PARTICIPANT INFORMATION SHEET

Randomised Control Trial on Growing Up Milk ‘Lite’

GUMLi TRIAL

INVITATION

You are invited to participate in a study which aims to investigate if consuming Growing up milk ‘lite’ (GUMLi) compared to standard cow’s milk improves your child’s health.

This study is being conducted by:

- Professor Peter SW Davies, University of Queensland
- Associate Professor Clare Wall, University of Auckland
- Associate Professor Cameron Grant, University of Auckland
- Dr Rebecca Hill, University of Queensland
- Ms Tania Milne, University of Auckland
- Ms Misa Matsuyama, University of Queensland
- Miss Amy Lovell, University of Auckland
- Mr Simon Forsyth, University of Queensland

This Participant Information Sheet will help you decide whether you would like to take part. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. We will go through this information with you and answer any questions you may have. You do not have to decide today, please take the time to read the following information carefully and discuss it with others, such as family, whānau, friends or health care providers, if you wish.

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 the Participant Information Sheet and the Consent Form to keep.

1. What is the purpose of this study?
   The purpose of this study is to compare whether drinking toddler milk (Growing up milk ‘lite’) instead of cow’s milk for 12 months improves nutritional status, cognitive development and levels of body fat in children aged 1-2 years.

2. 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 guardian of a child who is going to turn 1 year old in the next few months.

3. 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; you get to choose whether or not you want to take part. If you decide NOT to take part in this study, it will not affect the treatment you receive now or in the future. It will not influence any future involvement with the University of Auckland. You are free to withdraw from the study or withdraw your child from this study at any time without having to explain why. The research team will not collect additional personal information from you or perform any further tests. Your personal information and the test results already collected will be retained to ensure that the results of the research project can be measured properly, unless you specifically ask for these to be removed. If you are concerned about this, one of the researchers will be happy to discuss this in more detail with you.
4. **What does this study involve?**

This study will involve asking the parents/guardians of 160 children who are about to turn 1 year of age to take part. This study will take place at the same time in two cities, Auckland, New Zealand and Brisbane, Australia. In each city 80 children will be enrolled. You must be willing to give your child either Cow’s Milk or Growing up Milk ‘lite’ (Danone Pty Ltd) for the period of 12 months. Neither you nor the researchers will know what milk your child was drinking until the study has completely finished.

You will be supplied with all the milk necessary to take part in this research over the 12 months of the study at no cost to you. Milk will be supplied every three months in a powdered form. By being part of this study you are agreeing to give your child the required amount of milk (300ml per day) over the 12 months of the study (this is equal to two “small” 150mL bottles).

The milk is to be made up using the scoop inside the tin. To make the correct amount, add three level scoops (filled lightly and level) of milk powder to 130mL of drinking water. This will provide the required 150mL serve of milk. This is to be done twice daily. If your infant requires more milk, please use standard cow’s milk.

As mentioned, your child will be part of this study for a 12 month period. Over that time we will need your child to participate in several measurements at 5 time points: baseline (the beginning), 3 months, 6 months, 9 months and 12 months. At each of these time points we will also give you the milk your child will need to consume over the next 3 months. The measurements your child will need to perform are outlined below. You will also be telephoned once a month over the 12 months of the study, just to make sure you have no concerns or issues and to check on your child’s health.

**a. Baseline:** When your child turns 1 year old (12 months of age), they will enter the study and have their baseline measurements performed. This will be done at the School of Medical and Health Sciences, Grafton Campus, Auckland City. We will be measuring:

- **Height and weight:** Using standard methods.

- **Waist measurements:** This involves passing a flexible tape measure around the waist of your child.

- **Body composition (referred to as Bioelectrical Impedance):** This involves placing electrodes on the ankles and wrists and a small current (which cannot be felt) is passed through the body. Measuring the resistance to the current allows us to calculate the amount of water in the body. This measurement will only take 5 minutes.

- **Blood:** A sample of your child’s blood will be taken either from a vein, or via a heel or finger prick. You are free to choose which method you wish to be performed. All samples will be collected by an experienced person and analysed for full blood count, vitamin D, iron, and sensitive C-reactive protein (a marker of inflammation in the body). Less than 1 teaspoon of blood needs to be collected (approximately 3ml) and this measurement only takes 5 minutes.

- **Dietary intake:** Using a Food Frequency Questionnaire (FFQ) we would like to find out the types of foods your child usually eats and ask if your child takes any dietary supplements or traditional herbs. We would also like to know when you introduced solid food into your child’s diet, and also ask questions about breastfeeding. This measurement will take approximately 30 minutes.
• Cognitive development: Using The Bayley Scales of Infant Development. This involves a number of play activities to see if your child’s thinking, language, and movement (sitting, walking) skills are similar to children his or her own age, this combined with “The Social-Emotional Adaptive Behaviour Questionnaire” (completed by you) which looks at your child’s social skills (such as expressing emotions or talking with others) and behaviours (such as playing with others or dressing). These questions help us find out your child’s range of skills. This takes between 45 - 60 minutes to administer. We will also ask you to complete a short questionnaire about your child’s temperament (how they act in different situations), which takes approximately 20 minutes.

Temperament will be assessed using The Infant Behaviour Questionnaire – Revised Version (IBQ-R).

• You will also be asked some questions about you and your partner regarding employment and education.

d. 3 months: Your child’s 3 month measurement session will occur when they turn 1.25 years old (15 months of age). During this session, a researcher will visit your house to measure the following:

• Height and weight;
• Waist circumference.

c. 6 months: Your child’s 6 month measurement session will occur when they turn 1.5 years old (18 months of age). This will be done at the School of Medical and Health Sciences, Grafton Campus, Auckland City. We will be measuring:

• Height and weight;
• Waist circumference;
• Bioelectrical impedance;
• Dietary intake (FFQ).

d. 9 months: Your child’s 9 month measurement session will occur when they turn 21 months of age. During this session, a researcher will visit your house to measure the following:

• Height and weight;
• Waist circumference.

e. 12 months: Your child’s 12 month measurement session will occur when they turn 24 months of age. This will be their final measurement session. This will be done at the School of Medical and Health Sciences, Grafton Campus, Auckland City. We will be measuring:

• Height and weight;
• Waist circumference;
• Blood for vitamin D, iron and sensitive C-reactive protein;
• Bioelectrical impedance;
• Cognitive development using the Bayley III Scales, and Early Childhood Behaviour Questionnaire;
• Dietary intake (FFQ).
Aside from the measurements described above, we will be asking you to give consent to a few other items involved in this study, and if you are interested, an additional side study.

i You will be required to give consent for your General Practitioner (GP) to be contacted. If your child should show abnormalities in blood tests, the paediatrician involved in this study (Associate Professor Cameron Grant) will phone you to discuss these results and will also advise you that he is required to pass these results onto your child’s Doctor. No other information will be discussed with your child’s Doctor.

ii We will ask you to give consent to allow the researchers access to your child’s immunisation records via “The National Immunisation Registry” in New Zealand. This information will only be used to confirm the details you have provided in the questionnaires and will not be shared with any other parties, other than those involved in the GUMLi Trial. If you chose not to consent to this, this will not affect your child’s inclusion in the GUMLi Trial and any other involvement with The University of Auckland.

iii We will ask you to give consent allow the researchers access to any allergy testing information or skin prick test results that may be stored with your child’s GP/Medical Centre Records. That this information will only be used to confirm the details you have provided in the questionnaires and will not be shared with any other parties, other than those involved in the GUMLi Trial. If you chose not to consent to this, this will not affect your child’s inclusion in the GUMLi Trial and any other involvement with The University of Auckland.

iv We will ask you to give consent to the collect additional dietary information recorded in a Record Assisted 24 Hour Recall. This allows us to look at your child’s dietary patterns and nutrient intake. Determining nutrient intake would involve us asking some additional questions during the monthly telephone calls in months 7, 8, 10, and 11 about the quantities of foods and drinks your child has consumed in the 24 hours before the phone call. Therefore, the collection of this additional information will be added after month six of the GUMLi Trial and will be incorporated into the monthly phone calls you receive as part of the main trial. If you chose not to consent to this, this will not affect your child’s inclusion in the GUMLi Trial and any other involvement with The University of Auckland.

5. What is Growing Up Milk – Lite (GUMLi)

Growing Up Milk (GUM) was developed in recognition that the dietary transition from infancy to toddlerhood can sometimes be difficult and that some toddlers are vulnerable to inadequate nutrition.

Growing Up Milk – Lite (GUMLi) is a cow’s milk based toddler milk that is largely similar to an available and compliant commercial product, but has a reduced energy content. Growing Up Milk is also fortified with additional nutrients, probiotics and prebiotics in comparison with standard cow’s milk.

6. Can my child drink other milk?

The GUMLi team require your child to have 300mL (two bottles of 150mL) of study milk each day. If your child required milk in addition to the formula, we ask that you provide standard cow’s milk only.

If you are breastfeeding and would like to take part in this trial as well, that is fine – as long as you are willing to give your child 300mL (two bottles of 150mL) of study milk each day. Breastfeeding on top of this will not affect study outcomes.

7. Will I benefit from the study?

Taking part in this study may help you understand the growth and development of your child over their second year of life. By consuming the study milk, completing the measures and questionnaires we hope you gain an understanding of how your child’s eating habits and nutrition can influence their development; physically, mentally and emotionally. This is useful information and is likely to benefit you and your child medically.

You should also understand that your involvement in this study is of great value to the researchers, and provides them with the opportunity to determine whether toddler milk is of benefit in the growth and development of children. Your participation is greatly appreciated by the research team, thank you for considering taking part in this study.
8. Are there risks to me or my child in taking part in this study?

If you participate in this study, you need to be aware that completing this study will involve your child consuming the required amount of supplied milk (300ml per day) over the 12 months of this study. You also need to be aware that one of the measurements to be performed is a blood test. Please be assured your child’s blood will be collected by an experienced person with minimal to no distress for your child. All of the measurements in this study will be performed by experienced people.

The research team have designed the questionnaires with the potential for inconvenience in mind, and have removed or avoided any unnecessary questions. We have attempted to ensure these questionnaires are as easy as possible to complete.

The researchers treat protection of your personal information as a matter of high priority. Your confidentiality and privacy are assured during your participation in this study; the researchers will de-identify all personal information provided by you. There is no risk that you will be able to be identified should the results of this study be published (see point 7 below). You will only be identified by number in resultant manuscripts, reports or publications. No names will be used.

As with any research, there may also be risks associated with the research that are presently unknown or unforeseeable.

9. What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will 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.

10. How will my and my child’s confidentiality be protected?

Any identifiable information that is collected about you, your family or your child during this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers listed on page 1 of this document will have access to your details and results, these will be held securely at the University of Auckland.

11. What happens with the results?

If you give us your permission by signing the consent form, we plan to use the results to provide evidence for the use of toddler milks from 1-2 years of age. The results of this study are expected to be published in a scholarly journal.

However, in any publication, information will be provided in a way that you cannot be identified. Results of the study will be provided to you at its completion, upon your request.

12. What happens if I or my child suffers harm, injury or complications as a result of the study?

If you suffer any harm or complications as a result of this study, you should contact one of the researchers as soon as possible, who will help you in obtaining appropriate care as required. It is not thought that being a part of this study will cause any harm, injury or complications.

13. 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. When visiting the School of Medical and Health Sciences, Grafton Campus, for measurement sessions, reserved parking will be arranged for you by the research team.

Please let the research team know if there is a problem with you and your child getting to the Grafton Campus, as transport arrangements can be made or transport vouchers provided.

All the milk over the 12 months of the study will be supplied to you at no cost.
14. What should I do if I want to discuss this study further before I decide?

When you have read this information one of the research team will discuss it with you and any questions that you may have. If you would like to know more at any stage, please do not hesitate to contact the research team at:

   Email: gumli@auckland.ac.nz
   or contact the project manager, Mrs Tania Milne directly
   Phone: 027 807 5917
   Email: t.milne@auckland.ac.nz.

Alternatively, more information can be found on the GUMLi Website: www.gumli.auckland.ac.nz

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

This research has been approved by Northern B Health and Disability Ethics Committee.

You are free to discuss your participation in this study with the project staff

   Email: gumli@auckland.ac.nz
   or contact the project manager, Mrs Tania Milne directly
   Phone: 027 807 5917
   Email: t.milne@auckland.ac.nz.

or

   Senior Lecturer at the University of Auckland
   Associate Professor Clare Wall on 09 923 9875.

If you would like to speak with someone not involved in the study, you may contact the ethics officer at either of the institutions listed below:

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

   Phone: 0800 555 050
   Fax: 0800 2 SUPPORT (0800 2787 7678)
   Email: advocacy@hdc.org.nz

For Maori health support please contact :

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

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

   Phone: 0800 4 ETHICS
   Email: hdecs@moh.govt.nz