

WHAT WILL HAPPEN TO MY INFORMATION COLLECTED IN THIS STUDY?

All information gathered about your baby, such as personal and health details, and questionnaire answers, will be treated with confidence. No information that could identify you or your child will be released to any person not associated directly with the study. All members of the Cashew Nut 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 your baby will not be identified in any way

WILL YOU BE USING INFORMATION COLLECTED AS PART OF ORIGINS?

We will ask your consent to examine the allergy skin prick test results and blood sample collected from your child at 1 year of age as part of the ORIGINS study. We will also request permission from you to share the information we collect as part of the Cashew Study with the ORIGINS data and biobanks.

DO I HAVE TO TAKE PART IN THIS RESEARCH 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 Cashew 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 9408 3113 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 Cashew Study are Professor Susan Prescott, Professor Desiree Silva and Dr Debbie Palmer from the University of Western Australia, Joondalup Health Campus and Telethon Kids Institute.

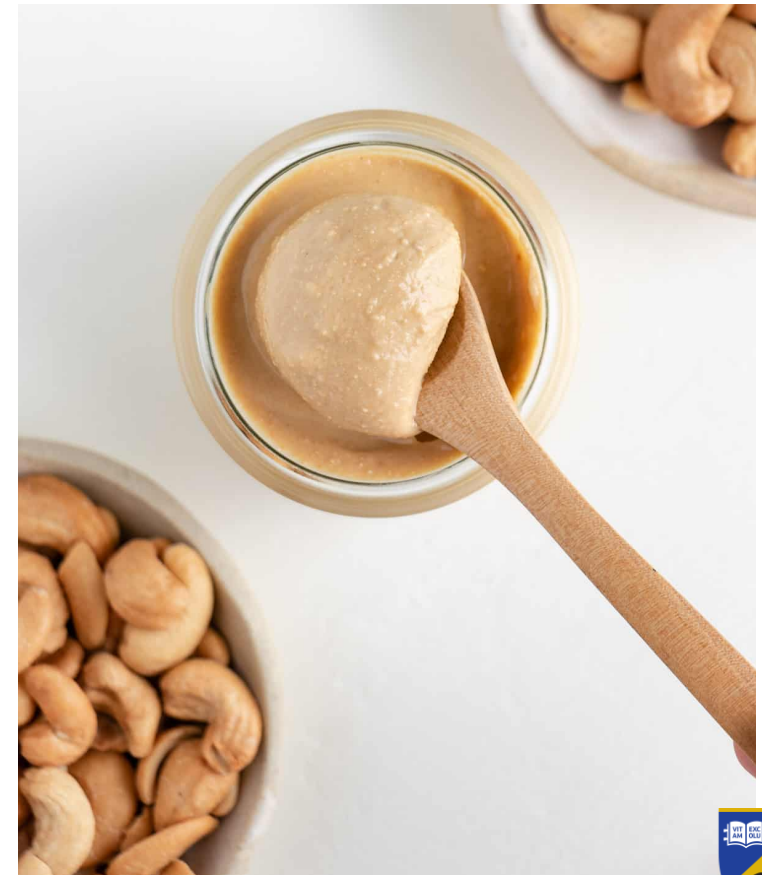
WHO TO CONTACT IF YOU HAVE ANY CONCERNS ABOUT THE ORGANISATION OR RUNNING OF THE STUDY?

The ethical aspects of this study have been approved by the Joondalup Health Campus Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact JHC Executive Office on (08) 9400 9404. Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome. .



Introducing cashew nuts during infancy

The Cashew Study



ANY QUESTIONS?

If at any time during the Cashew Study you have any questions, please ring our office on 9408 3113 or email the Cashew Study Chief Investigator, Dr Debbie Palmer at Debbie.Palmer@telethonkids.org.au



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WHAT IS THE CASHEW STUDY?

You are invited to participate in a study that aims to reduce the risk of food allergies in children. Recent Australian research has found that approximately one in twenty school students have a food allergy, and peanut and cashew nut allergies are most common.

The 2016 revised Australasian Society of Clinical Immunology and Allergy (ASCIA) allergy prevention guidelines recommend: all babies should be given allergenic (can cause allergic reactions) foods including peanut butter, cooked egg, dairy and wheat in the first year of life. However there is no specific mention of cashew nut. Cashew nut spreads are a paste like peanut butter and could be introduced into the diets of babies after they commence eating solid foods.

The aim of the Cashew Study is to investigate different doses of cashew nut spread regularly eaten by babies from 6 months of age to 1 year of age.

WHO CAN PARTICIPATE IN THE CASHEW STUDY?

- **Babies who are born ≥ 37 weeks gestation.**

WHO CAN NOT PARTICIPATE IN THE CASHEW STUDY?

- **Babies who are participating in the SYMBA or BENEFIT studies.**

HOW MANY PARTICIPANTS?
This study will involve 141 babies.

WHAT DOES PARTICIPATION INVOLVE?

In addition to your baby's participation in the ORIGINS Project, we would ask you to follow the Cashew Study dietary advice you are given for the amounts of cashew nut spread to be given to your baby from 6 months of age to 1 year of age.

Eating Cashew Nut spread

- Your baby will be randomly assigned (like tossing a coin) to one of three groups. Neither you nor the research team will be able to choose which group your baby is in. The amounts of cashew nut spread will be:
 - Group 1: 1 teaspoon three times per week
 - Group 2: increasing from 1 teaspoon to 3 teaspoons three times per week
 - Group 3: no specific recommendations to introduce cashew nut spread
- Babies in groups 1 and 2 will be provided with a supply of cashew nut spread to reduce costs of participation in this study.

Telephone calls

We will telephone you for approximately 10 minutes when your baby is 7, 8, 9, 10 and 11 months of age to ask how your baby is going with eating the cashew nut spread and about the introduction of other allergenic foods including peanut butter, cooked egg, dairy and wheat. You will also be asked about your baby's breastfeeding and/or formula feeding and about any symptoms of allergies.

Attending Appointments and Sample Collection

In addition to the appointments and sample collections as part of the ORIGINS Project, as detailed in the ORIGINS Participant Information Booklet, participation in the Cashew Study would also involve the following:

An additional appointment when your baby is 6 months of age

- We will weigh and measure your baby.
- You will be asked about usual family dietary intakes of cashew nuts and peanuts, family history of allergic disease, ethnicity, parental education, household smoking and pet ownership.
- A sample of your baby's blood (5mL = 1 teaspoon) will be collected.
- If your baby is in group 1 or 2 the first taste of the cashew nut spread will be under medical supervision at Joondalup Health Campus. Your baby will be given a rub of the cashew nut spread inside their bottom lip and watched for 15 minutes. If your baby has no symptoms of an allergic reaction, then 1 teaspoon of cashew nut spread will be mixed in with 2 tablespoons of one of their previously eaten solid foods (for example fruit or vegetable puree or yoghurt). Firstly 2 teaspoons (from total of 9 teaspoons) of this food mixture will be given to your baby. After 15 minutes, if your baby has no symptoms of an allergic reaction, then the remainder of this food mixture (7 teaspoons) will be given to your baby, and we will continue to observe your baby for any allergic reaction symptoms for a further 1 hour. If an allergic reaction occurs the study team will treat the allergic reaction accordingly.

An extended length appointment (up to 90 minutes longer than the standard ORIGINS appointment) when your baby is 1 year of age

- in addition to the allergy skin prick test, questions asked and samples collected as part of your baby's participation in the ORIGINS Project 1 year of age visit, we will also give all babies (groups 1, 2 and 3) participating in the Cashew Study 2 teaspoons of cashew nut spread under medical supervision. Your baby will be observed for 1 hour to check for any signs of an allergic reaction. If an allergic reaction occurs the study team will treat the allergic reaction accordingly.

Both of 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.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART IN THIS STUDY?

Medical procedures and sample collections sometimes cause side effects. Your baby may have none or some side effects. Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

At both the 6 month of age and 1 year of age appointments, if there are any signs of an allergic reaction after your baby eats the cashew nut spread, the cashew feeding will cease and the study team will treat the allergic reaction accordingly. You will also be provided with education on recognising the signs and symptoms of an allergic reaction and advice of what to do in such circumstances.