BEOND

Behaviour and Emotional Outcomes in Neurodevelopmental Disorders

Information Pack

Thank you for your interest in the BEOND study.

If you have any questions or concerns please feel free to get in touch with us by emailing k.a.wade@bham.ac.uk

Behavioural and Emotional Outcomes in individuals with Neurodevelopmental Disorders (BEOND)

Study Directors: Dr Caroline Richards, Dr Hayley Crawford, Dr Jane Waite & Dr Jo Moss

Participant Information Sheet

Thank you for your interest in the Behavioural and Emotional Outcomes in Neurodevelopmental Disorders study (BEOND). Please make sure you read through the following information carefully to decide whether or not you wish to participate in this study.

BEOND is a UK based study hosted by the University of Birmingham. BEOND conforms to ethics protocols within the UK and has received approval from a UK Research Ethics Committee.

Background

The BEOND study is a large-scale survey being run by the Cerebra Network for Neurodevelopmental Disorders (www.cerebranetwork.com). We know that genetic syndromes, neurodevelopmental disorders, and intellectual disabilities can affect people's lives in lots of different ways. As a research group we are particularly interested in the changes in behaviour, emotion, physical and mental health that people might experience, and the impact that these can have on families. To better understand these changes we have designed this survey. Our hope is that in collecting a range of data from lots of people with different syndromes at different points in their lives, we can develop a better understanding of common areas of difficulty, as well as challenges that might be specific to certain individuals or groups within this broad community. Through this work we may be able to offer better ideas for how to support people with genetic syndromes, neurodevelopmental disorders, and intellectual disabilities in the future.

Who can take part

You can take part if you are the parent/guardian/carer of someone who meets these criteria:

1. Any of the following diagnostic categories:
    a. *Those with a rare genetic syndrome that is associated with intellectual disability*
    b. *Those with autism*
    c. *Those with intellectual disability without a known genetic syndrome*
    d. *Typically developing children without any known neurodevelopmental disorder, intellectual disability, or genetic syndrome*
2. The person you care for is at least one year old

All of the questionnaires are 'informant based'; this means they are designed to be filled out by someone else and cannot be self-completed by the person with the diagnosis.
All of the questionnaires are in English, and we are not able to provide translated versions at this time.

What will participation involve

This study takes the form of a survey. There are a number of different questions, most of the questions are multiple choice or offer a rating scale for you to use. We expect the questionnaire to take approximately 60 minutes to complete depending on your answers. If you need to take a break you can come back to this at a later time, but we do ask that you complete the questions in the order in which they are presented in the questionnaire pack.

The study may involve follow up phone interviews depending on how you respond to the questions asked during the survey. A member of the research team may contact you at a time suited to you to ask you some further questions about the person you care for. The phone interviews can last up to 90 minutes, though some may be slightly shorter or longer depending on your responses. There is a form at the end of the pack to let us know what times are best to contact you.

What if I can't complete the survey online?

If you would rather complete the survey on paper, then a hard copy can be sent to you. If you contact Dr Kelly Wade (k.a.wade@bham.ac.uk) then we can arrange for the survey to be sent to you via post. The survey will be sent with a prepaid return envelope for you to return it to us in your own time at no cost to yourself.

What will you ask me?

There are a range of different questions on topics covering your child/person you care for's diagnosis, health, behaviour, and mood. There are also some questions about your own wellbeing and mental health, and some questions about your family situation. We appreciate that some of these questions touch on quite sensitive topics, and that they might not be things that you often talk about with others. We invite any participants or family members to contact the research team if any of the questions make you feel uncomfortable or upset.

Further contact

We ask that you supply us with your contact details so that we can get in touch about your survey responses if we need to, for example, we might need to clarify your answers, talk to you in more detail about something that you have shared, or invite you to an additional phone interview. The BEOND study is a longitudinal study which means we intend to look at changes over time – in total the study will run for twenty years with participants being invited to complete the survey every two years. We will get back in touch with you approximately 24 months after you complete the survey to invite you to complete it again so that we can see how your responses change over time. While we hope that some participants will continue to participate for the full duration of the study, you are under absolutely no obligation to do so.

