



## **PARTICIPANT INFORMATION SHEET**

### **The SMART diet**

#### **Who are we?**

This study is funded by the National Health and Medical Research Council and is being conducted by a group of researchers from the Smart Foods Centre at the University of Wollongong. Professor Linda Tapsell, the study leader, is Director of the National Centre of Excellence in Functional Foods. Marijka Batterham, Karen Charlton and Yasmine Probst are academic staff members of the Smart Foods Centre in the School of Health Sciences, Jane O'Shea is study co-ordinator, Rebecca Thorne is a research dietitian while Anne McMahon is a PhD student and academic within the Smart Foods Centre.

#### **Study investigators**

- Professor Linda Tapsell
- Dr Marijka Batterham
- Dr Karen Charlton
- Dr Yasmine Probst
- Jane O'Shea (ph 4221 5124)
- Rebecca Thorne (ph 4221 5992)
- Anne McMahon (ph 4221 4829)

*Study Mobile:* 0405051300

#### **Why are we doing this?**

The project aims to assess the benefits and achievability of different dietary approaches in the management of overweight. The results of this research will contribute to better understanding of the role of food components in diets for weight loss and healthy weight maintenance and thereby more effective treatment.

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

This research is a 12-month dietary intervention study in which you will receive dietary advice from a qualified dietitian. Your diet will be assessed and then you will be prescribed a weight loss dietary plan to follow for 12 months, with monthly follow up with a dietitian for the first three months, followed by 3-monthly visits thereafter. You will also be required to take one capsule every day for the 12 month period, which may contain either fish oil or an inactive ingredient.

The study also involves the use of a facility known as the Wollongong Room Calorimeter, before, during and after the dietary intervention, to assess your energy balance and ability to burn fat. The facility is a closed room which measures oxygen consumed and carbon dioxide produced by the person staying inside. From these measurements we are able to calculate energy expenditure, which is important in understanding how body weight is controlled.

If you decide to participate in the study, we will require you to attend for a total of 15-17 separate visits for various measurements and procedures. At the start of the study and at months 3 and 12, you will be required to attend the research facility three times: (1) once for dietary assessment, anthropometry (weight, height, body fat) and to be fitted with a 24-hour blood pressure (BP) monitor; (2) once for the 24-hr calorimeter visit and blood sampling; and (3) once for a dual energy x-ray absorptiometry (DEXA) scan (to be performed at Wollongong Hospital) A DEXA scan tells us how much fatty tissue is in your whole body. Dietary assessments and anthropometrical measurements will also be performed at months 1, 2, 6, 9 (ie. four visits).

You will also be invited to participate in two interviews. The first will take approximately ½ - 1 hour in the first three months and the second similarly take ½ - 1 hour in the last three months of the trial. Anne McMahon will try to co-ordinate this interview with one of your required visits. If time constraints are an issue for you Anne McMahon will contact you to arrange another suitable time and meeting place.

Blood pressure (BP) will be measured for a continuous 24-hr period at baseline and at 3 and 12 months of follow-up using a Spacelabs monitor. The monitor will be programmed to take readings every 20 minutes during awake time (06h00-22h00) and every 30 minutes during asleep time (22h00-06h00). The information will be downloaded to a computer software programme for analysis.

Fasting blood samples taken at the beginning of the study and at 3 and 12 months will be analysed for fatty acids, cholesterol and other blood lipids, insulin, glucose and leptin (a hormone) concentrations. Additional blood samples for fatty acid analyses will be taken at six and nine months. DNA material will be extracted from baseline blood samples in order to assess the prevalence genetic markers associated with energy expenditure and different response to the weight loss diets.

The study also involves questionnaires to be completed at home and to be returned to the university in a timely manner. Participants are asked to fill in a food diary, complete a physical activity questionnaire and to wear an activity monitor at home over 3 days at the start and the end of the study.

