

What will happen to my information collected in this study?

All information gathered about you, such as personal and health details, and questionnaire answers, will be treated with confidence. No information that could identify you or your baby will be released to any person not associated directly with the study. All members of the PrEggNut Study team are required to sign confidentiality agreements and are committed to protecting the confidentiality and privacy of data and biological samples. In exceptional circumstances, disclosure of your health information can be required by law, for example, as a result of a court order. Such requests are rare; however, we have an obligation to inform you of this possibility. The results from the study may eventually be published in medical journals or at professional meetings, but you will not be identified in any way.

What are the possible risks of taking part in this study?

Medical procedures and sample collections sometimes cause side effects. You and your baby may have none or some side effects. If you or your baby has any new or unusual symptoms talk with the study researchers, who will also be looking out for side effects. Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

Will you be using information collected as part of ORIGINS?

Yes, we will request permission from you to access the questionnaire information you have provided to the ORIGINS project. We will ask your consent to examine the blood and breast milk samples that were collected from you and your baby. We will also request permission from you to share the information we collect as part of the PrEggNut Study with the ORIGINS data and biobanks.

Any Questions?

If at any time during the study you have any questions, please call our office on 9400 9340 or email Dr Debbie Palmer at debbie.palmer@telethonkids.org.au



Do I have to take part in this study?

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part in the PrEggNut Study and later change your mind, you are free to withdraw from the study at any stage. Should you choose to withdraw, please notify Dr Debbie Palmer on phone 9400 9340 or email debbie.palmer@telethonkids.org.au. The information and samples that you provide will continue to be kept securely and used for the purpose of the study unless you request for them to be disposed of.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your partner, nor your relationship with the Joondalup Health Campus

Who are the researchers leading this study?

The Chief Investigators on this study are Dr Debbie Palmer from the Telethon Kids Institute and Professor Susan Prescott from the University of Western Australia.

Who to contact if you have any concerns about the organisation or running of the study?

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 complaints or reservations about any ethical aspect of your participation in a research project, please contact the Consumer Liaison Office at the Joondalup Health Campus on 08 9400 9404 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.

THE
ORIGINS
PROJECT



TELETHON
KIDS
INSTITUTE
Discover. Prevent. Cure.

Joondalup
Health Campus
Part of Ramsay Health Care



THE PRÉGGNUT STUDY

PARTICIPANT INFORMATION BROCHURE

Maternal diet rich in eggs and peanuts to reduce food allergies: a randomised controlled trial



HOW MANY PARTICIPANTS?

Around Australia, there will be 2136 women and their babies

What is the PrEggNut Study?

You are invited to participate in a study that aims to reduce the risk of food allergies in children. By 1 year of age, 10% (1 in every 10) babies will develop a food allergy. We now know that regular consumption of traditionally allergenic (causing allergic reactions) foods, like egg and peanut, in solid foods can help to reduce food allergies. However, this is too late for some babies, who have an allergic reaction to a food the first time they eat it after commencing solids.

We think that during pregnancy and breastfeeding could be the ideal time to prevent food allergy prior to solid food introduction. We know that the food proteins in allergenic foods, like egg and peanut, can be detected in breast milk. The more egg that is eaten by a breastfeeding mother, the higher the amount of egg protein that can be measured in her breast milk. However, we do not know whether more or less eggs (or peanuts) eaten during pregnancy or by a breastfeeding mother will help to reduce the risk of her baby developing food allergies.

The aim of the PrEggNut Study is to answer the question of whether the amount of eggs and peanuts a mother eats during pregnancy and breastfeeding has an influence on her baby's food allergy development.

Who can participate in the PrEggNut Study?

- Women whose babies have at least two family members (mother, father or siblings) with medically diagnosed allergic disease (asthma, eczema, hayfever or food allergy). Babies who have at least two family members with allergic disease have a higher risk of developing food allergy.
- Women who are planning to breastfeed for at least 4 months.
- Women who do not have an egg or peanut allergy.
- Women who are not participating in the SYMBA or BENEFIT studies.

What does my participation involve?

In addition to your participation in The ORIGINS Project, we would ask you to follow the PrEggNut Study dietary advice that you are given about amounts of eggs and peanuts to eat per week from 22 weeks of pregnancy until your baby is 4 months of age.

Eating eggs and peanuts

- You will be randomly assigned (like tossing a coin) to one of two groups. Neither you nor the research team will be able to choose which group you are in. The amounts of eggs and peanuts will be either:
 - **Group 1:** at least 6 eggs and 60 peanuts (= 3 tablespoons peanut butter) per week
 - **Group 2:** no more than 3 eggs and 30 peanuts per week
- You will be able to include all forms of egg and peanut, and egg and peanut containing foods, towards your weekly target of egg and peanut ingestion. You will be provided with a conversion table showing the amount present in common egg or peanut foods, for example peanut butter, or egg in quiche, or in baked goods.
- You will be provided with a supply of both peanuts and peanut butter to reduce costs of participation in this study. Due to the reduced shelf-life of eggs you will need to purchase these yourself.
- Once a month we will ask that you complete a short survey of 4-5 questions on your mobile phone to tell us about how you are going eating eggs and peanuts and, after birth, any breastfeeding problems.

Telephone calls

We will telephone you for around 10 minutes when your baby is 2 weeks of age to ask how you are going with eating the eggs and peanuts. In addition we will gather information about your baby's birth and any illnesses or health problems you are having. You will also be asked about your baby's feeding and any symptoms of allergies. We will also telephone you for approximately 10 minutes when your baby is 8 months old, to ask about any allergic reactions your baby may have had after commencing solid foods.

Attending appointments and sample collection

In addition to the appointments and sample collections as part of your participation in the ORIGINS Project, as detailed in the ORIGINS Participant Information Booklet, your participation in the PrEggNut Study would also involve one additional appointment when your baby is 4 months of age.

At this additional appointment:

- We will ask about any illnesses or health problems you are having.
- You will be asked about your baby's feeding and any symptoms of allergies. Your baby will have a full skin assessment to check for signs of eczema.
- Your weight will be measured, as well as your baby's weight, length and head size.
- A sample of your and your baby's blood (5mL = 1 teaspoon) will be collected.
- These visits will be at no cost to you, nor will you be paid. All the tests and medical care required as part of the study will be provided to you free of charge.

Food challenge at 12 months of age

If your baby has a positive allergy skin test to egg and/or peanut there is a chance they may have an egg and/or peanut allergy, so you will be given the opportunity for your baby to have a medically supervised egg and/or peanut challenge to determine if s/he can eat egg and/or peanut safely at home.

During the egg and/or peanut challenge your baby will be given increasing amounts of egg and/or peanut and watched for any signs of an allergic reaction. After finishing all of the egg and/or peanut your baby will be observed for 2 hours, as most serious reactions (i.e. anaphylaxis) occur within this time. Very rarely, a baby might have a mild reaction after leaving the challenge appointment and we ask parents to report these delayed reactions (rashes, diarrhoea etc) to study staff as soon as possible.

Please note that if your baby has ever had a confirmed severe reaction (called "anaphylaxis") after eating egg and/or peanut s/he will not undergo this challenge. If your baby needs both an egg and peanut challenge, you will have the egg challenge on one day and will then need to return on a separate day for the peanut challenge.

