

VOLUNTEER INFORMATION SHEET

Health benefits of dairy consumption

Purpose of Study

The governments of South Australia and Manitoba (Canada) are jointly funding research on the health benefits of foods. An initial evaluation of the benefits of low fat dairy will be undertaken jointly by the Nutritional Physiology Research Centre and the Richardson Centre for Functional Foods and Nutraceuticals, University of Manitoba.

Dairy is a nutritious source of protein, vitamins and minerals (vitamin D, calcium), antioxidants and peptides. The Australian Dietary Guidelines recommend two to three daily servings of dairy as part of a balanced diet to deliver these nutrients. However concern remains about the saturated fat content of dairy and its potential to raise blood cholesterol as hypercholesterolemia is one of several risk factors associated with the development of cardiovascular disease (CVD). Thus milk and dairy have received an unhealthy image resulting in changes or reduction in consumption of some dairy products, in particular butter. However other studies have shown that dairy intake can actually improve blood cholesterol levels.

To date there is no conclusive evidence from epidemiological data that milk or dairy consumption is linked with increased risk of CVD. In fact a number of studies have independently shown that dairy intake can improve a number of CVD risk factors such as improved glucose control and insulin sensitivity and risk of type II diabetes, reductions in normal to high blood pressure, reduced obesity and improved weight control, improved dyslipidemia and reduced risk of stroke.

Some of these cardiometabolic risk factors cluster in a condition known as Metabolic Syndrome, which results in an almost three-fold increase in the risk of CVD morbidity and mortality. Changes in lifestyle habits such as physical activity as well as dietary modification such as reducing saturated fat can counteract risk factors. Recent attention has been given to the role that low fat dairy products might play in reducing cardiovascular and metabolic disease.

Low fat dairy consumption may also improve cognitive function and psychological wellbeing. We have recently found in a cross sectional study with 1183 individuals that low fat dairy intake was associated with better cognitive functioning including reduced stress and better memory recall.

We believe that regular consumption of dairy may improve cardiometabolic health, particularly by improving body composition and also improve cognitive and psychological wellbeing.

What it Involves

The study will be conducted at the Nutritional Physiology Research Centre which is located in the Bonython Jubilee Building at the University of South Australia's City East Campus on Frome Road. The study co-ordinator is Dr Karen Murphy. The principal investigators responsible for the study are Professor Peter Howe, Assoc. Prof Jon Buckley and Dr Janet Bryan.

If you would like to participate in the study, you will be invited to attend a screening appointment at the Centre at the University of South Australia to complete a diet and lifestyle questionnaire and have your height and weight and blood pressure measured to determine eligibility and to provide an opportunity to ask any questions about the study.

Participants and Groups:

50 volunteers, with the following criteria, will be needed to take part in this study.

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none">• aged 18-75 years• overweight, BMI ≥ 25 kg/m²• eat ≤ 2 serves of dairy per day• non-smoker• age-related healthy individuals	<ul style="list-style-type: none">• Person considered by the investigator to be unwilling, unlikely or unable to comprehend or comply with the study protocol.• Lactose intolerant or allergy to dairy.• medication that may interfere with the outcomes of the study (i.e. blood pressure or lipid lowering medication that has not been stable for greater than 3 months).• weight ≥ 135kg (maximum capacity for DEXA)• Diagnosed diabetes• Diagnosed cardiovascular disease• Liver or renal disease• Regular use of appetite suppressants or Orlistat (Xenical);• Eat > 2 serves of dairy per day• Unable to consume dairy for 12 months.• BP >170/100• Regular non-steroidal anti-inflammatory drug therapy• Taking fish oil (if consumption is >1g/d or recently modified ie. within the last 3 months (fish oil may interfere with outcomes of the study such as blood lipids, body fat etc).• Participation in another study within 30 days of commencement of the present study• Pregnancy• Any other treatment or condition that in the opinion of the investigators may interfere with the outcomes of the study

If you are eligible to participate, we will invite you to attend an information session where we will explain the study protocol in further detail and show you how to complete a food diary. We expect to make a final selection of participants by the end of October 2008 and the study will commence in October 2008.

You will then be randomly allocated (i.e. by chance) to one of two groups, either:

1. a high dairy diet: you will consume at least 4 serves of dairy/d for 12 months, at least 3 of which will be the supplied low fat dairy products (milk and or yoghurt etc)
2. or a low dairy diet; you will consume no more than 1 serve of dairy/d for 12 months.

All participants will be asked to continue their usual lifestyle and physical activity throughout the 12-month intervention period. Those allocated the high dairy diet will be asked to incorporate the additional serves of dairy into their diet by substituting the dairy for other foods which they may have eaten, so as not to change their overall energy (calorie) intake..

