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File: O/has/diabetes/corporate/service development/obesity clinic

Dear Participant,

**Subject: PARTICIPANT INFORMATION LETTER – TREATMENT GROUP**

**PROJECT TITLE:** Assessment and Management of Obesity and Self-Maintenance (AMOS) Clinic:  
Evaluation of the AMOS Model of Care

**PRINCIPAL INVESTIGATORS:** Giuliana Murfet

**ASSOCIATE INVESTIGATORS:** Dr Kelly Shaw (Epidemiologist)

**What is the project about?**

This study will look at the effect of care that is tailor-made to obesity on the overall health of people. Many people struggle with this health issue and often the medication used in diabetes can add to weight gain. The data gained from the study will assist us to develop a framework to support people with issues of obesity in rural areas.

**Who is undertaking the project?**

This research is being conducted by the Diabetes Centre of the Tasmanian Health Organisation (North West). It will also be supported by Population Health of the Department of Health and Human Services. Giuliana Murfet is Principal Investigator for this project; Dr Kelly Shaw has a conjoint position with the University of Tasmania.

**Are there any risks for me if I participate in this project?**

The study will involve no foreseeable risks. You may find some of the physical activities challenging - if this becomes part of your health care plan. You should discuss this with the health professional at the time. You may also find the psychological sessions distressing if you are referred for this care. The study protocol only directs those with higher levels of stress for this therapy to reduce anxiety and distress. Some people may be referred for review for bariatric surgery to decide if this is a desired option for care. Any surgery brings risks that would be discussed with you by the surgeon. However, the project aims to assess the model of care and not the surgery.

**How was I selected?**

All people with type 2 diabetes that attend the Diabetes Centre were ranked in order of Body Mass Index (a measure for being overweight). Each person was ranked from highest to lowest and provided a number – 'one' being the highest BMI. A random number generator was then used to create numbers for the two groups of the study – those that would receive normal care and those that would be provided with AMOS care. You have been chosen at random for the AMOS clinic.

### **What will I be asked to do?**

You will be asked to provide written consent before being placed in the AMOS clinic. Firstly, you will be invited to a clinic where you will be asked to complete a number of hand written assessments about sleep, pain, stress, how you feel and how your health problems affect your work and other activities. If you have trouble with reading staff will read the forms out aloud to you. We will also take some measurements of your body shape and some blood tests – this will occur each 6 months for 12 to 24 months. Some of these are routine tests for normal care that you have had done before. Others are specific to the study – this will not increase the amount of times you need to give blood. You will then see a physiotherapist that will assess any pain, your balance and strength.

Like what occurs now - you will be offered an appointment to attend the service each 3 months. These 4 visits per year may last 30 to 90 minutes. At these times you may see other health professionals such as a psychologist or dietitian. This will be on an individual basis at first and then may be in a group format. You will always be advised of others that you will see prior to arrival at the clinic. The group programs will involve learning about ways to stop the cycle of obesity and/or some physical activity. If no weight loss is achieved you may be offered other medicines and these will be discussed with you at the time – some for a short 3 month period. You will be contacted by the research assistant to see how you are doing overall. If suitable and willing you may be referred to see a surgeon to discuss other options to deal with obesity if no weight loss occurs.

### **How much time will the project take?**

You will be invited to an initial assessment clinic. At this visit we will collect base line information. This visit will take 90 minutes. We estimate that each visit after this will be between 30-90 minutes each 3 months. You may be invited to attend a group program or other individual sessions. These visits will last around 60 minutes for up to 6 visits.

### **Will this cost me more money to attend the AMOS clinic?**

You can expect no other costs for caring for your diabetes other than those you already have.

### **What are the benefits of the research project?**

You may directly benefit from being in the study as a result of lower health markers, such as HbA1c (3 monthly diabetes test), cholesterol, blood pressure and weight. A reduction in these markers may reduce your risk of other diabetes complications (eg kidney or eye disease) and cardiovascular disease (eg stroke or heart attacks).

The study will also help to gather information to better understand how to care for people with issues of being overweight. This may support the development of a framework to improve obesity care in rural areas. Also it may help to provide information to drive policy change.

### **Can I withdraw from the study?**

Your participation in this study is completely voluntary. You can withdraw from the study at any given time – without giving a reason should you wish. This will not impact on your care. On withdrawal from AMOS we will organise for your next appointment to be booked into the normal Adult Diabetes Clinic in the expected time frame.

Also at any given time whilst you receive care in the AMOS clinic you can decline any treatment that is offered to you.

**Will anyone else know the results of the project?**

The findings from this study will be shared through presentations and publications. Whenever the information is shared all data will be presented in a de-identified manner. When data is collected no names are used – thus, once it is analysed it is not possible to identify who the information is about.

**Will I be able to find out the results of the project?**

We will not write directly to you with the results of the study. Results will be published in 2016-2017 and shared at conferences. At the end of the study a small report with findings will be left in the waiting rooms of the diabetes centre for your interest.

**Who will I contact if I have questions about the project?**

You may contact Giuliana Murfet if you have further questions, by email [giuliana.murfet@ths.tas.gov.au](mailto:giuliana.murfet@ths.tas.gov.au) or phone 03 6493 6100.

**What if I have a complaint or any concerns?**

The study has been approved by the Human Research Ethics Committee (HREC) of the University of Tasmania [Ethics Reference number: H0014324]. If you have any complaints or concerns about the conduct of the project, you can write to the Chair of the HREC.

Chair  
Health and Medical Human Research Ethics Committee  
Research Integrity and Ethics Unit  
Office of Research Services  
University of Tasmania  
Private Bag 01  
Hobart TAS 7001

**I want to participate – how do I sign up?**

You can phone the Diabetes Centre on 6493 6100 and advise that you would like to be involved in the study. You can also email Giuliana via the email address above.

Yours sincerely

Giuliana Murfet and Dr Kelly Shaw  
Nurse Practitioner (Diabetes) / Epidemiologist and Medical Advisor

6<sup>th</sup> July 2016

## PARTICIPANT CONSENT FORM

### PROJECT TITLE:

**Assessment and Management of Obesity and Self-Maintenance (AMOS) Clinic: Evaluation of the AMOS Model of Care**

**PRINCIPAL INVESTIGATOR/S: Giuliana Murfet**

**Please tick the box that applies, sign, date and give to researcher**

I agree to take part in the Tasmanian Health Organisation (North West) Diabetes Centre's research project specified above. Yes  No

I understand the information about my participation in the research project, which has been provided to me by the researcher. Yes  No

I agree to be assessed by the endocrinologist and other health professionals as needed as part of my health plan. Yes  No

I agree to make myself available for further assessments as required. Yes No I understand that my participation is voluntary and I understand that I can cease my participation at any time. Yes  No

I understand that my participation in this research will be treated with confidentiality. Yes  No

I understand that any information that may identify me will be de-identified at the time of analysis of any data. Yes  No

I understand that no identifying information will be disclosed or published. Yes No I understand that all information in this research will be kept confidentially. Yes  No

I am aware that I can contact the researcher at any time with any queries. Their contact details have been provided to me. Yes  No

I understand that this project has been approved by the University of Tasmania's Human Research Ethics Committee (H0014324). Yes  No

Participant's name: \_\_\_\_\_

Participant's signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness's signature: \_\_\_\_\_

Date: Designation: \_\_\_\_\_