DEAKIN UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE
PROJECT DESCRIPTION/PROTOCOL

Instructions for preparing the project description/protocol

1. The purpose of the Project Description is to provide the scientific and academic background and context of a research project.
2. A Project Description is a **mandatory** component of a submission using the Human Research Ethics Application (HREA).
3. The section headings in this Project Description template represent a structure for presentation of information about a research project that meets the needs of an ethics review body.
4. Not all headings or sub-headings in this template are relevant for each research project. Where a question is not relevant please enter NA into the response box. Please do not delete the question.
5. Researchers may use visual aids embedded in the project description/protocol to assist in describing their project where appropriate (e.g. images, videos etc.).
6. Submissions of clinical trial proposals may use alternative protocol templates, such as the SPIRIT statement.
7. Researchers may choose to submit an existing document (such as a protocol or project description that has already been developed) instead of developing a new document.
8. If researchers choose to submit an existing document instead of using one of the templates provided, they may need to provide indications to the ethics review body of where in the submitted document the content corresponding to the relevant fields in the template are located.
9. There is no need to duplicate information in the HREA into the Project Description or vice versa.
10. Language that is understandable to non-technical reviewers should be used.

COVID-19

All research must comply with current COVID-19 restrictions, as well as with Deakin's COVIDSafe Management Plan. Any activities considered as having high COVID-19 risk (e.g. requiring safety measures over and above the COVIDSafe Management Plan and risks covered by the general requirements of entry to campus) must have an approved COVIDSafe Activity Plan in place. This includes any on-campus research involving a face-to-face element, as well as off-site research (e.g., site visits, fieldwork etc).

1. Project details:

1.1 Please provide the project title - Dose response of alpha lactalbumin supplementation on serum TRP:LNAA ratio.

1.2 Please provide an acronym for the project (if appropriate) N/A

1.3 Please provide the project description/protocol version number N/A

2. Project Team Roles & Responsibilities:

2.1 Please provide the names, affiliations, positions and responsibilities of individuals involved in the project beyond those outlined in the HREA (e.g. technical or support staff).

Name: Mr. Jackson Barnard

Affiliation: Centre for Sport Research, Deakin University

Position: Research Assistant

Responsibility: External researcher to provide participants with supplement to ensure double blinding

3. Resources:

3.1 Please provide details of the resources necessary for the project to be conducted, and the funding or support being sought or secured.

This project will be partially funded by an industry grant with Agropur US, who manufactures an alpha-lactalbumin protein supplement. In addition to providing complimentary supplement samples for the clinical trial, the additional funding provided by Agropur will cover the cost of meal provided to participants and the biochemical analysis of the blood samples. All questionnaires, diaries used in this study will incur no further cost for the project, as these subscriptions are provided by the University. Biochemical analysis will be completed in-house at Deakin University, with consumables such as venepuncture needles, vacutainers, and syringes to be purchased for this study.

The student researcher will perform biochemical and data analysis, which will incur no further cost to the project.

4. Background:
Please provide:

4.1 A lay summary of the literature review (approximately 1 A4 page)

Sleep, in humans, is defined as a complex reversible behavioural state where an individual is perceptually disengaged from and unresponsive to their environment(1). Sleep deprivation adversely affects several physiological mechanisms and can affect appetite, mood, alertness, glucose metabolism and protein synthesis (2).

Sleep is a dynamic process largely regulated by two factors: the circadian systems and the sleep homeostat. The homeostatic process is a function of sleep and waking, while the circadian process is controlled by a circadian oscillator(2). The circadian process is independent of sleep and waking and receives cues e.g. light from the environment. Core body temperature and melatonin rhythms are markers of this process. The suprachiasmatic nucleus (SCN) in the brain has melatonin receptor cells and as darkness falls melatonin is secreted by the pineal gland making the individual sleepy (3).

Tryptophan, an essential amino acid, acts as a precursor to Serotonin and Melatonin production and can influence the rate of synthesis and function of these neurotransmitters depending on its availability in the brain (1). Tryptophan is transported across the blood brain barrier by a system that shares transporters with several other large neutral amino acids (LNAA). Thus, it must compete with the other LNAAs to cross the blood brain barrier. The ratio of Tryptophan: LNAA can be increased

through consumption of tryptophan rich foods(4). Dietary sources of tryptophan include milk, turkey, chicken, fish, eggs, pumpkin seeds, beans, peanuts, cheese, and leafy green vegetables. However, the milk protein, alpha lactalbumin (ALAC) derived from whey has been reported as having the highest natural levels of tryptophan among all protein food sources (5).