A flow chart of your commitments is as follows:

Interested in the study

Call us

Screening questionnaire completed and eligibility assessed

Pre study assessment (<2 hours)

- Visit to calorimeter facility
- Weight and height
- Body composition
- Diet history interview
- Activity & health questionnaires
- 3 day food records to be taken and filled out at home and returned prior to calorimeter visit
- Activity monitors to be worn for 3 days and returned with

DEXA scan (Wollongong Hospital) t = 0

Calorimeter visit (overnight stay; Room 41. 302) + blood collection + BP monitor to be worn for 24 hours

Start of diet

Diet counselling (1 hour). Capsules provided. Weight, body fat.

t = 1 month\*

Diet support (½ hour) Weight,, body fat, 3-day food records.

t = 2 months\*

Diet support (½ hour) Weight,, body fat, 3-day food records.

t = 3 months\*

Calorimeter visit (overnight stay; Room 41. 302) + blood collection + BP monitor to be worn for 24 hours

DEXA scan (Wollongong Hospital)

t = 12 months

Post-study assessment (1 hour)

- Weight
- Body composition
- Diet history interview
- Activity, health questionnaires, 3 day food records to be filled in and returned within 1-2 weeks

t = 12 months\*\*

Calorimeter visit (overnight stay; Room 41. 302) + blood collection + BP monitor to be worn for 24 hours

t = 9 months\*\*

Diet support (½ hour) + Blood collection (fatty acids) + 3-day food records

t = 6 months

Diet support (½ hour) + Blood collection (fatty acids) + 3-day food records

Diet support (½ hour) Weight,, body fat, 3-day food records.

DEXA scan (Wollongong Hospital)

\* First interview to be arranged for preferably for one of these times  
 \*\* Second interview to be arranged preferably at one of these times

### **Pre study assessment (Visit 1)**

This involves providing us with background information and will take around two hours. You will also be shown the Wollongong room calorimeter during this visit and be orientated to protocols used in the calorimeter. You will be given a number of questionnaires on activity levels and food intake. You will be asked to wear an activity monitor (the size of a pager) on your waist for a three day period (two weekdays and one weekend day). It is taken off when you shower and go to bed. You will also be asked to complete a three-day food diary on these same three days.

At this visit we will measure:

- a) Weight, height and waist circumference measures.
- b) Body composition using bioelectrical impedance analysis using Tanita scales.
- c) An Accredited Practising Dietitian will conduct a diet history interview to assess usual dietary intake.

We will also show you examples of menus for your stay in the calorimeter to ensure that you are willing to consume those foods in the amounts provided.

### **Calorimeter Stays (Baseline, 3 months, 12 months)**

At baseline and at 3 and 12 months of follow-up, you will be required to stay in the calorimeter for a 24-hour period. The calorimeters are enclosed spaces (3.0 x 2.1 x 2.4 m) which may cause discomfort to some people. A computer with internet access is provided in the room, as well as a TV with a number of DVDs for your viewing enjoyment. The room contains a desk and chair, fold-away bed, toilet, sink and is air-conditioned. There is also a window providing an ocean view. You will be shown the calorimeter when you attend for your pre-study assessment (see Figure on previous page) and will have the opportunity to ask questions about the facility at that visit.

The procedure for the calorimeter stay is as follows:

You should arrive at 8:00am after following an organised meal plan for the 24 hours beforehand and having fasted for at least 10 hours.

At these visits we will measure:

- a) Your resting energy expenditure where you will need to lie down in a supine position rest for 30 minutes without falling asleep.
- b) Your weight and body composition.
- c) Your urine output which helps us determine your energy expenditure. We will need to collect all urine during your 24 hour calorimeter stays.

*Bloods:* Blood pressure and a blood sample will be taken the morning you leave the calorimeter for analyses of glucose, insulin, lipids levels, fatty acids and DNA markers associated with energy expenditure and different response to the weight loss diets.

*Meals:* You will be asked to eat all of the food provided by us and only the foods provided by us during your stays in the calorimeter. All meals will be prepared using normal foods, and will be designed to contain recommended amounts of vitamins and other essential nutrients. Meal times will be set to replicate your usual meal pattern.

*Physical activity:* During your stays in the calorimeter your physical movements will be monitored using a digital Doppler motion sensor. These units operate in the same way as common burglar alarms. You will also wear the activity monitor while you are awake. You will be asked to do certain activities (e.g. walking around the chamber, stepping on wooden block) at set intervals to replicate the activities you perform outside the chamber.

