



Brain, Immune, Gut, Skin (BIGS) Trial Participant Information

Principal Investigators

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You are invited to participate in a research study about how the type of protein in cow's milk could impact brain, immune, gut, and skin health. This research is being conducted independently by [Nutrition Research Australia](#) (NRAUS).

Knowing more about this study will help you decide if you want to take part. Please read this information carefully and ask questions about anything that you don't understand or want to know more about. You can view this Participant Information any time by following the same link previously used to access this form. We encourage you to save a copy for your own records.

Before deciding whether or not to take part, you might want to talk about this study with a relative, friend, or a health professional. If you decide you want to take part in the research project, you will be asked to indicate your consent by ticking a box on the next page.

Purpose of the study

We know that what we eat can affect different systems of the body. There is some evidence which suggests that certain types of proteins in cow's milk could affect our brain, immune, gut, and skin health.

This study will be used to compare two different types of cow's milk, each with a different type of cow's milk protein, on biomarkers (molecules or compounds within the body that can be measured) of brain, immune function, and gut function, as well as skin health.

Why have I been invited to participate?

You have been invited because you are a healthy person aged 16 to 65 years, living in Australia who can read and speak English and can tolerate drinking milk daily. If you have been diagnosed with a chronic disease (such as an autoimmune condition, kidney or liver disease, cardiovascular disease, or diabetes), or you are currently pregnant or breastfeeding, you should not participate in this study.

All aspects of this study are voluntary, and you do not have to participate if you don't want to. If you agree to participate, you can change your mind at any time without any negative effects. If you decide to withdraw from the study, researchers will not collect any more data from you. However, any data collected up until the point of your withdrawal from the study will be retained and may be used to inform study results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project. The meals provided to you during the study will also end when you withdraw from the study.

What will I be asked to do?

This is a pragmatic randomised controlled open-label trial. This means that over the course of the study, you will receive one intervention (i.e. either 28 days of drinking only a2 milk, or 28 days of drinking only conventional milk) that you will be randomly allocated to, and both you and the researchers will know which type of milk you will be drinking during the study.

During the intervention period, you will be asked to drink a minimum of 250mL of milk each day for 28 days, which will contain either A1/A2 beta-casein proteins, or A2/A2 beta-casein proteins. Both A1/A2 and A2/A2 beta-casein proteins naturally occur in milk. We would also ask you to keep other dairy products, such as cheese and yoghurt, to no more than one serving each day (e.g. 200g yoghurt, 40g hard cheese, or ½ cup ricotta).

If you agree to participate, you will be asked not to make other changes to your current diet, including medications and supplements, for a period of 30-days, which includes a 2-day run-in period and a 28-day intervention period.

You will also be asked to:

- Complete two 24 hour food recalls, recording everything you've had to eat and drink in an online portal, once at the beginning and once at the end of the study.
- Complete 30 minutes of online surveys, about your physical and mental wellbeing, on each of the 3 different days at the beginning, middle, and end of the study.
- Provide two fasting saliva samples using kits that will be provided for you and send them in the mail.
- Provide two stool (poo) samples by taking swabs with kits that will be provided for you and send them in the mail.

What are the potential benefits of participating in this study?

The results of this study will be used to contribute to product design and potentially to dietary recommendations aimed at improving the health of Australian adults. Results may also help to inform future research to help improve adult's brain, gut, immune, and skin health. By participating in this study, you will have the cost of milk purchased for the 28 days of the study period reimbursed for you. You will receive a \$300 Visa e-gift card to compensate you for your time participating in the study. We cannot guarantee participation in this study will provide other direct benefits for you.

Are there any risks?

Participating in this study is extremely low risk and unlikely to cause you any harm. However, some participants may find some questions in the surveys distressing. There is a small risk of contamination when you are collecting your saliva and stool samples. To reduce this risk make sure you wash your hands thoroughly before and after collecting each sample and follow the instructions for collection, storage, and shipping carefully. We will provide you with detailed instruction videos on how to collect the samples and our research team is available at bigstrial@nraus.com, if you need any further information.

Due to the nature of the study, the research team cannot offer support if you feel distressed or need health or medical assistance. If participation raises negative emotions, it is recommended that you contact Lifeline on 13 11 14, or Beyond Blue on 1300 22 4636, infoline@beyondblue.org.au.

If you need medical assistance, it is recommended that you speak to your GP, or contact 000 in an emergency.

Reimbursement

You will be required to purchase milk from a Coles or Woolworths supermarket to drink throughout the study. You will be emailed an electronic gift voucher to your preferred supermarket (Coles or Woolworths) each week to purchase the milk required for the study. Each electronic gift voucher sent weekly will equate to \$12 to \$15, depending on milk prices in your area, which will enable you to purchase over twice the minimum amount of milk required for the study. Alternative electronic gift vouchers will be arranged for remote participants who do not have access to a Coles or Woolworths supermarket. You will be asked to upload a copy of your milk receipt each week.

The travel and time you give to this study will be reimbursed by the provision of a \$300 Visa e-gift card at the completion of the study.

How will your privacy be protected?

The study will gather certain personal information about you such as your name, date of birth and address. This information will be held by NRAUS and its authorised representatives, and your personal data will be strictly confidential. Your identifiable data will be collected online by the QuestionPro platform and by de-identified saliva and faecal samples. QuestionPro hosts data in Australia and is secure; subscribers own the data collected. QuestionPro does not keep data after the survey account has been closed. This means your personal data will only be stored with NRAUS, not QuestionPro, after the completion of the study. All saliva and faecal data will be deidentified and stored in password protected accounts. This means your name, address or any other personal details will not be stored with your saliva and faecal data. Biological samples will be identified by a unique identifier, and analysed within Australia by Microba Life Sciences (faecal sample) and Stratech Scientific APAC (saliva samples). Collected samples will be destroyed during analysis. Companies will retain deidentified data for 90 days (Microba Life Sciences) and 30 days (Stratech Scientific APAC) after analysis, after which it will be deleted from their servers. Your data will be saved and stored in Dropbox Business which uses Advanced Encryption Standard to protect data in a secure storage server. Storage servers are located in data centres across the United States. Data will be kept for a minimum of 5 years as recommended by the National Statement on Ethical Conduct in Human Research. In most cases, you have the right to access personal information collected from you in connection with the study and request corrections of any such personal information that is incorrect.

NRAUS researchers will use online project management software (Trello.com and ClickUp.com) to co-ordinate the study. This information will be accessible only to researchers working on the study, and no survey data or identifiable information will be stored, shared, available on Trello and ClickUp.

How is this study funded?

NRAUS has received a research grant from The a2 Milk Company to conduct this study. The a2 Milk Company does not hold decision rights on the data collection, data analysis, or the publication of

results in a peer-reviewed scientific journal; however, may provide comments that will be considered at the discretion of NRAUS.

Who will see the results of the study?

Results of the study's findings will be shared with The a2 Milk Company, the study funder. Study findings will also be published in a peer-reviewed scientific journal and may be presented at national and international conferences.

Participants can request a summary of the study findings to be sent to them by indicating this on the next survey page.

Can I become pregnant?

Yes. The intervention is safe to consume if you are attempting to fall pregnant; however, if you are currently pregnant or breastfeeding you should not participate in this study.

Has this study received ethical approval?

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited, on 08 8361 3222.

Further information

If you would like further information, please don't hesitate to contact Flavia on **0432 700 270** or email bigstrial@nraus.com.

Thank you for considering this invitation to participate in this research study by Nutrition Research Australia.

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