gain a deeper insight into the potential impact of early life experiences between children born at different gestational ages (pre-term and full-term) on their development. Because this data is sensitive, we will take extra care to ensure it is protected and used appropriately. All data will be anonymised as described above and sensitive data will not be stored with your personal details. As with all our questionnaires, you are always free to not give a response to a question or to withdraw your data after taking part in the study, without having to give a reason

Your personal data will be securely stored at the Baby/ToddlerLab for at least 10 years, as we may receive funding for future follow-up studies and would like to inform you of these opportunities. You can request to break the link between the study data and personal details at any time.

At the end of the consent form, we ask you if you are interested in signing up to the Babylab database so we can inform you about other research at the Babylab that you might be interested in. This is optional. If you do not want to be included in the database, we will only contact you for any follow-up of the SENSE study, unless you let us know you prefer us not to contact you about the study again.

What will happen to the results of the project?

In the long term, this study will help us better understand sensory processes, how children perceive the world around them, in full-term and pre-term born children.

The results of this project will be written up for student projects/theses and results will be presented at conferences and published in international research journals. Results are typically presented in terms of groups of individuals. If any individual data are presented, the data will be totally anonymous, without any means of identifying the individuals involved.

Your child's involvement in the study will remain confidential except in the highly unlikely event that the researcher has a serious concern regarding a child protection issue.

Who is funding the research?

This study is funded by the Medical Research Council (www.mrc.ac.uk).

Who has reviewed the study?

The project has received ethical approval from the School of Science Research Ethics Committee, Birkbeck, University of London. If you have concerns about this study, please contact the School's Ethics Officer at: ethics@psychology.bbk.ac.uk

School Research Officer
School of Science, Department of Psychological Sciences
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You also have the right to submit a complaint to the Information Commissioner's Office https://ico.org.uk/

For information about Birkbeck's data protection policy please visit:
http://www.bbk.ac.uk/about-us/policies/privacy#7

Contact information

This is a project conducted by Dr. Tessel Bazelmans (tessel.bazelmans@bbk.ac.uk) and Ms. Nicole Gregorio (n.gregorio@ucl.ac.uk) and supervised by Prof. Emily Jones (primary investigator - ubejon01@mail.bbk.ac.uk).

Thank you for participating in this study!