Development of Baby Foods for A Healthy Gut

PARTICIPANT INFORMATION SHEET

STUDY PROCOTOL ID: DBF001

HUMAN RESEARCH ETHICS COMMITTEE NUMBER: 2022_048_HREC

INTRODUCTION

Each year CSIRO performs a number of research projects involving human participants. We examine the effect of different diets on health, disease and other related outcomes. This study is an investigation into the prebiotic effect of new complementary food ingredients (e.g. BARLEYmax) in shaping heathy gut microbiota at early-weaning stage in a laboratory based fermentation model.

Gut microbiota impacts health and development from the beginning of life. Feeding during infancy plays significant roles in shaping your child's gut microbiota. The MOSH (Microbiomes for One Systems Health) Human Gut team at CSIRO aims to develop new complementary foods with BARLEYmax as a key ingredient to shape infant gut microbiota with healthy configuration and resilience.

BARLEYmax is a wholegrain developed by CSIRO with a superior dietary fibre profile and prebiotic properties. Effect of BARLEYmax in altering gut microbiota has been demonstrated in animals and human adults. However, the prebiotic effect of BARLEYmax has not been assessed using infant samples and it is unclear when the infant gut microbiota starts to possess the ability to ferment specific dietary fibres in BARLEYmax.

This project aims to assess the prebiotic potential of BARLEYmax to be used as a functional complementary food to shape the healthy gut microbiota at early weaning stage. Additionally, this project aims to obtain a better understanding of the development of fermentation capability of infant gut microbiota at early stage of weaning.

This is a laboratory-based study, and no intervention is involved. Your child will be on his/her habitual feeding and does not need to eat anything from the study. The study only needs to collect your child's faecal sample for a fermentation study carried out in laboratory tubes. The collected faecal samples may be used to assess prebiotic effect of other food ingredients in addition to BARLEYmax. We will also need you to provide information on your baby's feeding and diet (using a two-day food diary and a food frequency questionnaire) prior to faecal sample collection.

WHAT IS THE AIM OF THIS STUDY?

Using a laboratory-based fermentation model, we aim to assess whether BARLEYmax can alter infant faecal microbiota toward a healthy pattern and promote the production of beneficial metabolites. Additionally, this study is also designed to obtain a better understanding of the developmental trajectory of fermentation capability of infant gut microbiota during weaning.

HOW WILL THE STUDY BE CARRIED OUT?

Who can participate?

To be eligible to take part in this research, there are a few criteria you and your child must meet. Please read the criteria below. If you feel this describes you, and you are keen to take part, then please complete the screening survey. If you are unsure or have any questions, do not hesitate to contact the study coordinators, either by phone 08 8305 0615 or email CRUstudies@csiro.au and we can assist.

Inclusion criteria:

- Infants who are at least 4 months old
- Infants have not yet commenced solid food
- Caregiver is willing to collect and provide faecal samples of their children
- Caregiver is willing to complete a study survey and food record to collect child feeding information
- Live in Adelaide and surrounding areas (within 20 km from Adelaide CBD)
- Caregiver can read and write in English
- Caregiver willing to provide informed consent on behalf of themselves and their infant
- Caregiver has access to a computer/tablet with video capabilities

Exclusion Criteria:

- Infants born prematurely (gestational age <37 weeks)
- Infants with birth weight <2500g
- Infants have received antibiotics since birth
- Have been diagnosed of any medical conditions (e.g. feeding intolerance, gastrointestinal conditions, cystic fibrosis and other genetic defects) that may affect gut microbiome as determined by the Principal Investigator

What is involved?

You will be contributing to the study by:

1) completing an online survey;

2) providing your baby's faecal samples five times during the study;

3) record what you feed your baby prior to each faecal sample collection using a two-day food diary and a food frequency questionnaire.

What is going to happen?

Virtual appointment

If you and your child are eligible to participant in the study, you will be contacted by the study team for a virtual appointment. One of our team members will explain the study purpose, procedure, roles of participants (caregivers), and any potential risks (inconvenience). You will be asked to show your photo ID

for identity proof during the virtual appointment. You can ask any questions regarding the study during the virtual appointment. If you decide to participate in the study, an e-consent form will be provided to you, which you can sign electronically.

After consenting to participate in the study, you will be asked some demographic questions for both you (or the child's mother) and your child. An information session on how to collect faecal samples and complete the feeding records may take place during the virtual appointment.