It is hypothesized that nutrition interventions that act on altering the serum TRP:LNAA ratio levels could positively impact sleep (2). Dietary precursors such as ALAC have previously been found to increase the serum TRP:LNAA ratio by as much as 46 -130% and can further influence the rate of synthesis and function of neurotransmitters serotonin and melatonin(5, 6).
Most of the existing literature surrounding ALAC and sleep is conducted amongst healthy trained participants or athletic population groups with regards to improving sleep efficiency (7-10). However, across these studies, varying doses ranging from 20 g to 60 g of alpha-lactalbumin (ALAC) were supplemented without clear indication of the rationale behind the dosage strategy. Additionally, while one study supplementing two separate 20 g ALAC doses at dinner meal and before bedtime found a positive outcome on morning after sleepiness (5); another study supplementing 20 g ALAC after morning exercise and 40 g ALAC before bedtime showed no significant difference in morning sleepiness measures (11). Hence, the specific effect of ALAC on sleep architecture and the optimal timing of consumption has yet to be investigated and warrants further research.

Further, there exists no body of research surrounding the dose response effect of ALAC supplementation on serum TRP:LNAA ratio, independent of other factors such as glucose intake and carbohydrate rich poor protein (CRPP) diets. Literature suggests that the presence of other amino acids as well as glucose around the ALAC consumption can alter the serum TRP:LNAA ratio by further increasing the LNAA levels or by mechanisms such as insulin secretion that promotes the uptake of branched-chain amino acids into the muscle (1).

The proposed study aims to answer this question of identifying an optimal dose and time of evening alpha-lactalbumin (ALAC) supplementation to raise the serum TRP:LNAA ratio, without the influence of any other dietary factors such as glucose or other proteins.

4.2 A rationale/justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice)
Tryptophan is a precursor of serotonin and melatonin, which are known to be involved in the regulation of various fundamental behavioural and physiological functions including sleep, wakefulness, circadian rhythms, cognition and even mood. Previous studies have reported that evening ALAC supplementation can effectively increase the TRP:LNAA ratio up to 130%. However, dose response studies for evening ALAC supplementation to identify the optimal dosage and time response to the ratio are yet to be explored.
Through this study we aim to be able to identify this optimal dosage of ALAC for further research and recommendations of this supplement in sleep and mood outcomes.

4.3 The research questions/aims/objectives/hypothesis

Research Question: What is the optimal dosage and timing of evening alpha-lactalbumin supplementation to increase the serum TRP:LNAA ratio?
Aim: To identify the optimal dosage of evening alpha-lactalbumin supplementation required to increase the serum TRP:LNAA ratio in healthy active population.
Objectives:
a) To study the dose response of 4 different doses i.e. 10, 20, 30, 40 g of ALAC supplementation on the TRP:LNAA ratio.
b) To observe the difference between the serum melatonin levels 3 hrs post consumption of 4 different ALAC dosages.
c) To test the palatability and appetite post 4 different dosages of ALAC supplementation.

Hypothesis:

1. There will be linear relationship between increasing ALAC dosages and serum TRP:LNAA ratio before reaching a plateau at ~40g.

2. Higher doses of ALAC will increase TRP:LNAA ratio for a longer time period

3. The palatability, appetite and preference will reduce at higher ALAC doses

4.4 The expected outcomes

The outcome of this study will be to identify the optimal dosage and timing of evening alpha-lactalbumin supplementation required to raise the serum TRP:LNAA ratio. This finding can be useful for further research on improving sleep outcomes with alpha-lactalbumin supplementation which requires the optimal TRP:LNAA ratio for its influence on sleep architecture.

5. Project Design:
Please provide details of:

The research project setting

5.1 This may include physical sites, online forums, and alternatives.

This research project will occur at the Deakin University Burwood campus, located in Burwood, Victoria, Australia. Participants will visit the testing laboratories of the Burwood campus, with testing to occur in this setting.