Each week or fortnight volunteers allocated to the high dairy diet will be asked to attend our clinic (approx 15 minutes) to collect their allocated dairy products. At baseline (beginning of the study) you will be asked to visit the centre twice in one week. At your first visit (baseline, day 1), 3 months, 6 months and 12 months, you will be required to fast (water is allowed) for 12 hours prior to their visit. At these visits you will be required to:

- Have your height (measured once only), weight and waist circumference measured.
- Have your % body fat and bone mineral density measured using dual x-ray absorptiometry (DEXA)
- Have your blood pressure measured.
- Undertake assessment of blood vessel function. This is a non-invasive test that is similar to having your blood pressure taken. The test measures stiffness of blood vessels determined from an artery in the arm.
- Have your resting metabolic rate measured.
- Provide a small blood sample (~20 ml).
- Collect your weighed food record, food frequency questionnaire, dairy food logs and physical activity questionnaire.

This visit will take around 90 minutes.

At visit 1 (baseline) day 2, you will be required to fast (water is allowed) for 12 hours prior to your visit and provide a small fasting blood sample. This is for the repeated measurement of triglycerides as the level of triglycerides in the bloods can vary substantially from day to day. From the two triglyceride measurements we will take the average value. We will then undertake a series of tests of thinking and memory. During the testing session you will be provided with breaks at your request, in which refreshments will be provided. During the testing session you will be asked to complete a series of tasks that assess different aspects of thinking such as planning, memory, attention and problem solving. Most people find these tasks interesting and enjoyable.

It is important to point out that these tasks cannot and will not be used to detect any impairments in thinking and memory.

In addition, you will be asked to complete a questionnaire containing items that ask you about your psychological well-being. This will take no longer than 10 minutes to complete. There is a very small risk that some individuals may find completing this questionnaire distressing. If this is the case, we will provide appropriate referral or immediate assistance.

You can decline to answer any of the items or questions in the testing session. The session is expected to take around one to one and a half hours.

Possible Risks

All procedures will be carried out by qualified personnel. However, to assist you in making an informed decision, the risks associated with procedures are set out below:

Blood Sampling: will be taken by venepuncture. The associated risks are:

- *Infection* - although all of the needles will be sterile and all reasonable precautions will be taken, in any situation involving penetration of the skin there is a slight risk of infection.
- *Blood Clotting* - insertion of a needle into a blood vessel involves a risk of a blood clot forming which can travel through the circulation and block a smaller blood vessel somewhere else. However, the danger of this occurring is considered to be remote.
- *Bruising* - it is possible that you may experience slight bruising around the area where the needle was inserted. This is nothing to worry about as any such bruising should clear up within a few days. Blood thinning agents, such as aspirin and ginkgo, should not be taken three days prior to sampling.

DEXA scan: your % body fat and bone mineral density will be determined by a DEXA scan.

In this project you will undergo a DEXA scan on 4 occasions. In this project, you will be exposed to radiation at a level considered safe as long as you have not also been exposed to radiation in other research projects or as a part of investigation (x-rays) or treatment (Radiotherapy) in the past year. Please advise the researcher if you have had any exposure to radiation for any reason in the last year.

We are all exposed to low levels of ionising radiation every day, mainly in the form of natural background radiation from the environment. DEXA machines use radiation, called ionising radiation, to create an image of the body. As with most medical procedures, there are some risks associated with exposure to ionising radiation. Each DEXA scan will expose you to an effective dose of 0.08 μ Sv of ionizing radiation per scan, thus the total effective dose for 4 DEXA scans will be 0.32 μ Sv or 0.00032 mSv. This dose of radiation is negligible in that the annual dose from natural background radiation in Australia is between 2 and 2.5 mSv per year (i.e. ~8,000 times the dose that will be delivered in this study) and therefore poses a negligible risk of detrimental effects from radiation exposure. The dose of radiation in this study also falls well within the dose constraint of 0.3mSv per year for the general public as stated in Ionising Radiation Safety Policy (HR-29.1) of the University of South Australia.

If you are pregnant, or suspect you may be pregnant will not be allowed to participate in the study. Females (fertile) who are pre-menopausal and not taking contraception will be offered a pregnancy test. All procedures are undertaken by experienced staff and in accordance with strict OHS guidelines.

All information collected as part of the study will remain confidential and no information that could lead to identification of any individual will be released. The information collected in this study will be stored on a CD-ROM the Nutritional Physiology Research Centres' secure data store in the Bonython Jubilee building, City East campus for a period of 7 years. Participants in the study may withdraw at any stage without prejudice. Participants will be provided with a copy of their personal results and a summary of the research findings within 6 months of completing the study.

Prior to your participation in the study, we may advise your GP of involvement. However, this will only be done with your approval. Participants randomized to the high dairy diet will receive 28 standard serves of low fat dairy (eg. milk, yoghurt) per week for 12 months. Participants randomized to the low dairy diet (regular diet) will receive an honorarium of \$200 and a dairy hamper for their time upon completion of the study.

Further Information

If you would like to participate in the study, or if you, or any member of your family, require more information to help you arrive at a decision, please contact:

Dr. Karen Murphy

Phone: 8302 1033, E-mail: karen.murphy@unisa.edu.au

This project has been approved by the University of South Australia's Human Research Ethics Committee and if you, or any member of your family, would like to discuss any ethical concerns they have with the study, please feel free to contact:

Ms. Vicki Allen

Ethics and Compliance Officer

University of South Australia

Phone: 8302 3118

E-mail: vicki.allen@unisa.edu.au