THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Participant Information Sheet

Research Study Title
The PEER Study: Peer support for the maintenance of high intensity intermittent exercise and health following an exercise training intervention in cancer survivors.

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1.0 Introduction

The following information describes the study and your role as a participant. The information contained in this Information Sheet will also outline the risks and benefits of your involvement as well as your rights and responsibilities as a participant. Please note that your participation is voluntary and 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.

2.0 Purpose of the Study

This randomised controlled trial will examine whether the Cancer Council Queensland's (CCQ) world-renowned peer-support program can improve exercise adherence and the health of cancer survivors beyond the duration of a short-term supervised training program. In turn, it will provide recommendations about the safety, feasibility and efficacy of peer support for long-term exercise adherence following cancer.

More specifically, this research study is being conducted to assess the influence of access to peer support networks on cancer survivors' adherence to high intensity interval training (HIIT) and exercise oncology guidelines for twelve months following a short-duration HIIT program compared to no peer-support. This project also aims to determine whether access to peer support results in better maintenance of exercise-induced improvements in cardiorespiratory fitness, body composition, biomarkers of health and quality of life beyond the supervised HIIT program compared to those without peer support.

3.0 Are you eligible to participate in this study?

Men and women with previously histologically-confirmed colorectal, prostate, breast or skin cancer will be included in this study. Furthermore, you must be: (i) aged 18 years older; (ii) equal to or more than one-month post-treatment for cancer and not anticipating undergoing treatment during the study period; (iii) not currently meeting exercise oncology guidelines* or performing regular HIIT sessions; and (iv) free of any musculoskeletal, neurological, respiratory, metabolic or cardiovascular conditions that may prevent safe completion of the exercise demands of the study. You will be required to obtain physician guidance regarding participation in the program, and will be individually screened via a medical history form and interview with the investigators to determine eligibility.

*Note: We will provide assistance during the initial contact to confirm whether you are eligible. The current aerobic component of the exercise oncology guidelines, the component that we are most concerned with, recommends 150 minutes of moderate intensity aerobic exercise or 75 minutes of vigorous aerobic exercise per week, or an equivalent combination. Moderate intensity exercise equates to 3-4 on a 10-point scale and vigorous intensity exercise equates to 5-6 on a 10-point scale.

4.0 Study Procedures

All participants will exercise three times per week for 4 weeks at The University of Queensland, St Lucia. You will then be randomly assigned to one of two groups: (i) access to peer support, or (ii) no access to peer support (usual care)

for the 12-month maintenance phase. You will complete a battery of tests (see section 4.3) at the beginning of the study (baseline), at the end of the supervised phase (after 4 weeks of exercise training) and at 3, 6 and 12 months following randomisation (see section 5.1).

4.1 Supervised Phase (High Intensity Interval Training Sessions)

During the first 4 weeks of the study an Accredited Exercise Physiologist will supervise all exercise sessions. All exercise sessions will be performed on stationary bicycles. These sessions will require you to exercise at 85-95 % of your individual maximum capacity for 4x4 minute intervals, interspersed by 3-minute periods of recovery at a lower intensity. All exercise sessions will include a 10-minute warm-up and a 3-minute cool-down; totalling 38 minutes of exercise per session (see Figure 1).

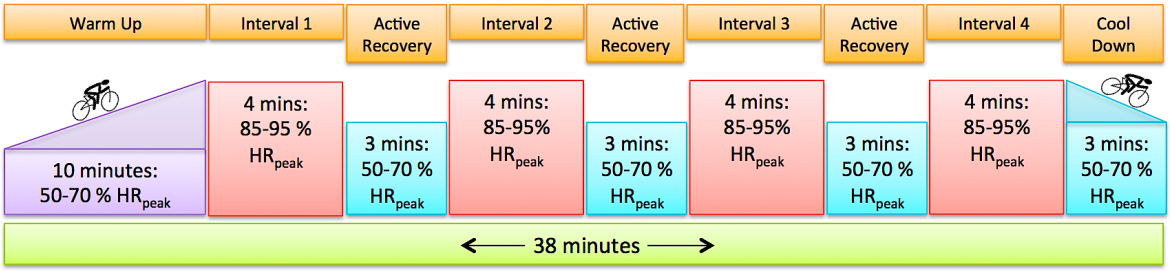

Figure 1: High intensity interval training (HIIT) protocol. HR_{peak}: peak heart rate, as determined by the most recent peak oxygen consumption ($\dot{V}O_{2peak}$) test.

The type of exercise training used in this study has been previously investigated in clinical populations including patients with heart failure, type 2 diabetes and cancer. No adverse events were reported in these trials. Blood pressure, heart rate and perceived exertion will be monitored during exercise testing and training sessions to further ensure the safety of all participants.

