School of Life Sciences

Department of Physiology, Anatomy and Microbiology

COLLEGE OF SCIENCE, HEALTH AND ENGINEERING

PARTICIPANT INFORMATION STATEMENT

PROJECT TITLE:

A COMMUNITY BASED CROSS-SECTIONAL STUDY ON ASSOCIATION BETWEEN VITAMIN B12 STATUS AND SLEEP QUALITY

INVESTIGATOR:
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WHAT IS THE STUDY ABOUT?

You are invited to participate in a study that will investigate the association between Vitamin B12 and sleep quality in healthy people aged between 18 and 65 years in a community based setting. This study, unlike other sleep studies, will be conducted in a community based setting and not in sleep clinics. Sleep clinics do not mimic the actual sleep environment and potentially affect sleep quality and bias the results. Using activity monitors, we aim to produce more comprehensive data on sleep quality. Moreover, blood samples will also be analysed to get nutritional bio-markers of the participants and will draw possible association with sleep quality. Furthermore, with the aid of one week food diary, this study will also aim to interrogate if consuming different variety of food affects sleep quality.

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WHO CAN PARTICIPATE?

In order to participate you must:

- Be aged 18 - 65 years
- Understand and be able to communicate well in English
- Be willing to wear activity monitors on wrist for 7 successive days
- Be able to make 2 visits to La Trobe University Bundoora campus for equipment collection, drop off and data collection over 7 days.
- Be willing to have blood samples collected and analysed
- Be willing to have one DXA body scan.

WHAT DOES THE STUDY INVOLVE?

Once you have been accepted as a participant in this study you will be required to attend 2 appointments held at La Trobe University, Bundoora campus in 7 days at the start and end of trial. You are free to withdraw at any time for the duration of the study. First appointments is to have an activity monitor fitted, DXA (dual-energy X-ray absorptiometry) scans for body composition assessment will be carried out and blood samples will be collected. Second visit will be to return the activity monitor, food diary and questionnaires. These appointments will run for approximately 20 – 45 minutes each. The schedule for data collection is given below.

First Visit: ~ 45 minutes

- Registration and sign agreement
- An experienced blood collector will take a sample of your blood.
- Your body composition will be measured using DXA.
- The investigator will fit the activity monitor at your wrist that you will wear until you return to have it removed after 7 days; the wrist band to be worn will be attached to a small monitor the size of a watch. The monitor takes continuous readings, and you may move freely during this time. You need to take it off to shower and don't forget to put it back on your wrist after shower.
- You will be free to ask any questions you may still have.

Second visit: ~ 20 minutes

- You will return the activity monitor, along with your filled depression scale and sleep questionnaires as well as diet diary.
- You will be free to ask any questions you may have.

Following the collation and analysis of results:

- You will receive a free personal body composition and blood nutritional biomarkers profile (if you have indicated on this form that you wish to receive one).
- You will be mailed or e-mailed a summary of the findings.

ARE THERE ANY RISKS?

Wearing the activity monitor wrist band for seven days may result in slight irritation of the skin in the surrounding area; this should not cause any adverse effect beyond slight tenderness and the inconvenience.

Withdrawing venous blood may result in soreness or slight bruising of the selected area. This should not cause any adverse effect beyond slight tenderness, bruising and/or soreness. Besides, continuous bleeding and infection may happen. Researchers are trained on venipuncture and first aid services and are capable of handling such circumstances. Exceptional cases will be referred to appropriate health professionals.

DXA imposes minimal risk. This research study involves exposure to a very small amount of radiation from DXA scans that you would not normally receive. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year.
The effective dose you will receive from one DXA scans will be less than 0.01 mSv. At these dose levels, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. The risk is believed to be minimal.

HOW WILL THE DATA BE USED AND STORED?

After the completion of the consent forms, each participant will be given an identification code. The list of names and identification codes will be stored in a locked filing cabinet and only accessible by the researchers listed above. Your information will then be de-identified and the researchers will not be able to identify your individual results. If you would like feedback on your results your information will be re-identified so that the investigator can provide you with accurate individual feedback, no one besides the researchers will have access to this information. The data will not remain identified for future use by the research team – this is simply for individual result reporting. Participants may request a copy of their personal data collected in the course of the research. During the study, project documentation will be kept in a secure, lockable filing cabinet in Dr Markandeya Jois's office at La Trobe University, Bundoora campus. All electronic data will kept on a password protected computer.

Following the completion of the study hard copies of records will be kept in a locked filing cabinet in the office of lead researcher, Dr Markandeya Jois; consent forms for a period of 7 years and research data for 5 years. Electronic data will be saved in a password protected folder on a USB device/DVD that will also be stored in the lockable filing cabinet for the specified time, after which they will be destroyed. Data may be preserved for possible future use in another project and access to data may be given to suitable researchers who will be bound to the confidentiality and security measures described above. At the completion of the study, participants will be provided with a summary of the results of the research.

The data collected from this study is part of a research project. Group results from the project may be published in peer reviewed journals, student thesis and presented at conferences. No identifiable data that can be linked to an individual will be reported. The data used for reporting and publications will

be in both hard copy and electronic formats. Participants will be mailed or e-mailed a copy of the results if requested.

COMPLAINTS:

If you have any complaints or concerns about your participation in the study that the researcher has not been able to answer to your satisfaction, you may contact the Senior Human Ethics Officer, Ethics and Integrity, Research Office, La Trobe University, Victoria, 3086 (P: 03 9479 1443, E: humanethics@latrobe.edu.au) . Please quote the application reference number HEC 16-022.

SHOULD I PARTICIPATE?

Participation in this study is completely voluntary. This means that you do not have to do this study if you do not want, and you can stop at any time without judgment. If you wish to participate in the study, you are required to thoroughly read the information sheet and consent form, and then sign the consent form. You are encouraged to ask any questions you may have, and the investigator will allow participation only if the investigator believes you have a clear understanding of what will be required of you during the study. Student or participants from La Trobe University can participate voluntarily and their decision to participate or not will not in any way affect their studies or association with La Trobe.

You have a right to withdraw from active participation in this project at any time and, further, to demand that data arising from your participation are not used in the research projected provided that this right is exercised within four weeks of the completion of you participation in the project. You are asked to complete the 'Withdrawal of Consent Form' or to notify the investigator by e-mail or telephone that you wish to withdraw your consent for your data to be used in this research project.

There are no disadvantages, penalties or adverse consequences for not participating or for withdrawing prematurely from the research.

We invite you to participate in this study!

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