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

Study Directors: Prof 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

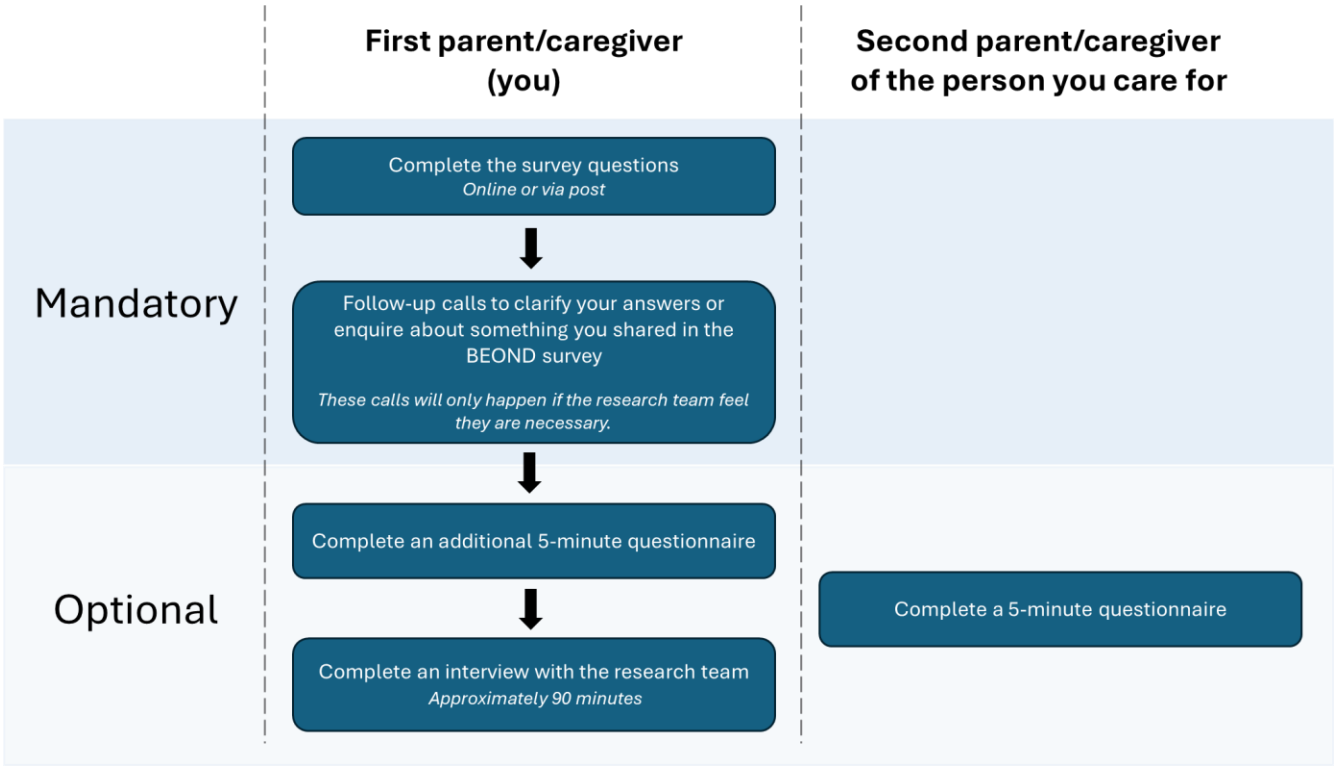
You can take part if you are the parent/guardian/carer of someone who meets these criteria:

1. Any of the following diagnostic categories:
    a. *Those with a rare genetic syndrome that is associated with intellectual disability*
    b. *Those with autism and an intellectual disability*
    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

The illustration below explains what participation in the BEOND study involves. Each section is explained further below. There are mandatory parts of the study (completing the survey questions and responding to follow-up calls about your survey answers). There are also optional parts of the study (completing the additional 5-minute questionnaire and interviews). The mandatory parts of the study are completed before the optional parts, in the order shown in the illustration.



What will participation involve: mandatory

The main part of the study is 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 survey 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 that they are presented in.

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.

We ask that you supply us with your contact details in case we need to get in touch about your survey answers. In particular, we may want to clarify your answers to the survey or enquire further about something that you have shared.

What will participation involve: optional

A short while after you have completed the survey, you have to option to answer another 5-minute questionnaire about the person you care for. This additional questionnaire is entirely optional. Your participation in the BEOND study will not be affected if you choose not to complete it.

After completing the survey, you may also be invited to an optional interview (depending on how you respond to the questions asked during the survey). This interview may be done over the phone or via video conferencing software (e.g. Zoom or Microsoft Teams). 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 interviews can last up to 90 minutes, though some may be slightly shorter or longer depending on your responses. Audio recordings will be collected for video conferencing interviews. Phone interviews will not be recorded. If you do not consent to the audio recordings, you will not be able to participate in the video conferencing interviews but you can still take part in the phone interviews. All recordings will be converted into anonymised transcripts and quotes from this transcript may be shared beyond the BEOND study team in publications, study dissemination materials, presentations, and teaching materials. You can still take part in the interviews if you do not consent to your individual anonymised quotes being shared. The interviews are entirely optional. Your participation in the BEOND study will not be affected if you choose not to take part in the interviews.

After the survey has been completed, a second parent/caregiver (e.g. mother, father, sibling, grandparent, carer, etc.) of the person you care for has the option to complete a 5-minute questionnaire. This questionnaire will ask about the everyday skills of the person that you care for. This additional questionnaire is entirely optional and your participation in the BEOND study will not be affected if a second parent/caregiver chooses not to take part.

Taking part in the BEOND study again

The BEOND study is a longitudinal study which means we intend to look at changes over time. The study will run for twenty years and participants have the option to take part every three years. If you think you would like to take part in the BEOND study again in the future, you can sign up now to receive an invitation when the study next opens to families. If you choose to take part in the BEOND study in the future, we will ask for your consent to participate again. Taking part in future waves of the BEOND study is entirely optional and will not affect your current participation in the study.

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 Prof Caroline Richards (c.r.richards@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 are the benefits of participating in the study?

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*. Parents/caregivers of typically-developing children will receive personalised feedback reports with comparisons against other typically-developing children of a comparable age. In addition to the feedback report, all participants who complete the survey are entitled to a £20 Amazon voucher** as a token of appreciation for their time spent completing the survey.

There are also indirect benefits to participating in the BEOND study. The study will provide comprehensive descriptions of the strengths and needs of people with different diagnoses. These descriptions will cover areas such as wellbeing, health, behaviour, everyday abilities, and cognition. The study should also improve our understanding of how people with rare genetic syndromes and/or intellectual disabilities change as they get older. Altogether, this information should give us a better understanding of individuals' and families' support needs at different times of life and subsequently inform better support provision.

**If you do not wish to receive a feedback report then please select 'no' on clause ten in section one of the consent form. **The BEOND study team retain the right to withhold Amazon vouchers from participants if the survey responses are found to be fraudulent. Fraudulent responses will be identified using pre-determined criteria.*

What are the potential risks of participating in the study?

Some participants may find certain questions distressing as they require you to reflect on your child's/person you care for's wellbeing, abilities, and behaviour, as well as your own wellbeing. If you find any of the questions distressing, you have to option to skip parts of the survey without leaving any answers. If you would like to seek further support, you may also contact charity support groups or your usual healthcare professional(s). Details for UK-based support groups are provided at the end of this information sheet. For participants based outside the UK, please search the internet for your local support groups.

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 42 months to allow us to invite you to participate in the follow up. Participation in the follow up is entirely optional. 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)*.

Confidentiality

Your participation in the BEOND study and any data you provide will remain confidential. However, if you share something that causes the BEOND team to have concerns about your health and/or welfare or that of the child/person you care for, then the BEOND team may need to breach this confidentiality. For example, confidentiality might be breached in cases of concerns about safeguarding.

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 nine 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 or concerns about any aspect of the study you are welcome to get in touch with any of our study leads:

Prof Caroline Richards
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Support group contacts

The support groups listed below are all UK-based and is by no means exhaustive. For participants based outside the UK, please search the internet for your local support groups.

Autism and/or intellectual disability: Mencap (https://www.mencap.org.uk/), Sense (https://www.sense.org.uk/our-services/contact-us-about-our-services/)
Angelman syndrome: AngelmanUK (https://www.angelmanuk.org)
Bardet-Biedel syndrome: Bardet-Biedel Syndrome UK (https://bbsuk.org.uk/)
CHARGE syndrome: CHARGE Family Support Group (http://www.chargesyndrome.org.uk/)
Cornelia de Lange syndrome: CdLS Foundation UK and Ireland (https://www.cdls.org.uk/)
Down syndrome: Down Syndrome Research Foundation (https://dsrf.org/)**;** Down's Syndrome Association (https://www.downs-syndrome.org.uk/); Down Syndrome UK (https://downsyndromeuk.co.uk/)
DYRK1A syndrome: DYRK1A Syndrome International Association (https://www.dyrk1a.org/dsuk)
Fragile X syndrome: Fragile X Society (https://www.fragilex.org.uk/)

Jansen de Vries syndrome: Jansen de Vries Syndrome Foundation (https://jansen-devries.org/)
KBG syndrome: Unique (https://rarechromo.org/)
Kleefstra syndrome: Kleefstra Syndrome UK (https://www.kleefstrasyndrome.org/)
Lowe syndrome: The Lowe Syndrome Trust (https://lowetrust.org.uk/)
Mucopolysaccharidosis type I, type II, and type III: MPS Society (https://mpssociety.org.uk/)
Pallister-Killian syndrome: PKS UK (https://pksuk.org/)
Phelan-McDermid syndrome: Phelan-McDermid Syndrome Foundation (https://www.pmsf.org.uk/)
Pitt Hopkins syndrome: Pitt Hopkins UK (https://pitthopkins.org.uk/)
Prader-Willi syndrome: Prader-Willi Syndrome Association UK (https://www.pwsa.co.uk/)
Rubinstein-Taybi syndrome: Rubinstein-Taybi Syndrome Support Group (https://www.rtsuk.org.uk/)
SATB2-associated syndrome: SATB2 Gene Trust UK (https://satb2gene.org.uk/)
Smith-Magenis syndrome: SMS Foundation UK (https://smith-magenis.org/)
Soto syndrome: Child Growth Foundation (https://childgrowthfoundation.org)
SYNGAP1 syndrome: SYNGAP1 UK (https://syngapuk.org)
Tuberous sclerosis complex: The Tuberous Sclerosis Association (https://tuberous-sclerosis.org/)
Wiedemann-Steiner syndrome: National Wiedemann-Steiner Syndrome Warriors (https://nwsswarriors.org.uk/)
Williams syndrome: Williams Syndrome Foundation (https://williams-syndrome.org.uk/)
Wolf-Hirschhorn syndrome: Wolf-Hirschhorn Syndrome Trust (http://whs4pminus.co.uk/)
1p36 deletion syndrome: The 1p36 Family Trust (https://www.1p36.co.uk/)

Can't find the syndrome you were looking for? Try: Child Growth Foundation (https://childgrowthfoundation.org), Unique (https://rarechromo.org/)

Please read the GDPR privacy statement before continuing