Participant Information

GUMLi Trial – Randomised Control Trial on Growing up milk ‘lite’

Invitation
You are invited to participate in a research project which aims to investigate if consuming Growing up milk ‘lite’ (GUMLi) compared to standard cow’s milk improves nutritional status, cognitive development and body composition profile (and health outcomes) in children 1-2 years old.

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
- Ms Amy Lovell, University of Auckland
- Mr Simon Forsyth, University of Queensland

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. Please take the time to read the following information carefully and discuss it with others if you wish.

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, or not.

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 toddler 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?**
Participation in this study is entirely voluntary. It is completely up to you whether or not you participate. If you decide NOT to participate, it will not affect the treatment you receive now or in the future. Your participation and/or withdrawal will not influence any future involvement with the University of Queensland or the University of Auckland. If you do withdraw your consent during the research project, the research team will not collect additional personal information from you or perform any further tests, although personal information and test results already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. 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 recruiting up to 160 toddlers who are about to turn 1 year of age. This study will be running in two sites; Brisbane, Australia and Auckland, New Zealand. In each of the sites 80 toddlers will be recruited. 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 be part of this research over the 12 months of the study at no cost to you. Milk will be supplied every three months. By being part of this study you are agreeing to give your child the required dose of milk (300ml per day) over the 12 months of the study.

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, 3 months, 6 months, 9 months and 12 months. The measurements your child will need 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.

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 Children's Nutrition Research Centre, Brisbane. We will be measuring:
   - Height and weight: Using standard methods.
   - Waist circumference: This involves passing a flexible tape measure around the waist of your child.
   - Body composition (referred to as Bioelectrical Impedance): This involves placing surface electrodes on the ankles and wrists and a small electrical current (which cannot be felt) being passed through the body. Measuring the resistance to the current allows us to calculate the amount of water in the body. This measurement only takes 5 minutes.
   - Blood: A sample of your child’s blood will be taken either directly 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.
   - You will also be asked some questions about you and your partner regarding employment and education.

b. **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;
   - Dietary intake (FFQ).
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 Children's Nutrition Research Centre, Brisbane. 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 1.75 years old (21 months of age). During this session, a researcher will visit your house to measure the following:
- Height and weight;
- Waist circumference;
- Dietary intake (FFQ).

e. 12 months: Your child’s 12 month measurement session will occur when they turn 2 years old (24 months of age). This will be their final measurement session. This will be done at the Children's Nutrition Research Centre, Brisbane. 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 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 things involved in this study, and if you are interested, a couple of additional measurements (as described in ‘iv’ and ‘v’ below).

i. We will ask you to give consent for your General Practitioner (GP) to be contacted for anything relevant to your child’s care. For example, if your child should show abnormalities in blood tests, the paediatrician involved in this study (Associate Professor Cameron Grant) would like to pass these results onto your child’s GP. If you do not wish us to contact your child’s GP you do not have to give consent for us to do so and this will not in any way affect your child’s inclusion in the GUMLi Trial and any other involvement with The University of Auckland and The University of Queensland. If you do not wish to have your child’s GP contacted, you will be notified directly of any concerning results.

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 either Australia or 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 and The University of Queensland.

iii. We will ask you to give consent to 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 and The University of Queensland.

iv. We will ask you to give consent to the collection of additional dietary information. The FFQ you will complete for your child in the main GUMLi Trial allows us to look at dietary patterns. We would like to collect further information that will allow us to look at nutrient intakes as well. This 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 commence 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 and The University of Queensland.

v. We will be monitoring the change in intestinal microorganisms that play a very important role in our health. To do this, we will ask you to collect a small (5-10g) ‘poo’ sample when you are changing your child’s nappy each month, starting at the beginning of study. A sample collection kit will be provided to you. We would also like to collect a small (5-10g) ‘poo’ sample from the biological mother of the participating child to analyse the similarity in microorganism composition between a mother and her child. This will only be done once, at the beginning of the study. A sample collection kit will be provided to you. 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 and The University of Queensland.

5. Will I benefit from the study?
Your participation in this study may help you understand the growth and development of your child over their second year of life. By completing the various measures and surveys you may gain a measurable understanding of how your child is growing, their body composition, their cognitive development, and their eating habits. This is useful information and is likely to benefit you and your child medically.

You should also understand that your participation in this study is of great value to the researchers, and provides them with the opportunity to determine whether toddler milk is of benefit for growth and development of children. Your participation is greatly appreciated by the research team, thank you for considering participation in this study.

6. Are there risks to me or my child in taking part in this study?
If you participate in this study, this will involve your child consuming the milk supplied in the specified amount over the 12 months of the study. We understand that in addition to drinking the required amount of milk for participation in this study, your child will be eating other foods and drinking other drinks as well. There are differences in the formulation of the Growing Up Milk ‘Lite’ and the cow’s milk. We have designed the study in this way to see which milk, or whether both milks, are beneficial for the health of your toddler. As your child is eating and drinking other foods and drinks during the study, we are not concerned that the different composition of the milks will be a risk to your child’s nutrition. Growing Up Milk ‘Lite’ complies with Food Standards Australia New Zealand guidelines with regards to manufacturing standards and compliance with food safety requirements, including allergy management. This product is manufactured in a registered facility. There are no known ingredients included in, or missing from, the Growing Up Milk ‘Lite’ formulation compared with cow’s milk, which might conceivably cause harm.

Compared with standard cow’s milk, the Growing Up Milk ‘Lite’ has 21 kcal less energy (12%) per 300ml daily amount. This is not a large difference, and is equivalent to eating less than 1/3 of an apple, but we are interested if a ‘lite’ product might have an effect on a toddler’s body fat. The
differences in energy between the Growing Up Milk ‘Lite’ and the standard cow’s milk are because the Growing Up Milk ‘Lite’ has less saturated fat and protein, but a little bit more carbohydrate. Growing Up Milk ‘Lite’ has higher levels of iron and vitamin D compared with standard cow’s milk. Iron deficiency anaemia affects approximately 8% of preschool aged children (Medical Journal of Australia, 2010), and vitamin D deficiency affects approximately 10% (Grant et al, 2009). In addition, there are more B vitamins, niacin, folic acid and vitamin C in the Growing Up Milk ‘Lite’. In comparison to the standard cow’s milk, the Growing Up Milk ‘Lite’ has less vitamin A and iodine. Vitamin A deficiency is not common in developed countries such as Australia and New Zealand, whereas, iodine deficiency may occur in up to 6% of young children in Australia (Australian Bureau of Statistics, 2014).

The Growing Up Milk ‘Lite’ has a particular strain of probiotic added: Bifidobacteria Breve M-16V. Probiotics modulate gut bacteria and can be beneficial for the immune system, and this strain has been associated with a reduced risk of skin allergy (Enomoto et al, 2014).

The key point, however, is that the milks your child will be randomised to receive over the 12 months of the study are not the only source of nutrition for your child, and while there are differences in their composition, because your child will be consuming other foods and drinks over the study, we believe there are no risks to your child’s nutritional health because of drinking either milk.

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 collected by experienced people 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.

You should also be aware that there is a potential for you or your partner to be identified. The researchers undertake to protect 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). Participants 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.

7. How will my and my child’s confidentiality be protected?
Any identifiable information that is collected about you, your family or your child in connection with 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 Queensland and the University of Auckland.

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

However, in any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you at its completion, upon your request.
9. **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 assist you in obtaining appropriate care as required. It is not anticipated that being a part of this study will cause any harm, injury or complications.

10. **Will taking part in this study cost me anything, and will I be paid?**
Participation in this study should not cost you anything apart from your time, for which we thank you. When visiting the Children's Nutrition Research Centre for measurement sessions, your parking will be paid for by the research team. All the milk over the 12 months of the study will be supplied to you at no cost.

11. **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 queries you may have. If you would like to know more at any stage, please do not hesitate to contact the research team at: GUMLi@uq.edu.au; or the project manager (Dr Rebecca Hill) on 0428 093 998, or at: rj.hill@uq.edu.au.

12. **Who should I contact if I have concerns about the conduct of this study?**
The investigators conducting this study abide by the principals governing the ethical conduct of research and at all times avow to protect the interests, comfort and safety of all participants.

This research has been approved by the following Human Research ethics Committees:
- The University of Queensland’s Medical Research Ethics Committee; and
- The Health and Disability Ethics Committee.

You are free to discuss your participation in this study with the project staff (GUMLi@uq.edu.au; or Dr Rebecca Hill 0428 093 998 or rj.hill@uq.edu.au), or the director of the Children’s Nutrition Research Centre, Professor Peter Davies on (07) 3636 1981. 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:

- The University of Queensland Medical Research Ethics Committee
  The Ethics Coordinator
  UQ Research & Innovation
  Cumbrae-Stewart building (72)
  The University of Queensland, QLD 4072
  Telephone: 07 3365 3924

- The Health and Disability Ethics Committee
  0800 634 758 (or +64 4 974 7675)
  hdecs@moh.govt.nz