6. Methodology:

6.1 The methodological approach

A double blind crossover design has been selected. The double-blinded approach means both the researchers and participants will not know which dosage of the supplement is being received. Through a crossover design, each participant will receive all four dosages of the experimental supplement (α-lactalbumin), on four separate occasions, separated by a washout period of no lesser than 3 days (17, 18). As is the nature of a crossover trial, each participant will serve as their own control.

6.2 The rationale for choices of method/s (tied to project aims/objectives)

Double blinding ensures that both the research team and participants are unaware of the treatment dosages throughout the intervention, minimising the risk of bias. The crossover design allows for the participants to act as their own controls, thus limiting confounding influences of across subject variability. Assigning participants dosages via a latin square design model reduces the carryover effects from other within subject variables such as gender and other confounding variables and ensures proper balance such that the sequencing of experimental conditions does not affect outcomes of the trial.

7. The participants including:

7.1 A description and the number of participants

Sixteen participants (both genders i.e., male and female) will participate in the study.

7.2 The inclusion and exclusion criteria

Inclusions: Participants must be aged 18-35yrs, recreationally active i.e. completing at least 150 to 300 min moderate-intensity activity or 75–150 min of vigorous-intensity activity a week, plus muscle-strengthening activities 2 or more days a week (Tier 1 activity level) (12).
Exclusions: Partipicants must not be facing any existing sleeping disorders such as insomnia or consuming any nutraceutical or herbal sleeping aids such as melatonin gummies, chamomile or other herbs which could influence exogenus melatonin production (13). Participants will be screened using the Pittsburgh Scale Quality Index (PSQI) questionnaire and a score of >5 will be excluded from the trial (14). Excessive beer or wine consumption (>17 standard drinks per week), dairy allergy, high caffeine use (e.g., >5 mg·kg-1·d-1), antidepressant or sleep medication use, current or recently finished night shift work (14), recent transmeridian travel, fluctuating bedtimes, and pregnancy are also exclusions from this trial due to confounding influences that may have on the circadian rhythm, exogenous melatonin production or the plasma TRP:LNAA ratio (15).

7.3 The sample size and statistical or power issues

Sixteen participants are to be recruited as per the statistical power analysis outlined in 11.4. This statistical power analysis was completed in consultation with a Deakin IPAN biostatistician and was performed using G-Power Analysis and Sample Size Software (Version 3.1).

7.4 Your participant recruitment strategies and timeframes (as required in addition to that outlined in the HREA)

Ms. Mascarenhas (student researcher) will be the primary researcher involved with recruitment. Participants will be recruited through flyers (Appendix 5) placed at Deakin University, local gym settings and sporting clubs, with online platforms (e.g., social media) also used to reach a wider audience. With permission from university unit chairs within the School of Exercise and Nutrition Sciences (see attached Organisation Consent Form), recruitment talks will be completed during lectures and classes within relevant units. Recruitment posts will be uploaded on CloudDeakin pages with permission from unit chairs. All interested individuals will be provided with a plain language statement (Appendix 6) and are to return a consent form to either Ms Mascarenhas or Dr Condo. No data collection will take place before written consent is received by the research team. Recruitment will commence in February 2024 (on approval of ethics) and will continue until a sample size of 16 individuals are recruited.

Before the first participant is recruited, this study will be registered within the ANZCTR

7.5 Your approach/es to provision of information to participants and/or consent (as required in addition to that outlined in the HREA)

Any interested individuals will be provided with a digital and hard copy of the plain language statement and consent form to keep (via REDCap). The plain language statement outlines the study design, contact details and states that an individual's decision to be involved in the study will not jeopardise their relationship with Deakin university and the research team. The consent form is to be signed and returned before any data collection is commenced.

7.6 If necessary, the type of consent provided to different participant groups, when and where, and any arrangements to confirm that consent

Written consent. All participants will be provided with a plain language statement and are to sign a consent form before participating in the trial.

7.7 If necessary, details of who will be confirming or re-negotiating consent with participants and the process/es that will be undertaken

Participants will be able to withdraw their consent at any time during the study which will not jeopardise their relationship with Deakin University. Participants must complete the 'withdrawal of consent form' (attached to the Plain Language Statement) and return it to a member of the research team.

8. Research Activities:

What you are going to do? Please include:

8.1 The participant commitment

Methods

Briefly, the screening phase will involve determination of study eligibility and will be administered via an online questionnaire. Upon selection post screening, each participant will be contacted to be explained the experimental protocol and to be scheduled to report to Deakin University (Burwood campus) on four separate occasions for the intervention separated by a washout period of no lesser than 3 days (17, 18).

