THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Participant Information Sheet

Study Title: Morning versus evening exercise: Its effect on body composition and weight loss

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Introduction

We invite you to participate in this study. The following information describes the study and your role as a participant.
The principal investigator will answer questions you may have about the study. The information contained in this Information Sheet will help you to understand the possible risks and benefits involved in the study, and what would happen. Also your rights and responsibilities will be outlined. Please note you *cannot* receive any reward for being a part of this study. If after reading this document you have questions about the study, please do not hesitate to ask the principal investigator for further information.

Purpose

The purpose of this study is to compare the effect of exercise performed at different times of the day (morning and evening) on weight loss and other health outcomes (e.g. physical activity and diet), as part of a lifestyle intervention.

The results of this research may lead to recommendations about the time-of-day at which exercise should be performed for maximal health benefits in previously inactive individuals.

Am I eligible to participate?

We are looking for 95 individuals to participate in this study.
To be eligible for this study, you must be:

- aged between 18 – 60 years
- have a body mass index ≥25 kg/m^2 (we can help you measure this)
- weight stable (±3 kg) in the previous 3 months
- insufficiently active (<150 minutes of exercise per week)
- working 'regular' hours (i.e. no shift work), if you are employed

To determine whether you fit the criteria, you will be asked to complete a short screening questionnaire (by telephone or online survey).

What's involved?

If you are deemed eligible for the study based on your responses to the screening questionnaire, you will be invited to complete baseline testing (**weeks 1-2**). Shortly after this, you will be randomly assigned (similar to tossing a coin) to one of three groups: 1) The control group, 2) the morning exercise group, or 3) the evening exercise group.

Exercise intervention groups

The intervention is designed to increase activity levels to a dose of ≥250 minutes per week to elicit clinically significant weight loss. The exercise programme will include a combination of supervised and unsupervised exercise sessions. The supervised sessions will last approximately 50 minutes, and will consist of brisk walking or running on a motor-driven treadmill. All supervised exercise sessions will be performed at the Exercise and Nutrition Clinic at The University of Queensland St Lucia Campus.

Exercise timetable for the Intervention groups

Week	# supervised sessions to be performed at the University of Queensland	# unsupervised sessions to be performed in your own environment
Weeks 3 – 6	5	
Weeks 7 – 8	4	1*
Weeks 9 – 10	3	2*
Weeks 11 – 14	2	3*

*Please note: these are the minimum number of sessions, you may undertake more sessions if you wish.

Those in the morning exercise group will be required to carry out their exercise programme **between 6am and 9am**, whereas the evening esercise group will complete their exercise between **4pm and 7pm**. You are welcome to undertake additional exercise outside of the intervention, providing you complete the minimum dose of exercise during your alloted time frame.

Control group

If you are assigned to the Control group, you will be asked to carry on with your typical day-to-day activities, and will be waitlisted to receive the exercise programme upon completion of all study assessments described below.

Outcome measurements

In addition to the screening and baseline assessments, all participants will need to be available for periodic testing throughout the study (including a 3 and 6 month follow-up), detailed below.

Fitness testing (VO_{2peak})

Your aerobic fitness will be measured via a peak cardiorespiratory fitness test. You will be placed on a treadmill and asked to exercise until you fatigue while breathing through an apparatus that measures oxygen consumption.

Questionnaires

You will be asked to complete several short questionnaires so we can gather information about your sleep patterns, food preferences, eating patterns, and whether you are a morning-type or an evening-type person.

Anthropometry

- Height and body weight
- Waist and hip circumferences

Body composition
Fat and muscle mass will be measured by Dual Energy X-ray Absorptiometry (DXA), a routine technique for the measurement of body composition. You will lie on the scanning table for approximately 7 minutes while the scanning arm moves above the table, as shown below.

Blood sampling – finger prick*
A small finger-tip sample of blood will be taken to measure your triglyceride and cholesterol levels using a single-use contact-activated lancet.

Blood sampling – venous blood draw (optional)*
A small blood sample will be drawn for us to assess inflammation, cholesterol and renal function. All blood will be sampled at The University of Queensland's School of Human Movement and Nutrition Sciences biochemistry laboratory by a qualified phlebotomist.

Resting metabolic rate*
Resting metabolic rate (RMR), is a measure of the amount of energy you use when you are at rest.

You will be asked to lie still in an air-conditioned room for approximately 45 minutes under a hood, shown here, and the air that you exhale will be collected and analysed.

****You are required to fast for 12 hours prior to blood sampling and RMR measurement, so we encourage you to bring a snack to consume after testing. Light refreshments will also be provided.***

Physical activity level (accelerometry)
You will be asked to wear a wrist-worn activity monitor (accelerometer) for 7 days to measure your daily minutes of physical activity. You will also be asked to keep a brief log of your wake and sleep times.

Use of time
You will be asked to complete two telephone interviews at each measurement period. During the telephone interview, we will ask you to recall your activities for the previous 2 days. This will give us detailed information about your daily activities.

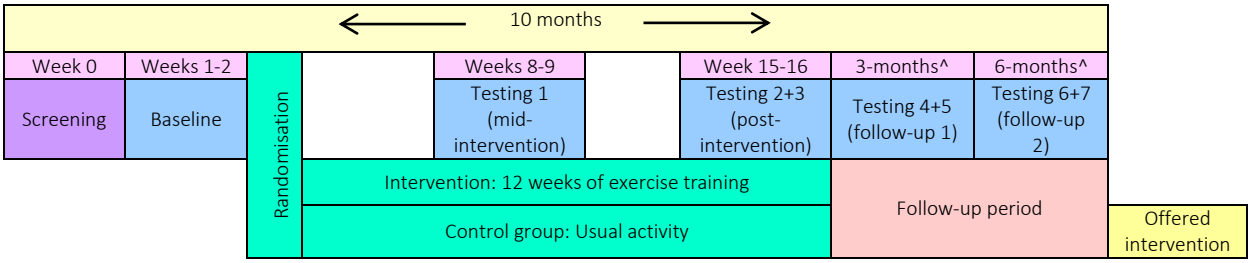
Multiple pass 24 hour food recall
To gather dietary intake, during a telephone interview you will be asked to recall all the foods and beverages you consumed the previous day. We will ask you questions to prompt you to remember typically forgotten foods so we get an accurate measurement.

How much time will the study take?

Your expected overall participation in this project is 10 months. If you are allocated to the control group, you will be wait-listed to receive the exercise programme at the conclusion of all study assessments.

The time commitment for measurement sessions is the same for all participants, regardless of whether you are randomised to the control group or one of the intervention groups. If you are assigned to either intervention group, you will also be required to complete 12 weeks of exercise training, approximately 50 minutes per session.

All testing sessions will be held at the Exercise and Nutrition Clinic at The University of Queensland St Lucia Campus, and some measurements will be taken via a telephone interview.



^ Following intervention

Measurement sessions timetable for control and intervention groups (face-to-face appointments at The University of Queensland)

Week	Session description	Visit duration
Baseline	Baseline 1: Anthropometry, RMR, DXA, blood sampling, questionnaires +accelerometry*	2 hrs
	Baseline 2: VO_{2peak}, questionnaires	1 hr
8 – 9 (mid-intervention)	Testing session 1: Anthropometry, DXA +accelerometry*	15 min
15-16 (post-intervention)	Testing session 2: As per baseline 1	2 hrs
	Testing session 3: As per baseline 2	1 hr
3 months^	Testing session 4: Anthropometry, DXA, questionnaires +accelerometry*	15 min
	Testing session 5: VO_{2peak}, questionnaires	45 min
6 months^	Testing session 6: Anthropometry, DXA, questionnaires +accelerometry*	15 min
	Testing session 7: VO_{2peak}, questionnaires	45 min

*You will be given an accelerometer to wear for 7 days; ^ Following the intervention

Measurement sessions timetable for control and intervention groups (telephone interview)

Week	Measurements taken
1 – 2	Time-use recalls, food recalls Phone appointments will be made for the time use and food recalls. Each phone call will last approximately 35 mins, and each measure will be taken twice over a 2 week period. This equates to a total duration of 70 minutes (just over 1 hour) for each testing period.
8 – 9	
13-14	
3 months^	
6 months^	

^ Following the intervention

Are there any risks or discomforts to me if I participate in the study and what will you do about it?

Pregnancy
Please advise the PI immediately and you will be withdrawn from the study.

Exercise testing
The exercise training may cause mild, temporary discomfort, including increased heart rate, sweating and muscle fatigue as a result of physical exertion. Delayed onset muscle sorness is a common occurrence after exercise training, particularly in untrained or sedentary individuals. Exercise sessions will be run by trained personnel who will prescribe appropriate warm-up and cool-down procedures to assist in minimising delayed onset of muscle soreness, and you will remain at the testing faccility until you have returned to your resting level.

Exercise poses an increased risk of cardiac injury. All personnel conducting training sessions are well trained to recognise and prevent any early signs and symptoms of a cardiac event occurring. In addition, the Exercise and Nutrition Clinic is equipped with defibrillation equipment and first aid kits.

Additionally, there is a minimal risk of sustaining an injury such as an acute muscular strain. The likelihood of this occuring is minimal as you will be supervised and monitored during the first four weeks of the intervention, whereby your heart rate and blood pressure will also be monitored. During this time you will be educated on correct exercise technique so you are equipped to carry on with the programme unsupervised, in your own environment, with a reduced risk of injury.

Blood sample
The discomfort associated with the blood drawing procedures is minimal but there is a risk that bruising and infection may occur and that the arm might become sore. Risk of bruising or infection from the blood draws will be minimised as all blood draws will be performed by a trained phlebotomist and by following recommended hygiene practice. Other risks may include excessive bleeding, fainting or lightheadedness hematoma or infection

The total amount of blood drawn during each testing session will not exceed 16 ml, which is equivalent to approximately 5 teaspoons. No syringes, lancets, needles or other devices capable of transmitting infection from one person to another shall be reused. All of these items, which are disposable, will be destroyed after each use. As an additional safeguard in preventing contamination, new disposable gloves will be worn for all blood draws. All contaminated items will be disposed of promptly in sharps containers.

