Can seaweed supplementation reduce CVD risk?

EXPLANATORY STATEMENT

All volunteers

Project: Can Seaweed Supplementation reduce CVD risk?

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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

This information sheet is for you to keep

What is the aim of the study?

A number of foods in our diet (for example tea, coffee and beetroot) contain compounds called polyphenols that are known to be good for our health. The aim of this study is to examine how the intake of polyphenols from seaweed impact on blood cholesterol levels, blood sugar and insulin levels, and inflammation. A secondary aim is to assess how well long term supplementation with polyphenols is tolerated, which will be assessed using a questionnaire that asks about how you feel after taking the extract. Another secondary aim of this study is to assess the effect of polyphenols from seaweed on mood and cognition, which will be assessed using a series of computerised tests.

What does the research involve?

We will be testing the polyphenol supplement, compared to a placebo. A placebo is something that is similar to the supplement, but doesn't contain any polyphenols. You will receive either the supplement or the placebo to take daily for the course of the study (12 weeks). In order to properly evaluate the results, you will not know whether you are taking the supplement or the placebo.

Before you start the study

Participation will involve a screening visit and then, those deemed eligible, will be asked to return for three testing visits to the Be Active Sleep Eat (BASE) facility at Notting Hill. At the screening visit your weight, height, waist circumference, body composition and blood pressure will be measured, a finger prick test will be performed to measure your blood cholesterol level and some basic demographic information will be collected. You will be asked to fast for 12 hours overnight before you come in for screening. If you are eligible to participate you will be given a 3-day food diary, food frequency questionnaire and physical activity diary to complete before your first testing visit. This visit will take approximately 30 minutes.

There is an option for you to choose to participate in the cognitive part of this research. If you choose to participate, you will be asked to complete a series of questionnaires to determine your eligibility for this part. Then, if eligible, you will complete a series of practice runs through the cognitive tests to allow you learn how to complete them prior to beginning the study. This will add up to another 90 minutes to this visit, making it approximately 2 hours long.

During the study

The three testing visits, held at the BASE facility, will occur over the course of 12 weeks. The first testing visit will be held approximately one week after the screening visit. The following two visits will be six weeks apart (Fig 1).

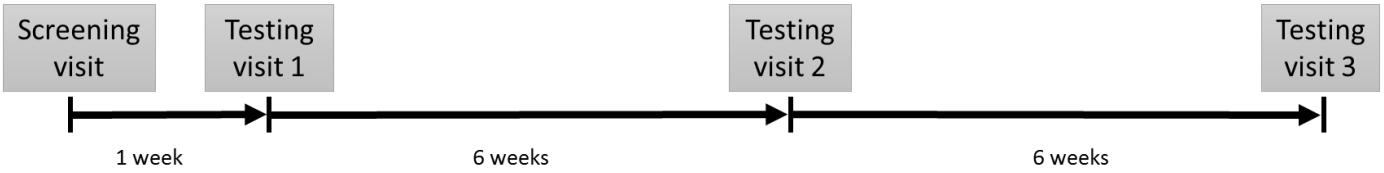


Figure 1. Sequence of study visits

At the first and second visit you will be given a supply of the supplement, which you are to take daily. For the night before your testing visits we will provide you with a dinner meal to consume between 7 – 9 pm, then you will need to fast until the time of testing, only drinking water. In the week prior to the first and last testing sessions we also require you to complete a 3-day food diary, food frequency questionnaire and physical activity questionnaire.

On testing days you will be required to attend the BASE facility for approximately 30 to 60 minutes in the morning. During your visit you will have a blood sample taken from a vein in your arm and will have your weight, height, body composition, waist circumference and blood pressure measured. At your final visit you will be asked to complete a questionnaire about any intolerance symptoms you might have experienced.

If you participate in the cognitive part of the study, you will also be asked to complete a series of computerised tests to measure mood and cognitive function at each testing session. This will add approximately 45 minutes to each visit.

Summary of measurements:

- Weight
- Height
- Body composition
- Waist circumference
- Blood pressure
- Fasting blood cholesterol (finger prick test)
- 3-day food intake diary
- Physical activity questionnaire
- Food frequency questionnaire
- Fasting venous blood samples
- Intolerance symptoms questionnaire
- Mood (optional)
- Cognitive function (optional)

Criteria for Exclusion

To ensure that only suitable participants are included, we have a number of criteria that, if met, will exclude you from participating. Please advise the researcher if you meet any of the following criteria:

- Younger than 18 or above 65 years of age

- BMI less than 27 or above 35 kg/m^2 (for individuals of an Asian background, BMI less than 25 or above 35 kg/m^2) (BMI is a measure of your weight divided by your height)
- Fasting blood LDL cholesterol level of 2.0 mmol/L or below
- Gastrointestinal conditions that may affect polyphenol action
- Taking medications that affect cholesterol level
- Taking other natural health products that affect polyphenols (e.g. fish oil)
- Pregnancy, planning a pregnancy or breastfeeding
- Any serious health conditions that may affect participation e.g. liver or thyroid dysfunction, recent major surgery
- Taking medication for blood pressure control
- You consume more than 4 alcoholic drinks per day, or 14 per week
- You smoke
- You have an implanted cardiac defibrillator
- You have depression, anxiety or cognitive impairments (cognitive part only)

Consenting to participate in the project and withdrawing from the research

In order to participate in this study, the written consent form must be read, signed and returned to Margaret Murray. Participation in this research is voluntary. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Possible risks to participants

There may be mild discomfort from the venous blood sample, but no other discomfort is anticipated. To minimise discomfort, the tests will be performed by a researcher trained in phlebotomy.

It is unlikely that participants will experience an adverse reaction to the supplement. But in the event of an adverse reaction, the participant's experience will be documented by the research team, and if necessary, the participant will be advised to seek medical advice.

Confidentiality

Any information obtained in connection with this project that can identify you will remain confidential. This information will only be disclosed with your permission or as required by law. Your name will be assigned a code, which will be used in discussing data, so that your identity is not disclosed. Only de-identified results will be presented in meetings, conferences, as part of a thesis or published in scientific journals or reports.

The company who are donating the supplement (Marinova Pty Ltd) will not have access to any of the results until they are published in a de-identified, grouped manner.

Storage of data

Data collected will be stored in accordance with Monash University regulations. The collected and coded data will be stored either on a password protected computer or in a locked filing cabinet on University premises for five years, after which it will be destroyed.

Use of data for other purposes

In accordance with the National Health and Medical Research Council Statement on Data Sharing, de-identified data should be made available for use by the other researchers unless this is prevented by ethical, privacy or confidentiality matters. This data will be held on secure public repositories and is a requirement of some journals prior to publication. Any shared data will remain anonymous and there will be no way that you can be identified.

Blood samples will, with your permission, be retained for possible use in future research examining related outcomes.

Results

If requested, participants will be given their body composition results and fasting blood sugar levels at the end of the study.
If you would like to receive a report of the aggregate research findings please contact Margaret Murray, PhD candidate at Monash University, on (03) 9902 4199 or email margaret.murray@monash.edu. The findings are accessible for 6 months following completion of the study.

Compensation

Upon completion of the study you will receive a $50 Coles/Myer voucher to thank you for your time and effort in participating in this study. You will also go into the draw to win an iPad, and, if you choose to, may attend a free 30 minute nutrition consultation including a free body composition report.

Funding

This research has received funding from Marinova Pty Ltd.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Building 3e
Research Office
Monash University VIC 3800

Tel: +61 3 9905 2052
Email: muhrec@monash.edu
Fax: +61 3 9905 3831

Counselling Services

Although we do not expect that this research will cause you any distress and anything more than minor discomfort, it should be noted that the optional screening questionnaires and mood state questionnaires may involve issues of depression, anxiety and cognitive impairment. Although unlikely, should you become concerned about your level of depression, anxiety or cognitive impairment throughout or after the study, please consult the list of services below and speak to your GP about your concerns.

We will inform you if any of the questionnaires you complete indicate that you may be at risk of experiencing depressive symptoms which are above what would be expected in day-today life, and will be available to discuss the options available to you should you wish to seek help.

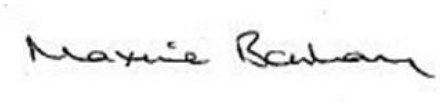
For everybody 24/7

Service	Phone	Hours of operation
Lifeline	13 11 14	24 hours
Suicideline	1300 651 251	24 hours
Suicide Call Back Service	1300 659 467	24 hours

For Monash students & staff

Service	Phone	Hours of operation
Monash counselling	9905 3020	Monday – Friday 9am-5pm
Monash counselling after hours	1800 350 359	5pm-9am weeknights, 24 hours weekends

Thank you,



Dr Maxine Bonham