PARENT / GUARDIAN INFORMATION STATEMENT

Title of Project:
Prem Baby Triple P- A Randomised Controlled Trial

Thank you for taking the time to read this Information Statement.
This information statement is 5 pages long. Please make sure you have all the pages.

What is an Information Statement?
These pages contain information about a research project we are inviting you and your preterm baby or babies to take part in. The purpose of this information is to explain to you clearly and openly all the steps and procedures of this project. The information is to help you to decide whether or not you would like to take part in the research. Please read this information carefully. You can ask us questions if you wish. You may also wish to talk about the project with others e.g. friends or a health care worker. When you understand what the project is about, you can sign the consent form attached if you agree to take part. You will be given a copy of this information and the consent form to keep.

What is the Research Project about?
This project is about infants who are born early before 32 weeks gestation. Some babies who are born prematurely can have problems later in life (for example with learning or movement delay). We know that social and environmental factors play an important role in helping babies born prematurely to develop to their full potential. The Triple P-Positive Parenting Program is a system of parenting and family support that incorporates a range of interventions. The purpose of this research project is to trial a new Triple P intervention called Prem Baby Triple P. Families that take part will be randomly put into one of two groups (like the flip of the coin, completely by chance). The first group of families will receive the normal care that all premature infants have now. The second group of families will receive normal care plus the Prem Baby Triple P intervention. This will involve 4 x 2-hour group sessions in the NICU delivered by trained psychology graduates and 4 x 30 minute telephone consultations with a trained psychology graduate after discharge from hospital. These sessions will guide you to: recognise your baby's needs, teach your baby new skills, recognise stress and crying types, develop a positive relationship with your baby, deal with infant behaviours, develop parenting routines, develop your own coping skills and enhance supportive couple relationships (or enhance your relationship with your main parenting support person). If you are transferred from this hospital to a regional hospital before completing the 4 group sessions you will be able to complete the sessions by watching the session on DVD followed by a brief telephone consultation. We would like your family (yourself, your spouse or support person and your baby) to take part in our project.

Who is Funding the Research?
This research project is funded by the National Health and Medical Research Council (NHMRC).

Who are the Researchers?
Professor Paul Colditz is a neonatologist who is responsible for leading the research team, particularly at the Royal Brisbane and Women’s Hospital. A/Professor Peter Gray is a neonatologist who is responsible for leading the research team at the Mater Mothers’ Hospital. Professor Matthew Sanders is the founder of the Triple P- Positive Parenting Program and a leading researcher on family
interventions. Professor Roslyn Boyd is a paediatric physiotherapist who will be leading the research team at the Royal Children’s Hospital. Other researchers involved in this project include; Dr Margo Pritchard, A/Professor Michael O’Callaghan, Prof Virginia Slaughter, Dr Koa Whittingham, Dr Leanne Winter, Dr Kylee Forrest, Karen Taylor and Judith Macey.

**Why are we being asked to be in this research project?**
You are invited to participate because your infant was born at less than 32 weeks gestation. We are inviting 330 families to take part whose infants were born at less than 32 weeks into their pregnancy.

**What are our alternatives to participating in this project?**
There is no obligation to participate in this project. Should you choose not to participate in this project you and your baby will have all the usual access to treatment.

**What do we need to do to be in this research project?**
Every family that takes part in our project will be randomly put into one of two groups. This will be done by chance (like the flip of a coin), and you will not know which group you will be in when you decide whether or not to take part. Before being put into groups all families will complete an initial assessment taking approximately 30-40 minutes. This initial assessment will also include information that is routinely collected and stored in the NICU database. In some cases it may be necessary to access your baby’s medical records or your own medical records for the purposes of clarification of this information.

Your family will then be put into one of two groups:

**Group One:**
If your family is put into group one, you and your baby will receive the normal care that any baby born pre-term receives at this hospital.

