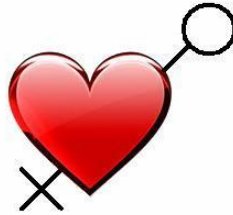




## RESEARCH PARTICIPANT INFORMATION SHEET



### HEALTHY HEART IN YOUNG WOMEN

Thankyou for your interest in participating in this study conducted by Cassandra Sparkes and Dr Barbara Meyer at the University of Wollongong. Docosahexaenoic acid (DHA) is a long chain omega-3 polyunsaturated fatty acid which has beneficial effects on the heart when consumed at moderate doses, yet less is known about the benefits of lower doses. Little is known about the dose-response effects of low doses of DHA-rich tuna oil (fish oil) on blood lipids in young females with elevated triglyceride (blood lipid) levels in regards to:

- Lowering of plasma triglyceride levels
- Favourable effects on HDL and LDL levels and particle size,

all of which reduce the risk of cardiovascular disease

#### Research Plan

We require 132 pre-menopausal women aged 18-40 to consume either DHA-rich tuna oil supplements or placebo Sunola oil supplements supplied by our sponsor for an eight-week period. Volunteers will be assessed for eligibility in this study at a screening visit at which a qualified person will take a small blood sample, and your body weight and height will also be measured. You will also complete a volunteer screening questionnaire that assesses general health and lifestyle habits. If you have mildly elevated triglyceride levels, regular menstrual cycles and do not suffer from a hormonal disorder you will be eligible to participate. You will then be randomly assigned to consume one of the three doses of fish oil or placebo capsules for two menstrual cycles (approximately eight weeks). Both at the beginning and at the end of the eight-week period you will need to attend the research clinic on two consecutive days, specifically on days three-five of your menstrual cycle. During these clinic visits you will provide blood samples after an overnight fast (up to 40mL or two tablespoons), and also provide small blood samples by finger-prick at baseline and post-intervention on one of the two consecutive clinic visits. Other measurements to be taken include at the clinic visit include height (screening visit only), weight, blood pressure, and the completion of two questionnaires that assess dietary habits (first clinic visit only).

We will supply all of the necessary supplements as capsules that you will require for the study, which is scheduled to commence in May-June 2008.

#### Assessment of Outcomes

Blood samples and records of blood pressure will be used to assess whether regular consumption of the DHA-rich tuna oil supplements can reduce the risk of cardiovascular disease compared with the placebo Sunola oil supplements. The following assessments will be made:

- Your dietary intake of nutrients and polyunsaturated fatty acids
- Blood samples will be used to assess the fatty acids in various components of the blood
- Blood lipids, i.e. triglycerides, total, HDL and LDL cholesterol, will be measured; which all provide information about cardiovascular disease risk
- Blood levels of hormones, glucose, insulin, and apo-E phenotype

- Blood pressure which will be assessed at the clinic visits

### **Potential Risks and Benefits**

Apart from the possibility of minor bruising which may occur when a blood sample is taken, minimal risk to participants is anticipated in this study. In participants with borderline anaemia or iron deficiency, loss of blood through blood sampling may worsen their condition. Some participants may experience gastrointestinal discomfort due to consumption of capsules. Is so, they will complete the adverse events form and will be free to withdraw from the study.

Participants in this study are expected to benefit from the detailed information on their blood lipids and blood pressure results, omega-3 status and dietary assessment. Participants will be informed of the overall outcomes of the study at an information session as well as receiving a written summary of their individual assessments at the end of the study.

### **Confidentiality**

All data obtained will remain confidential. This will be achieved by de-identifying your information once enrolled by using a code number rather than names, and all files will be stored in a locked filing cabinet at the University. Study outcomes are to be published in the form of Cassandra's PhD thesis, in peer-reviewed scientific journals, and in two reports to industry sponsors, though no individual results will be revealed at any stage.

In summary you will be asked to:

- Attend a research clinic at the University on five occasions
- Complete three questionnaires concerning your diet, health and lifestyle
- Consume the capsules provided for approximately eight weeks
- Record capsule intake and menstrual cycle status
- Provide a fasting blood sample after an overnight fast on five separate occasions (including screening sample)
- Provide a small blood sample by finger-prick on two occasions
- Undergo other laboratory measures including height (first occasion), weight and blood pressure.

Your participation is entirely voluntary and you are free to decline to participate in the study or having consented, to withdraw at any time without affecting your relationship with the School of Health Sciences or the University of Wollongong.

You are encouraged to ask any questions you may have concerning the research by contacting either Cassandra Sparkes (02 4221 4504) or Barbara Meyer (02 4221 3459). An ARC-Linkage grant and APA-I scholarship and the Smart Foods Centre have provided funding for the present study. Any concerns or complaints regarding the conduct of this research can be directed to the Complaints Officer, Human Research Ethics Committee, Research Services Office, University of Wollongong at 02 4221 4457.

We look forward to your participation.

***Cassandra Sparkes and Dr Barbara Meyer***  
***Chief Investigators***