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Dietary patterns and sleep: effects of animal origin and plant origin diet on sleep health in healthy adults.

PARTICIPANT INFORMATION STATEMENT

1. What is this study about?

You are invited to take part in a research study examining the effect of dietary pattern on sleep health. The main aim of this study is to assess sleep changes due to the adoption of different diets: diet with animal origin (Omnivores Diet) or plant origin (Vegan Diet). The Omnivores Diet is adjusted with the same proportion of protein, fat and energy from plant origin. This study will take place for a period of 8 weeks.

You have been invited to participate in this study because we are interested in real data from healthy adults on dietary intakes and sleep health. Knowing what is involved would help you decide on your participation in this research. This Information Statement tells you certain details about the research. Please read these details carefully and ask questions about anything that you do not understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

2. Who is running the study?

Mitchel Bones is conducting this study as the basis for the degree of Doctor of Philosophy in Health Sciences at The University of Sydney. This will take place under the supervision of Associate Professor Chin Moi Chow (Discipline of Exercise and Sport Science), Senior Lecturer, Dr Mark Halaki (Discipline of Exercise and Sport Science) and Professor Victoria Flood (Professor of allied health, Faculty of Health Sciences, Western Sydney Local Health District).

3. What will the study involve for me?

Once your eligibility to take part in the study has been confirmed, baseline assessments will be taken of your health and physical capabilities as well as your quality of sleep. You will then follow a diet regimen for eight weeks. The first diet condition and the third diet condition will be your normal omnivore diet and the middle condition will be the vegan diet. The same assessments done at baseline will be repeated at the end of

second week, third week, fifth week, sixth week and final week of the study. The study on dietary pattern changes will take place in your home. You will attend the Cumberland Campus, Lidcombe, on six occasions for assessments.

The key assessments are sleep patterns and sleep-wake cycles (measured by the Actiwatch, a wristwatch which automatically records the sleep-wake patterns) for the entire study period of 8 weeks, and recording of your dietary intake, a short sleep and activity questionnaire for a total of 9 days during the study period. In addition, your fasting blood glucose, blood pressure, mood and alertness, and working memory will be assessed at six time points, with visits to the University Sleep Laboratory at Lidcombe.

In the first session at the Laboratory, you will be guided, with an instruction sheet, on what food to be eaten and their quantities over the study period. You need to follow the dietary requirements as instructed.

4. How much of my time will the study take?

- a) Mainly at your Home:
 - i) about an hour each day to complete the food diary for 3 days of each week for 8 weeks. For the first diet condition, you will record in your food diary two days from weekdays and one day from a weekend day during the first week. On the second and the third diet conditions, you will record in your food diary two days from weekdays and one day from weekend during the second week of starting those diets. So the diary completion is needed in week 1, week 4 and in week 7. The details on how to complete the food diary will be provided in forms as per your participation.
 - ii) about 20 minutes each day for daily completion of the questionnaires regarding your sleep and physical activity for eight weeks.
- b) Only six visits at sleep lab at Lidcombe:
You need to attend the sleep lab in maximum of six visits and approximately spending one and half hours in each visit to return the Actiwatch for charging and for physiological measurements.

5. Who can take part in the study?

If you are a healthy adult of more than 18 years of age and do not match any of the following exclusion criteria, you can participate for the study.

Exclusion Criteria:

- a) Those with mental illness: depression, bi-polar, schizophrenia, Sleep disorders: insomnia, periodic leg movements, sleep apnoea, narcolepsy, REM sleep behaviour disorder and/or other major medical conditions (such as cardiovascular and respiratory diseases, anorexia nervosa, bulimia, metabolic syndrome, diabetes)
- b) Those who are on any medication, including herbal and vitamin that affect sleep.
- c) Those who are pregnant or planning to become pregnant within next eight weeks, shift workers, vegans and people who consume ≥ 5 standard alcohol drinks on any day will be excluded from the study.

6. Do I have to be in the study? Can I withdraw from the study once I've started?

Participating in this study is completely voluntary. Your decision on whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney.

If you first decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by informing the researcher (Mitchel Bones) your decision on withdrawal from the study.

If you decide to withdraw from the study, we will not collect any more information from you. Any information that we have already collected, however, will be kept in our study records and may be included in the study results.

7. Are there any risks or costs associated with being in the study?

No intentional risk involves in this study because the study design and screening has been designed taking considerations into possible risks involved. Anyone allergic to any food products should avoid eating those products in this study despite the instruction sheet on food intake. In the event that you have any medical problem or food allergy, please contact your GP.

Apart from giving up your time and cost for travelling to Lidcombe sleep lab, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?

We cannot guarantee that you will receive any direct benefits from being in the study. An attempt will be made to reward all participants with some compensation for your time (a \$50 voucher). You will be provided with a food weighing scale, measuring spoons, and measuring cups to be used through-out the study period and are welcome to keep at the completion of the study. From the results of this study, we expect to determine whether different diet conditions are beneficial or detrimental to sleep health in healthy adults. Therefore, we value your participation, which would add valuable knowledge to the wider community.

9. What will happen to information about me that is collected during the study?

The University approved Research Data Management Plan (RDMP) will be used to enter and maintain your Research Data. As per RDMP protocols the data will be stored securely. The data will be retained for 5 years before it is subjected for disposal.

If you give us your permission by signing the consent document, we plan to publish the results in peer-reviewed journals, presentation at conferences or other professional forums. In any publication, information will be provided in such a way that you cannot be identified.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

10. Can I tell other people about the study?

Yes, you are welcome to tell other people about the study. You can tell your spouse, partners, flatmates, other family members and friends if they would like to take part in the study.

11. What if I would like further information about the study?

When you have read this information, at the time of consent, Mitchel Bones will be available to discuss the project with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Associate Professor Chin-Moi Chow, Dr Mark Halaki, Professor Victoria Flood and Mitchel Bones for further information on this valuable research.

12. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box in the consent form. This feedback will be in the form of a one page lay summary. You will receive this feedback after the study is completed.

13. What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney (Protocol number will be inserted once approval is obtained]. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep