The SMILEY Study
Parent/Caregiver Information Sheet and Consent

Invitation

You are invited to participate in a pilot research study to explore the effect of an early weaning food product based on oats mixed with either sheep or cow milk on the infant gut microbiota (the bacteria within the digestive tract). This study is being conducted by Professor Clare Wall and her colleagues from The University of Auckland, AgResearch, Plant and Food Research, Massey University, and Otago University.

This Participant Information Sheet and Consent Form tells you about the study. It explains the tests and research involved, any benefits and risks, and what will happen after the study ends. Knowing what is involved will help you decide if you would like to take part. Please take the time to read this information sheet carefully. You may wish to talk about this study with other people such as family, whānau, friends, or healthcare providers. You will have the opportunity to discuss the information presented here with the study team, who can answer any questions you may have.

If you agree to take part in this study, you will be asked to sign the Consent Form. You will be given a copy of this information sheet and the signed consent form for your records. This document is 9 pages long, including the consent form. Please make sure you have read and understood all the pages.

What is the purpose of this study?

We know the human gut microbiota (gut bacteria) plays an important role in our health. Babies are initially born with few gut bacteria, which are subsequently influenced by delivery, milk feeding, and the introduction of food during the first year of life. The purpose of the SMILEY study is to compare the impact of consuming an infant oat-sheep milk product with an infant oat-cow milk product on the infant gut bacteria. We are also interested in exploring how the changes in microbiota may impact on digestive comfort and sleep.

Who designed the study?

The study is led by Professor Clare Wall and was designed by researchers at the University of Auckland, AgResearch (Palmerston North), Riddet Institute (Massey University), Plant and Food Research and Otago University. The study has received funding as part of the National Science Challenge – High Value Nutrition (www.highvaluenutrition.co.nz).

Why have I been invited to participate in this study?

You have been invited to participate in this study because you are the parent or legal guardian of a baby who has not yet started solids. You also plan to introduce your baby's first solids at around 6 months of age, as per the Ministry of Health Food and Nutrition Guidelines.

Who can participate?

You can participate in this study if your baby:

- Is healthy
- Has not started solids
- Is exclusively breastfed
- Will have their first foods introduced at around 6 months of age
- Born after 32 weeks gestation
- Has no developmental disability
- Has no significant health issues
- Has no feeding problems
- Is not currently taking antibiotics

- Is not currently taking a probiotic or prebiotic
- Is immunised according to the New Zealand Immunisation Schedule

If your baby is taking a probiotic or prebiotic (as a supplement or in infant formula), you can still participate in the study if you are willing to stop taking these.

What does my participation in the study involve?

This is a pilot study and will involve 105 infants who have **not yet started solids** and their mothers. The oat-milk based interventions will start at around 6 months of age (the recommended age for introduction of complementary feeding, according to the NZ Ministry of Health and World Health Organisation recommendations). The study will be completed **four weeks** after the introduction of solids (i.e. when your baby is around 7 months of age).

If you decide to take part, your baby will be **randomly assigned** (like flipping a coin) to one of three groups (35 infants in each group). One group will receive the infant oat-sheep milk-based product, another group will receive the infant oat-cow milk-based product, and a third group will be the control group. The control group will not be required to give their child any product. Neither you nor the study team will be able to choose which group you are in. This study has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions.

If randomised to the food groups, you will be asked to gradually introduce the food until your baby is consuming approximately 12g (3 scoops) of product per day. The product is prepared by mixing the powder with hot (not boiling) water to form an age-and stage-appropriate consistency. It will take time for your baby to be able to consume the full 12g product after starting solids. You will be supplied with all the food product required for your participation in this study at no cost.

Both infant food products involve the use of accepted ingredients in infant nutrition and are manufactured in a registered facility that complies with Food Standards Australia and New Zealand Guidelines, with respect to manufacturing standards and compliance with food safety requirements, including allergy management.

If randomised to control group, you will receive a gift voucher to the value of the food product provided.

What if I don't want my child to take part in this study, or if I want to withdraw later?

Taking part in this study is your choice. If you decide not to take part in this study, it will not affect the treatment you receive now or in the future, nor will it influence any future involvement with the University of Auckland. You are free to withdraw your baby from this study at any time without having to explain why. If you decide to withdraw your baby from the study, the information collected about your baby up to the point of withdrawal may continue to be used. If you are concerned about this, one of the researchers will be happy to discuss this in more detail with you.

Sample collection

Over the four-week duration of the study, we will need to collect remotely (via phone, email or video) information, several measurements and samples from **you and your baby. This will be at three time points**: when your baby is around 4-5 months of age and then 2 weeks and 4 weeks after this when they have commenced solids. At the beginning of the study, you will be given the right amount of food product (or vouchers) that you will need until the end of the four-week period. During the study period you will also be able to contact the research team if you have any concerns or issues. If needed, you will have the opportunity to request corrections to mistakes and omissions of any data collected during the study.

The study will involve the collection and analysis of stool (poo) samples. If you have any cultural considerations or questions that relate to your potential participation in this study, please ask the study team before signing the consent form. It is the role of the investigators to ensure that you understand all procedures and risks.