*DietAdvice website:* During your stay in the calorimeter we request that you use an automated dietary assessment website developed by the University of Wollongong to help to pass the time. The website has

been developed to ensure your privacy is upheld and information will not be accessible by anyone other than the researchers on the study. The website will ask you about your usual food intake similar to your pre-study visit and your dietary counselling sessions. The information will be used to validate the accuracy of the information reported on the website. The website is managed by Dr Yasmine Probst who will be available by telephone and on email if you have any difficulties with using the website. You will be able to withdraw at any time from using the website without any penalty or prevention from participating in the trial.

### **Dietary Counselling**

**4<sup>th</sup> Visit:** At this visit you will receive dietary counselling and a dietary plan for the twelve month intervention period and be supplied with a 6-month supply of capsules.

**1, 2, 3, 6, 9 & 12 month visits:** At these visits, the Dietitian will go through your dietary plan and determine if you have any questions or problems with your program. At the 6 and 9 month visits, blood samples will be drawn in addition to dietary counselling.

### **Interviews**

**First Interview** At one of your visits in the first three months you will be asked to participate in a ½ - 1 hour interview on general health and wellbeing issues and about what might have attracted you to participate in the trial.

**Second interview** The last interview will be scheduled to occur within the last three months of the trial and will be similarly on your thoughts and understanding of general health and wellbeing and your views on the trial itself. It is expected that the interview will again be approximately ½ - 1 hour.

Anne McMahon will contact you to confirm a time for both interviews. There is no preparation necessary for these interviews as Anne McMahon is looking to hear your views. The interviews will be recorded so your thoughts are transcribed exactly. Anne McMahon is a PhD student and will be utilising this information for her doctoral study. Any individual comments will not be identifiable in any reports or publications developed from these interviews. The recordings and transcribed documents of the interviews will be kept in a locked secure cabinet. You will be able to withdraw at any time from the interview/s without any penalty or prevention from participating in the trial.

### **Three and twelve month visits**

This is a repeat of your initial assessment. At this visit we will again measure:

- a) Weight and waist circumference measures.
- b) Body composition.
- c) Conduct a diet history interview
- d) Questionnaires and activity monitors will be provided for return within 1-2 weeks
- e) DEXA scan
- f) 24-hr calorimeter stay, including blood analyses
- g) 24-hr blood pressure monitoring.

### **Who can participate?**

We are looking for healthy male and female participants aged 18 - 45 years who are overweight. ***It is important that you are willing to consume only the types and amounts of foods provided to you during your stays in the calorimeter.***

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

- Know or suspect that you are pregnant.  
Your energy requirements will be increased during pregnancy and this will compromise some of the calculations.
- Are breast feeding

Your energy requirements will be increased during breastfeeding and this will compromise some of the calculations.

- Suffer from diseases that may alter the energy expenditure pattern e.g. cancer, endocrine disorders, diabetes, AIDS
- Wear a pacemaker.
- Smoke cigarettes regularly
- Are taking regular medication (except the oral contraceptive pill)
- Suffer from any food allergies
- Be unwilling to consume fish
- Have lost or gained more than 3 kg over the past six months, or are on a weight-reducing diet
- Regularly take fish oil supplements and are unwilling to stop taking them during the study
- Cannot understand English.

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

The taking of blood samples may produce some temporary discomfort and may result in mild bruising at the site of sampling. Any bruising would be expected to resolve in a few days. The DEXA scan which will be conducted at Southern IML Pathology is associated with an extremely small radiation dose which is 700 times less than a chest x-ray and 100 times less than a coast to coast plane flight. We do not foresee any other risks or any disadvantages (except for the time commitment required of you) in taking part in this study.

If you feel too uncomfortable, for example whilst in the calorimeter, you may 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 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. Nothing which identifies individual participants will be published. Standards of medical confidentiality will apply. As a result of the study you will be able to gain some information about your body fat percentage, how many calories you are using in a day and your dietary intake. Blood samples will be stored for no less than five years on site at the University of Wollongong.

**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 of the University of Wollongong Human Research Ethics Committee on (02) 42214457.**