**Group Two:**
If your family is put into group two you will receive normal care plus the Prem Baby Triple P intervention. This will involve 4 x 2-hour group sessions in the NICU delivered by trained psychology graduates and 4 x 30 minute telephone consultations with a trained psychology graduate after transfer from hospital. These sessions will guide you to: recognise your baby’s needs, teach your baby new skills, recognise stress and crying types, develop a positive relationship with your baby, deal with infant behaviours, develop parenting routines, develop your own coping skills and enhance supportive couple relationships. If you are transferred from hospital to a regional hospital before completing the 4 group sessions you will be able to complete the sessions by watching DVDs of the session combined with brief telephone consultations. Some group sessions may be videotaped and some of the telephone consultations may be audio recorded so that we can check the quality of the sessions for research purposes. Neither the video footage nor the recordings of the telephone consultations will be used for promotional purposes and all recordings will be deleted at the conclusion of the study. In addition to videotaping, the researchers may take still images that can be used in scientific presentations; if the images are used, your baby’s identity will remain private. After discharge from hospital you will also receive regular parent information tip-sheets and ongoing phone support if necessary.

**Assessment:**
All families who participate in this study will take part in four assessments. These will take place at the beginning of the study, at approximately 6 weeks corrected age, at 12 months corrected age and at 24 months corrected age.
Surveys: All of the assessments will involve you completing questionnaires (taking 45 minutes, on average, each time).

Neurodevelopmental assessment: At 24 months corrected age we will perform an in depth neurodevelopmental assessment (taking approximately 1.5 hours). This assessment will occur at this hospital and will involve assessing your baby’s motor, cognitive and language development. The
information gained from the neurodevelopmental assessment will be provided to you in the form of a report.

While you are at the hospital for the 24 months corrected age assessment we will ask you to complete a mother-toddler observational task. This will involve mothers interacting with their child for 15 minutes. The observational task will be video-taped for research purposes and you will receive a copy of the video to keep. 

Couple-Communication Task: If you are in a couple relationship you will be asked at 24 months corrected age to complete a 10 minute couple-communication task. This will be conducted either at the hospital or at home and recorded using an audio-recorder.

Is there likely to be a benefit to my child or children?
Families in both groups will have the opportunity to have an in depth neurodevelopmental assessment at 24 months (corrected age). We will be assessing your baby's behavioural, motor, cognitive and language development. The information gained from this assessment will be provided to you in the form of a report. All families will also receive copies of their video-taped mother-child interactions. In addition, families in group two will receive the Prem Baby Triple P intervention from trained psychology graduates.

Is there likely to be a benefit to other children in the future?
If this study shows that Prem Baby Triple P is beneficial then it is likely to become standard practice. If Prem Baby Triple P is beneficial then this would benefit preterm babies and their families in the future.

What are the possible risks and/or side effects for my child?
There are no known risks of Prem Baby Triple P.

What are the possible discomforts and/or inconveniences for me or my child?
The only inconvenience to you and your child is the time that the assessments will take, and the trip you will have to make to the hospital when your baby is 24 months corrected age (all families). We will make the appointments at a time to suit you. For families living outside of Brisbane compensation for some travel costs may be available.

What will be done to make sure the information is confidential?
All results of all assessments will be stored without your name or your child’s name on it. All hard copy data will be stored in a secure filing cabinet only and only the researchers will have access to these, unless required by law. These will be kept for 23 years at the Royal Brisbane and Women's Hospital. If we talk or write about the results of this project, we will not use any names. All data is only accessible to the study personnel.

Will I be informed of the results when the research project is finished?
You will receive a report following your child’s assessment at 24 months (corrected age). A regular 6 monthly newsletter will also be sent to you to keep you updated on study recruitment and progress. At the conclusion of the study all families will be sent a meaningful summary of the overall study results.

You can decide whether or not you wish to take part in this research project. You can decide whether or not you would like to withdraw from this research project at any time. No explanation is needed. You may like to discuss your participation in this research project with your family and with your doctor. You can ask for further information before deciding if your child will take part.

If you would like more information about the study or if you need to contact a study representative in an emergency, the people to contact are:

Dr Leanne Winter, Project Coordinator Ph: (07) 3646 2349 or
Karen Taylor, Research Nurse Ph: (07) 3646 8734
Email: prembabytriplep@psy.uq.edu.au
What are our rights as participants?

1. I am informed that except where stated above, no information regarding my child’s medical history will be released. This is subject to legal requirements.

2. I am informed that the results of any tests involving my child will not be published in a manner that would reveal my child’s identity or my own identity. This is subject to legal requirements.

3. The detail of the procedure proposed has also been explained to me. This includes how long it will take, how often the procedure will be performed and whether any discomfort will result.

4. It has also been explained that our involvement in the research may not be of any benefit to my child. I understand that the purpose of this research project is to improve the quality of medical care in the future.

5. I have been asked if I would like to have a family member or a friend with me while the project is explained to me.

6. I understand that this project follows the guidelines of the National Statement on Ethical Conduct in Human Research (2007).

7. I have received a copy of this document.

This study has been approved and reviewed by Children’s Health Services Queensland Human Research Ethics Committee. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, at any time, you may contact the Co-ordinator on the ethics committee, Children’s Health Services Queensland Human Research Ethics Committee, c/o Dept of Paediatrics and Child Health, Level 3, Foundation building, Herston. QLD. 4029. Telephone (07) 3646 9167. If this phone is unattended, there is a 24 hour contact number.

This study has been cleared by one of the human research ethics committees of the University of Queensland in accordance with the National Health and Medical Research Council’s guidelines. You are of course, free to discuss your participation in this study with project staff (contactable on (07) 3646 2349 or PremBabyTripleP@psy.uq.edu.au). If you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Officer on (07) 3365 3924.
STANDARD INFORMED CONSENT FOR PARENT / GUARDIAN TO GIVE CONSENT TO PARTICIPATE IN A RESEARCH PROJECT
(Attach to Parent Information Statement)

Title of Project:
Prem Baby Triple P - A Randomised Controlled Trial

Study Coordinator: Dr Leanne Winter
Principal Investigators: Prof Paul Colditz, A/Prof Roslyn Boyd, Prof Matthew Sanders, Dr Margo Pritchard, A/Prof Peter Gray, A/Prof Michael O’Callaghan Prof Virgina Slaughter and Dr Koa Whittingham

I (Parent’s/Guardian’s name) ________________________
Parent / Guardian of (baby’s name) ________________________

voluntarily consent to taking part in the above titled Research Project, explained to me by
Mr / Ms / Dr / Professor _______________________________________

- I have received a Parent/Guardian Information Statement to keep and I believe I understand the purpose, extent and possible effects of my and my baby’s involvement
- I understand that some of the group sessions I attend may be videotaped
- I understand that on occasion, the researchers may take still images (photos) to be used in scientific presentations about the research project; if the images are used, my baby’s identity will not be identified.
- I have been asked if I would like to have a family member or friend with me while the project was explained
- I have had an opportunity to ask questions and I am satisfied with the answers I have received
- I understand that the researcher has agreed not to reveal results of any information involving me or my baby, subject to legal requirements
- If information about this project is published or presented in any public form, I understand that the researcher will not reveal my/my child’s identity
- I understand that if I refuse to consent, or if I withdraw my baby from the study at any time without explanation, this will not affect my baby’s access to the best available treatment options and care from Women’s and Children’s Health (The Royal Women's Hospital OR The Royal Children's Hospital OR the Mater Hospital).
- I understand I will receive a copy of this consent form

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<tr>
<th>Printed Name</th>
<th>Signature</th>
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<td>PARENT/ GUARDIAN</td>
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I have explained the study to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible effects of their involvement in this study.

RESEARCHER’S SIGNATURE ________________________ Date: _____________

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