What do I get for participating?

We are hugely appreciative of the time and effort given by all of our participants, and we hope that the data we collect can be helpful to you on an individual level. Once you have completed the survey we would like to send you a personalised feedback report detailing the results of your child/the person you care for, including a summary of what these results mean and how their results compare to other participants of a similar age or those with a comparable diagnosis.

If you do not wish to receive a feedback report then please select 'no' on clause nine in section one of the consent form.
In addition to the feedback report, all participants who complete the survey will be entered into a prize draw to win Amazon/Love2Shop vouchers (or equivalent).*

Diagnosis Confirmation
If your child / the person you care for has a diagnosis of a genetic syndrome and/or neurodevelopmental disorder, then it would be helpful if you could provide some confirmation of their diagnoses. You may choose to send us a physical or digital copy of any medical letter or document with details of prior diagnostic assessments - we will send you a secure link where you can do this. You may also provide us with the contact details for your child/the person you care for's GP so we can confirm the details of any diagnoses with them.

If we are unable to confirm a genetic syndrome diagnosis via existing test results, we may send you a kit to collect a sample of your child/person you care for's saliva. After you return the sample to us, we can carry out genome sequencing which will allow us to confirm the syndrome diagnosis and the specific genetic mutation which caused the syndrome. All of the saliva samples we collect will be stored and processed by genetic laboratories based at the University of Birmingham, headed by Dr Andrew Beggs. The team conducting the genetic tests will not be provided with your child/the person you care for's personal information and we will not use the saliva sample to identify your child/the person you care for or. We regret that we are unable to share genetic test results in feedback reports.

Providing any confirmation of diagnosis is completely optional and choosing to opt out of this element of the study will not affect your ability to participate in the survey.

What happens to my data and that of the person I care for?
We take data security very seriously. All data from this survey will be stored on secure servers housed at the University of Birmingham. This data can be accessed by members of the Cerebra Network research teams via a system called REDCap.
Our **General Data Protection Regulation (GDPR) privacy statement** is important to help you make an informed decision about how the information you provide to us is being used. Please ensure you have read the GDPR statement before making a decision about participation.
Because BEOND is a longitudinal study we will need to keep your personal details for 24 months to allow us to invite you to participate in the follow up. If at that point we cannot contact you, or you decide not to participate in the follow up, then we will consider your participation as ended and remove your personal details from the BEOND study. Once your personal details are removed from the BEOND study the research team will no longer be able to trace the results of your assessments back to you or your child/the person you care for. You can request that your personal details be removed earlier than this by contacting any member of the study team (*see the section on 'withdrawal' below)*.

*Date of draw and prize details to be confirmed. One entry per participant conditional on a completed survey being submitted to the research team. The BEOND study team reserve the right to withhold payment to participants found to be submitting fabricated responses.

Confidentiality

As a research group we will publish our findings in scientific journals, as well as giving talks to other researchers, clinicians, and families. When we share our data, the results are given at a group level e.g. “Of the 100 participants, 55% were male” rather than talking about the results of any one specific person. This means no one will be able to identify you or your child/the person you care for from what we publish.

Following the study we would like to make the survey data available to other researchers so that they can learn more about genetic syndromes and neurodevelopmental disorders. The data will be completely anonymous, so it would only contain your survey answers but without details such as name, date of birth, or contact information for you or the person you care for. *If you would like to opt out of this dataset please select ‘no’ on clause eight in section one the consent form.*

Withdrawal

At all points during this study you retain the right to withdraw. That means that even after giving your consent, you may change your mind and decide you no longer wish to participate. You do not have to give a reason for this. All you need to do is contact the study team and inform them that you wish to withdraw, and your contact details will be removed from our database, and you will receive no further contact from our team. Any data you have provided us with will remain with the research team but in an anonymised form so it cannot be connected back to you or the person you care for.