We would like to collect the following measurements and samples from **mothers and their baby's**:

Time point	Baby age	Data collected
Baseline	4-5 months	**Baby**: length, weight (Well Child book), stool sample **Mother**: sleep questionnaire, health questions
Halfway	2 weeks after starting solids	**Baby**: stool (poo) sample, digestive comfort questionnaire, dietary Intake **Mother**: sleep questionnaire, digestive comfort questionnaire
End	4 weeks after starting solids	**Baby**, stool (poo) sample, digestive comfort questionnaire, dietary Intake length, weight (Well Child book) **Mother**: sleep questionnaire, health questionnaire, intervention adherence

Baby sample and data collection

Length and weight	Information from the Well Child book.
Stool (poo)	You will be provided with a sample collection kit with instructions for the successful collection, and couriering of the sample to University of Auckland (the university will then arrange for samples to be couriered to AgResearch). Stool collection is not an invasive or upsetting procedure for your infant and a small quantity can be collected from the nappy. Samples will be used to measure the microbiota and fatty acids and will take 5 minutes to collect at home.
Dietary intake	Infant food intake will be collected using parent-completed, 3-day food records. This measurement will be collected twice (halfway and completion).
Sleep Data	Infant sleep will be recorded using a parent-completed sleep diary, which captures sleep-wake timing data across a 24-hour period and the Brief Infant Sleep Questionnaire (BISQ), which is used to assess sleep.
Digestive Comfort	Infant digestive comfort will be measured using a questionnaire (IGSQ) which captures how well baby tolerates feeding.

Mother data collection

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Sleep data	Parent sleep quality, impairment, and disturbance will be measured using brief validated questionnaires. These measurements will take approximately 15 minutes to complete via an online questionnaire.
Questionnaires	We will gather information on your family, household, participating baby's health and feeding, and fortnightly progress throughout the study. These questions will be completed via online questionnaires and will take approximately 30-45 minutes to complete.

Will I benefit from the study?

Taking part in this study will help us understand how the introduction of complementary solid foods and changes in milk consumption impacts infant gut bacteria, sleep behaviour and digestive comfort. Your involvement in this study is of great value to the researchers; thank you for considering taking part.

Are there risks to me or my baby taking part in this study?

Overall, there are no major risks associated with taking part in this study. If you participate in this study, you need to be aware that this may involve your baby consuming up to the required amount (12g) of oat-milk based product per day from study entry until your baby is around 7 months old.

The study team have designed the questionnaires and methods for data/sample collection used throughout the study to have as much minimal impact on you as possible. As with any research, there may also be risks that are presently unknown or unforeseeable.

How will my confidentiality be protected?

We treat confidentiality and protection of your personal information as a matter of high priority during your participation in this study. The researchers will de-identify (remove) all personal information provided by you and there is no risk that you will be able to be identified should the results of this study be published, or samples be sent overseas. Any identifiable information collected about you, your whānau/family or your baby during this study will remain confidential and will only be revealed with your permission, or except as required by law.

On entering the study, you will be given a unique study identification number (SMILEY ID), which will be used for identification on all forms, questionnaires, and measurements. This ensures that your baby cannot be identified in any way. All documents, including paper copies of questionnaires, data collection forms or measurements will be stored in locked filing cabinets in a secure swipe-access area at the University of Auckland, where only the research team has access. The SMILEY study researchers will ensure the study is carried out according to the guidelines for Good Clinical Practice.

Whilst the SMILEY team have endeavoured to protect participant confidentiality, if your baby attends a day care facility and dietary intake is recorded by your day care provider, there could be a possibility that other people will know your baby is participating in the study.

What will happen with our stool samples

Stool: Your baby's stool samples will be analysed to assess changes in gut microbiota (through identifying and classifying the types of gut bacteria present), measuring bacterial diversity and production of short chain fatty acids.

Samples will be analysed at AgResearch (Palmerston North). All samples will be labelled with your SMILEY ID number, not your name and will be stored in secure freezers in an access-restricted area at the AgResearch Palmerston North. Your samples will be kept until 2026 after data and sample collection have been completed to allow for any re-testing that may be required.

What happens with the results?

If you give us your permission by signing the Consent Form, findings from the study will be used in internal reports, conference presentations, and research publications. Participating whānau/family will be provided with a report detailing the main study findings and any implications this may have for you.

The results will be stored using a coded number on a computer at the University of Auckland. Any data collected in paper form will be stored in a locked room. After completion of the study, we will keep your data for 10 years after the youngest participant has turned 16 years-of-age. You will only be contacted in the unlikely event that we would like to perform further unspecified analysis. If we cannot contact you at this time, we will not perform this analysis on your samples.

What happens if my baby or I suffer harm, injury or complications because of the study?

It is unlikely that your baby will suffer any harm or complications because of this study. If you have any concerns, you should contact one of the researchers who will help you to obtain appropriate care as required. You would be eligible to apply for compensation from ACC, just as you would if you were injured in an accident at work or at home. This does not mean that your claim will be automatically accepted. You would have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health insurance, you may wish to check with your insurer that taking part in this study won't affect your cover. It is not thought that being a part of this study will cause any harm, injury, or complications.

