



Centre for Children's Health Research (CCHR)
Level 6, 62 Graham Street
South Brisbane QLD 4101

Queensland Cerebral Palsy &
Rehabilitation Research Centre
(QCPRRC)
Faculty of Medicine

PARENT/GUARDIAN INFORMATION SHEET

Ethics Approval: HREC/19/QCHQ/50131, 2019000558

Title of Project: Environmental enrichment for infants; parenting with Acceptance and Commitment Therapy (**ENACT**)

Chief Investigators: Dr Koa Whittingham, Dr Andrea McGlade, Miss Kavindri Kulasinghe, Dr Amy Mitchell, Prof. Roslyn N. Boyd, Associate Professor Honey Heussler, Dr Kristelle Hudry

Associate Investigator: Dr Jacqui Barfoot

Thank you for taking the time to read this Information Sheet.

This information statement and consent form is 7 pages long. Please make sure you have all the pages. These pages contain information about a research project that we are inviting you to take part in. **It is okay to say no if you would not like to participate in this study.** Please read this information carefully as it explains clearly and openly what participation involves. Before you decide, you can ask us any questions you have about the project. If you decide you would like to participate in this study then you need to sign and return the consent form attached.

What is the Research Project about?

We have developed a new early intervention approach for infants who have an increased chance of having Autism Spectrum Disorders (ASD), targeting social interaction from the earliest months through parent-child interactions. We have integrated support for parental mental health and parenting challenges into this early intervention, and developed a means of delivering the intervention online through an e-course combined with online consultations. We are calling our early intervention approach 'Environmental Enrichment for Infants: Parenting with ACT', or 'ENACT'. The e-course we are trialing in this research project is called 'ENACT101'. This research project is about trialing ENACT with families of infants who have an increased chance of having of developing an Autism Spectrum Disorder (ASD). We are aiming to discover whether ENACT is effective and whether or not families find it useful.

Can I participate?

You can participate in this study if you are **currently pregnant with a baby who has a first-degree relative (sibling or parent) with a diagnosis of an Autism Spectrum Disorder (ASD)**. This might mean that you, your baby's biological father, or your baby's sister or brother may have a diagnosis of an Autism Spectrum Disorder (ASD). As ENACT is delivered online, participation is restricted to families with **reliable internet access**. The intervention, ENACT, and the majority of assessments will be conducted via online questionnaires for your convenience. All participating families will **need to be able to travel to the Child Health Research Centre in Brisbane when their infant is 6 and 12 months of age** for their babies to have assessments in person.



Queensland Cerebral Palsy &
Rehabilitation Research Centre
Faculty of Medicine

What does participating involve?

If you choose to participate in this study, you will be randomly allocated to one of **two groups**: ENACT or care-as-usual.

- ❖ **The ENACT group** will get immediate access to the ENACT101 e-course and online consultations with a clinician, who will answer any questions you might have and help to tailor the intervention to best meet your own individual needs and those of your baby. The ENACT intervention will include targeting your baby's social interaction from the earliest months during ordinary parent-child interactions. It also includes strategies to support your mental health and support you in coping with parenting challenges such as infant sleep. Our support for parental mental health is grounded in the psychological therapy Acceptance and Commitment Therapy (ACT). ENACT101 includes videos, text, questions and a discussion board.
- ❖ **The care-as-usual group** will receive their usual care without access to ENACT. This will allow us to determine if there are benefits to participating in ENACT.

Whether you are allocated to ENACT or to care-as-usual, you will still need to complete assessments **four times during the study: when you sign up and when your child is 3 months, 6 months, and 12 months old**. All of the assessments will include online questionnaires asking about family, feelings, wellbeing, and your relationship with your child, as well as your child's development.

At 3 months of age, you will be asked to record your baby's movements via the Baby Moves app, which we will ask you to download onto your phone. The Baby Moves app helps to record your baby's movements for the General Movements Assessment (GMA), which is a neurodevelopmental assessment tool. When your child is 6 months and 12 months old, we will ask you to bring your child for a visit to the **Centre for Children's Health Research in Brisbane** for a **comprehensive assessment of your baby's development with a developmental paediatrician. We will provide you with free parking.**

Can I get a copy of the assessment results and find out about my baby's development?

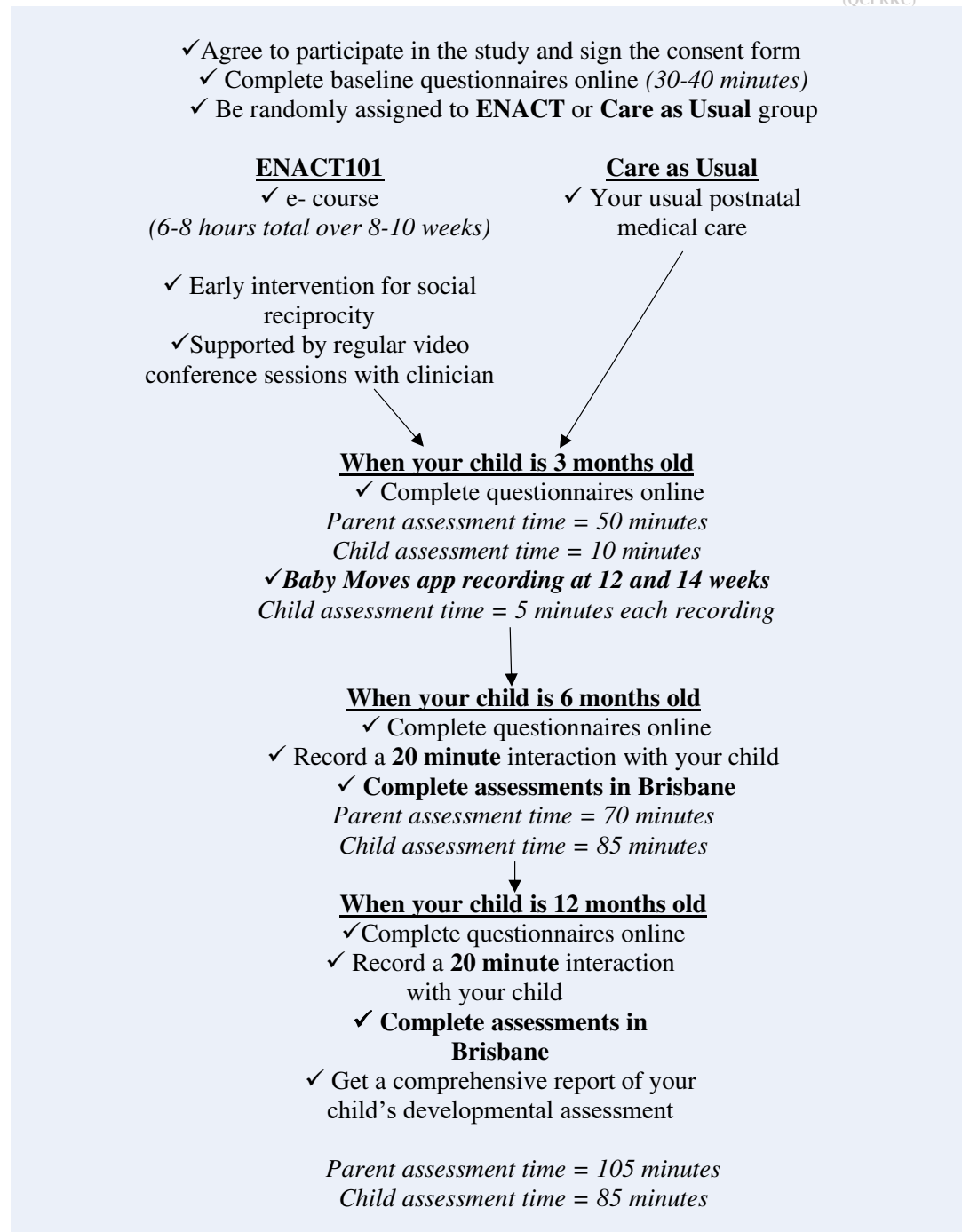
Absolutely! We hope that this is one of the benefits of participating, whether you are in the intervention group or not. We know that finding out about your baby's development is important to you. All participating families will receive a developmental report after their baby's 12 month assessments. If earlier assessments indicate neurodevelopmental risk, particularly the general movements assessment at 3-4 months of age and the HINE at 6 months then you will be informed and assisted in finding appropriate support. All babies participating in the study will have a report provided to their parent/s after their last assessment and a copy will also go to your baby's general practitioner. If there are any findings of concern you will also be informed via the report and your general practitioner. As these assessments have been performed as part of a study, we cannot provide individual recommendations for management. The report will be able to make some general recommendations though for you to be able to discuss further with your general practitioner (or your child's paediatrician if they have one), so that you know what management options are available.