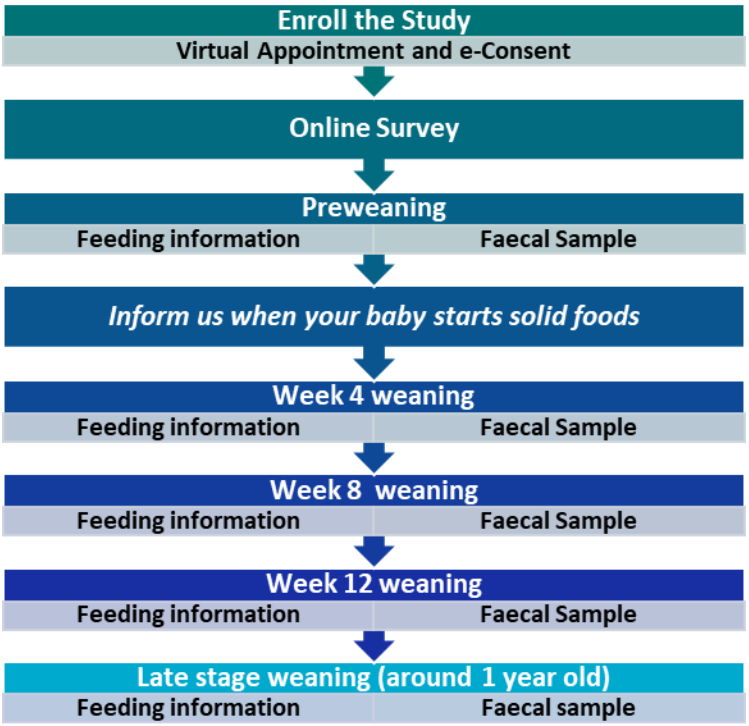
Online survey

Once enrolled to the study, you will be asked to complete an online survey asking questions about demographics of you and your child, childbirth information and other gut microbiota related information (e.g. history of antibiotic intake).

Feeding information and faecal sample collection

The study team will schedule the days for you to complete feeding record (using a Complementary Food Frequency Questionnaire and a two-day Food Diary) and collect faecal sample. You will also receive a following-up telephone interview for food record content clarification, and you may be asked more questions about your baby's feeding pattern during the interview. There will be five faecal sample collections during the study and the feeding record needs to be done prior to each faecal sample collection. The first faecal sample collection will happen before your child starting solid foods (preweaning samples); and three faecal sample collections will happen at the week 4 ,8 and 12 after your child starting solid foods; the fifth sample will be collected at the late stage weaning when you child is around 12 months old. Please see below for an illustrative guide on the study process.

Study Process



It is important for us to know when your baby starts their solid foods. You will be asked to inform the study team of the date when your child start to have the first solid foods (text or call 0448 752 928; email yanan.wang@csiro.au). Before the study team hear from you about the solid food commencement date, you will receive text message (SMS) asking a simple question whether your child has started solid food and you will need to respond "Yes" or "No". The text message question will be sent fortnightly between 4-5 months and weekly after your child is 5 months old.

We will guide you on how to complete the food record and collect faecal samples. Materials used for making feeding record and collecting faecal samples will be delivered to your home address. You will be provided detailed instructions in an information session on how to collect the faecal samples and complete the feeding records (two-day Food Diary and Complementary Food Frequency Questionnaire). The information session may take place during the virtual appointment.

You will need to weigh the amount of food that your baby consumes using a kitchen scale, except for breastmilk, formula or drinks fed with a bottle with scale. If you do not have a kitchen scale at home, the study will provide.

You will also receive a reminder of food record and faecal sample collection one day before the scheduled date through text message. After we receive your food record, a follow-up interview through telephone will happen to clarify the content of food records and more questions may be asked regarding your child's feeding pattern.

In this study, we want to remain impartial to normal feeding practice of the participants and the project will work around your plan of weaning and feeding.

We will come to your home address to pick up the food record and faecal samples. After completing the Food Diary Booklet, please put it back into the sample collection kit. We will collect the Food Diary together with the faecal samples.

Once faecal samples are collected, you will be asked to contact the study team as soon as possible. A study coordinator will come to pick up the samples from your home (or your preferred location). You will be provided a cooler bag with ice packs to keep the samples at low temperature before the arrival of sample collectors. You will also need to complete a questionnaire regarding use of antibiotics and nappy rash cream etc. prior to the faecal sample collection.

You will be asked to avoid applying nappy rash cream (or similar baby products) on your baby's nappy area prior to faecal sample collection, if your baby does not have nappy rash. However, when your child experience nappy rash, please do your routine procedure to treat the nappy rash and let us know what baby product is used by completing the Sample Collection Questionnaire.

The collected samples and data from you and your child may be used for the purpose of research related to this study. For example, faecal samples may be used to test prebiotic effect of other food or food ingredients under the same research goals for developing functional weaning food for shaping healthy gut microbiota.