Will taking part in this study cost me anything, and will I be paid?

Taking part in this study should not cost you anything apart from your time, for which we thank you. The study is run remotely, and you do not have to attend a designated research venue. The food product will be supplied to you at no cost for the duration of the study or you will receive gift vouchers to the value of the food product. All participants will receive a koha (gift) in the form of vouchers as an expression of thanks for dedicating time to this research.

What should I do if I want to discuss this study further before I decide?

When you have read this information a member of the study team will discuss it with you and answer any questions that you may have. You may wish to talk about this study with other people such as family/whānau, friends, or healthcare providers. If you would like to know more at any stage, please do not hesitate to contact the trial coordinators, Sophia Amjad (TBA) and Philippa Miskelly (027-2032638); email: thesmileystudy@auckland.ac.nz.

Who should I contact if I have concerns about the conduct of this study?

The investigators conducting this study follow the rules governing the ethical conduct of research and at all times aim to protect the interests, comfort and safety of all participants.

You are free to discuss your participation in this study with the project staff: Professor Clare Wall (c.wall@auckland.ac.nz)

Ngā Tāngata hei whakapānga atu - For more information please contact:

Independent Health & Disability advocate
Phone: 0800 555 050
Email: advocacy@advocacy.org.nz

Māori cultural support
Professor Papaarangi Reid
Phone: (09) 923 1922
Email: p.reid@auckland.ac.nz

Health and Disability Ethics Committee (HDEC)
Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

This research has received Ethical Approval from HDEC; Reference Number2023 FULL 1557

The SMILEY team

The University of Auckland
Dr Philippa Miskelly
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Professor Clare Wall
Dr Amy Lovell
Dr Robyn Lawrence
Miss Xiaoxi Fu

AgResearch
Dr Jane Mullaney
Dr Karl Fraser

Riddett Institue
Professor Warren McNabb

Plant & Food Research
Dr Janine Cooney

Otago University
Professor Nicole Roy

Thank you for considering participation in this study!

The SMILEY Study Consent Form

The researchers seek your consent to participate in the above research.

The investigators conducting this research project abide by the principles governing the ethical conduct of research as set out by the World Medical Association, *Declaration of Helsinki (2008)* and the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* and at all times, avow to protect the interests, comfort and safety of all subjects. This form and the accompanying participant information sheet have been given to you for your own protection.

As a participant in the above-mentioned study please tick to indicate consent to the following:

Consent – *Adult providing consent on behalf of your baby*

As a participant:

I have received the Participant Information Sheet, and I have read, or have had its contents read to me, and I understand what is required of me. I have been given the opportunity to discuss the contents with my family/whānau and study investigators prior to the commencement of the study;	Yes ☐
I understand that taking part in this study is voluntary (my choice) and that I may withdraw my baby from the study at any time without this affecting medical care or my relationship with the University of Auckland;	Yes ☐
If I decide to withdraw my baby from the study, I agree that the information collected about my baby up to the point of withdrawal may continue to be used;	Yes ☐
I am aware that the research will involve recruiting up to 105 babies who have not yet been given solid food and their mothers. I also understand that my baby will be randomised to receive one of two oat-milk based products or to receive vouchers to the same value;	Yes ☐
I understand that my baby may be required to eat approximately up to 12g of the oat-milk based product each day for the 4 weeks of the study;	Yes ☐
I understand that my participation in this study is confidential and that no material which could identify me, or my baby will be used in any reports on this study;	Yes ☐
I understand that my de-identified data will be accessed by study monitoring committees, and DMC, who are responsible for the interests and safety of the study participants (mothers and their baby's);	Yes ☐
I know who to contact if I have any questions about the study in general;	Yes ☐
I wish to receive a summary of the results from the study	Yes ☐ No ☐

Data collection:

I consent to the research staff collecting and processing information about my baby including information about their health, feeding and sleep behaviour;	Yes ☐

I understand that I will be required to complete a set of questionnaires, which are designed to provide the researchers with valuable information about, my baby's growth and development, food intake and sleep habits;	Yes ☐
I understand that I will be required to complete a set of questionnaires, which are designed to provide the researchers with valuable information about my household situation, and my sleep habits;	Yes ☐
I understand that I will have the opportunity to request corrections to mistakes and omissions of any data collected during the study;	Yes ☐
I understand that a researcher will contact me weekly to check my baby's progress with this study;	Yes ☐
If at any point my baby attends day care during the study, I consent to the study team contacting them for further information on food intake;	Yes ☐ No ☐

Collection, storage, use and disposal of samples:

I consent to the collection of my baby's stool (poos) at 3-time points;	Yes ☐

Declaration by parent/guardian on behalf of participating infant:

I_____ (full name) hereby consent to my

baby_____ (name) participating in the SMILEY study.

Signature: Date:

Declaration by mother:

I_____ (full name) hereby consent to my

participation in the SMILEY study.

Signature: Date:

Declaration by member of study team:

I have given a verbal explanation of the study to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Project explained by:

Project role:

Signature: Date:
