Bioavailability of omega-3 long-chain polyunsaturated fatty acids (LCPUFA) from foods enriched with vegetable-encapsulated omega-3 oils

PARTICIPANT INFORMATION SHEET

HUMAN RESEARCH ETHICS COMMITTEE NUMBER: 2020_026

INTRODUCTION

Each year CSIRO perform a number of research projects involving human participants. We examine the effect of different diets on diseases, such as heart disease, diabetes and bowel disease, which are leading causes of death in Australia. CSIRO Health and Biosecurity is working with collaborators and food industry partners to develop foods with substantiated nutritional and health benefits.

Omega-3 long-chain polyunsaturated fatty acids (omega-3) consumption is associated with many health benefits including improved brain, heart, joint and eye health. However, less than 20% of the world’s population consume adequate amounts of these fatty acids. Individuals who don’t consume fish (major dietary omega-3 source) and particularly vegans/vegetarians are at greatest risk of omega-3 deficiency. Convenient strategies empowering consumers to increase their omega-3 intake have potential to significantly impact health outcomes.

CSIRO’s Food Program has developed a new product using vegetables that is able to encapsulate omega-3 fats. This omega-3 encapsulated vegetable product can then be further used as an ingredient in a range of food products such as biscuits, yoghurts etc. The development of this product using an omega-3 source from algae (algal oil) also provides a potential method for vegans and vegetarians to increase their omega-3 intake.

It is unknown, however, whether the encapsulation of omega-3 in this new vegetable product affects the amount of omega-3 absorbed by the body once eaten. As these products are intended for global markets, it is also unknown whether ethnic differences may affect omega-3 bioavailability.

This study is funded by the Department of Industry, Innovation and Science as part of the 1st Australian-Singapore Programme on “Innovations in Food for Precision Health”.

HREC approval No 2020_026
WHAT IS THE AIM OF THIS STUDY?

This study aims to compare the bioavailability of omega-3 from two test foods containing vegetable (cauliflower)-encapsulated algal oil (the “ingredient”) against a control test product (algal oil gel capsules) across two ethnicities (Australian European vs. Chinese Singaporean).

HOW WILL THE STUDY BE CARRIED OUT?

To be eligible to take part in this research, there are a few criteria you must meet. Have a look through the criteria below. If you feel this describes you, and you are keen to take part, then please complete the screening medical questionnaire and return it to us. If you are unsure or have any questions, do not hesitate to contact the nutrition and health research clinic, either by phone 8305 0615 or email CRUstudies@csiro.au and we can assist.

Inclusion Criteria

1. Healthy men, 21-50 years old
2. BMI 18-27.5 kg/m²
3. Consume less than 2 meals of fatty fish/week
4. Not consume fish oil supplements over the past 3 months
5. Identify as Australian European in ethnicity (Australian with European heritage)

Exclusion Criteria

1. Self-reported history of chronic disease - cancer, type 2 diabetes, cardiovascular disease, liver disease or any condition that may, in the opinion of the principle investigator, influence the study outcomes.
2. Self-reported history of gastrointestinal disease, pancreatic insufficiency, conditions resulting in fat malabsorption - chronic pancreatitis, cystic fibrosis, coeliac disease, Crohns disease, gastric bypass surgery, small bowel resection, abnormal thyroid function
3. Bleeding disorders, currently taking anticoagulants or has received anticoagulants within 28 days of Day 1 of the trial, with the exception of low dose aspirin up to 150 mg daily
4. Any medical procedures deemed by the principal investigator to affect study outcomes
5. Known food allergies, hypersensitivity, dietary avoidance or intolerance to the study foods
6. Taking medications/supplements known to influence lipid metabolism and gastric emptying
7. On any weight-loss program
8. History of smoking during the 6 months prior to the study
9. Persons considered by the investigator to be unwilling, unlikely or unable to comprehend or comply with the study protocol.
10. Self-reported history of drug abuse or alcoholism
11. Participation in another research study within 30 days preceding the start of this study
Once you have read and had time to consider the detail in this information sheet, and if you decide to take part in this study, you will be asked to complete a screening medical questionnaire which will take around 10 minutes to complete and a telephone screen which will also take around 15 minutes to complete, to ensure that you fit the criteria required to participate in the clinic screening for this study. The study will consist of 6 clinic visits:

Visit 1: Duration – 9 hours
- Participants will attend the CSIRO Nutrition and Health Research Clinic after an overnight fast, where they will have their eligibility for the study confirmed through height and weight assessments and subsequent BMI calculation
- Using Bio-impedance scales, body composition will be measured to capture baseline characteristics of study participants
- Vital signs assessment will also be performed – blood pressure and body temperature
- Participants will then have a cannula inserted into their arm and have a blood sample taken (6 mL)
- Participants will then consume test product, products are randomly assigned to participants
- Throughout the day, participants will be provided with low fat meals (breakfast, lunch as well as mid-morning and mid-afternoon snacks). Further blood samples will then be collected after 2, 4, 6 and 8-hours following test product consumption
- Participants will be provided with a low-fat meal for their dinner and provided further instructions on consumption of other food/beverages

Visit 2: Duration – 30 minutes
- Participants will attend the CSIRO Nutrition and Health Research Clinic the day following visit 1 after an overnight fast
- Vital signs assessment will also be performed – blood pressure and body temperature
- A single blood sample (24-hr time point) will be collected and the participant will then be permitted to leave the clinic

Visit 3: Duration – 9 hours
- 1 week following visit 1, participants will again attend the CSIRO Nutrition and Health Research Clinic after an overnight fast
- Height, weight and vital sign assessments will be performed
- Participants will then have a cannula inserted into their arm and have a blood sample taken (6 mL)
- Participants will then consume the 2nd randomly assigned test product
- Throughout the day, participants will be provided with low fat meals (breakfast, lunch as well as mid-morning and mid-afternoon snacks). Further blood samples will then be collected after 2, 4, 6 and 8-hours following test product consumption
- Participants will be provided with a low-fat meal for their dinner and provided further instructions on consumption of other food/beverages

Visit 4: Duration – 30 minutes
- Participants will attend the CSIRO Nutrition and Health Research Clinic the day following visit 3 after an overnight fast
- Vital signs assessment will also be performed – blood pressure and body temperature
- A single blood sample (24-hr time point) will be collected and the participant will then be permitted to leave the clinic
Visit 5: Duration – 9 hours
- 1 week following visit 3, participants will again attend the CSIRO Nutrition and Health Research Clinic after an overnight fast
- Height, weight and vital sign assessments will be performed
- Participants will then have a cannula inserted into their arm and have a blood sample taken (6 mL)
- Participants will then consume the 3rd randomly assigned test product
- Throughout the day, participants will be provided with low fat meals (breakfast, lunch as well as mid-morning and mid-afternoon snacks). Further blood samples will then be collected after 2, 4, 6 and 8-hours following test product consumption
- Participants will be provided with a low-fat meal for their dinner and provided further instructions on consumption of other food/beverages

Visit 6: Duration – 30 minutes
- Participants will attend the CSIRO Nutrition and Health Research Clinic the day following visit 5 after an overnight fast
- Vital signs assessment will also be performed – blood pressure and body temperature
- A single blood sample (24-hr time point) will be collected and the participant will then be permitted to leave the clinic

The test products (randomly assigned) consumed on visits 1, 3 and 5 with a standardised breakfast include:
- 1 x algal oil gel capsule (control)
- 200g serve yoghurt + “ingredient”
- 50g serve savoury snack + “ingredient”

For all extended (9 hr) visits (visits 1, 3 and 5) an IV cannula will be inserted into the participant’s arm by a qualified health practitioner for collection of venous blood samples. The cannula will remain in the arm until completion of the respective clinic visit. For one-off samples (visits 2, 4 and 6) blood samples will be collected by venepuncture. When collecting blood samples, there is a minor risk of bruising and/or infection at the site of sampling.

Participants will be required to remain in the clinic for the entire duration of each visit

Throughout the duration of the study, participants will be requested to maintain their usual lifestyle patterns and to avoid fatty fish and omega-3 containing supplements. Participants will be provided with a checklist to record any non-compliance or accidental consumption of these foods and return the checklist at their subsequent visit.