4.2 Maintenance Phase

Following completion of the four-week supervised training phase, you will be stratified by age and gender and randomly assigned to either a peer-support group or a non-peer-support group. You are encouraged to complete three HIIT sessions per week or an alternative equivalent to meet the exercise oncology guidelines (i.e. complete 150 min per week of moderate or 75 min per week of vigorous aerobic exercise or an equivalent combination). Participants in both the peer support and non-peer support groups will be provided with free access to CCQ exercise training facilities located in the greater Brisbane area. The CCQ facilities will have a minimum of two cycle ergometers and two heart rate monitors to enable you (and your peer supporter, if you have one) to perform your exercise sessions. Each facility will be fitted with first aid kits, automated external defibrillators, falls monitors, telephones and staff in close proximity to provide ready access should untoward symptoms or an adverse event occur.

4.2.1 Peer Pairing and Support Process

Participants will be partnered with a peer supporter by the study investigators. In the instance that participants or peer supporters feel that they require a new

partner, they will have the opportunity to speak confidentially with the primary investigator and a re-pairing will occur.

Peer supporters will initiate contact with you by means of face-to-face contact, phone call, text message or email – preferred mode of contact will be discussed between you and your supporter when you first meet. Contact will be made 3 times per week, as a reflection of the 3 exercise sessions per week. This will include a minimum of one face-to-face contact at the exercise sessions per week.

The contact from your peer supporter aims to assist you to stay on track with the exercise regime and additional discourse will aim to:

- build self-efficacy
- increase exercise and health knowledge
- increase enablers and motivation for exercise
- decrease barriers to exercise

Additional interaction, outside of the scope of this study is discouraged due to the scientific nature of this research. Furthermore, if you are not satisfied with the contact from your peer supporter, or if they are not meeting the above requirements of contact 3 times per week, you are encouraged to contact the study investigators to discuss this as soon as possible.

4.3 Assessments

Assessments will take approximately 2.5 hours to complete and you will need to be fasted (yet suitably hydrated with water) for 12 hours prior to each session. As previously mentioned, assessments will be performed by an Accredited Exercise Physiologist at baseline, the end of the supervised phase (after 4 weeks of exercise training) and at 3, 6 and 12 months following randomisation. You will also be provided with a familiarisation session prior to baseline testing. This will help you become familiar with the testing procedures and improve the validity of future sessions. The assessments will include the following measures:

4.3.1 Exercise Adherence

- Your adherence to exercise oncology guidelines will be assessed using the Actigraph GT3X+ accelerometer. You will be asked to wear the waist worn monitor for seven days immediately prior to each assessment (baseline, the end of the supervised phase and at 6- and 12-months follow up) to determine time spent per week in light, moderate and vigorous physical activity.
- Adherence to the prescribed high intensity interval training program will be measured throughout the study via attendance records (confirmed via ergometer software) and heart rate monitoring. You will be required to record your attendance and exercise session data performed at the CCQ facilities. Power output and cadence will be continuously measured throughout the sessions and analysed using specialised stationary bike software.

4.3.2 Body Composition

- Height and body weight.
- Waist and hip circumference measurements.

- Muscle and fat mass of the whole body will be measured by dual energy x-ray absorptiometry (DXA), a routine technique for the measurement of body composition. You will lie on a specially designed table for approximately 7 minutes and a scanning arm will move above the table.
- There is no pain or discomfort associated with these measures.

4.3.3 Cardiorespiratory (Aerobic) Fitness

- Aerobic fitness will be measured via a maximal cardiorespiratory fitness test. The test will involve cycling on an exercise bike for 10-15 minutes whilst participants breathe through an apparatus that measures oxygen consumption.

4.3.4 Strength

- Grip strength will be measured with a dynamometer device. Participants will hold the dynamometer in the hand to be tested, with the arm at right angles and the elbow by the side of the body. When ready, participants will squeeze the dynamometer with maximum effort for about 3 seconds. Three trials will be performed on each hand.

4.3.5 Blood Samples: Biomarkers of Cancer Growth

- One blood sample will be drawn for us to assess markers that have been linked to cancer growth and inflammation. All blood will be sampled and analysed at The University of Queensland's School of Human Movement and Nutrition Sciences biochemistry laboratory by a qualified phlebotomist. You will be required to avoid food and drink (except water) for 12 hours before each testing session to ensure validity of this measure.

Destruction of blood and tissue sample

- Samples will be stored in a de-identified state for up to 7 years after the last action/publication of the study. At this time, all samples will be destructed in accordance with the University Sector Retention and Disposal Schedule and

the General Retention and Disposal Schedule for Administrative Records (GRDS).

4.3.6 Questionnaires

- Your health history, general information, quality of life and cancer related fatigue will be assessed by brief questionnaires. Levels of self-reported physical activity will be assessed by the leisure score index from the Godin Leisure-Time Exercise Questionnaire and dietary information will be collected using a 3-day food diary.
- You will also complete brief questionnaire's to assess various psychological domains related to the maintenance of exercise (e.g. self-efficacy and motivation).

5.0 Treatment Schedule

As previously mentioned, you will perform baseline testing before engaging in supervised exercise three times per week for 4 weeks at The University of Queensland, St Lucia. You will perform another assessment in week 5 before being randomised to: (i) access to peer support, or (ii) no access to peer support (usual care). You, the peer supporter, will be matched with one of the group (i) *access to peer support* participants. Additional testing sessions will occur at 3, 6 and 12 months after baseline (see Figure 2).

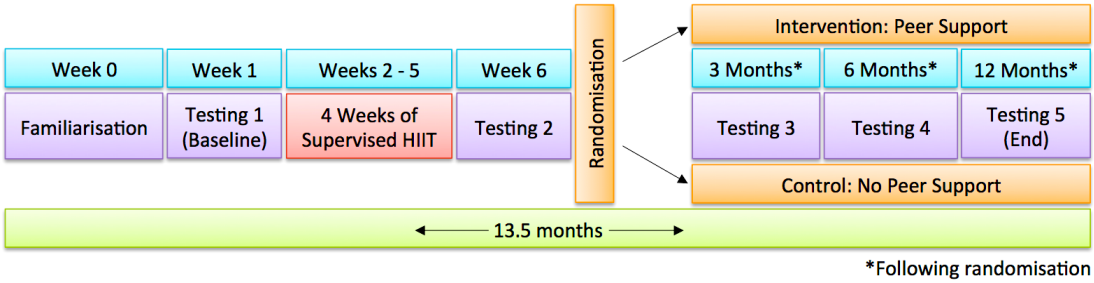

Figure 2: Timeline schematic of The PEER Study.

5.1 Length of Treatment Time Including Length of Each Visit

The time commitment is the same for all participants (regardless of which group you are randomised to).

Time Point	Session Description	Visit Length
Week 0	Familiarisation testing session	2.5 hours
Week 1	Testing session 1 (Baseline)	2.5 hours
Week 2	Exercise training week 1	3 x 1 hour sessions
Week 3	Exercise training week 2	3 x 1 hour sessions
Week 4	Exercise training week 3	3 x 1 hour sessions
Week 5	Exercise training week 4	3 x 1 hour sessions
Week 6	Testing session 2	2.5 hours
3 Months*	Testing session 3	2.5 hours
6 Months*	Testing session 4	2.5 hours

12 Months*	Testing session 5 (End Point)	2.5 hours
Duration: 12 months	**Total number of sessions:** 18	**Total time:** 27 hours

*Following randomisation

Please note that the total time expressed above (27 hours) is only representative of the face-to-face sessions with the investigators in the study. You are strongly encouraged to perform additional unsupervised exercise sessions (e.g. 3 x HIIT sessions per week) for the 12-month period following randomisation.

6.0 Risks and Discomforts

Risks

- *Pregnancy*:
  In the event you become pregnant during the course of the study, you will be withdrawn from the study and advised on the best locations to seek pregnancy-specific exercise prescription.
  Hepatitis B, Hepatitis C and/or HIV:
  As notifiable diseases, participants will be required to alert investigators if they have HPV or HIV prior to commencement of the study. Your General Practitioner will also be asked to note any pertinent information regarding your Hepatitis B, Hepatitis C and/or HIV status on the Medical Doctor Consent Form. This information is pertinent in order for all investigators to be able to maintain health and safety standards.
- Temporary mild discomfort (for example, elevated heart rate and sweating) may arise during exercise testing or training as a result of physical exertion. In addition, delayed onset muscle soreness (DOMS) is a common occurrence after exercise testing/training, especially in untrained or sedentary individuals. Your exercise physiologists will teach you appropriate preventative strategies and symptom management if necessary. You also have the right to withdraw from the study at any point if you feel the exercise is too uncomfortable.
- Warm-ups and cool-downs are an integral strategy to preventing physical distress to the participant and will be incorporated in each testing session to reduce muscle soreness and return the individual to their resting level before leaving the testing facility.
- There is also a very minimal risk of participants sustaining injuries such as acute muscular strains or events such as hypoglycaemic episodes occurring. However these minimal risks will be significantly reduced through the careful supervision and monitoring of participants by Accredited Exercise Physiologists (AEP's) whom are university qualified exercise professionals certified by the governing body Exercise and Sports Science Australia (ESSA).
- Cardiovascular disease or reduced physical fitness can increase the risk of a cardiac event occurring during exercise, such as a heart attack or changes in heart rhythm. However, the supervising AEP's are well trained to recognise any early signs and symptoms of a cardiac event occurring and seek appropriate treatment. Furthermore, the Adult Pre-Exercise Screening Tool will be used to assess your risk of an adverse event during

exercise, and appropriate medical advice (from your treating physician or cardiologist) will be sought if the risk is deemed high. Additionally, your general practitioner will be informed of your request to participate in the study (via the medical doctor consent form) and will be asked to notify us of any individual risk factors that need to be considered.