Who can I talk to if I have any issues?

We hope that you find the BEOND survey fairly straightforward and that you find the feedback report helpful. However, if you have any questions, concerns, or worries about any aspect of the study you are welcome to get in touch with any of our study leads:

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Please read the GDPR privacy statement before continuing

GDPR Statement

Version 2, 05/09/2022

This page explains how we use information from participants and should be read in conjunction with the study information sheet (BEOND Participant Information Sheet, *v2, 08/09/2022*) before any decisions about participation are made. In this document, we use the term ***participant*** to **refer to the person with a neurodevelopmental disorder**.

What is participant data?

Participant data is a broad term used to refer to the information that the research team collects from study participants. In the BEOND study this information includes survey responses and medical information including saliva samples. When participant information recorded about your child/person you care for is joined with information that can show who they are (like their name or address) it is called **identifiable participant information**. It's important to all of us that this identifiable **participant information** is kept confidential to you, your child/person you care for and the people who need to know relevant bits of that information. There are special rules to keep confidential participant information safe and secure.

What sort of participant data will the research study use?

If you and the child/person you care for agree to take part in this study, the research team will collect participant information from questionnaires, and may collect patient information from your child/person you care for's GP and genetic information in the form of a saliva test or a medical letter you can share with us (sharing genetic information with us is optional). The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is called **research data.**

Why does the research study use information from participants?

We hope that this information will enable us to further understand the behaviours, skills and impairments associated with genetic syndromes including challenging behaviour, social functioning, mood, hyperactivity, sleep and health problems and the impact that these behaviours have on the family. The genetic information your child/person you care for provides will be used to identify genetic variation that might be important in understanding the causes and consequences of genetic syndromes. In the future we hope to follow up the progress of the people who take part in this study. However, participation in this study of will not mean that you are obliged to participate in further research with us in the future.

All research should only use the participant data that it really needs to do the research. We describe the specific aims of our study and participant information we will collect to help us reach these aims in the Participant Information Sheet (*v2, 08/09/2022*), However, if you have questions about the study that haven't been fully answered by the information sheet you are welcome to contact the study team.

How does research use participant data?

We intend to use the data we collect to answer the research questions laid out in the participant information sheet. Most of the research team will not need to know your name, the name of your child/person you care

for or any other information that could show who you are. In these cases, your name, the name of your child/person you care for and any identifiable information will be removed from the research data and replaced with a code number. This is called **coded data**, or the technical term is **pseudonymised data.** For example, your saliva test will be labelled with your child/person you care for's code number instead of their name. It can be matched up with the rest of the data relating to them by the code number. When there is no information that could show who you are, this is called **anonymous data.** Only a small number of the team will have access to your contact details, and they will only use it to contact you for the reasons laid out in the section called 'Future Contact' in the Participant Information Sheet (*v2. 08/09/2022).*

Where will my data go?

Information about data storage is detailed in the BEOND Participant Information Sheet (*v2. 08/09/2022).* Survey responses are held on secure servers housed at the University of Birmingham. Any saliva samples collected will be stored and processed by genetics laboratories at the University of Birmingham run by Dr Andrew Beggs. Participation in the online survey requires the transmission of data over the Internet which can never be guaranteed to be entirely secure. By taking part in this study the risk to your personal information is no greater than at any other time that you provide this information online (e.g. shopping, banking). Nevertheless, please participate in this research only if you are comfortable with this. The alternative to online participation is to fill out a hard copy of the questionnaires which we can post to you with a return envelope. Questionnaires completed in this way are manually input to the Redcap servers by research team members.

Information will be treated as strictly confidential and handled in accordance with the provisions of the General Data Protection Regulation, however in the unlikely event that any of your responses raise concerns about the safety or wellbeing of any person in your household, the decision may be taken to share information with relevant support services such as your GP or the local safeguarding team. We will always endeavour to speak to you first and will inform you of these kinds of decisions.

What are my choices about my participant data?

- You and your child/person you care for can stop being part of the research study at any time, without giving a reason, but the research team will keep the research data you and your child/the person you care for have already provided. You can find out more about your choices and right to withdraw by asking any questions you may have before you agree to take part in the study.
- On the consent form there are some clauses which are listed as 'optional' – these clauses include options about information that you can choose whether or not to share with us, as well as options about what you are happy for us to do with your information. For any optional clause you are free to select 'yes' or 'no' as you see fit without it affecting your participation in the survey. Please make sure you have read each option carefully before submitting the consent form.

What happens to my research data after the study?

Because BEOND is a longitudinal study we will need to keep your personal details for 24 months to allow us to contact you to invite you to participate in the follow up. If at that point we cannot contact you, or you request to no longer participate in BEOND, then we will remove your personal details from the BEOND study. Once your personal details are removed from the BEOND study the research team will no longer be able to trace the results of your assessments back to you.

The Cerebra Network Participant Database information sheet *(v2. 07/09/2022)* gives information about a database that we use to store the personal details of some participants who may wish to take part in other studies run by The Cerebra Network. Please read that sheet carefully in order to decide if you would like to join the participant database – we will only add your details to the database if you complete the consent form that is attached to the Cerebra Network Participant Database information sheet. Any information that

could show who you are, either as part of the BEOND study or as part of the participant database, will be held safely with strict limits on who can access it. Research data obtained from saliva samples collected during the BEOND study will be held indefinitely. We may use your samples in other studies associated with the Cerebra Network for Neurodevelopmental Disorders research team, including genetic testing.
You will be able to decide whether or not you want to make your research data available to any professionals or clinicians working with you and the person you care for should they wish to see it. This is optional and will not affect your participation in the current study. However, once your details like your name or telephone number have been removed, we will not be able to make your research data available and other researchers won't be able to contact you to ask you about future research. Your data will never be used to sell you anything.

Will the use of my data meet GDPR rules?
GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using participant data must follow UK laws and rules. Universities, NHS organisations and companies may use patient and/or participant data to do research to make health and care better. When we do research, we have to be able to prove that we need participant data for this research, and that we need to do the research to further understand the behaviours, skills and impairments associated with neurodevelopmental disorders and rare genetic syndromes. In legal terms this means that we are using participant data to complete a '**task in the public interest'**.
Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

What if I don't want my participant data used for research?
You have the choice to take part in this research study. If you choose not to take part, that is fine. You are also free to change your mind about participation at any point, as detailed in the 'Withdrawal' section of the BEOND Participant Information Sheet *(v2 08/09/22)*. You also have a separate choice about whether you want your data to be held on the Cerebra Network Participant Database.

Further information?
The University of Birmingham is the sponsor for this study based in the United Kingdom. They will be using information from you in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly.
The only people at the University of Birmingham who will have access to information that identifies you will be the immediate research team who will contact you about your participation in the research study and sometimes the sponsor / other regulatory organisations auditing the data collection process. You can find out more about how we use your information by visiting https://www.birmingham.ac.uk/privacy and/or by contacting our data protection manager.

Who can I contact if I have a complaint?
If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter, you can contact them by emailing dataprotection@contacts.bham.ac.uk. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) – information about the ICO and how to raise concerns can be found on their website https://ico.org.uk/.

BEOND

You can take part in the survey online now – just scan the QR code below or go to redcap.link/beond

If you would prefer to complete the survey on paper then we will happily send you a paper copy of the survey along with return envelopes at no cost to yourself*. You can request a paper copy by:

- Filling out the request form at www.cerebranetwork.com/beond
- Emailing Dr Kelly Wade at k.a.wade@bham.ac.uk
- Giving us a call on 0121 414 7209

*Please note – we apologise that we are unable to provide prepaid return envelopes to participants outside of the UK, however we will reimburse postage costs.