Screening Session

To determine participant eligibility, participants will be screened, upon consent, using online questionnaire (Appendix 1) on REDCap to assess their eligibility for this study. The screening questionnaire will also involve questions around their training status to exclude any participants who are not recreationally active i.e., completing at least 150 to 300 min moderate-intensity activity or 75–150 min of vigorous-intensity activity a week, plus muscle-strengthening activities 2 or more days a week which classifies them as Tier 1 activity level. Sleep quality will be screened through the Pittsburgh Sleep Quality Index (Appendix 2) to exclude any participants with as PSQI score >5 as well as the presence of any pre-existing sleeping disorders such as insomnia will be screened at this stage.

Experimental Measures

Following screening, shortlisted participants with confirmed eligibility, will be contacted by the research team to explain the experimental protocol of the trial and to schedule their visits to the Deakin University Burwood Laboratory subsequently. At this point, participants will also be informed to complete a simple three day diet recall, prior to their first visit, using a smartphone app (Easy Diet Diary), to quantify the participants regular dietary intake, establish any dietary allergies and/or sensitivities, as well as, to ensure regular meal timings. This would help identify and eradicate any potential bias to the trial due to irregular meal patterns or extreme calorie restriction which could influence circardian cues and melatonin production (15).

Randomisation

Participants will be randomly allocated a single dose of the α-lactalbumin (BiPRO Alpha 9000; Agropur Inc, Appleton, WI), in a crossover design (each participant will complete all 4 doses on 4 different occasions) on their scheduled lab visit dates. A latin square design will be used for a counterbalanced randomisation of the dosages to the participants to avoid any potential carryover effects or within participant variability. To blind both participants and the research team, the experimental drinks will be matched for taste and provided to the participants by an external researcher. The latin square model will ensure adequate sequencing of the dosages across at the participants to avoid within subject variability.

Intervention

Participants will be required to report to the university at **17:00 hrs with a fasting period 2.5 hrs before arrival (14:30 hrs)**. Upon their arrival, simple height and weight measures will be taken by the researchers. Within the first hour of arrival, a trained researcher will insert a cannula into a forearm vein of the participants for blood samples to be taken. Baseline blood and saliva samples will be collected before the experimental supplement consumption. Further, each participant will be provided the experimental ALAC protein shake and a Visual Analog Scale (VAS) -sensory evaluation questionnaire to assess the preference of the ALAC shake at immediately post consumption of the drink (T=0 mins). Participants will also complete a Visual Analog Scale VAS -GI symptoms questionnaire, at two time points i.e. baseline (T=0 mins) and 2hrs post supplement consumption i.e. (T= 120 mins). Small amounts of blood will be drawn (5 mL) at half an hour interval from the time of the supplement consumption (pre supplement and 90 mins, 120 mins, 180 mins and 210 mins post supplement). During the experimental protocol, from T=0 to T= 210 mins, the participants will be asked to relax in an environment consistent lighting and discouraged from using screens. A saliva swab collection will once again be repeated at 3 hrs (210 mins) post supplement consumption. A simple chronotype questionnaire will also be administered to all the participants at this stage. At the end of the study protocol i.e., **21:00hrs**, the participants will be screened for alertness via Karolinska Sleepiness Scale (KSS)(Appendix 4) to assess their ability to drive back home post the intervention and in the event a participant scores >6.8 on the KSS scale, alternate arrangements to travel back home or temporary sleeping arrangements at Deakin University Campus will be made to ensure the participant's safety. Participants will also be handed a boxed dinner meal before leaving the lab. This procedure will be replicated for each of the four visits made be every participant, during the intervention. Participants will also receive a reimbursement via $100 gift card on successfully completing all 4 intervention sessions.

Wash-out

The wash-out phase is defined as a period of minimum three days to limit any carry-over effect of the ALAC supplement on the serum Tryptophan:LNAA ratio before administering the next dose. This ensures that the experimental protein dosages are adequately separated. This period is defined based on previous literature which has observed that a gap of 1-3 days to be sufficient to reverse the effect of a single dose of tryptophan on TRP:LNAA ratio (17,18). During the wash-out period, the participants will be required to continue eating and training as per their usual routine. No supplement will be provided during this phase.

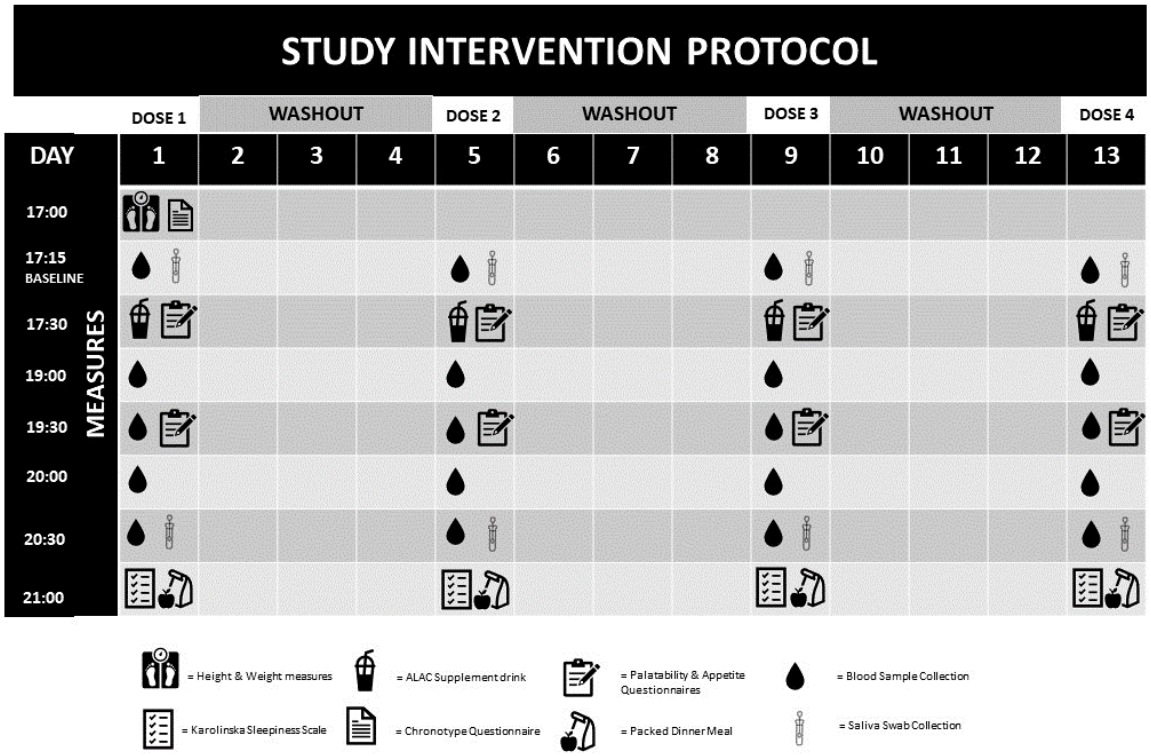

Figure 1 -Graphical description of the study protocol. Example of a participant prescribed all 4 doses of alpha -lactalbumin supplement in random order and the measures taken at different time intervals.

8.2 The project duration

This project is planned to be completed within two years, with recruitment to start in February 2024 after the ethics approval. This timeline is inclusive of all aspects of the research project.

8.3 Any participant follow-up

There is no planned follow up following the cessation of the study.
Participants will be provided with a copy of the research report after publication if this option is selected on the consent form

Please ensure your responses to Sections 9-12 comply with Deakin's Research Data Management procedure and accurately reflect the details you have included in your Research Data Management Plan (a compulsory document for all Deakin research).

9. Data Collection/Gathering:

9.1 What information are you going to collect/gather/generate? (as required in addition to that outlined in the HREA)

Please note that prior to the recruitment of the first participant, this clinical trial is to be registered within the ANZCTR.

Personal information

- Name

-Contact number

- Email address (to be sent electronic PLS and consent form, and if selected, publication of study)

Screening measures

- Participant age

- Habitual dietary intake prior to the intervention

- Sleep quality via PSQI questionnaire

- Dietary allergies

-Chronotype measures via morningness eveningness questionnaire (MEQ)

Outcome measures

- Biochemical measures (plasma amino acids and plasma melatonin)

- Palatability of ALAC supplement doses via VAS-GI symptoms questionnaire administered

-Preference of the ALAC supplement doses via VAS -sensory evaluation questionnaire administered

Data Collection

- Blood samples across five timepoints during each intervention session on each of the four separate lab visits i.e., all four supplement doses, to be collected.

-Saliva sample at two time points during each intervention session, on four separate occasions i.e., all four supplement doses to be collected.

9.2 Data collection/gathering techniques: How will you collect/gather the information? Will any third parties be involved in any aspects of recruitment or data collection?

Screening measures

Participant characteristics – age, training level, medication use, alcohol and caffeine consumption, travel history across time zones, recency of night shift work will be collected at baseline using a simple questionnaire (Appendix 1).

Sleep quality – Participants will be screened using the Pittsburgh Sleep Quality Index (Appendix 2) to ensure the participants do not face any pre-existing sleeping difficulties.

Diet Recall - Participants will be asked to record a 3 day diet recall using Easy Diet Diary (EDD) mobile app prior to their first lab visit.

Outcome measures

Biochemical measures – Blood samples will be collected by a researcher with phlebotomy training across five-timepoints on each intervention day. Plasma amino acid analysis will then be completed at Deakin University through liquid chromatography triple-quadrupole mass-spectrometry.

Plasma melatonin will be assessed through enzyme-linked immunosorbent assay according to manufacturer's instructions.

Palatability and preference will be assessed through a validated VAS -GI symptoms and VAS- sensory evaluation questionnaire to gauge the palatability and acceptance of the different supplement doses.

9.3 Impact of and response to participant withdrawal

Participants will be informed about their right to withdraw from the study at any time, which will not jeopardise their relationship with the research team or Deakin University.

Data collected from a participant selecting to withdraw from the study will only be destroyed if this is requested (optional tick box on the withdrawal of consent form), otherwise all collected data will be retained for research integrity purposes.

Forms will be returned to a member of the research team, who will review the withdrawal form and store this within a locked filing cabinet.

If the number of participants that withdraw themselves from the study impacts the sample size required (n=16) then recruitment will continue in order to reach this sample size

10. Data Management:

10.1 How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather? (as required in addition to that outlined in the HREA)

Digital and hard copies of data will be collected throughout this research. Digital data will be stored using the software sharing program 'Syncplicity', which is a secure program that is regularly backed up. Only the research team listed will have access to this data. Physical copies of data will be stored in a private lockable filing cabinet in an area of the Deakin University campus that requires security clearance to access.

Each participant will be allocated a unique study ID code. These ID codes will be linked to the participant names and stored within a spreadsheet. This spreadsheet linking participants to an ID code will be stored on this same network drive, which will only be accessible to the research team.

During the study, blood samples will be stored in -80 degree Celsius freezers in the level 2 analytical laboratories of building J at the Burwood campus. These laboratories are limited to swipe access only.

Collected data will be archived and stored for a period of 15 years following publication of results from this study. Following this 15-year period, data will be destroyed. All sensitive data contained as a physical copy will be shredded, any electronic data will be permanently deleted, and blood samples will be destroyed.

Include a Research Data Management Plan in accordance with National Statement 3.1.45 and 3.1.56 and Deakin's Research Data Management procedure.

11. Data Analysis:

11.1 How will you measure, manipulate and/or analyse the information that you collect/gather?

Initially, data cleaning will be performed to identify missing and corrupt data. Data will be analysed using generalised linear mixed models within StataIC 16 (StataCorp LLC, TX, USA). The effect of dietary intervention (dose response effect of α-lactalbumin) and time period (i.e., sequence receiving condition) and their interaction, will be fitted as fixed effects to determine whether there was a difference in the effect of dietary intervention over period on dependant variables of amino acid analysis and plasma melatonin. Participant identification number will be used as a random factor to account for repeated measures in each model.

11.2 Please describe your matching and sampling strategies

There will be no requirement to create matched groups due to the repeated measures study design. Each participant will act as their own control.

11.3 Please outline how you will account for potential bias, confounding factors and missing information

Bias

- Double-blinded study

-The different α-lactalbumin dosages to be matched for taste. An external researcher is to provide participants with the supplement to ensure the research team remains blinded to the experimental dosage.

- Diet – As protein and carbohydrates can influence the TRP:LNAA ratio, participants will be asked to come in fasting for a period of 3 hrs before the alpha-lactalbumin supplement consumption.