Your involvement is genuinely appreciated.

Your active participation in refining ENACT is highly valued. We will ask you to share your thoughts and experiences with us as you work through the program.

The steps of the study participation are summarised below:

Queensland Cerebral Palsy &
Rehabilitation Research Centre
(QCPRRC)



What does ENACT involve?

ENACT101 is flexible online course, and participants will be able to move through the content at a pace that suits them. We estimate that it will take approximately 6-8 hours in total to complete the content, with most participants beginning antenatally. We aim to ensure that



participants have worked through all of the ENACT101 content by the time their infant is 8 weeks of age. ENACT101 can be accessed from any device that can connect to the internet.

The social interaction component of ENACT should be practiced regularly from when your infant is 2 weeks old, with a target of 30 minutes per day/5 days per week. However, the social interaction practice is designed to be done during ordinary, everyday activities and interactions with your baby, and shouldn't take up extra time in your day. The clinical consultations will support you in finding ways to practice ENACT in the midst of everyday life.

How will this research help people in the future?

This is the first time an early intervention approach for ASD has been trialed from birth. With your help, we hope to refine ENACT. We have chosen to use an online delivery method, including the development of the e-course ENACT101, so that if ENACT is found to be effective, ENACT101 can be made accessible to families with children who have an increased chance of having Autism Spectrum Disorder across the world.

Are there any risks to participation?

ENACT101 will be exploring your relationship with your newborn child as well as your thoughts, feelings and general well-being. This study contains no risks beyond everyday living.

Will my information be confidential?

Yes! All information that we collect from you and your child, including your questionnaires, videoed parent-child interaction, child assessments and your feedback will be stored in a confidential manner. The information in this study will only be used in ways that will not reveal who you are. You will not be identified in any publication from this study or in any data files shared with other researchers. All information will be held in strict confidence, and will be used for statistical purposes only. Confidentiality will only be breached if a child is deemed at risk of harm or neglect. Data collected from you or your child will be de-identified, by replacing any identifying information (e.g. your name) with a participant number. Identified or de-identified research data may be made available for review by ethics review committees or other regulatory authorities for the purposes of monitoring ethical and scientific conduct of the study.

What if I change my mind?

You do not have to take part in this research project. Your participation will not affect any treatment that you or your child receives. If you do agree to participate, and change your mind at a later date, you are free to withdraw from the study at any time without any negative consequence.

Who is involved?

Chief Investigators

1. **Dr Koa Whittingham** is a clinical and developmental psychologist and a senior research fellow at the University of Queensland. She is experienced in working with parents of children with Autism Spectrum Disorder as well as in Acceptance and Commitment Therapy.
2. **Dr Andrea McGlade** is a developmental paediatrician and is undertaking this project as part of her PhD within the Faculty of Medicine at the University of Queensland.
3. **Miss Kavindri Kulasinghe** is a medical student within the Faculty of Medicine at the University of Queensland. She is undertaking this project as a part of her PhD.
4. **Dr Amy Mitchell** is a paediatric nurse and a research fellow at the University of Queensland with expertise in working with parents.



5. **Professor Roslyn Boyd** is the Scientific Director of Queensland Cerebral Palsy and Rehabilitation Research Centre. She has clinical and scientific expertise in working with children with cerebral palsy and developmental delay and their families.
6. **Associate Professor Honey Heussler** is a developmental and behavioural paediatrician and a researcher with the Centre for Children's Health Research. She has extensive experience working with children with developmental and behavioural problems.
7. **Dr Kristelle Hudry** is a Senior Lecturer within the Department of Psychology and Counselling at the La Trobe University. She is experienced in working with parents of children with Autism Spectrum Disorder.

Associate Investigators

1. **Dr Jacqui Barfoot** is an occupational therapist with clinical and research experience in parent-infant relationship focussed interventions to support infant development. She is the clinician delivering the ENACT intervention.

Do you have any questions?

Please take the time to ask us any questions that you may have. You can contact:

Miss Kavindri Kulasinghe or Dr Andrea McGlade (Chief Investigators) on (07) 3069 7547 or email uqenact@uq.edu.au

University of Queensland Ethics Contact:

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with project staff, if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinators on (07) 33653924 / (07) 34431656, or email humanethics@research.uq.edu.au.

HREC Information:

The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) has approved this study. If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact the HREC Coordinator on: 3069 7002 or email CHQETHICS@health.qld.gov.au



Centre for Children's Health Research (CCHR)
Level 6, 62 Graham Street
South Brisbane QLD 4101
Tel: (07) 3646 5542

Queensland Cerebral Palsy &
Rehabilitation Research Centre
(QCPRRC)
Faculty of Medicine

PARTICIPANT CONSENT FORM

Project Number: HREC/19/QCHQ/50131, 2019000558

Title of Project: Environmental enrichment for infants; parenting with Acceptance and Commitment Therapy (ENACT)

Chief Investigators: Dr Koa Whittingham, Dr Andrea McGlade, Miss Kavindri Kulasinghe, Dr Amy Mitchell, Prof. Roslyn N. Boyd, Associate Professor Honey Heussler, Dr Kristelle Hudry

I/We,

voluntarily consent to participate in the above titled Research Project explained to me by:

Mrs/Ms/Dr/Professor _____

- I/We have read the information statement for this study and I/we believe I/we understand the purpose, extent and possible effects of my involvement.
- I/We have had an opportunity to ask questions and I/we am satisfied with the answers I/we have received.
- I/We understand information collected will be stored confidentially and my/our identity will not be revealed.
- I/We understand that I/we can refuse to participate and can withdraw from this study at any time without any negative consequence. In particular, I/we understand that my/our participation will not affect my child's access to usual medical care.
- I/We understand that the purpose of this study is to pilot an innovative, online approach to early intervention and that my/our active involvement, including critical feedback, is valued.
- I/We understand that in order to evaluate the new early intervention I/we will be asked to complete online questionnaires as well as record an ordinary parent-child interaction during the study.
- I/We consent to having videos of my/our child recorded via the Baby Moves app when my/our child is 12 and 14 weeks of age and scored by an independent assessor.
- I/We understand that I/we will receive a developmental report covering my baby's 12 month assessments and that if neurodevelopmental risk is found at the earlier assessments particularly on the general movements assessment or the HINE I/we will be informed as soon as possible.
- I/We understand that in order to evaluate the new early intervention I/we will be asked to complete a developmental assessment at the Children's Health Research Centre in Brisbane when my child is 6 and 12 months of age.
- I/We understand that a report of my child's developmental assessments will be provided at the completion of the assessments and that in the event of any adverse findings I may be contacted by a member of the assessment team to notify me of these findings.



Queensland Cerebral Palsy &
Rehabilitation Research Centre
(QCPRRC)
Faculty of Medicine

- I/We consent to provide the name and contact details of my child's General Practitioner and Paediatrician (if your child has a paediatrician).
- I/We consent for my nominated General Practitioner (and paediatrician) to be contacted and a report provided to them for further follow up with your child, including any concerns identified in the assessments performed.
- **I/We consent to participate in this research project.**

My child's GP or Paediatrician:

Name: _____

Address: _____

Phone: _____

Signature _____ **Date** _____

I have explained this study and I believe that the participant/s understands the purpose, extent and possible effects of involvement.

Researcher's Signature _____ **Date** _____

Note: All parties signing the Consent Form must date their own signature.