If you are eligible to participate, we will inform you of a date for your initial clinic visit where we will discuss the study in more detail and obtain your informed consent.

At the completion of the study you will be provided with $550 (in cash) to thank you for your time taking part in this research project. Should you be unable to complete the study, you will receive a pro-rata payment scaled to reflect the duration of your study participation. Payment is determined proportional to the time and inconveniences involved in participating in the study and not used as enticement to participate.
WHAT ARE THE BENEFITS OF PARTICIPATING IN THE STUDY?

You may not benefit directly from participation in this study, but you will be providing a valuable contribution to the scientific knowledge in this field. Your personal results will be mailed out to you at the completion of the study, and the overall group results will also be provided.

ARE THERE ANY RISKS INVOLVED?

There is a very minor risk of bruising and/or infection from venous blood sampling. Blood samples will be collected by a trained and experienced phlebotomist/health practitioner to minimise risk.

All human research undertaken by the CSIRO must comply with the values, principles, governance and review process specified in the NH&MRC National Statement on Ethical Conduct in Human Research (2007, Updated 2015). A copy of the National Statement can be found at: www.nhmrc.gov.au/guidelines/ethics/human_research/index.htm

HOW WILL MY PRIVACY BE PROTECTED?

CSIRO is governed under the Privacy Act 1988 (Cth). CSIRO is collecting your personal information for the purposes of conducting the study and related scientific research. CSIRO will only use and disclose your personal information in accordance with the Privacy Act 1988 and the NH&MRC National Statement on Ethical Conduct in Human Research (2007, Updated 2018) as amended from time to time, and as otherwise required by law.

In relation to studies conducted by CSIRO, it is customary for all personal information to be identified by a code and stored at CSIRO under lock and key for a period of at least 15 years. Except where otherwise required by law or a government body, at the end of this period your records will be destroyed or permanently de-identified.

Where third parties are assisting CSIRO in relation to the conduct of this study (such as university staff, students and other health professionals), we may disclose your personal information to those third parties for this purpose on a confidential basis. CSIRO will require such third parties to keep this information confidential and to only use your personal information for the purposes of the study and otherwise in accordance with the Privacy Act 1988. No phone numbers, emails, address or other personal information will be shared. Any samples/information/data collected during the trial will be included in the analysis of the study, unless you formally request that they be withdrawn. We will not use or disclose your information for direct marketing purposes.

You and, with your permission, your doctor will be notified of any medical condition deemed significant by the Clinical Research Unit Medical Officer. We will not use or disclose your information for direct marketing purposes.

CSIRO may publish study results and data in research publications and press releases, however, CSIRO will de-identify any personal information contained in the data and results so that you cannot be identified.
**WHAT IF I WISH TO WITHDRAW?**

You are free to withdraw at any time during the study. If you choose to withdraw, all samples provided by you will be destroyed, however your personal details will be retained along with those of the continuing participants. Your details up until your withdrawal are an important part of the data set for analytical purposes.

You are free to withdraw at any time during the study. However, you will note in the consent form a request to maintain any data collected prior to your withdrawal from the study. Your data up until your withdrawal are an important part of the data set for analytical purposes. Your personal information will be kept with those of continuing participants for a period of at least 15 years, with all personal information identified by a code and stored at CSIRO under lock and key. It is also important to understand that we can choose to end your participation, too. That decision would be made if we decided that the study is not in your best interest, if you are unable to follow the protocol of the study, or if the study is discontinued. If we ever have to end your participation, we will make sure you understand the reasons why.

**YOUR OBLIGATIONS AS A PARTICIPANT.**

You will need to inform a study staff member of any changes in your health as some changes could have an effect on your participation in the study and the study findings. You must also be able to attend all visits and undertake all relevant procedures during the study period.

**IF YOU HAVE FURTHER QUESTIONS**

Please call (Project Leader/contact person for the study) on 8305 0615 or via email CRUstudies@csiro.au

This study has been approved by the CSIRO Human Research Ethics Committee. If you would like to speak with someone with respect to ethical matters or wish to register a formal complaint about the conduct of this research, please contact the Secretary of the Committee via email at chmhrec@csiro.au.