HEALTH & BIOSECURITY
www.csiro.au

SAHMRI North Tce, Adelaide SA 5000
PO Box 10097, Adelaide SA 5000
T (08) 8305 0615 1800 850 036 • **ABN** 41 687 119 230

Brain & Body Protein Powder and Sleep in Older Adults Study

PARTICIPANT INFORMATION SHEET

HUMAN RESEARCH ETHICS COMMITTEE NUMBER: 2023_018_HREC

INTRODUCTION

Each year CSIRO performs a number of research projects involving human participants. In this study we are interested in looking at the effect of tryptophan and phospholipids which are found naturally in dairy products. Tryptophan is a protein sourced from the diet that the body can process into serotonin and melatonin, which are involved in sleep, mood and cognition, while phospholipids may support brain structure and function.

In Australia, people are living longer than generations before them resulting in an ageing population. Good sleep quality is an important factor in maintaining mood and brain functions such as memory and attention, however the ageing process can interfere with an individual's sleep quality. This project aims to explore the effects of a dairy-derived protein powder containing elevated levels of tryptophan and phospholipids on sleep quality, among a range of other outcomes such as mood, vitality, cognition and brain activity.

This study is being conducted at the Nutrition and Health Research Clinic located at the South Australian Health and Medical Research Institute (SAHMRI). This study is being funded by a commercial sponsor, Fonterra.

WHAT IS THE AIM OF THIS STUDY?

The main objective of this study is to determine the short and longer-term effects of the Brain and Body Protein powder in older adults in the general population.

Specifically, we will be looking at the effect of increasing dairy-derived tryptophan and phospholipids in the diet of people who report experiencing poor sleep quality and observing any change in sleep in these individuals. In addition to sleep, effects on mood, vitality, cognition, brain activity and biochemical markers will also be investigated.

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 must meet. Have a look through the criteria below. If you are unsure or have any questions, do not hesitate to contact us, either by phone 8303 8803 or email sleepstudy@csiro.au and we can assist.

Inclusion Criteria

1. Aged 55 to 64 years of age (inclusive) at phone screen
2. Self-reported answer of yes to the following: "Do you feel as though you have poor sleep quality?"
3. BMI ≥18.5 or ≤35 at time of phone screen
4. Willing and able to provide informed consent
5. Access to a personal (i.e., not shared) and valid email address

Exclusion Criteria

1. Previous adverse reaction to milk or dairy proteins
2. Known allergy to rice, soy or soy lecithin
3. Current or recent participation, within the last 6 months, in any other clinical trial involving the administration of an active intervention for any purpose.
4. Current or previous sleep disorder diagnosis (e.g., sleep apnoea, insomnia)
5. Undiagnosed sleep apnoea (positive score in ≥2 categories of the Berlin Questionnaire)
6. Currently undergoing treatment to improve sleep (including psychotherapy and/or medication, e.g., Restavit, melatonin)
7. Currently engaged in ongoing shift work (i.e., any shift work undertaken in the last month)
8. Recent (~2 weeks) travel across time zones/jetlag
9. Score of ≤11 on the Montreal Cognitive Assessment-5min
10. Self-reported history of events that impact cognitive function defined as: concussion or brain injury requiring hospitalisation, transient ischemic attacks (mini-stroke), stroke, heart attack, coronary artery bypass surgery, or open-heart surgery.
11. Known history of Intellectual Disability or other developmental disorder (e.g., language disorder, ADHD, Autism)
12. A mental health condition that is being actively treated either pharmacologically or by a licensed mental-health professional (e.g., major depressive disorder, PTSD)
13. Diagnosed neurological disease including dementia (any type), Parkinson's Disease, Amyotrophic Lateral Sclerosis, Motor-neuron Disease, hippocampal damage, or Huntington's Disease
14. Known type 1 or 2 Diabetes
15. Known digestive disorder diagnosis (e.g., GERD, IBS)
16. Blood pressure systolic >160 mmHg and diastolic >100 mmHg
17. Recent (i.e., in the last 3 months) medication use related to or likely to affect sleep, cognition, mood or serotonin levels, or medication which is not recommended to be used with tryptophan
18. Current smoker/vaper (or history of smoking including within last 12 months)
19. Recent (~6-month) use of illicit or psychoactive drugs
20. Individuals living with children under 12 months of age
21. Needle phobia or fainting due to fear of needles
22. Alcohol consumption >7 standard drinks per week
23. Known eosinophilia or liver/kidney diseases
24. Known carcinoid syndrome