- *Blood Sample:* There may be some discomfort from having a blood draw undertaken and some bruising may result, however, the blood draw will be performed by a trained phlebotomist following all procedural guidelines.

Psychological discomfort

- *Peer-support protocol*:
  There is a potential for peer-supporters and participants to be mismatched in terms of personality. In turn, potential anxiety, stress or other undesirable distress may present. All participants will be encouraged to notify research staff of any distress so that the appropriate mitigating action can be taken (for example, re-pairing you with a new participant).
- *Questionnaires*:
  The psychosocial questionnaires are not expected to, but may elicit some anxiety or stress. If participants experience any anxiety or distress from completing any of the study surveys or procedures, they are encouraged to immediately notify a member of the research team.

7.0 Ionising Radiation

The use of the DXA for measurement of body composition will subject participants to ionizing radiation; however, the dosage from the DXA scans is approximately 52 μSv, which is less than 0.1% of the daily recommended dose constraint of 5mSv. This compares to 7 μSv for daily background exposure, 80 μSv for a return trans-Pacific flight, 100 μSv for a chest x-ray, and 2000 μSv for a lumbar spine x-ray. DXA is a routine method for bone density and body composition assessment in various age groups. This procedure may be additional to what you would have received if you were not in this study however, the exposure is regarded as extremely low. At this dose level, no harmful effects of radiation have been demonstrated and the risk is negligible.

This research project will adhere to the Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA's) Code of Practice "Exposure of Humans to Ionising Radiation for Research Purposes" (RPS No 8): www.arpansa.gov.au/pubs/rps/rps8.pdf

At the conclusion of the study 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 or find further information, please find details at: http://www.arpansa.gov.au.

8.0 Possible Benefits

Exercise has been shown to reduce various ongoing cancer-related symptoms, lessen enduring side effects of treatment, improve psychological wellness and even reduce recurrence rates. It can also play a particularly important role in preventing and managing chronic diseases which are increasingly recognised as side effects following cancer treatment.

By participating in this study you will also receive:

- Individualised exercise training from an Accredited Exercise Physiologist
- Multiple gold standard assessments of your fitness levels
- Multiple gold standard assessments of body composition and bone density
- Precise recordings of blood pressure and heart rate

9.0 Voluntary Participation/Withdrawal

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 medical treatment.

10.0 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.

Please note that your doctor will be notified of your participation in this study (by way of the Medical Doctor Consent Form) and of any clinically relevant information noted by the Principal Investigator in the conduct of the trial. For further information please refer to Confidentiality/Privacy Policy PI025 available at www.bellberry.com.au for further information.

11.0 Payment/Costs

This study does not provide any monetary reimbursement for participation. However, all study facilities will provide free parking.

12.0 Illness or Injury

If, as a result of being in this study, you become ill or are injured, please seek medical assistance from emergency services (000) or your General Practitioner as appropriate. Please also advise the Principal Investigator of any such occurrences.

13.0 Compensation for Injury

Since you are participating in a non-sponsored study any question 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.

14.0 Termination of the 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 not need further investigation and for any other ethical reason as specified by the Bellberry Human Research Ethics Committee.

15.0 Investigators Benefits

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

16.0 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 information and guidance to suit your exercising needs.

17.0 Results of Project

On completion of the intervention, a written summary of participants' individual results will be made available on request to the individual to whom they belong in hard copy in person or via post. On request, participants will also be provided access to the results and/or outcomes of the study once the research study has been completed. Should participants require any further explanation, or wish to discuss their results further, they will be able to do so by contacting the Principal Investigator.

18.0 Consent

You are required to obtain medical doctor consent prior to being enrolled in this study. A Medical Doctor Consent Form will be provided for you to discuss with your doctor (most likely your general practitioner).

A lead researcher 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. You are free to withdraw at anytime and if you do not participate you will not suffer any prejudice. The consent of a person to participate in this research study is entirely voluntary.

If you are confident that you understand the requirements and details of the research study, you will be asked to sign a participant consent form prior to commencing participation in the study.

19.0 Advice and Information

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.

If you have any further questions regarding this study, please do not hesitate to contact Principal Investigator Kirsten Adlard on 0421 011 511.

Thank you for your interest in this study.