

BEOND

Behaviour and Emotional Outcomes in Neurodevelopmental Disorders



UNIVERSITY OF
BIRMINGHAM



WARWICK
THE UNIVERSITY OF WARWICK



The Cerebra Network for
Neurodevelopmental Disorders



Aston University
BIRMINGHAM UK



UNIVERSITY OF
SURREY



CdLS Foundation
UK & Ireland



CdLS Foundation
Cornelia de Lange Syndrome Foundation, Inc.

Participant Information

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

BEOND

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 Cornelia de Lange Syndrome, other 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 Cornelia de Lange Syndrome, as well as identifying common areas of difficulty and challenges that might be shared with other syndrome groups or be specific to certain groups within this broad community. Through this work we may be able to offer better ideas for how to support people with Cornelia de Lange Syndrome, other 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

It would be helpful if you could provide some confirmation of your child/the person you care for's diagnosis of Cornelia de Lange Syndrome and other diagnoses that you choose to share with us. 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 the Cornelia de Lange 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:

Dr Caroline Richards

 c.r.richards@bham.ac.uk

 School of Psychology, University of Birmingham, Edgbaston, Birmingham, B15 2TT


Dr Hayley Crawford

 hayley.crawford@warwick.ac.uk

 Warwick Medical School, University of Warwick, Coventry, CV4 7AL

Dr Jane Waite

 j.waite@aston.ac.uk

 School of Life & Health Sciences, Aston University, Birmingham, B4 7ET

Dr Jo Moss

 j.moss@surrey.ac.uk

 University of Surrey, Guildford, Surrey, GU2 7XH

BEOND

If you have read the study information and would like to take part, use the QR code or link below. Once you have answered a few simple screening questions you can choose to complete the survey online or have a paper copy of the questionnaires sent to you free of charge*



<https://redcap.link/cnndbeond>

*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.