

RESEARCH PROTOCOL

Full Study Title:

**EFFECTS OF ANIMAL AND PLANT ORIGIN DIET ON
SLEEP HEALTH IN HEALTHY ADULTS**

Short Title:

Dietary patterns and sleep

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STATEMENT OF COMPLIANCE

This document is a protocol for a non-clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007).

This protocol is for Part 2. Experimental: designed experiment, crossover longitudinal study, one part of the PhD research program which consist of 3 parts:

1. Systematic review: with meta analysis,
2. Experimental: designed experiment, crossover longitudinal study
3. Explorative: large simple cross-sectional cohort survey



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PROTOCOL SYNOPSIS

Title	Dietary patterns and sleep: effects of animal origin and plant origin diet on sleep health in healthy adults
Aims	The main aim of this study is to assess sleep changes due to the adoption of an Omnivores Diet (OD) or Vegan Diet Adjusted (VDA) for a period of 8 weeks. A secondary aim is to investigate associations between changes in micronutrients and sleep parameters.
Objectives	<p>Primary:</p> <ol style="list-style-type: none"> 1. To examine the effects of transition (acute or habitual) from OD to VDA and vice versa on sleep and 2. To examine the effects of exposure (post habitual) to VDA and OD and vice versa on sleep. <p>Secondary: To examine the response measures associated with the sleep outcomes of OD and VDA diets. These measures include fasting blood glucose level, blood pressure, mood and alertness, and working memory</p>
Study Design	Crossover longitudinal study
Planned Sample Size	30 participants for the experiment will be enrolled in this study.
Selection Criteria	Healthy adults aged 18 years or over will be selected.
Study Procedures	During each dietary regiment, data on sleep pattern and sleep-wake circadian rhythm with actigraphy will be collected. Acti-watch (wrist watch) which automatically record sleep wake pattern will be provided to all participants. Secondary measures of fasting blood glucose level, blood pressure, mood and alertness, and working memory will be recorded as covariate for analysis.
Statistical Procedures Sample Size Calculation: Analysis Plan:	<p>Sampling survey and design of experiment will be conducted with reference to the standard formula using G power of sample size calculation.</p> <p>For the crossover experiment, analysis of variance will be performed with appropriate mean comparisons.</p>
Duration of the study	The experimental period is 8 weeks for participants
Completion of the Full study	The full study of the PhD will be completed within 3 years



GLOSSARY OF ABBREVIATIONS

ABBREVIATION	TERM
OD	Omnivore diet - diet high in meat, poultry, fish, eggs, fresh fruit, and dairy
VD	Vegan Diet - diet derived from plants, without eggs or dairy, or meat (red meat, poultry, seafood, and the flesh of any other animal, as well as by-products of animal slaughter)
VDA	Vegan diet adjusted (Same proportion of protein and fat as MD)
SD	Sleep Duration
TST	Total Sleep Time
SE	Sleep Efficiency
WTASOL	Wake Time After Sleep Onset Latency
SO	Sleep Onset
BDHQ	Dietary Habits Questionnaires
IPAC	International
PSQI	Pittsburgh Sleep Quality Index
FFQ	Food Frequency Questionnaires
OCD	Obsessive Compulsive Disorder
TD	Tryptophan Depletion
CHO	Carbohydrate
FAT	Fat
PRO	Protein
EEG	Electroencephalography
T/Tx	Treatment
REM	Rapid eye movement
NREM	Non rapid eye movement
Ex	Experiment
VL CHO	Very Low Carbohydrate Diet
GI	Glycemic Index
NHANES	National Health and Nutrition Examination Survey
VAS	Visual Analogue Scale
MD	Mediterranean diet
PMSQ	Profile of Mood States questionnaire
MST	Mid Sleep Time
PSG	Polysomnography
EOG	Electro-oculography
BMI	Body Mass Index
A-LAC	α -lactalbumin
SWS	Slow Wave Sleep
Trp:LNAA-Ratio	Ratio of plasma Tryptophan to large neutral amino acids
PMSQ	Profile of Mood States questionnaire
DIS	Difficulty Initiating Sleep
PQS	Poor Quality of Sleep

1. STUDY MANAGEMENT

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1.1 Sponsor

The University of Sydney

1.2 Funding and resources

Research Training Program (RTP) Fees Offset, which is a type of RTP Scholarship, to assist with tuition fees only for the student. For this study there is no other financial assistance.