Due to the sampling of blood, you will be counseled by the examining researcher during the course of your pre-study evaluation for Hepatitis B, Hepatitis C and/or HIV.

Questionnaires
Questionnaires are not expected to, but may elicit some anxiety or stress. If you experience any such signs from completing any of the study questionnaires, you are encouraged to immediately notify the principal investigator, who will recommend consultation with a GP as soon as possible to discuss this further.

Indirect calorimetry

There may be some discomfort, or feelings of claustrophobia while lying under the hood during resting metabolic rate measurement. In this unlikely occurrence, the hood will immediately be removed, and you will be asked to remain on the bed to rest/relax until you feel comfortable.

Ionising radiation

This research study involves exposure to ionising radiation. Body composition will be measured on five occasions over the study duration using DXA (as described above), which is additional to the exposure you would receive if you were not in this study. As part of every day living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this study is about 0.05 mSv. At this dose level, no harmful effects of radiation have been demonstrated and the risk is negligible.

You will be given a certificate that states the radiation dose you have received from participating in this study. You should keep the certificate for five years and show it if you are recruited for any other research studies in that time. If you would like to discuss your exposure to radiation with a radiation safety officer you may contact the radiation regulator in your state. See contact details at: http://www.arpansa.gov.au

What are the possible benefits to me?

Exercise has been shown to be beneficial in weight loss and weight management, and plays an important role in preventing and managing chronic diseases such as; Obesity, Type II Diabetes, heart disease and some cancers.

By participating in this study, you will also receive:

- Multiple assessments of body composition and visceral adipose tissue
- Multiple assessments of your fitness level and physical activity level
- Multiple assessments of dietary patterns and eating behaviours
- Detailed time use profiles
- Accurate measurement of your resting metabolic rate
- Precise recordings of triglycerides, HDL, LDL, and total cholesterol, heart rate and blood pressure

Can I withdraw from the study?

There is no obligation for you to be involved in this study. If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw from the study at any time without prejudice to any current or future involvement in other research studies at The University of Queensland.

Confidentiality:

Your records relating to this study and any other information received will be kept strictly confidential. However agencies authorised by law may inspect the records related to the study. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records.

Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published. For further information please refer to Confidentiality/Privacy Policy PI025 available at www.bellberry.com.au.

Payment/costs:

There is no financial reimbursement for your involvement in this study, however, free parking is provided at the University of Queensland.

Illness or Injury:

If, as a result of being in this study, you become ill or are injured, please immediately contact the principal investigator and your General Practitioner to discuss the appropriate course of action and receive appropriate treatment and care.

Compensation for Injury:

If, as a result of your participation in this study, you become ill or injured, please immediately advise the principal investigator of your condition. In the first instance they will advise you to seek further guidance from your General Practitioner and discuss appropriate referral pathways to other allied health professionals as required.

This study is not sponsored, therefore any questions about compensation must initially be directed to the principal investigator who will advise their insurer of the matter. It is the recommendation of the independent ethics committee responsible for the review of this study that you seek independent legal advice.

Termination of Study:

This research project may be stopped for a variety of reasons. These may include the following: Unacceptable side effects of the intervention, the intervention being shown to be harmful, the intervention being shown to work and does not need further investigation, and any other ethical reason as specified by the Bellberry Human Research Ethics Committee.

Investigators Benefits:

This study is not sponsored. The study researchers are not receiving any remuneration for conducting this study and declare no conflicts of interest.

New Information Arising During the Project:

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information at the earliest possible time. This new information may mean that you can no longer participate in this research. If this occurs, the investigator supervising the research will stop your participation. In all cases, you will be offered all available care to suit your exercise needs.

Results of Project:

When the intervention has finished, a written summary of your individual results will be available in hard copy, upon request. You will also be given the opportunity to ask any questions regarding the results and anything else to do with the study in a de-briefing session. You will also be provided access to the results and/or outcomes of the study once the research study has been completed.

Consent:

The principal investigator will provide you with all information regarding the nature and purpose of the research study, risks/benefits and you will be given the opportunity to discuss these. Participation in this study is entirely voluntary, and you are free to withdraw anytime without prejudice.

If you are satisfied that you understand the requirements and details of the research study, you will be asked to sign a participant consent form prior to the commencement of any testing in the study.

What if I need more information?

If you have any further questions regarding this study, please do not hesitate to contact the principal investigator, Paige Brooker, on 0406 773 998, or email p.brooker@uq.edu.au.

What if I have a complaint or concern?

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007). This Statement has been developed to protect the interests of people who agree to participate in human research studies.

Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

PARTICIPATION IS ENTIRELY VOLUNTARY AND PARTICIPANTS ARE FREE TO WITHDRAW FROM THIS STUDY AT ANY TIME WITHOUT PENALTY.

Thank you for your interest in the study