The Breast Milk Omega-3 Trial: Assessing the Uptake of Omega-3 Fatty Acids from Supplements into Breast Milk

The purpose of this study is to determine the efficiency of uptake of omega-3 fatty acids into breast milk from a specific type of omega-3 supplement. Omega-3 fatty acids support both maternal health and infant development. Fish is the major dietary source of omega-3 fatty acids, but fish consumption in Australia is low, and omega-3 supplements are an alternative way to increase omega-3 status. Previous studies have shown that the uptake of omega-3 fatty acids into human blood and breast milk can vary significantly between different types of omega-3 supplements according to the formulation and form in which the fatty acids are provided. In the case of women who are breastfeeding, the uptake of supplements into breast milk depends on both the efficiency of uptake into the maternal circulation, and the transfer of these fatty acids to the breast milk, both of which can vary between individuals.

What does this study involve?

If you consent to being involved, you will be randomly assigned (like tossing a coin) into one of two groups. One group will be asked to take capsules containing fish oil (omega-3 group) and the other group will take capsules containing olive oil (placebo group). At the first appointment, both groups will be provided with 1 bottle of 1000mg capsules and asked to take 2 of these capsules every day for four weeks.

At this first appointment one of our research staff will collect a dried blood spot sample from you. This blood sample is collected from a small fingerpick and a drop of blood placed on the collection card. You will also be asked to express a small amount of your breast milk (~10ml) into a sample collection pot (you will be given a private area to do this). These samples will be used to measure the baseline fatty acid status of your blood and total fat content and fatty acid composition of your breast milk. We will also ask you a few questions relating to your education, employment and general health (height, weight, any chronic health conditions) and some information about your baby (e.g. age, sex, weight and length).

We will then provide you with sample collection pots, collection cards and instructions on how to collect the blood spots and breast milk samples yourself at home for the rest of the study. You will need to collect the following samples:

- Blood spots onto the cards once a day for the first week and two days a week for the next three weeks of the study
- Breast milk samples (~10mls) once a day for the first week and two days a week for the next three weeks of the study.

We will send you SMS reminders regarding sample collection. All samples can be stored at home and breast milk samples can be stored in your home freezer until your final appointment or collection by one of our study staff. At the end of the 4 weeks, you will be asked to attend a final appointment at either your home or at the Women's and Children's Hospital, where we will collect all of your samples from you and you can return any spare capsules.

One of our study staff will contact you by your preferred means of contact each week during the study to check if you have missed any capsules for any reason and to collect information on any side effects you or your infant may have experienced.

You will be given $50 at the end of the trial to off-set expenses associated with taking part in this study (such as care for siblings, travel and car parking) and compensate you for your time.

Confidentiality

Your results will be kept securely at all times. Anyone who has access to your identified records is bound by law and by professional codes of conduct to keep your information confidential. Results from this research will be published in various ways, including conference papers, reports and journal articles. They will not be published in a form that could identify you. Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare; however we have an obligation to inform you of this possibility. Documents and electronic data will be retained for at least 30 years after study completion in line with the data retention schedules for research involving minors.

What are the benefits and risks?

There is unlikely to be any benefit to you taking part in this testing. However, it will help us determine how efficiently the omega-3 fatty acids from the specific type of omega-3 supplement are taken up into breast milk, which will help for providing accurate information to consumers. The dose of omega-3 in this study has been used in previous trials involving pregnant and breastfeeding women and shown to be safe, but there is a possibility that that you may experience side effects from the capsules, such as rashes, allergies or fishy burps. At an extremely high dose (12 times higher than in this study) fish-oil supplements may result in a 10% increase in blood clotting time and 10% decrease in blood pressure, neither of which is considered dangerous. The collection of fingerprick samples may cause mild discomfort.

What if I change my mind later?

If at any time you change your mind about being involved in this study you may withdraw your consent. If you withdraw from the study after we have obtained samples for assessment, we will ask that you allow these results to remain as part of the research, to ensure that the results are as useful as possible. However, you are free to require that all information that can be linked to your identity be removed from the project.

Possible future research

Omega-3 fats have a number of health benefits for the developing infant, but the uptake of these fats into breast milk can vary between individual women. We may use some of the information collected in this study to look at factors that can affect the efficiency of uptake of these fats into breast milk. These studies are very unlikely to produce any clinically significant findings, but will help us to understand more about omega-3 fats in breast milk.

Alternate contacts

We recognise that people often change their telephone number and address, and therefore cannot be contacted by researchers. To help keep in contact with you we are asking you to provide us with the names and contact details of persons who would be able to let us know your new contact details; these people are usually friends or relatives and are called alternate contacts. If we needed to use one of the alternate contacts we would call them, explain who we are and that you were involved in a study and have given us their contact details so that they can put us in touch with you.

For further information about the study

If you would like more information about this study, now or later, please ring our office on 8161 8045 and leave a message on our answering machine; one of our research staff will return your call as soon as possible.

For confidential enquires or to register a complaint

This study has been reviewed and approved by the Women's and Children's Health Network (WCHN) Human Research Ethics Committee Approval number HREC/17/WCHN/37. 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 should you wish to make a confidential complaint, you may contact the executive secretary of the Human Research Ethics Committee, Ms Brenda Penny, WCHN (8161 6521).

Yours Sincerely,

Bev Muhlhausler
Child Nutrition Research Centre
A Division of the Healthy Mothers, Babies and Children's Theme, South Australian Health and Medical Research Institute,
Women's and Children's Hospital
72 King William Road, North Adelaide SA 5006

Women's & Children's Health Network (WCHN)
Human Research Ethics Committee (HREC)

CONSENT FORM

I _____

hereby consent to my involvement in the research project entitled:

The Breast Milk Omega-3 Trial: Assessing the Transfer of Omega-3 Fatty Acids from Supplements into Breast Milk

1. The nature and purpose of the research project described on the attached Information Sheet has been explained to me. I understand it, and agree to taking part.

2. I understand that I may not directly benefit by taking part in this study.

3. I acknowledge that the possible risks, discomforts and inconveniences, as outlined in the Information Sheet, have been explained to me.

4. I understand that while information gained in the study may be published, I will not be identified and information will be confidential.

5. I understand that I can withdraw from the study at any stage and that this will not affect medical care or any other aspects of my relationship with this hospital.

6. I have had the opportunity to discuss this research project with a family member or friend and/or have had the opportunity to have a family member or friend present whilst the research project was being explained by the researcher.

7. I am aware that I should retain a copy of the Consent Form, when completed, and the Information Sheet.

8. I consent to providing blood samples by dried blood spot finger prick method and breast milk samples being collected as per instructions explained to me.

9. I understand that information will be kept confidential except where there is a requirement by law for it to be divulged.

10. I do/do not consent to any information collected in this study being used in any other research project, provided the project has the approval of the Women's and Children's Health Network Research Ethics Committee

Signed: .....

Full name of participant: .....

Dated: .....

I certify that I have explained the study to the participant and consider that she understands what is involved.

Signed: ..... Title: .....

Dated: .....