**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 FOR NON DRUG OR DEVICE CLINICAL TRIALS

This document is a protocol for a 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](https://www.nhmrc.gov.au/guidelines-publications/e72) (as updated) and the [Handbook for Good Clinical Research Practice (GCP)](https://extranet.who.int/prequal/sites/default/files/documents/GCP_handbook_1.pdf). The Therapeutic Goods Act has adopted [ICH Guideline for Good Clinical Practice](https://www.tga.gov.au/publication/note-guidance-good-clinical-practice).

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1. **GENERAL INFORMATION**

**CLINICAL TRIAL PROTOCOL OF EFFECTS OF ANIMAL AND PLANT ORIGIN DIET ON SLEEP HEALTH IN HEALTHY ADULTS – 14th of August 2018**

**1.1 Study Management**

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**1.2 Sponsor :** The University of Sydney

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

**1.4 Trial identifier and registry name.** Pending registration with clinicaltrials.gov or the Australian New Zealand Clinical Trials Registry (ANZCTR) <http://www.anzctr.org.au/>

|  |  |
| --- | --- |
| **Title** | Dietary patterns and sleep: effects of animal origin and plant origin diet on sleep health in healthy adults |
| **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. |
| **Objectives** | 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.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 |
| **Primary Hypothesis** | Does sleep health differ between people on a vegan (plant origin) vs omnivore (animal origin) diets? |
| **Design** | Crossover longitudinal study |
| **Outcomes** | During each dietary regiment, data on sleep pattern and sleep-wake circadian rhythm with actiography 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. |
| **Study Duration** | The experimental period is 8 weeks for participants  |
| **Intervention/s** | Animal origin(omnivore diet) and Plant origin(Vegan diet adjusted)  |
| **Number Of Participants** | **30** |
| **Population** | Healthy adults 18 – 70 years |
| **Selection And Enrolment**  | Inclusion: Healthy adults 18 – 70 years Exclusion: 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.  |

**2. PROTOCOL SYNOPSIS**

# 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](https://en.wikipedia.org/wiki/Plants), without [eggs](https://en.wikipedia.org/wiki/Egg_as_food) or [dairy](https://en.wikipedia.org/wiki/Dairy), or [meat](https://en.wikipedia.org/wiki/Meat)([red meat](https://en.wikipedia.org/wiki/Red_meat), [poultry](https://en.wikipedia.org/wiki/Poultry), [seafood](https://en.wikipedia.org/wiki/Seafood), and the [flesh](https://en.wikipedia.org/wiki/Flesh) of any other [animal](https://en.wikipedia.org/wiki/Animal), as well as [by-products](https://en.wikipedia.org/wiki/By-product) of [animal slaughter](https://en.wikipedia.org/wiki/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 Charbohydrate 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-lactaalbumin  |
| 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 |

**3. RATIONALE / BACKGROUND**

**Description of Diets**

1. [Vegan](https://en.wikipedia.org/wiki/Veganism) Diet (VD): diet derived from high amount of plant protein, without [eggs](https://en.wikipedia.org/wiki/Egg_as_food) or [dairy](https://en.wikipedia.org/wiki/Dairy), or [meat](https://en.wikipedia.org/wiki/Meat) ([red meat](https://en.wikipedia.org/wiki/Red_meat), [poultry](https://en.wikipedia.org/wiki/Poultry), [seafood](https://en.wikipedia.org/wiki/Seafood), and the [flesh](https://en.wikipedia.org/wiki/Flesh) of any other [animal](https://en.wikipedia.org/wiki/Animal), as well as [by-products](https://en.wikipedia.org/wiki/By-product) of [animal slaughter](https://en.wikipedia.org/wiki/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](https://en.wikipedia.org/wiki/ATP-binding_cassette_transporter) and [nutrients](https://en.wikipedia.org/wiki/Nutrient) from materials originating from [plant](https://en.wikipedia.org/wiki/Plant) and [animal](https://en.wikipedia.org/wiki/Animal) origin. Often, omnivores also have the ability to incorporate food sources such as [algae](https://en.wikipedia.org/wiki/Algae), [fungi](https://en.wikipedia.org/wiki/Fungus), and [bacteria](https://en.wikipedia.org/wiki/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](https://en.wikipedia.org/wiki/Olive_oil), [legumes](https://en.wikipedia.org/wiki/Legume), [unrefined cereals](https://en.wikipedia.org/wiki/Whole_foods), [fruits](https://en.wikipedia.org/wiki/Fruit), and [vegetables](https://en.wikipedia.org/wiki/Vegetable), moderate to high consumption of fish, moderate consumption of dairy products (mostly as cheese and yogurt), moderate [wine](https://en.wikipedia.org/wiki/Wine) consumption, and low consumption of non-fish meat products[3].
6. Vegetarian Diet: is the diet of abstaining from the consumption of [meat](https://en.wikipedia.org/wiki/Meat) ([red meat](https://en.wikipedia.org/wiki/Red_meat), [poultry](https://en.wikipedia.org/wiki/Poultry), [seafood](https://en.wikipedia.org/wiki/Seafood), and the [flesh](https://en.wikipedia.org/wiki/Flesh) of any other [animal](https://en.wikipedia.org/wiki/Animal)), and may also include abstention from [by-products](https://en.wikipedia.org/wiki/By-product) of [animal slaughter](https://en.wikipedia.org/wiki/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.