As a thank you for contributing to this study you will be provided with a $140 gift card. Should you be unable to complete the study, you will receive a pro-rata payment scaled to reflect the duration of your

study participation ($15 for completing the online survey; $25 for each of the stool sample collection and food assessment). Payment is determined proportional to the time and inconveniences involved in participating in the study and not used as enticement to participate.

Your data will be collected and managed by REDCap (Research Electronic Data Capture), a secure web application for building and managing online surveys and databases. Your data and samples collected during this study may be used for future studies at CSIRO which have been approved by a Human Research Ethics Committee.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THE STUDY?

You may not benefit directly from participation in this study, but you will be providing a valuable contribution to the scientific knowledge in this field. Overall group results of the study will be sent to you via email at the completion of the study.

ARE THERE ANY RISKS INVOLVED?

There is no risk to the individual providing the faecal sample for this project other than the inconvenience. The study team will provide detailed instruction on how to collect faecal samples and child feeding data using a food record. The study team will also call you to provide a step-by-step information session to ease the potential difficulties for collecting faecal samples and completing the food records.

All human research undertaken by the CSIRO must comply with the values, principles, governance and review process specified in the *NH&MRC National Statement on Ethical Conduct in Human Research* (2007, Updated 2018). A copy of the National Statement can be found at https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

YOUR OBLIGATIONS AS A PARTICIPANT.

You will need to inform a study staff member of any changes in your child's health as some changes could have an effect on your child's participation in the study and the study findings. You must undertake all relevant procedures during the study period.

Participants should also avoid providing identifying information about themselves, or others, during the course of the study beyond what is being requested from you.

FEEDING GUIDLINES

The current recommendation is to introduce solid foods around 6 months. For more information of weaning, please refer to the "First foods for babies – Parent Easy Guide" by visiting the webpage https://parenting.sa.gov.au/pegs/PEG86-First-foods-for-babies.pdf. If you have future concerns about feeding and weaning, please contact the Child and Family Health Service (phone 1300 733 606) or see a doctor, dietitian or other health professional.

HOW WILL MY PRIVACY BE PROTECTED?

Your personal information is protected by the *Privacy Act 1988* (Cth) (Privacy Act). CSIRO will handle your information in accordance with this Act and the National Health & Medical Research Council (NH&MRC) National Statement on Ethical Conduct in Human Research (2007, updated 2018), or as otherwise required by law.

Your personal information, including your names, contact details (email and phone number), home address and date of birth of your child, is being collected for the purposes of conducting the Development of Baby Foods for A Healthy Gut project, and related scientific research.

As part of the Project, CSIRO will also collect your sensitive information, including ethnic origin, biological sex, health information and medical information for the purposes of the study as outlined above. Results from the project will be de-identified and/or aggregated and published/presented or shared in a variety of forums and with third parties. This includes conferences, scientific journals and meetings with stakeholders.

While CSIRO will make all attempts to ensure you cannot be reidentified from the information contained within the publications, this risk can never be completely removed. It is possible that you may be able to be reidentified within the publications due to the unique information that may already be known to an individual (such as personal friend or acquaintance).

Your personal details, such as your name, will only be published with your express consent.

For further information on how CSIRO handles your personal information and our access, correction and complaints process please read our privacy policy available on our website or by contacting us at privacy@csiro.au.

In relation to studies conducted by CSIRO, it is customary for all personal information to be identified by a code and stored at CSIRO under lock and key for a period of at least 15 years (in accordance with the *Archives Act 1983* (Cth)). Except where otherwise required by law or a government body, at the end of this period your records will be destroyed or permanently de-identified.

WHAT IF I WISH TO WITHDRAW?

You are free to withdraw at any time during the study. However, you will note in the consent form, a request to maintain any data collected prior to your withdrawal from the study. Your data up until your withdrawal are an important part of the data set for analytical purposes. Your personal information will be kept with those of continuing participants until the end of the study.

It is also important to understand that we can choose to end your participation, too. That decision would be made if we decided that the study is not in your best interest, if you are unable to follow the protocol of the study, or if the study is discontinued. If we ever have to end your participation, we will make sure you understand the reasons why.

IF YOU HAVE FURTHER QUESTIONS

Please call Dr. Yanan Wang (Principal Investigator of the study) on 8305 0692 or via email: yanan.wang@csiro.au

This study has been approved by the CSIRO Human Research Ethics Committee. If you would like to speak with someone with respect to ethical matters or wish to register a formal complaint about the conduct of this research, please contact the Secretary of the Committee via email at chmhrec@csiro.au.