What is going to happen and what tests will be done?
Once you have read and had time to consider the details in this information sheet, and if you decide to take part in this study, you will be asked to complete a medical screening questionnaire which will take around 10 minutes to complete and a telephone screen which will also take around 25 minutes to complete, to ensure that you fit the criteria required to participate in the study. If you are deemed eligible following the phone screen, you will be invited to enrol in the study which will involve attending the Nutrition & Health Research Clinic at SAHMRI on two (2) occasions, as well as consuming the study product at home and completing a sleep diary each day for 6 days.

PHONE SCREEN:
During the phone screen with a staff member you will complete the following to determine if you are eligible to take part in the study:

- confirm details about your medical history, surgical history and medications
- confirm eligibility criteria
- a brief cognitive screening tool and a sleep apnoea questionnaire

VISIT 1 (Baseline & Acute Session)
If you are deemed eligible to participate in the study after the phone screening, you will make an appointment that is suitable for you to attend your first visit at the Nutrition & Health Research Clinic. Prior to your Baseline & Acute Study visit, you will have been randomised into one of two groups (Brain & Body Protein Powder or placebo) of which neither you nor we can determine which group you will be allocated to. The Brain & Body Protein Powder group will consume a dairy product with elevated levels of phospholipids and protein, including the amino acid, tryptophan. The placebo group will consume a rice starch product.

The Baseline & Acute Study visit will take ~5 hours. At this visit you will:

- Be asked to sign a formal consent form and provide demographic information.
- Confirm inclusion/exclusion criteria (age, BMI, blood pressure)
- Have your vital signs, i.e., blood pressure, heart rate, temperature, respiratory rate, as well as height and weight checked by a member of the study team
- Report any changes to medications that has occurred since the phone screening
- Provide a fasting blood sample (total of ~18ml), which will be taken by a trained nurse or phlebotomist.
- Complete three questionnaires on mood, vitality and sleep quality
- Brain activity recording using electroencephalography (EEG) (see below for more information on EEG) and complete a computer based cognitive task with a trained assessor
- Consume a dose of the study product
- After a 90-minute break, you will repeat the following assessments:
    - provide a blood sample (total of ~6ml), which will be taken by a trained nurse or phlebotomist.
    - complete one questionnaire on mood
    - undergo an EEG recording and complete a computer based cognitive task
- Report any feeling of being unwell or significant adverse events that has occurred since the beginning of the clinic visit
- Be provided with a snack at the end of your visit