2. INTRODUCTION AND BACKGROUND

2.1 Background Information

Description of Diets

1. Vegan Diet (VD): diet derived from high amount of plant protein, without eggs or dairy, or meat (red meat, poultry, seafood, and the flesh of any other animal, as well as by-products of animal slaughter) and fruits and vegetables (roots, tubers, flowers, stems, seeds, legumes, grains and shoots)[1].
2. Omnivores Diet (OD): diet have the capability to obtain chemical energy and nutrients from materials originating from plant and animal origin. Often, omnivores also have the ability to incorporate food sources such as algae, fungi, and bacteria into their diet as well [2].
3. Vegan Diet Adjusted (VDA): A vegan diet adjusted with the same proportion of protein and fat from plant origin as omnivores diet.
4. Omnivore Diet Baseline(ODB): OD as per baseline
5. Mediterranean diet: diet include proportionally high consumption of olive oil, legumes, unrefined cereals, fruits, and vegetables, moderate to high consumption of fish, moderate consumption of dairy products (mostly as cheese and yogurt), moderate wine consumption, and low consumption of non-fish meat products[3].
6. Vegetarian Diet: is the diet of abstaining from the consumption of meat (red meat, poultry, seafood, and the flesh of any other animal), and may also include abstention from by-products of animal slaughter[4].

Previous research has shown that diet and sleep play a vital role in promoting physical health, longevity and emotional well-being of humans [5, 6]. Numerous studies have examined the relationship between dietary components (individual/ combined micronutrients or macronutrients) and sleep (quantity and quality) [7-11]. For an example, a study where participants consumed fatty fish 3x per week for six months showed no change in Sleep Onset Latency (SOL) or Wake-time After Sleep Onset (WASO) as measured by actigraphy [12]. Their counterparts who consumed an alternative meal (replacing fish with chicken, pork, beef) showed a delay in SOL and an increased WASO. Both groups reported a reduction in sleep efficiency. However, the study did not report details of food consumption by the participants.

Notably, foods are usually consumed in combination and in many experiments with feeding trials, it is difficult to ascribe the specific sleep effects to an individual nutrient. Therefore, researchers use dietary patterns - the summary measures of individual foods and nutrients. For instance [13] dietary pattern analysis has emerged as an alternative approach to examining the relationship between diet, cardio metabolic functions, sleep and the risk of chronic diseases. For the same reason, "Defining what represents a macro-nutritionally balanced diet remains an open question and a high priority in nutrition research" [14]. To answer this open question one should focus on the sources and amounts of nutrition that would result in better health outcome.

It was reported that the choice of protein sources inevitably influences other components [14] of diet and may be of critical determinant for the health outcome. The amount of protein may have



specific effects, from a broader dietary perspective. Additionally, high animal protein intake was positively associated with cardiovascular mortality, while high plant protein intake was inversely associated with cardiovascular mortality, especially among individuals with at least one life style risk factor. The same researchers reported that the substitution of plant protein for animal protein, especially that from processed red meat, was associated with lower mortality. Their findings suggested the health-related importance of protein source [14]. Nevertheless, the association between consumption of animal protein and high cardiovascular mortality remains speculative since it was an epidemiological survey with no real substitution of animal protein with plant protein.

Unsurprisingly, Mediterranean and vegetarian diets might have been promoted for weight loss and health improvement. Although the amount and type of protein may have specific effects such as insulin like growth factor levels [14] and tryptophan and melatonin level in proteins [15, 16], the choice of protein sources will inevitably influence the composition [17] of the diet, including macronutrients, micronutrients, and phytochemicals.

It is noteworthy that high concentration of tryptophan in the brain promotes sleep [18], since it is a precursor to serotonin, and melatonin which is a sleep inducing agent. Serotonin is one of the most important brain chemicals for regulating the sleep-wake cycle. Animal proteins contain not only tryptophan but also the other large neutral amino acids (LNAA). A high ratio of tryptophan to LNAA is necessary for tryptophan entry into the brain. Hence, tryptophan that is present in meat may not be readily available for conversion to melatonin. Furthermore, even though foods in the omnivore diet is slightly high in protein of animal origin protein only few animal origin food products are high in tryptophan compared to protein rich plant origin foods [17].

A study showed that both the protein-rich modern omnivore diet and the carbohydrate-rich traditional wheat base diet predicted decreased insomnia prevalence [15]. On the other hand, a diet from plant origin, when used as a balanced diet, may act as a natural sleeping aid, given that vegan diets contain high amount of tryptophan [17]. Additionally, published literature lends support to vegan diet in endorsing health benefits such as reduced mortality, risk of obesity, diabetes, heart disease, and some type of cancer as well as increased longevity [19]. It is possible that these health benefits are due to protein and fat from plant origin rather than from animal sources. However, it is unknown as to how protein and fat from different origins (plant vs animal) impact on sleep. Indeed, there is very limited research into the comparable effects of plant and animal origin diet on sleep, sleep health and insomnia - a serious health threat affecting nearly one third of the human population. This study addresses this gap of knowledge. Therefore, our study aims to evaluate the effects on sleep of a vegan diet when consumed with similar proportions of protein and fat to that of the omnivore diet.

To this end, a crossover longitudinal study of two-month duration will be conducted with 20 healthy participants by introducing them to a vegan diet and then a return to an omnivore diet as per baseline (ODB) both with similar proportions of fat and protein to their baseline animal origin



diet. From the outcomes of this study it will be possible to assess whether the effects of exposure to a vegan diet regimen would be beneficial or detrimental to the human sleep health and to examine the secondary response measures associated with the sleep outcomes due to the ODA and VDA diets(as per the figure 1 and 2).

Associations between sleep and blood glucose levels and that with blood pressure have been reported [19]. Therefore, fasting blood glucose levels and resting blood pressure will also be measured as a secondary- outcomes.

In addition, sleep affects cognition. People with poor sleep tend to have lower mood and alertness as well as a lower working memory capacity [20]. Therefore, mood and alertness as well as a lower working memory capacity will also be measured as a secondary- outcomes.

2.2 Research Question

Does sleep health differ between people on a vegan (plant origin) vs omnivore (animal origin) diets?

2.3 Rationale for Current Study

Vegetarian diets are known to provide desirable health outcomes but nothing is known on how vegan diet affect sleep. If the research proves that vegan diet provide similar or better outcome to omnivore diet, it could be useful for formation of policy on vegan diet for better sleep health. Further if that is not the case, the outcome is also useful to formulate future research on how to improve sleep.

3 AIMS/ OBJECTIVES / HYPOTHESES

3.1 Aim: To conduct a crossover longitudinal study to determine whether replacement of protein and fat from animal sources in OD with same proportion of protein and fat from plant origin in VDA while maintain the overall energy intake has an effect on sleep pattern and their day-to-day sleep-wake cycle in healthy adults.

3.2 Objectives:

- 3.2.1 Primary:**
1. To examine the effects of transition (acute or habitual) from OD to VDA and vice versa on sleep and
 2. To examine the effects of exposure (post habitual) to VDA and OD and vice versa on sleep.

3.2.2 Secondary: to examine the response measures associated with the sleep outcomes of OD and VDA diets. These measures include fasting blood glucose level, blood pressure, mood and alertness, and working memory.



