

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM - PARENT

You do not have to agree to participate, it is ok to say no – this study is entirely voluntary.

Project Number: HREC/18/QRCH/82

Title of Project: Early Parenting Acceptance and Commitment Therapy 'Early PACT' for parents of infants with cerebral palsy

Chief Investigators: Dr Koa Whittingham, Dr Jeanie Sheffield, Professor Roslyn Boyd and Dr Catherine Mak

Associate Investigators: Ms Lynda McNamara, Dr Marnie Fraser, Dr Cheriya Abdulla, Dr Priya Edwards, Dr Nicola Previtera, Dr John Coghlan, Dr Peter Schmidt, Ms Rhiannon German, Dr Pieter Koorts, Prof Paul Colditz, Dr Mark Patrick, Mrs Rebecca Caesar, Dr Anthony Brown, Dr Clea Banda

We would like to ask you to participate in a research project.

Please read the following information sheet carefully, as it explains details of the research project and states clearly what participation involves. Before you decide to participate 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 an innovative approach to parenting support for families with infants diagnosed as at risk of having cerebral palsy. Our approach is based on a psychological approach called Acceptance and Commitment Therapy (ACT). We are calling the approach Early Parenting Acceptance and Commitment Therapy (Early PACT). Early PACT has been adapted from our original PACT program, which is for parents of older children (2-10 years) diagnosed with cerebral palsy. With diagnosis of cerebral palsy occurring much earlier than previous, we are passionate about exploring ways to support families in this earlier time frame. Online delivery has the potential to reach every parent with internet access across the world, so we are delivering Early PACT as an online course called Early PARENT101.

We need your help to ensure that Early PARENT101 is beneficial for families. This study is about testing whether Early PARENT101 makes a difference in the lives of families with infants diagnosed as at risk of having cerebral palsy. It is also about finding out what you think of Early PARENT101. Your active participation in refining Early PARENT101 is highly valued.

Can I participate?

You can participate in this study if you are the parent (including adoptive, step parent or legal guardian) of an infant (currently under 24 months of age) who has been diagnosed with or at risk of cerebral palsy. This study is testing an online course so you need to have: reliable internet access, a mobile phone (text messages are part of the course), and basic computer and internet literacy.

What will participation involve?

If you choose to participate in this study you will be randomly (like tossing a coin) allocated to one of two groups: immediate or waitlist. The immediate group will get immediate access to the course. The waitlist group will wait for the immediate group to complete the course. This allows us to identify whether there are any specific benefits to participating in the course. All study participants will access Early PARENT101 before the end of the study. You will need to complete assessments either three or four times during the study (depending upon whether you are allocated to the immediate or to the waitlist group).

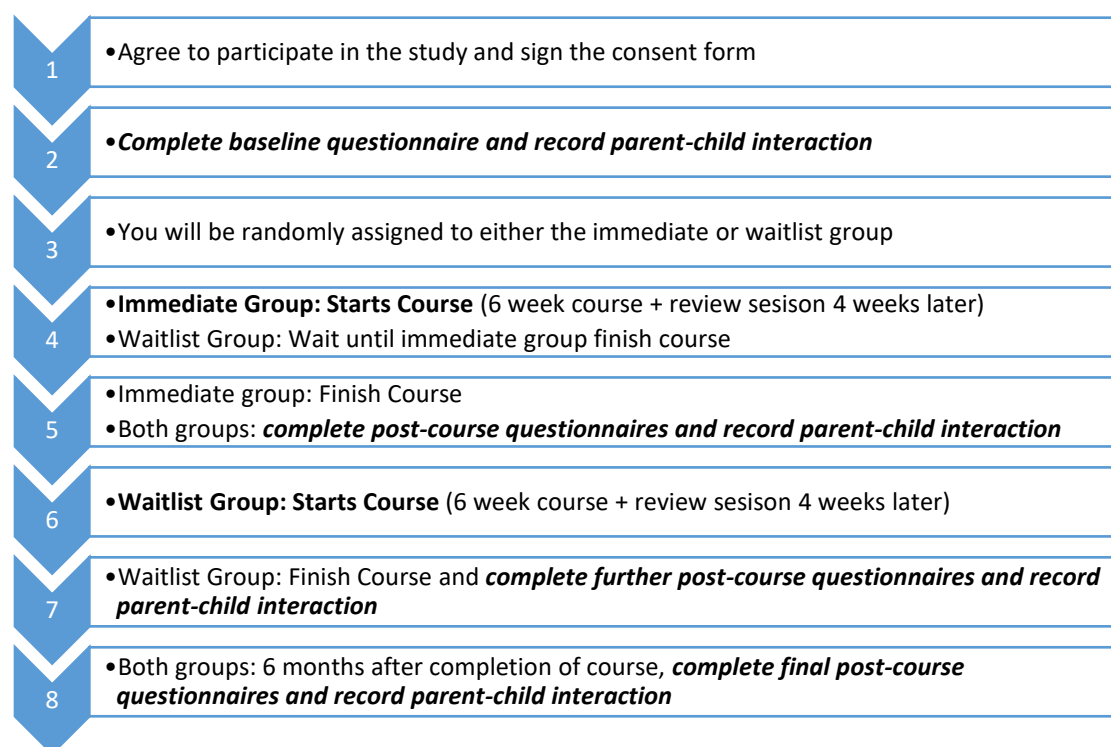


The assessments for this study include:

- *An online questionnaire* (which takes approximately 20 minutes) about your family, feelings and well-being, as well as your child's behaviour, quality of life and abilities, and your own relationship to your child.
- *Recording a twenty-minute interaction* with your child to get a flavour of how the two of you interact together. We will assist you with this recording and it can be done via a video call (Zoom) or you can use your own recording device. We will help you record in an entirely secure way.

If both parents are participating, then both will be asked to complete these assessments. We will also ask you to share your thoughts on Early PARENT101.

The steps of study participation are detailed below:



What does Early PACT involve?

Early Parenting Acceptance and Commitment Therapy (Early PACT) is a new approach to parenting grounded in Acceptance and Commitment Therapy. The online course, Early PARENT101, involves exploring what matters most to you as a parent and as a person. You explore building a stronger relationship with your child, building a rich, rewarding life, and coping with difficult thoughts and feelings. Early PARENT101 is based on online educational courses and uses the platform edX, which is used by universities across the world.

Early PARENT101 is a six-week course with a review lesson one month later. The course will take approximately 1 hour per week to complete but this will vary person to person. Completion of the course content is flexible; participants will work through the course content at their own pace within the timeframe. Early PARENT101 includes short videos, online activities, and experimenting with the content in your daily life. You can also choose to access an optional discussion board. You will touch base with a psychologist via video conference or phone to help you apply the content. This can be brief (e.g. 5 minutes) or lengthy (e.g. 30 minutes) depending on your needs. You will also have the opportunity to provide feedback about all aspects of the course.



How will participation benefit me?

By participating, you will get early access to an innovative new online course. You will also play a valuable role in evaluating the usefulness of the course.

Is there likely to be a benefit to other people in the future?

Yes! With your help, we hope to develop Early PARENT101 into an effective and useful online parenting support package. We will be making Early PARENT101 accessible to parents of children with cerebral palsy across the world.

Are there any risks to participation?

Early PARENT101 involves exploring your relationship with your child as well as your own happiness and well-being. It also includes ideas that you might find strange at first, so you need to be willing to explore these topics and to experiment with ideas that might be new to you. Should you choose to participate in the discussion board and use your name, it is possible other participants will identify you, so we encourage participants to use a screen name that is not identifiable to others. Apart from that, this study contains no risks beyond everyday living. If participation raises any concerns for you these are some potential sources of assistance:

beyondblue: 1300 22 4636 **Lifeline:** 13 11 14 **PANDA:** 1300 726 306 Your local **GP**

Will my information be confidential?

Yes! All information that we collect from you, including your questionnaires, videoed parent-child interaction and your feedback will be stored in a confidential manner on a password-protected University of Queensland secure server. De-identified, collated data will be shared with other researchers and clinicians at conferences and through publications.

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 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.

Research Contacts:

Chief Investigators

1. Dr Koa Whittingham is a clinical and developmental psychologist. She is experienced in working with parents of children with cerebral palsy as well as in Acceptance and Commitment Therapy and developed the PACT program.
2. Dr Jeanie Sheffield is a clinical psychologist experienced in Acceptance and Commitment Therapy and in working with families of children with disabilities and the co-author of the PACT program.
3. Professor Roslyn Boyd is the Scientific Director of Queensland Cerebral Palsy and Rehabilitation Research Centre. She is experienced working with infants and children with cerebral palsy and their families.
4. Catherine Mak is a registered psychologist experienced in working with children and families, including families of children with cerebral palsy.



Associate Investigators

Cairns and Hinterland HHS:

Central Queensland HHS:

Central West HHS:

Children's Health Queensland HHS:

Darling Downs HHS:

Gold Coast HHS:

Mackay HHS:

Metro North HHS:

North West HHS

Sunshine Coast HHS:

Torres and Cape HHS:

Dr Marnie Fraser and Ms Lynda McNamara

Dr Cheriya Abdulla

Dr Clare Walker

Dr Priya Edwards and Dr Nicola Previteria

Dr John Coghlan

Dr Peter Schmidt

Ms Kirsty Bell

Prof Paul Colditz and Dr Pieter Koorts

Dr Roelos Lourens

Mrs Rebecca Caesar

Dr Anthony Brown

Do you have any questions?

Please take the time to ask us any questions that you may have.

Our contact details:

Early PACT study coordinator: Dr Catherine Mak: +61 (7) 3069 7360 or earlypact@uq.edu.auChief Investigator, Dr Koa Whittingham: +61 (7) 3069 7346 or koawhittingham@uq.edu.au**Ethics Contact:**

Children's Health Queensland Hospital and Health Service Human Research Ethics Committee has approved this study. Should you wish to discuss the study with someone not directly involved, in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or if you wish to make a confidential complaint, please contact the HREC coordinator on: T: (07) 3069 7002 E: CHQETHICS@health.qld.gov.au



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I/We, _____

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

Mr/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/our 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 treatment.
- I/We understand that the purpose of this study is to pilot an innovative, online approach to parenting support and that my/our active involvement, including critical feedback, is valued.
- I/We understand that in order to evaluate the new online parenting support package I/we will be asked to complete online questionnaires as well as record a parent-child interaction with my/our child three or four times during the study.
- **I/We consent to participate in this research project.**

OPTIONAL – Further Research

- I would like to be contacted about any future research trials that I may be eligible to participate in. (NB. full ethical approval would be sought by the research team and a new consent process undertaken) **Yes / No**

Signature _____ **Date** _____

Signature _____ **Date** _____

(Signatures of two parents are required ONLY if two parents intend to participate in the course. All parties must date their own signature.)

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** _____

