

Who is carrying out the study?

The study is being conducted by researchers from Edith Cowan University and The ORIGINS Project (Telethon Kids Institute, Joondalup Health Campus).

Principal Investigators:

Dr Roslyn Giglia, A/Prof Therese O'Sullivan, Prof Desiree Silva, Dr Matt Cooper, Prof Valerie Verhasselt, Ms Anita Moorhead

Research team:

Julie Hill (Project Coordinator), Fran Patey (Research Assistant), Kathryn Webb (Research Assistant), Niamh Green (Midwife), Natasha Tolley (Midwife), Cassandra Cuffe (PhD Student)

The ACE Study is also a sub-project of The ORIGINS Project.

Further information

If you have any questions, require any further information about the study, or would like to request a copy of the results of the study on completion, please contact:

Julie Hill, Project Coordinator e: ace@ecu.edu.au
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Complaints or concerns

The ethical aspects of this study have been approved by the Ramsay Health Care WA | SA Human Research Ethics Committee (RHC WA | SA HREC).

If you have any concerns or complaints about this research project and wish to talk to an independent person, you may contact the Research Ethics Officer at either of the below organisations, who will direct your complaint to the most appropriate person.

Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome.

▶ **Joondalup Health Campus Consumer Liaison Office**
p: (08) 9400 9404
e: RamsayHREC.WA-SA@ramsayhealth.com.au

▶ **Edith Cowan University**
p: (08) 6304 2170
e: research.ethics@ecu.edu.au



THE ACE STUDY

PARTICIPANT INFORMATION BROCHURE

Are you expecting your first child?
Interested in learning how to hand express during pregnancy?

Images courtesy of lyssphotostories.com



What is this study about?

The Antenatal Colostrum Expression (ACE) Study aims to determine whether hand expressing of colostrum in the last few weeks of pregnancy can help new mothers to breastfeed. We are comparing two education approaches - hand expressing education by a midwife and watching an instructional video. Results of this study will better inform how we provide pregnant mothers information on antenatal expressing of colostrum.

Who can participate?

The study is looking to recruit pregnant women from ORIGINS families who:

- ▶ Are less than 30 weeks pregnant
- ▶ Have not previously had children
- ▶ Are pregnant with only one baby (not twins or triplets)
- ▶ Are planning to breastfeed and are open to the idea of learning and trying hand expressing
- ▶ Do not have any complications around pregnancy (eg. cervical incompetence or placenta praevia).

What you will be asked to do

If you meet the criteria and agree to participate, you will be randomised into one of two groups for hand expressing instruction;

- ▶ Midwife group: you will attend a face-to-face session with a midwife; or
- ▶ Video group: provided with a link to watch a 15-minute instructional video at home.

You will be asked to have a go at hand expressing according to the instructions given (2 to 3 times per day, from week 37 gestation). You will be asked to keep an electronic expressing diary and you may bring any collected colostrum into the hospital when you come to give birth.

We will also ask you to complete a questionnaire to determine your thoughts around breastfeeding prior to birth (5-10 minutes to complete).

From your medical records, we will be collecting information on you and your baby's medical information, and how you feed your baby.

After your birth, we will give you a call at around one, four, eight, 12 and 16 weeks after the birth of your baby, to collect some more information. Calls will take approximately five minutes each. We will ask you to repeat the breastfeeding questionnaire again at the four week mark.

Are there any risks with participation in this study?

Previously conducted research, involving women with gestational diabetes, found practising antenatal colostrum expression was safe for this group. This research has led to recommendations by midwives and obstetricians for women with gestational diabetes to practise colostrum expression while pregnant.

The ACE Study want to investigate if it is something that would also be beneficial for all women with low-risk pregnancies.

There is a very remote and highly unlikely chance that practicing hand expression may bring on the onset of labour however, this has also not been proven by research. The research staff will explain what signs to look out for, and what action to take if you do experience any signs of early labour.



Optional: Provision of a colostrum sample

Participants will also be given the opportunity to take part in an optional component of the study. This involves collecting a sample of colostrum or 'first milk' before and after the birth of your baby. The samples will be frozen for analysis at a later date to compare the nutritional profile of colostrum of mothers who hand express against colostrum of mothers who do not hand express. You will be asked at around 36 weeks gestation if you would like to be a part of this component of the study.

Your responses will be anonymous and your information will be kept confidential

Your answers will be used for research purposes. All responses you provide will be reported anonymously, so no one will know you participated. Information from the study will be placed securely in password protected computer storage. Results may be presented to the wider community in the form of a journal article or presentation.

Your participation in this study is voluntary

It is completely fine if you decide you do not wish to participate in the study. If you decide to participate and then change your mind, you are free to withdraw from the study at any time and this will not impact on how the hospital staff care for you.

Consent

Prior to providing consent, please feel free to discuss participation in this study with your obstetrician if you have any health concerns.

A team member from the ACE study will contact you to discuss the project prior to your due date and answer questions you may have. We will then send out a link via email to complete an electronic consent form. By consenting to participate in this study, you accept that your de-identified information will be used for research and reporting purposes, for this study and for potential future studies related to this topic.