3.3 Research Questions and hypotheses:

1. Is there a difference in sleep outcomes between OD and VDA?

Hypothesis: There is a difference between sleep outcomes between VDA and OD.

2. How does the transition (acute) from OD to VDA and VDA to OD affect sleep?

Hypothesis: There is a transient effect on sleep outcomes when switching between VDA and OD

3. Is there an association between micro and macronutrients with any sleep VDA or OD outcomes?

Hypothesis: There is an association between micro- and macro-nutrients with any sleep outcomes.

4. Whether secondary response measures are associated with sleep out comes due to the OD and VDA?

Hypothesis: There is an association of in the secondary measures of glucose metabolism, blood pressure, mood and alertness and working memory with the sleep variables.

4. STUDY DESIGN

4.1 Type of Study

crossover longitudinal study

4.2 Study Design

The study is to conduct. crossover longitudinal study of vegan diet vs modern diet using healthy adults The crossover experiment study is designed in order to assess the effects of exposure to different diet regimen, plant origin diet (VD) vs animal origin diet (MD), with the same proportion of nutrients except difference in type of protein, CHO and fat (plant protein and fat vs animal protein and fat), and the benefits or detriment of human sleep health as measured by sleep patterns and sleep-wake circadian rhythm, and the consequence of sleep outcomes including fasting blood glucose, mood and alertness, and cognitive functioning in working memory.

The OD is participants' normal mixed diet with meat, poultry, fish, eggs, dairy, vegetables, fruit and beverages. The VDA will be made with reference to the proportional dietary intake of OD. The Foodworks 9 nutrition software will be used to convert daily food intake into the nutritional components (protein, fat, carbohydrate, tryptophan, caffeine, zinc, alcohol, and sugar).

OD during the baseline period will be used to calculate the portion of plant energy, CHO, protein and fat in VDA similar to the portion of animal protein and fat in OD. The serve sizes are taken from Australian dietary guidelines and recommended daily intakes from NHMRC

and these sizes also will be used to calculate nutritional components. People with food allergy will be catered for their diet instructions.

4.3 Number of Participants Thirty (30)

4.4 Study sites

Faculty of health sciences, Cumberland Campus, The University of Sydney, NSW 2006, AUSTRALIA

4.5 Expected Duration of Study

In this particular study, the participants require to allocate their time only for 8 weeks. The PhD research program is planned to complete over three years as explained in the figure 1 and table 1 below.