DURING THE STUDY

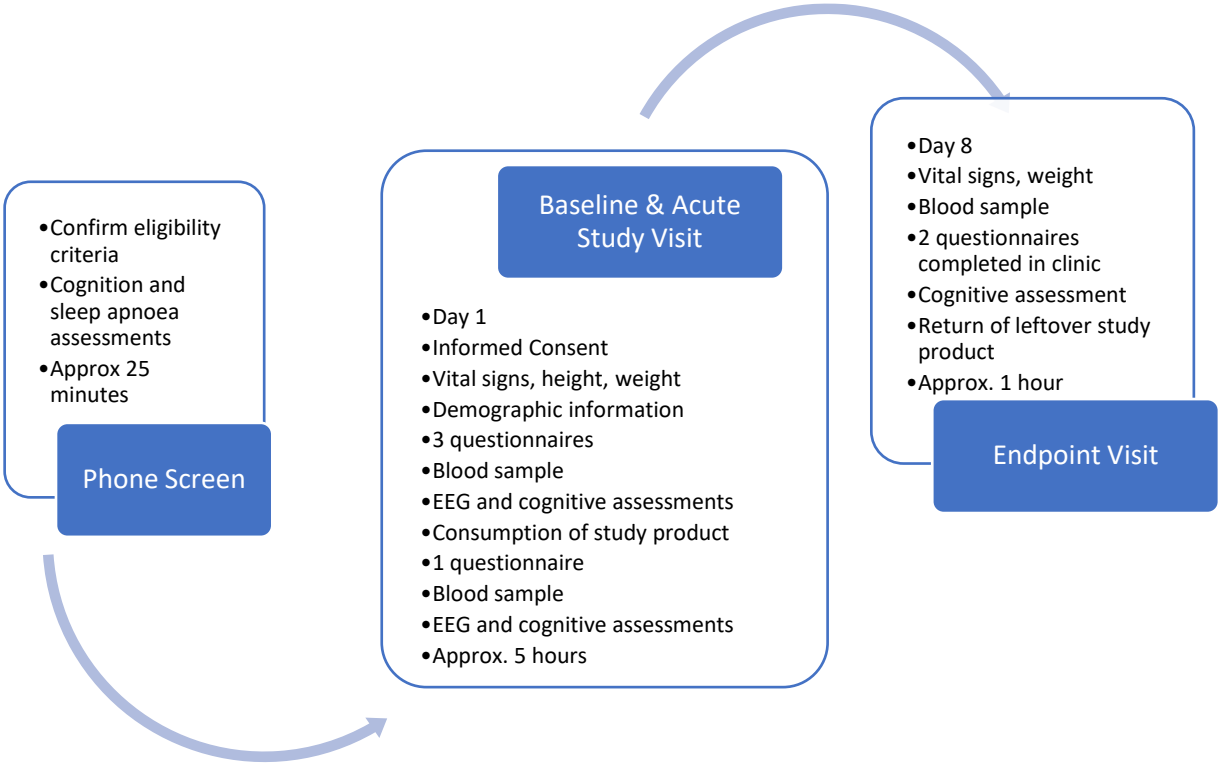
Starting from the day ***after*** your baseline visit, there will be a period of 6 days where you will consume the study product once each day, approximately 90 minutes prior to bedtime. Each morning you will also fill out a sleep diary.

VISIT 2 (Endpoint Session)

After this 6-day period, you will attend the clinic for the Endpoint visit. At this visit you will:

- Have your vital signs, i.e., blood pressure, heart rate, temperature, respiratory rate, as well as weight checked by a member of the study team
- Report any changes to medications, feeling of being unwell or significant adverse events that has occurred since your last visit.
- Provide a fasting blood sample (total of ~18mL), which will be taken by a trained nurse, phlebotomist or trained member of staff.
- Complete two questionnaires on vitality and sleep quality
- Complete a computer based cognitive task with a trained assessor
- Return any leftover study product
- Be provided with a snack at the end of your visit

SUMMARY OF VISITS:



It is important to note that:

- You will be expected to consume the supplement product every day
- You will not be asked to alter your diet or exercise habits for this study
- You will be required to fast (not to eat or drink anything except water) overnight before both of your clinic visits

- You will not be offered beverages that contain caffeine until the end of the final cognitive test due to the nature of the testing

Upon completion of all the clinic visits you will be remunerated to the total value of $200 to thank you for your time and any travel costs incurred by taking part in this research project. Vouchers will be provided at the conclusion of your Endpoint visit.

INTERVENTION PRODUCT
Ingredients list: Whey Protein Isolate, Whey Protein Concentrate, Cacao Powder, Milk Phospholipids, Flavors, Xanthan Gum, Acesulfame Potassium, Sucralose.
Allergen statement: Contains dairy, traces of soy and soy lecithin.

PLACEBO PRODUCT
Ingredients list: Rice powder, Cacao Powder, Flavors, Xanthan Gum, Acesulfame Potassium, Sucralose.
Allergen statement: Contains rice powder.

QUESTIONNAIRES
During your visits you will complete three questionnaires. One will ask you questions about your current mood, one will you questions about your sleep quality and the last will ask you questions about vitality. All questionnaires are brief and are expected to take around 10 minutes in total, to complete.

EEG RECORDING
Electroencephalography (EEG) is a non-invasive method of recording the electrical activity of the brain. This involves a material cap containing sensors being placed on the head. An exfoliating gel and a Q-tip will be used to clean the skin beneath the sensor sites. A signal amplifying gel will also be used to improve the signal quality during the recording. Both gels are removable with hair-washing, however you may wish to bring a hat or beanie to wear following the appointment. The set up of the EEG recording takes approximately 1 hour, and the cognitive testing takes approximately 1 hour.

