Queensland University of Technology
Brisbane Australia

PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Verifying continuous glucose monitoring with diet and exercise interventions for men at risk of diabetes

QUT Ethics Approval Number 1400000394

RESEARCH TEAM

Principal Researcher:	Stephanie Zietek	Masters candidate, Queensland University of Technology (QUT)
Associate Researchers:	Nuala Byrne	Principal supervisor, QUT and Bond University
	Rachel Wood	Associate supervisor, QUT
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DESCRIPTION

Daily blood glucose (sugar) monitoring is important for optimizing glycemic control in individuals with diabetes. Continuous glucose monitors (or CGM's) are a new, minimally invasive technology that assesses blood glucose continuously for up to 96 hours. However, the accuracy of CGM's during fluctuating glucose levels needs to be determined.

The aim of this study is to establish the precision of measuring glucose levels by continuous glucose monitors compared to directly from venous blood, in response to diet and exercise interventions.

We are seeking men (aged 20 to 50 years) that do not currently exercise and have a high risk of developing diabetes. We will assess your risk of diabetes with the Australian Diabetes Risk Assessment questionnaire (10 questions). Men that score 12 points or higher are eligible to participate in this study. You are unable to participate in this study if you have a history of heart disease, liver disease or any additional conditions/injuries that prevent you from exercising.

PARTICIPATION

Your participation will involve up to 9 visits to the Energy and Metabolism laboratory at IBHI, QUT Kelvin Grove campus. You will be required to abstain from eating (for 8 hours), drinking caffeine (for 24 hours) and alcohol (for 48 hours), and performing strenuous physical activity (for 48 hours) prior to all testing. Your first visit will include preliminary tests to assess your body composition and current fitness status. Preliminary testing will be conducted in the morning and is expected to take a total of 2 hours.

Preliminary Testing

Test 1 - Body Composition

Your body composition will be assessed to determine your fat and fat free mass. This procedure requires you to sit quietly inside an enclosed chamber, called the BOD POD (see **Figure 1** below, left), for up to 2 minutes while the space that your body takes up within the chamber is measured. It is necessary that you wear tight fitting clothing, such as swim shorts or bike shorts.

Test 2 - Exercise test

The exercise test is conducted to determine your current fitness status. It involves cycling on an indoor stationary cycle for as long as you possibly can while the pedaling resistance gets harder and harder. The intensity of exercise will progressively increase every 2 ½ minutes. This test is expected to last around 10 minutes and will end when you can no longer continue exercising. During the test you will be required to breathe into a mouthpiece, similar to a snorkel, which permits a machine to sample the air you breathe in and out (see **Figure 1** below, right). The results from this test provide you with a highly accurate reading of the maximum amount of oxygen you can extract from the air and deliver to your muscles and peak power output (PPO) you can generate (Watts of energy) which are information related to your cardiovascular health and fitness. The data will be used by the researchers to set appropriate exercise intensity for each experimental trial involving exercise.

Additional Tests

You will be required to have your blood sampled at a QML collection centre of your choice, within one week of completing the preliminary tests. This test is at no additional cost to you. The blood sampled will be tested for blood glucose, insulin and cholesterol levels. You will also be required to complete two questionnaires. Your habitual food intake will be assessed by completing a Food Frequency Questionnaire and your physical activity level will be assessed by completing the International Physical Activity Questionnaire (IPAQ).

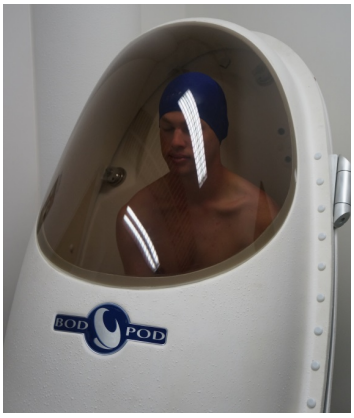

Figure 1. A participant sitting in the BOD POD whilst having their body composition assessed (left) and a participant performing the exercise test with the mouthpiece (right).

You will then attend four, 12 hour experimental trials, each conducted on a separate day one to three weeks apart. You will be required to remain at QUT for the duration of each experimental trial due to regular meal provision, exercise and blood sampling. Additional visits to QUT may be necessary before or after each experimental trial for the insertion or removal of the continuous glucose monitor (CGM).

Experimental Trials

Continuous glucose monitor (CGM)

You will be required to wear a CGM during each trial. It will be inserted 24 hours prior to each experimental trial, will remain on your person for 72-96 hours and requires no further intervention until removed. The CGM consists of a sensor and data recorder. The sensor provides information on changes in glucose levels in the body. It contains a very small fibre that is inserted into the side of your torso just under your skin. Insertion does not require anaesthetic and is essentially painless. The sensor will then be attached to a data recorder approximately the size of a 50 cent piece (see **Figure 2** below). The recorder will be taped to your skin surface and will be barely detectable throughout the day or night. The device is waterproof and does not prevent you from bathing or swimming activities. The glucose sensor measures the glucose concentration and stores an average value every 5 minutes (Medtronic, iPro2 professional model).

Figure 2. The inserter device (left) and glucose sensor inserted into the side of the torso and attached to the digital recorder (right).

Blood sampling

Blood samples will be taken at rest before commencing each experimental trial, and at regular intervals throughout each trial to measure your blood glucose concentration. This will involve inserting a catheter via a needle into a forearm vein, which will then be taped down to secure its position for the remainder of the day. You will need to wear a t-shirt and remove your jumper so that the inside of your elbow is easily accessible. The catheter will not prevent daily activities, however, you will be asked to remain seated for the majority of the day. A total of 22 samples of blood (~6 mL per sample) will be collected. The total volume of blood to be taken during the experimental trials does not exceed one third of the standard Red Cross donation volume. Each time a blood sample is taken, a small volume of sterile solution will be injected to keep the catheter clear and unblocked.

Diet intervention

All meals and snacks will be provided during each 12 h experimental trial. Breakfast, lunch and dinner will be interspersed with snacks but each meal will be separated by 5 hours and consumed at approximately 0730, 1230 and 1730 h. All meals and snacks during the two diet intervention only days will be matched for carbohydrate, protein and fat content but will differ in the glycemic index of the carbohydrate component. Glycemic index refers to the digestibility and rate at which blood

glucose (sugar) levels are changed. That is, meals on one occasion will rapidly increase glucose levels of the body to a high level but for a short time, while the other meals will slowly increase glucose to a moderate level for a more prolonged time.

Exercise Sessions

The exercise sessions will involve two 'types' of exercise. On one occasion you will undertake 3 x 15 minute bouts of cycling performed at a low intensity (one 15 minute bout of exercise will be undertaken prior to each meal). On another occasion you will undertake an 8 minute warm up followed by 12 x 60 second repetitions of cycling at a high intensity, each interspersed with 60 seconds of recovery at a low intensity. This single session of exercise will be undertaken before the first meal (breakfast). All exercise will be performed on a stationary indoor cycle. The two exercise experimental trials will generally use the same total amounts of energy but will differ in the exercise intensity and duration. Meals/snacks will be provided throughout the two exercise interventions using the eating schedule and content of the high glycemic index diet intervention. It is necessary that you wear comfortable clothing and appropriate footwear for exercise.

EXPECTED BENEFITS

Individuals who take part in this research study will benefit by receiving information about their current health and fitness status and their individual glucose response to different meals and exercise regimens. You will be provided with a copy of your individual daily glucose response at your request and an additional copy will be provided to your doctor with your permission. Participants will have access to free on-site parking and will be provided with free meals. Furthermore, while of no direct benefit to the participant the research outcomes will provide greater knowledge of the mechanisms and processes involved in management and treatment of type II diabetes.

RISKS

A catheter is a very small, flexible and hollow tube that is inserted into a vein for taking multiple samples of blood. The use of a catheter removes the need to puncture the skin and vessels each time blood is extracted. This procedure is slightly discomforting and can cause bruising. The use of sterile, disposable equipment significantly reduces the chance of infection. The procedure used at QUT replicates the procedures used in primary care and diagnostic centres (i.e. hospitals, clinics and pathology labs). The use of qualified and experienced staff will reduce the likelihood of bruising as this is primarily caused by poor techniques. The chance of infection, vein blockage and bruising is small, however, if it does occur, consult your doctor immediately and inform the researcher.

While all physical exertion involves some possible risk of injury or complication the exercise sessions in this study will not present any risk other than those experienced during activities of daily living (e.g. heavy lifting, brisk walk/run) or formal exercise sessions (e.g. social sport or fitness regimes).

PRIVACY AND CONFIDENTIALITY

Any data collected as part of this project will be stored securely as per QUT's Management of research data policy i.e., all information provided to or collected by the research team will be treated confidentially. Individuals will not be identified in any scientific reports of the findings of the present investigation.

CONSENT TO PARTICIPATE

We will ask you to sign a written consent form to confirm your agreement to participate at the first study visit.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

If have any questions or require further information please contact one of the research team members below.

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CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the QUT Research Ethics Unit on 3138 5123 or email ethicscontact@qut.edu.au. The QUT Research Ethics Unit is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.