* 1. **Research Question**

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

* + 1. **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.

**4. AIMS / OBJECTIVES / HYPOTHESES**

**4.1 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.

**4.2 Objectives:**

**4.2.1 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.

**4.2.2 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.

**4.3 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

**5. PARTICIPATING SITES**

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

**6. RESEARCH PLAN / STUDY DESIGN**

* 1. **Type of Study**

crossover longitudinal study

* 1. **Study Design**

The study is to conduct. crossover longitudinal study of plant origin diet vs animal origin 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 (OD), 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.

**6.3 Sample Size Estimation**

**Population to be analysed:** Healthy adults of 18 -70 years

For sample size estimation, we used the study findings from [11] (for a study that examined the effect of carbohydrate on sleep induction). We applied the two mean response scores of 9.0 min and 17.5 min and standard deviations of 6.2 min and 6.2 min respectively for Sleep onset latency. The G Power statistical software yielded an estimated sample size of 20 participants (alpha at 0.05 and beta at .80). Given the longitudinal nature of the study (over eight weeks), we will recruit 30 participants in case of attrition to cover dropouts and incomplete data.

**6.4 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

#  Participant Enrolment

* + 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.

* 1. **Eligibility Criteria**

**Target groups and inclusion criteria:**

Participants from healthy adults of 18 -70 years and 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.

## 6.7 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

**6.8 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.

**6.9 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.

 **6.10 STUDY VISITS AND PROCEDURES SCHEDULE**

Figure 2: Flow Chart of Study Plan.

Healthy participants assessed for eligibility and enrolment

Usual Omnivore Diet (ODB)

(two weeks) at Baseline

Vegan Diet Adjusted (VDA)

(one week, transition effect-acute or habitual phase)

Vegan Diet Adjusted (VDA)

(two weeks post habitual)

Omnivore Diet (ODB)

(one week, transition effect-acute or habitual phase)

Omnivore Diet (ODB)

(two weeks post habitual)

 **6.11 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)

Figure 2: Time line for longitudinal study

 **Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7Week 8**

 ODB VDA ODB

 OD Baseline VDA acute VDA Post Habitual ODB acute ODB Habitual

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **List procedures**All the measurements will be taken in the morning before breakfast. | **Enrolment** **Visit**Start of Week 1 | **Visit 2**End of Week 2 | **Visit 3**End of Week 4 | **Visit 4**End of Week 5 | **Visit 5**End of Week 7 | **Visit 6**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 |  |  |  |  |  |  |

**6.12 Participant Reimbursement:**

An attempt will be made to reward all participants with some compensation for your time (a $50 voucher). And 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 them at the completion of the study.

**7.** **ETHICAL CONSIDERATIONS**

All procedures will be approved by the human ethics committee of the University of Sydney.

 **7.1 Administrative requirements:**

This study has been registered with ANZCTR and the registration number is ACTRN12618001369213p.

**7.2 Amendments to the protocol:**

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

**7.3 Protocol deviations:**

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

**8. SAFETY CONSIDERATIONS**

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 vising the sleep lab six times during the study period.

**9. OUTCOMES**

* 1. **Methods of Study Outcome Measures**

**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 (r24). The Actiwatch will be worn on the non-dominant wrist for the entire period of the study. Participants return the Actiwatch for re-charging fortnightly. They take the Actiwatch off when they shower.

**Subjective sleep measures** will be collected from the participants using sleep diaries throughout the entire study.

**Food Diary:** A questionnaire will be completed by each participant to record all food and beverages intake as follows. 9 days to represent 3 days at startup for ODB, 3 days for VDA period and 3 days for end of ODB period during the 8 weeks of the study period. This enables documentation on the foods they consume (to permit provision of a replacement diet), and whether they are following the diet.

**Blood pressure** using an electronic sphygmomanometer

**Fasting blood glucose** using a glucometer

**Mood and alertness** using visual analogue scales within the sleep diary

**Physical activity level** using the Actiwatch and answering questions in the sleep diary

**Working memory** using the Mental Rotation Test[21$]$.

# 10. DATA MANAGEMENT

**10.1 Data Collection**

Sleep data and dietary intake data will be collected from participants as follows.

Objective sleep data will be collected from actiwatch (wrist watch) and subjective sleep data will be collected from sleep diary. Food data will be collected from food diary.

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.](https://informatics.sydney.edu.au/rdm/dashr/#rdmp) As per RDMP the data will be stored securely. The data will be retained for 20 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. TIMELINES / MILESTONES**

Figure 1: Gantt chart for work plan of PhD program

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.

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 |
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**12. FINANCIAL**

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**.**

**13. PUBLICATION POLICY / DISSEMINATION OF RESULTS**

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.

**14.** **FEASIBILITY**

We have addressed the issue of converting VD to VDA with the same proportions of protein and fat of OD by weeks of trialling and producing numerous Vegan replacement diets (using Foodworks 9) that match the Omniovore 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 Pemajayantha 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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