- Light will be controlled for after the supplement consumption and screen usage or viewing will be restricted to limit the impact of light on endogenous melatonin levels

Missing values will not be substituted in any circumstance (missing or otherwise). There are no planned data cleaning processes, with raw values only to be analysed.

11.4 Please include your statistical power calculation

A paired t-test achieves **85%** power to infer that effect size is above the mean difference of 0.5. When the total sample size of a cross-over design is **16**, the actual mean difference is 0.024, the square root of the within **mean square error** is **0.05**, and the significance level further adjusted from **0.05** to **0.01** to account for repeated comparisons within the group.

12. Data Linkage:

12.1 What linkages are planned or anticipated?

N/A

13. Outcome measures:

13.1 Please describe your outcome measures

Primary outcome measures include:

-Amino acid analysis (i.e., plasma TRP:LNAA ratio)

Secondary outcome measures include:

-Plasma melatonin

-Palatability, appetite, and preference of the different alpha-lactalbumin supplement dosages

14. For research involving an unapproved therapeutic good (such as a drug, device or biological):

14.1 Does this project involve an unapproved therapeutic good requiring a Clinical Trial Notification (CTN)? (See the Clinical Trials webpage for more information about CTNs)

☒ Yes – go to the next question.

☐ No – skip to Section 15 (results, outcomes and future plans)

14.2 Is Deakin intended to be the Sponsor?
☒ Yes – go to the next question
☐ No – skip to Section 15 (results, outcomes and future plans)

14.3 If Deakin is intended to be the Sponsor and the research requires a Clinical Trial Notification (CTN), has the CTN, Clinical Trial Sponsorship Request Form and Protocol been submitted to research-integrity@deakin.edu.au for assessment?

☐ Yes – assessment completed and the CTN must now be submitted to the Therapeutic Goods Administration (TGA) by Deakin (as Sponsor). Please attach evidence of assessment and the CTN form. You will be contacted by the Human Research Ethics Office regarding submission of the CTN to the TGA.

If not, please submit the draft CTN, Clinical Trial Sponsorship Request Form and Protocol to research-integrity@deakin.edu.au for assessment before submitting this application to DUHREC. See the Clinical Trials webpage for further information. The Clinical Trial Sponsorship Request Form can be requested by contacting research-integrity@deaknin.edu.au.

14.4 What is/are the drug(s) and/or device(s):

- Approved name BiPRO Alpha 9000
- Trade name (if any) N/A
- Manufacturer Agropur
- Supplier of drug/device (e.g. manufacturer/pharmacy) Agropur
- Approved therapeutic indication, dosage/duration in Australia N/A
- Believed mode of action Increased tryptophan availability → increases melatonin synthesis (tryptophan active ingredient)
- Dosage regimen 10g, 20g ,30, 40 g (tryptophan <1.9 g)
- Mode of excretion N/A
- Known adverse events None
- Known contra-indications or warnings Milk protein allergy and lactose intolerance
- If arrangements have been made for a Pharmacy Department to receive or dispense the drugs involved in this project, explain how the drugs will be received and dispensed for the purposes of the research project N/A

15. Results, Outcomes and Future Plans:

15.1 Please outline your plans for return of results of research to participants – include an ethically defensible plan in accordance with National Statement 3.1.65 or 3.2.15 or 3.3.36-3.3.61, as appropriate.

The research staff will not use the results to diagnose any medical conditions.

15.2 Please describe your plans for dissemination and publication of project outcomes

The final publication of the study will be provided to participants selecting yes on the consent form. Further, results from this study will be disseminated at relevant conferences through presentations,

and through publication in a peer-reviewed journal. For dissemination, all data will remain de-identified and participants will remain anonymous.

15.3 Please list other potential uses of the data at the end of the project

Data will not be used for any other purposes than previously described.

15.4 Please detail the project closure processes

Upon completion of all data collection and data analysis, results will be submitted to peer-reviewed journals for publication. Following publication, all data will continue to be stored per methods outlined in Section 10.

15.5 Please outline your plans for sharing and/or future use of data and/or follow-up research

The data and research findings from this study will be used to inform future research within the same field. This could include investigations of further blood markers related to α-lactalbumin supplementation. Any follow-up research will be conducted as a separate project. Extended consent will be sought to use collected data in future research projects that are extension of, or closely related to, the original project or in the same general area of research.

15.6 Please describe any anticipated secondary use of data

There is no plan to use data collected within this project for any secondary use.