COGNITIVE TASK
During the EEG session, you will be seated at a computer and your brain activity at rest and during a cognitive task will be recorded. In the cognitive task you will be presented with letters on a screen and asked to recall information about them throughout the duration of the task. Detailed instructions will be provided to you at the beginning of the task and you will have opportunity to practice the task.

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.

ARE THERE ANY RISKS INVOLVED?
There may be some inconvenience caused in adhering to the study protocol by attending the clinic visits and consuming the study product.

There is a small risk of infection/blood clotting and or bruising following blood collection, however this is minimised by having the blood samples collected by a trained phlebotomist/nurse and you will have ample opportunity for rest during each visit.

EEG is a non-invasive method of recording brain activity. No side effects are expected as a result of the EEG session, however if you feel discomfort or have questions at any stage, please discuss this with the assessor running the session.

There may be some discomfort completing the cognitive assessments due to you feeling more nervous than usual. The staff member conducting the visits will be there to ensure you are made to feel comfortable before completing tests and understand what is required for each of the tests performed. If you express any concern about the tests or your ability to perform well, every effort will be made to clarify the nature and purpose of the tests and to allay any uncertainty or tension. If you display signs of significant distress (e.g., increased tension), the staff member conducting the session will check in with you and check whether you would prefer to continue or cease the cognitive testing. At the discretion of the assessor, cognitive testing may cease.

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). A copy of the National Statement can be found at https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research

HOW WILL MY PRIVACY BE PROTECTED?

CSIRO is governed under the Privacy Act 1988 (Cth). CSIRO is collecting your personal information for the purposes of conducting the study and related scientific research. CSIRO will only use and disclose your personal information in accordance with the Privacy Act 1988 and the NH&MRC National Statement on Ethical Conduct in Human Research (2007, Updated 2018) as amended from time to time, and as otherwise required by law.

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. 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.

Where third parties are assisting CSIRO in relation to the conduct of this study (such as university staff, students and other health professionals), we may disclose your personal information to those third parties for this purpose on a confidential basis.

CSIRO may disclose your information overseas to the New Zealand based dairy co-operative, Fonterra Co-operative Group Limited, Swinburne University of Technology and the University of Adelaide who are assisting CSIRO with this study. CSIRO will require such third parties to keep this information confidential and to only use your personal information for the purposes of the study and in accordance with the *Privacy Act 1988* (Cth).

With your permission, your doctor will be notified of any medical condition deemed significant by the Clinical Research Unit Medical Officer. We will not use or disclose your information for direct marketing purposes.

CSIRO may publish study results and data in research publications and press releases, however, CSIRO will de-identify any personal information contained in the data and results so that you cannot be identified.

The CSIRO Privacy Policy available at https://www.csiro.au/en/About/Access-to-information/Privacy outlines how your personal information will be handled, including details about how you can seek access or correction of the personal information we hold about you and how you can complain about a breach of the APPs and how CSIRO will deal with the complaint. If you require further information on how your personal information will be handled please contact privacy@csiro.au.

WHAT IF I WISH TO WITHDRAW?

You are free to withdraw at any time during the study, without penalty. However, subject to any relevant legislation and depending on the date of publication, it may not be reasonable or practical to remove your information. Information collected up to the point of your withdrawal will be included in the analysis of the study, unless you request that they be withdrawn. Where you would like to withdraw your consent, please contact Stefanie Evas on 8303 8803 or email via sleepstudy@csiro.au.

It is also important to understand that we may choose to end your participation. That decision may 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 are made aware of the reasons.

YOUR OBLIGATIONS AS A PARTICIPANT

You will need to inform a study staff member of any changes in your health status as some changes could have an effect on your participation in the study and the study findings. You must also be able to attend all the clinic sessions and undertake all relevant procedures during the study period.

You are required to come to the baseline and endpoint visits fasted, if you have forgotten to fast overnight please call us first thing the morning of your appointment as we may need to reschedule your appointment.

IF YOU HAVE FURTHER QUESTIONS

Please call the student investigator (Ms Stefanie Evas) on 8303 8803 or via email sleepstudy@csiro.au. Please mention that you are ringing regarding the Brain & Body Protein Powder and Sleep in Older Adults Study.

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 or phone on (07) 3833 5693.

Signature: ..... Date: / /