

## **PARTICIPANT INFORMATION SHEET**

### **“The role of different breakfast cereals on cholesterol levels”**

The major preventable risk factors for coronary heart disease are tobacco smoking, high blood cholesterol, high blood pressure, physical inactivity, and overweight and obesity. Diet has an important role in the lowering of blood cholesterol levels, however much of the research to date has focused on the quantity and type of fat in the diet. This study will investigate the effect of different breakfast cereals on blood cholesterol levels.

The study seeks to address unanswered scientific questions about diet which will contribute to the development of up-to-date dietary advice for cholesterol-lowering. Please note that this is **NOT** a weight loss diet, but a 6-week study in which breakfast cereals will be provided. The study is sponsored by a food company. The research team has experience in conducting studies of this nature and has been involved in many short and long-term human dietary intervention trials.

#### **What will we ask you to do?**

- Following a telephone screening interview, you will be asked to attend the University for a finger-prick test for cholesterol and glucose concentrations, after having fasted overnight for 12 hours and having avoided alcohol for 24 hours. Your weight, height and body fat measurements, as well as a blood sample for cholesterol and other fats in the blood, will be taken at this visit as well as at the 3-week and 6-week visits.
- You will be asked to complete a 3-day diet record at home and return it to the research facility.
- Within a week, we will ask you to return to the University to be advised by a dietitian about a low fat eating plan, and to receive a 3-week supply of your breakfast cereal.
- After 3 weeks on the diet, you will have blood cholesterol measurements taken and see the dietitian again. At this visit, the remaining 3-week supply of breakfast products will be given to you.
- At 6 weeks of follow-up, you will once more have your fasting blood cholesterol measured.
- Participants will be asked to exclude foods containing plant sterols from in their diets during the trial. All participants will receive their individual results and will be informed of the study findings.

#### **Who can participate?**

We are looking for 90 men and women (equal numbers of each) 25 - 65 years who are overweight (BMI >25 kg/m<sup>2</sup>). Women should be pre-menopausal. To be eligible, your cholesterol level should be  $\geq 5$  mmol/l but not greater than 7.5 mmol/l and your LDL-cholesterol (“bad” cholesterol) should be  $\geq 2.5$  and  $< 4.5$  mmol/l. Your cholesterol level will be checked at the first visit using a finger-prick test and then this value will be validated with a blood sample analysed at a laboratory.

#### **You should not participate in this study if you:**

- Do not consume or are unwilling to consume breakfast cereal 4 – 5 times per week
- Have fluctuated in weight within 3 kg over the past 3-6 months
- Have a Body Mass Index (BMI) of  $< 20$  (underweight) or  $> 32$  kg/m<sup>2</sup> – you will be asked your weight and height in the telephone screening interview and your BMI will be calculated
- Have a major illness
- Take cholesterol-lowering medication

- Have fasting glucose > 5.6 mmol/l (this will be tested)
- Have Type 1 or Type 2 diabetes
- Been diagnosed with coronary heart disease or chronic renal failure
- Take dietary supplements that could influence cholesterol, such as fish oil
- Have food allergies or habits that prevent you from eating wheat or corn-based cereals
- Know or suspect that you are pregnant
- Cannot understand English.

### **What if I change my mind about participating?**

You are free to stop the study at any time. You may, if you wish also withdraw your consent for the use of your data in the study.

### **What are the possible disadvantages and risks of taking part?**

You will be required to attend the university on three separate occasions, for about an hour each visit. This may provide some inconvenience, however we will endeavour to find a day that best suits your home and work schedule. Parking vouchers for the University will be provided. On each of the three occasions you will need to have fasted overnight for 12 hours and have avoided alcohol for 24 hours.

### **What are the benefits of participating in the study?**

As a result of the study you will be able to gain some information about your weight and body fat percentage, and your dietary intake. You will also be screened for diabetes and find out what your blood pressure is.

### **What will we do with the information and samples we obtain?**

All information will be kept secure and identified by a code rather than by your actual name. No information that is able to identify individual participants will be published. Standards of medical confidentiality will apply.

If at any time you have any questions, please do not hesitate to ask. Your involvement in the research is entirely voluntary. You are free to withdraw from the research at anytime without penalty. If you have any enquiries regarding the conduct of the research please contact the Secretary, University of Wollongong Human Research Ethics Committee on (02) 42214457, quoting study HE08/036.

Thankyou for your interest in this study.

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