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DECLARATION AND SIGNATURES

I/We, the undersigned declare that the information supplied in this application (including the attached original application) is true and accurate to the best of my/our knowledge.

I/We the undersigned have read the *National Statement on Ethical Conduct in Human Research* and accept responsibility for the conduct of the project detailed in this application in accordance with the principles contained in the Statement and any other conditions laid down by Deakin University Human Research Ethics Committee.

I/We the undersigned, declare that where the research project may involve contact with a child or young person under the age of 18, I/we have a current Working with Children Check.

Principal investigator

Name: **Dr. Dominique Condo**

Human Ethics Quiz (please complete the appropriate box below):

☐ successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☒ exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID: 2021 -372*

Signature:  Date: **04/11/2023**

Associate investigator*

Name: **Dr. Spencer Roberts**

Affiliation (please select from the drop-down list by clicking on 'Choose an item'): Deakin Staff

Human Ethics Quiz (please complete the appropriate box below):

☒ successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☒ exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID: 2021 -372*
☐ external researcher (exempt from completing the Quiz)

Signature:  Date: **6/11/2023**

Associate investigator*

Name: **Dr. David Lee Hamilton**

Affiliation (please select from the drop-down list by clicking on 'Choose an item'): Deakin Staff

Human Ethics Quiz (please complete the appropriate box below):

☐ successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☒ exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID:* Click or tap here to enter text.
☐ external researcher (exempt from completing the Quiz)

Signature:  Date: **06/11/2023**

Associate investigator*

Name: **Dr. Kate Pumpa**

Affiliation (please select from the drop-down list by clicking on 'Choose an item'): External Investigator

Human Ethics Quiz (please complete the appropriate box below):

☐ successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☐ exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID:* Click or tap here to enter text.
☒ external researcher (exempt from completing the Quiz)

Signature:  Date: **06/11/2023**

Associate investigator*

Name: **Dr. Kathleen Miles**

Affiliation (please select from the drop-down list by clicking on 'Choose an item'): External Investigator

Human Ethics Quiz (please complete the appropriate box below):

☐ successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☐ exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID:* Click or tap here to enter text.
☒ external researcher (exempt from completing the Quiz)

Signature:  Date: **06/11/2023**

Student investigator*

Name: **Ms. Luana Agnes Mascarenhas**

Affiliation (please select from the drop-down list by clicking on 'Choose an item'): Deakin Student

Human Ethics Quiz (please complete the appropriate box below):

☒ successfully completed the Human Ethics Quiz (compulsory for Deakin staff and students)
☐ exempt from completion of the Quiz due to prior inclusion on an ethics application at Deakin. *Please indicate HEAG or DUHREC Project ID:* Click or tap here to enter text.
☐ external researcher (exempt from completing the Quiz)

Signature:  Date: **06/11/2023**

***All research staff involved in the project must sign the project description/protocol. Please add additional signatures blocks as required.

ACKNOWLEDGMENT OF HEAD OF SCHOOL/DIRECTOR OF RESEARCH**

I, the undersigned, acknowledge that the School/Faculty/Institute has considered and approved the academic worth of the project described in this application.

Name: **Prof. Clinton Bruce**

Signature:  Date: **08/11/2023**

****If the Head of School (or similar) is also a member of the research or supervisory team, a more senior member of University staff e.g. Dean or Associate Dean (Research), must sign the project as authorising officer.

A Project Description is a **mandatory** component of a submission using the Human Research Ethics Application (HREA).

Please submit all documents via direct email to <research-ethics@deakin.edu.au>.

Deakin University is collecting your personal information on this form for the primary purpose of processing your human research ethics application. It will also use this information for monitoring your compliance with the approved protocol. For these purposes Deakin may also provide this information to potential research participants, past or current research participants, or other interested parties in your research. You are not

required to provide the information requested, however if the information is not provided, Deakin may not be able to process your ethics application. Deakin manages personal information it holds, including requests by individuals for access to their personal information, in accordance with the Privacy and Data Protection Act 2014 (Vic). Deakin's Privacy Policy may be viewed on Deakin's Policy Library. Information on privacy at Deakin is available at http://www.deakin.edu.au/footer/privacy. Questions about privacy may be directed to the Privacy Officer on (03) 5227 8524 or by email to privacy@deakin.edu.au.