Figure 1: Gantt chart for work plan of PhD program

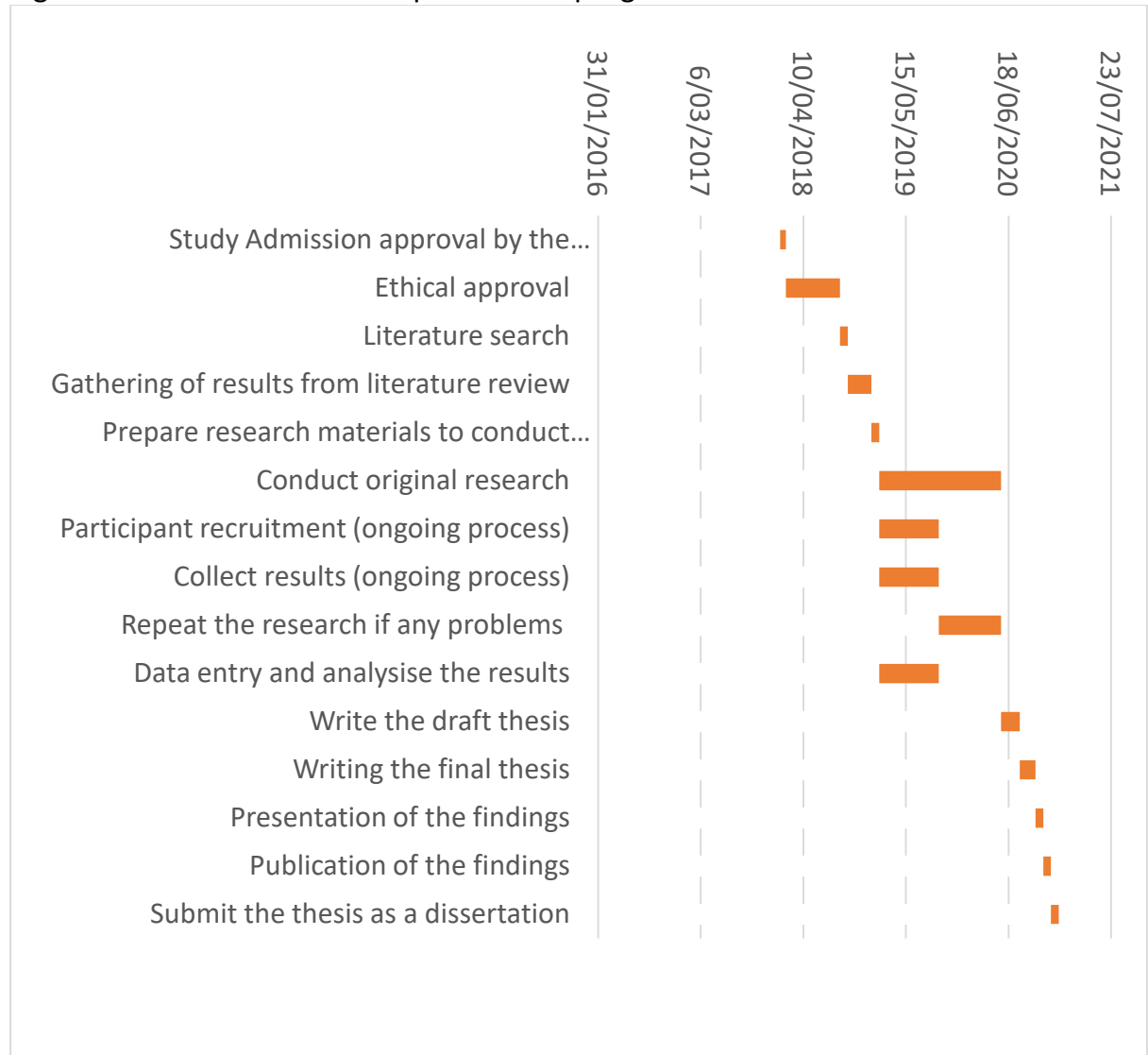


Table 1: work plan for the whole PhD program

Task Name	Task Number	Start Date	End Date	Duration (days)
Study Admission approval by the university and enrolment	1	10/01/2018	1/02/2018	22
Ethical approval	2	1/03/2018	31/08/2018	180
Literature search	3	31/06/2018	30/09/2018	30
Gathering of results from literature review	4	30/09/2018	31/12/2018	92
Prepare research materials to conduct the research	5	31/10/2018	15/11/2018	15
Conduct original research		31/10/2018	20/03/2020	515
Participant recruitment (ongoing process)	6	16/10/2018	20/09/2019	232
Collect results (ongoing process)	7	31/10/2019	20/09/2019	215
Repeat the research if any problems	8	20/09/2019	20/05/2020	243
Data entry and analysis the results	10	31/01/2019	20/09/2019	232
Write the draft thesis	9	20/05/2020	1/08/2020	73
Writing the final thesis	10	1/08/2020	1/10/2020	61
Presentation of the findings	11	1/10/2020	1/11/2020	31
Publication of the findings	12	1/11/2020	30/11/2020	29
Submit the thesis as a dissertation	13	30/11/2020	31/12/2020	31

4.6 Primary and Secondary Outcome Measures

Primary outcome: sleep patterns (sleep onset latency, sleep efficiency, wake after sleep onset and total sleep duration) and sleep-wake rhythms.

Secondary outcome: Blood pressure, fasting blood glucose, mood and alertness and working memory (Table 1)



5 PARTICIPANT ENROLLMENT

5.1 Recruitment

For Crossover longitudinal study Participants will be recruited by placing an advertisement in the university library, university e bulletin, café, community notice boards and local hospital news bulletin (where permissions have been granted – please see email letter of request), Advertisement will explain how the researcher obtain contact details for potential participants. If the recruitment rate is slow, we plan to recruit through local newspapers and newspapers.

Potential participants will be screened through inclusion and exclusion criteria and eligible participants will undergo baseline assessments of actigraphy and recording of normal food intake for a fortnight, fasting blood glucose, mood and alertness and working memory.

5.2 Eligibility Criteria

Target groups and inclusion criteria:

Participants from healthy adults of 18 years or over those who do not belong to the exclusion criteria listed below

Exclusion Criteria

people with mental illness: depression, bi-polar, schizophrenia, or sleep disorders: insomnia, periodic leg movements, sleep apnoea, narcolepsy, REM sleep behaviour disorder.

Other major medical conditions (cardiovascular and respiratory diseases, anorexia nervosa, bulimia, metabolic syndrome), diabetes, who are on any medication, including herbal and vitamin that affect sleep. Participants who are pregnant or planning to become pregnant within next eight weeks, shift workers, vegans, people who consume ≥ 5 standard alcohol drinks on any day will be excluded from the study.

5.3 Informed Consent Process

The subjects will be given their written consent to participate in the study and the participant information statement to comply with the study requirements throughout the study

5.4 Enrolment Procedures

The participant will be enrolled into the study after the informed consent process has been completed and the participant has met all inclusion criteria, none of the exclusion criteria and successful completion of the base line assessments. The participant will



receive a study enrolment number and this will be documented in the participant's personal record and on all study documents.

5.5 Participant Withdrawal

Any participant can withdraw from the study if they wish without any penalty but they should inform the researchers in writing the reason for withdrawing from the study.

6. STUDY VISITS AND PROCEDURES SCHEDULE

Figure 2: Flow Chart of Study Plan.

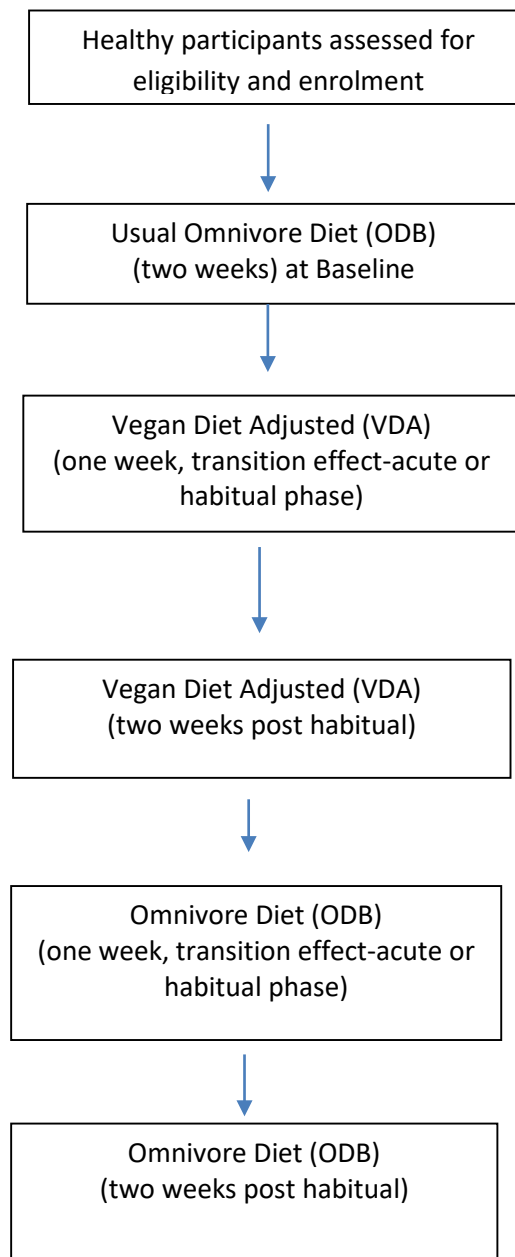


Figure 2: Time line for longitudinal study

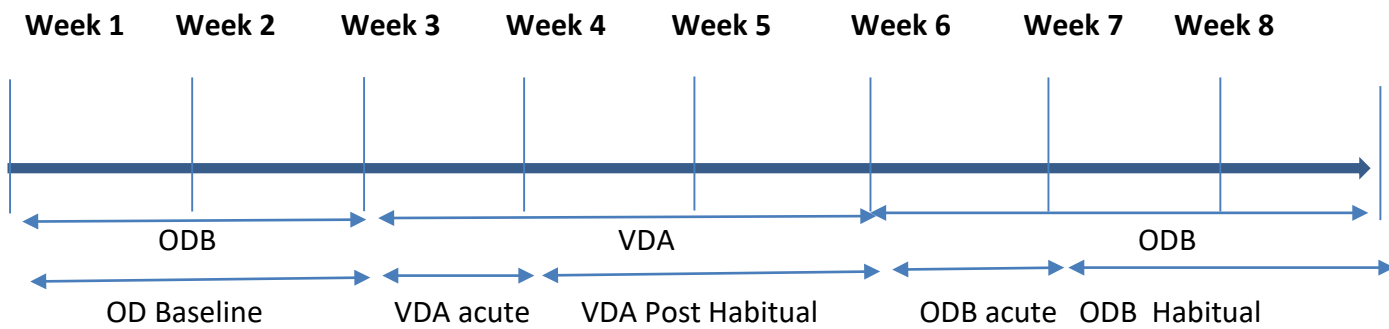


Table 2: Study visits and all study procedures conducted at each visit.

List procedures	Enrolment Visit	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
All the measurements will be taken in the morning before breakfast.	Start of Week 1	End of Week 2	End of Week 4	End of Week 5	End of Week 7	End of Week 8
Informed Consent	↑					
Inclusion / Exclusion criteria	↑					
Return of Actigraph for charging (measures throughout study)		↑		↑		↑
Blood Pressure	↑	↑	↑	↑	↑	↑
Fasting blood glucose	↑	↑	↑	↑	↑	↑
Mood and alertness	↑	↑	↑	↑	↑	↑
Working memory	↑	↑	↑	↑	↑	↑
Adverse Event Assessment		↑	↑	↑	↑	↑

As per the arrows indicated all measurements will be taken at the start of each week. At the enrolment and the first visit to the lab with the handover of the Actiwatch the blood pressure, fasting blood glucose measures will also be taken.

7. METHODS OF STUDY OUTCOME MEASUREMENTS

Objective sleep measures by Actigraphy using an Actiwatch 2, which measures sleep onset latency, sleep efficiency, wake after sleep onset and total sleep duration. The collected data will be assessed for sleep-wake rhythm disturbance by evaluating the autocorrelation coefficient at 24 hours (r_{24}).

Subjective sleep measures will be collected from the participants using sleep diaries, at each visit.

Secondary measures: Blood pressure using an electronic sphygmomanometer, fasting blood glucose using glucometer, mood and alertness using visual analogue scale in sleep diary, physical activity level using the actiwatch and sleep diary records and working memory using the Mental Rotation Test[21].

Screening questionnaires: Demographics of age, gender, ethnicity, income, physical activities, body mass index, smoking and alcohol intake, medical conditions related to heart, cancer, mental, diabetes, obesity and other chronic diseases, pregnant or planning to become pregnant, and food allergy.

