



Health
Illawarra Shoalhaven
Local Health District

PARTICIPANT INFORMATION SHEET

This is an invitation to participate

Title of the Study

Effect of a multi-component intervention in post-natal mother's groups on meeting the Physical Activity Guidelines for infants. A randomized controlled trial.

Who is conducting the study?

This study is being conducted by a group of researchers from the Illawarra Shoalhaven Local Health District (ISLHD), University of Wollongong (UOW) and Sydney Local Health District (SLHD). The researchers involved in this study are Dr Lyndel Hewitt (Senior Research Clinician, ISLHD, Lyndel.Hewitt@health.nsw.gov.au, 02 42534801), Ms Carolyn Frohmuller (Clinical Nurse Consultant, ISLHD, Carolyn.Frohmuller@health.nsw.gov.au, 02 42242916), Senior Professor Tony Okely (Early Start, UOW, tokely@uow.edu.au, 02 4221 3141) and Professor Li Ming Wen (Public Health, SLHD, LiMing.Wen@health.nsw.gov.au, 02 95159078). The study is also funded by the 2020 Illawarra Health and Medical Research Institute Clinical Translation Grant Scheme (\$20000).

Why are we conducting this study?

The aim of this study is to determine the efficacy of a multi-component intervention incorporating WhatsApp® and an online group tummy time class in post-natal mothers' groups, on infant physical activity levels. Given the importance of tummy time and the low levels of tummy time reported globally, there is a need for high-quality strategies to promote tummy time. This study will investigate the effectiveness of an intervention delivered to mothers and their infants attending local post-natal mother's groups. Results from this study can be used to refine existing programs and prioritize strategies for infant healthcare.

What will we ask you and your baby to do?

We will ask you to complete a questionnaire over the phone with a research assistant on two occasions. One before you start the study, and one at the end of the study. There will be questions about you, such as, in what country were you born? And questions about your baby, such as, what is your baby's current weight? This questionnaire will take approximately 15 minutes each time. On one occasion (at the end of the study), we will ask you to put a measurement device around your baby's waist for 3, 24-hour periods over 7 days. At this time, we will also ask you to complete a log of when the device is put on, off, and the position your baby is in when they are sleeping.

Once the initial measurements are completed, you (and your baby) will be randomised together to either:

1. Usual weekly mother's group sessions with your child and family health nurse
2. Usual weekly mother's group sessions with your child and family health nurse plus an online education workshop about physical activity. The workshop will be approximately 60 minutes. Mothers in this group will also be asked to create a closed WhatsApp® group to enable participants to share tips, encouragement and strategies they have found helpful during the week. Joining this social media group is voluntary and content will be monitored by the researchers to ensure social media etiquette is maintained at all times. This social media group will close and be permanently deleted at the completion of the study.

See picture below of an example of the measurement device around an infant's waist who is on their back:



Who can participate?

We are looking for mothers who have a healthy infant who will be attending their ISLHD mother's group. Your child should not participate in this study if he/she has a serious medical condition. You will be responsible for



placing the device on your baby but you will be shown how to put it on and have the opportunity to practice prior to commencing the study.

What are the side effects of taking part?

We do not foresee any side effects of taking part in this study

What are the possible disadvantages and risks of taking part?

We do not foresee any risks or any disadvantages (except for the time commitment required by you) of taking part in this study.

What are the anticipated benefits of the research?

Participants: Parents will gain information about physical activities that are suitable for infants.

Community: This project has many benefits to the broader research community. This study will help us explore the effectiveness of multi-component intervention in post-natal mother's groups on meeting the Physical Activity Guidelines for infants.

What will we do with the information we obtain?

All information will be kept secure and identified by a code rather than by your or your baby's actual name. Anything that identifies individual participants will not be published. We will publish the study in a peer-reviewed journal and present this study at a conference. Data (de-identified, meaning, you cannot be identified) may be uploaded to a publically available data repository if required to do so by a journal for publication.

This is an invitation to participate

Participation is entirely voluntary, and should you choose to participate, you are free to withdraw (yourself and your baby) from the research at any time. The decision not to participate, or to withdraw, will not affect your relationship with the ISLHD, UOW or SLHD. You are also free to withdraw the data that has been collected in this study up to 6 months after your mother's group has completed.

If at any time you have any questions, please do not hesitate to ask. You and your child's involvement in the research is entirely voluntary. You are free to withdraw your child from the research at anytime without penalty. This study has been reviewed and approved by the Health and Medical Human Research Ethics Committee of the University of Wollongong [Ethics number]. If you have any concerns or complaints regarding the way this research has been conducted you can contact the UOW Ethics Officer on (02) 4221 3386 or email rso-ethics@uow.edu.au.



Consent Form

Research Title: Effect of a multi-component intervention in post-natal mother's groups on meeting the Physical Activity Guidelines for infants. A randomized controlled trial.

Chief investigators: Dr Lyndel Hewitt (Ph: 02 42534801), Ms Carolyn Frohmuller, Senior Professor Tony Okely, Professor Li Ming Wen.

This study is being conducted by the team listed above.

I understand that the data collected will be used to determine the effectiveness of an intervention to promote physical activity among infants. I consent for the data to be used anonymously in that manner. I agree to the following:

Before the study:

1. Read the participant information sheet

Study period:

I agree for my **child and me** to participate in the following activities:

1. Completing a phone interview with the Research Assistant [name inserted here] where I will be asked questions and told about the accelerometer (Parent)
2. Providing basic demographic information such as age, sex, education level (Parent)
3. Wearing the accelerometer during the whole research period (3, 24-hour periods in total) (Child only)
4. Completing the Activity Monitor log (Parent).
5. Be randomly placed in either the intervention or the control group (Parent and Child)
6. Attend the intervention if placed in the intervention group (Parent and Child)
7. Attend the usual mothers group session weekly (Parent and Child)

I understand that my and my child's participation in this research is voluntary. I am free to choose not to participate and I am free to withdraw him/her from the research at any time. My refusal to participate or withdrawal of my consent (for both myself and my child) will not affect our treatment or relationship with the University of Wollongong, the University of Sydney or the Illawarra Shoalhaven Local Health District in any way.

I have read the participant information sheet and I understand what me and my child will be doing. I have been given the opportunity to speak with the researchers.

I, (Parent name) consent to my child

..... (Child's name) to participate in the research conducted by Dr Lyndel Hewitt, Ms Carolyn Frohmuller, Senior Professor Tony Okely and Professor Li Ming Wen as it has been described to me in the information sheet. I understand that the data collected from my child's participation will be used for determining the effectiveness of a physical activity intervention and I consent for it to be used in that manner.

Signed, Date

...../...../.....

Name

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I, (Parent name) consent to participate in the research conducted by Dr Lyndel Hewitt, Ms Carolyn Frohmuller, Senior Professor Tony Okely and Professor Li Ming Wen as it has been described to me in the information sheet. I understand that the data collected from my participation will be used for determining the effectiveness of a physical activity intervention and I consent for it to be used in that manner.

Signed, Date

...../...../.....

Name

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