Food and Sleep Diary: A questionnaire will be maintained by each participant to record all food and beverages that they consume and all sleep patterns for the study period of 8 weeks. This enables documentation on the foods they consume (to permit provision of a replacement diet), and whether they are following the diet and how their sleep patterns change during the study period.

8. ADVERSE EVENT REPORTING

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. Participants can choose from alternative vegan foods that they prefer to eat and the study is conducted at their homes except visiting the sleep lab six times during the study period.

9. STATISTICAL METHODS

9.1 Sample Size Estimation

Population to be analysed: Healthy adults of 18 years or over

A sample size of 20 participants is calculated using G power statistical software with reference to study findings from [11] considering the mean response scores of 9.0 min and 17.5 min and standard deviations of 6.2 min and 6.2 min for Sleep onset latency to produce a power level of



0.80 and an α of 0.05. for a study of how the effect of carbohydrate in sleep induction. We will recruit 30 participants in case of attrition to cover dropouts and incomplete data in view of an eight-week data collection.

9.2 Statistical Analysis Plan:

Categorical data analysis for classification of observations in relation to different sleep pattern and diet using the variables and attributes of age, sex, BMI, income status, education.

As mentioned in inclusion criteria age will also be considered as a covariate in the final analysis.

Autocorrelation coefficients for evaluating sleep wake rhythms for 24hrs will be computed. Analysis of Variance and comparison of mean will be performed to compare diets

10. DATA MANAGEMENT

10.1 Data Collection

The OD is participants' normal mixed diet with meat, poultry, fish, eggs, dairy, vegetables, fruit and beverages. The VDA will be made with reference to the proportional dietary intake of OD. The Foodworks 9 nutrition software will be used to convert daily food intake into the nutritional components (protein, fat, carbohydrate, tryptophan, caffeine, zinc, alcohol, and sugar).

OD during the baseline period will be used to calculate the portion of plant energy, CHO, protein and fat in VDA similar to the portion of animal protein and fat in OD. The serve sizes are taken from Australian dietary guidelines and recommended daily intakes from NHMRC and these sizes also will be used to calculate nutritional components. People with food allergy will be catered for their diet instructions.

10.2 Data Storage

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

10.3 Data Confidentiality

Passwords will be used on University provided laptop to PhD candidate during the project. Unique codes in place of participants' names are applied to all hard copy documents used in this project (e.g., food diary, screening questionnaire etc). After the project, all data all stored online on the University Storage data base. At the end of the project, study materials/information will not be stored in individually identifiable or re-identifiable form. No personal information will be revealed, and confidentiality of participants and privacy of their data will be protected in the dissemination of research results

10.4 Study Record Retention

In general, the minimum recommended period for retention of clinical research data is 20 years from the date of publication.

This is to allow ample time for the data and its subsequent analysis to be used for journal publication and for the purposes of thesis. In addition, the time selected ought to be sufficient in the event that the published analysis comes into question, and to facilitate compliance with relevant legislation from the State Records Authority of NSW

11. ADMINISTRATIVE ASPECTS

This study has been submitted to ANZCTR for registration.

a. Amendments to the protocol

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

b. Protocol deviations

Any protocol deviations will be submitted to the HREC for review.

c. Participant reimbursement

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 throughout the study period and are welcome to keep at the completion of the study..

12. USE OF DATA AND PUBLICATIONS POLICY

Lead by the chief investigator, the overall results of this research project will be disseminated as submit PhD thesis as a dissertation, publish in scientific journals and book chapters, and present in conferences and/or in media.

13. FEASIBILITY

We have addressed this issue by weeks of trialling and producing numerous Vegan replacement diets (using Foodworks 9) that match the Omnivore diet in protein, fat, carbohydrate and energy proportions. To facilitate the menial, time-consuming (but important) task, we have now arrived at using a Calculator spreadsheet via a mathematical formulation (acknowledging Pemajyantha Vithanage, Mathematician) to find food combination of vegan foods to match nutrient values of the food people eat. This Calculator works well, with minor adjustments

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