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School of Medicine, University of Wollongong

PARTICIPANT INFORMATION SHEET – ECCENTRIC CYCLING EXERCISE TRAINING

Project Title: "Can cycling backwards against a resistance improve older sedentary adults to move forward? A paradigm of combining aerobic fitness and muscle strength. **"**

A PhD study by Amelia Harrison
Primary supervisor: Dr. Gregory Peoples (UOW)
Co-supervisor: Dr. Herbert Groeller (UOW)
Co-supervisor: Dr. Simon Green (UWS)
Associate supervisor: Mr Marc Brown (UOW)

1 Purpose of the research:

You are invited to participate in a research study led by PhD student Amelia Harrison and a team of academics at the University of Wollongong. This research study is a continuation of previous work (2021/061) investigating the prescription and therapeutic efficacy of backwards resistive cycling, specifically in an older population (≥60 y).

We have designed and built a new type of stationary exercise bike that drives the pedals in the reverse direction (backwards resistive cycling). We are interested in understanding what training adaptations occur to improve markers of health, specifically at the muscle, when this type of cycling is implemented into an aerobic interval training protocol; work intervals interspersed with periods of recovery at lighter intensities. Specifically, the aim of the current study is to determine the degree to which 10 weeks of aerobic interval training that utilises backwards resistive cycling during recovery periods, improves markers of the physiological reserve (cardiorespiratory, musculoskeletal, functional and quality of life) in older adults.

Initial scientific evidence suggests that exercise on this type of bike requires less 'huff and puff' effort effecting your breathing and your heart, but that it promotes at least the same level of strength improvement as conventional (forwards) cycling exercise or weights training. We believe that this type of exercise has the potential to bring significant benefit to a variety of populations, such as older people, and especially those people who find more conventional forms of exercise difficult to perform.

2 PROCEDURES

2.1 Participants

Your participation is entirely voluntary and will not influence your ability to be involved in other research projects. To be eligible to participate you must be:

- 60 y (or older)
- No acute/chronic condition to prevent test/training performance, such as;

    - Any self-reported presence of any chronic disease or disability considered to increase the risk of injury when performing *light* to *moderate* backwards resistive cycling
        - This especially includes diseases which impair muscle strength (e.g., cardiovascular and respiratory diseases), increase joint pain (e.g., arthritis) and impair control of the lower limbs (e.g., stroke, neurological conditions).
- Able to walk independently
- No history of high intensity aerobic/resistance training in previous 6 months
- Normal resting ECG (determined during pre-screening)
- Clearance from a general practitioner for involvement in the study prior to commencement; dependent on screening via risk stratification evaluation from Exercise Physiologist.

If you have no major health or medical problems which preclude you from participating, you will be enrolled in the study.

2.2 Pre-experimental standardisation

You will be required to refrain from strenuous exercise and the consumption of alcohol and tobacco during the 12-hour period prior to each lab visit. We ask that you maintain a hydration level prior to arriving at the laboratory by consuming water at (1 $mL.kg^{-1}$). We also ask that you meet a required carbohydrate intake on the morning of the laboratory visits. This will be equivalent to consuming, 2 standard Weetbix (+ milk), 2 pieces of sliced bread, and 1 glass of juice (250ml). On arrival at the laboratory, you will be provided with supplementary water (5 $mL.kg^{-1}$) to consume before commencing the exercise.

2.3 Laboratory visits

Upon enrolment into the study, you will be randomly assigned by balanced order into one of two groups (Control and Experimental) for ten weeks of training. Groups will differ with respect to the type of cycling (forward, or backwards resistive) performed during the recovery periods of the aerobic interval training protocol, including subsequent workload performed over the training duration. Regardless, all participants will be familiarised to backwards resistive cycling prior to training.

For each exercise session you will be required to give approximately 1 hour of your time. Both groups will undergo 10 weeks of training, separated into three training blocks (Figure 1). During each training block, all participants will complete two exercise sessions per week. Training blocks 1 and 2 will involve 7 training sessions each, and training block 3 will involve 6 training sessions.

All exercise sessions will include a brief warm-up and cool-down, performed at a light intensity and on the upright bike. All work intervals and recovery periods will be performed for 3 minutes each, and progressed from 4 to 6 sets over training blocks 1-3, respectively. Therefore, total exercise time will progress from 34 to 46 minutes over the 10 weeks of training. Immediately after each exercise session, you will be asked some questions about

the task you just performed and any aches and pains you experienced. In addition, on some other days we will ask you to do a brief 'wall-sit' sit test and ask you to rate your muscle soreness. This will take less than 5 minutes and participants will be familiarised to this procedure before any exercise testing occurs.

Testing sessions will be incorporated pre- and post training, with follow-up testing sessions included between all training blocks (after training sessions 6 and 13 respectively; Figure 1). During these testing sessions, resting measures of the physiological reserve (cardiovascular, musculoskeletal and functional capacity) will be assessed, including an assessment of aerobic capacity pre- and post- training.

All work intervals will be performed on the upright bike, whereas all recovery periods will be performed on a recumbent ergometer (*i.e.* a bike that requires the individual to sit on a slight incline with their legs on the horizontal in front of them in order to pedal); with either forward or resistive backwards cycling.

Figure 1: Study design overview

Study phase:	Week(s):	Outcome:

Pre-training	**0**	**Pre-training measures**
		• Pre-screening
		  o Informed consent, screening questionnaires, short phone interview with EP, GP clearance**
		• Lab baseline testing day 1
		  o Familiarisation to resistive backwards cycling
		• Lab baseline testing day 2
		• No training week

Training block 1 and Follow-up testing 1	**1-4**	**Training block 1**
		• Training sessions 1-7
		  o 2 sessions of aerobic interval training per week*
		
		Follow-up testing session 1
		• To be performed following TS 7
		  o Follow up physical assessments performed

Training block 2 and Follow-up testing 2	**5-8**	**Training block 2**
		• Training sessions 8-14
		  o 2 sessions of aerobic interval training per week*
		
		Follow-up testing session 2
		• To be performed following TS 14
		  o Follow up physical assessments performed

Training block 3	**9-11**	**Training block 3** • Training sessions 15-20

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		○ 2 sessions of aerobic interval training per week*
Post-training	**12**	**Post-training measures** • Lab testing day 1 • Lab testing day 2 • No training week

Note: EP; Exercise Physiologist, **Indicates clearance is dependent on risk stratification evaluation from EP. TS; Training Session, * Indicates that the aerobic interval training protocol provided will be determined by the group you are allocated to [*i.e.* aerobic interval training with either forwards or resistive backwards cycling during recovery periods].

3 BURDENS

3.1 Time commitment

This study is all laboratory based, there will be no outside time commitment. It is anticipated that the time commitment will be a total of 30 hours over a 12 week period (pre-screening testing; 2 h/visit, training sessions; 1 h/visit, follow-up testing sessions; 1.5 h/visit, post-exercise testing; 2 h day 1 and 1 h day 2). All training sessions will be a minimum of 2-3 days apart.

3.2 Physiological testing

At various time points throughout the study, physiological testing will occur in the form of various measures, including;

- Heart function (blood pressure, heart rate, electrocardiogram)
- Muscle function (Dual energy x-ray absorptiometry, ultrasound)
- Strength tests (Dynamometer strength test, chair stand test, vertical jump test, and single leg balance test)
- Descriptive characteristics (Actigraphy, body mass, height)
    - Regarding Actigraphy, participants will be required to wear a wrist-worn device on their non-dominant hand pre, during, and for 2 weeks post training.
- Aerobic capacity (Peak aerobic power test)
- Resistive backwards cycling (familiarisation)
- Perception (Quality of Life survey; QOL, nutrition survey, Rating of Perceived Exertion; RPE, Task Load Index; TLX)

Furthermore, the testing frequency for each measure is displayed below;

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Physiological test	Measure	Time point of study				
		Pre-training	Follow up 1	Follow up 2	Post-training	Training blocks
Heart Function	BP resting	✓	✓	✓	✓	✓
	HR resting	✓	✓	✓	✓	✓
	ECG resting	✓	✓	✓	✓	x
Muscle function	DEXA	✓	✓	✓	✓	x
	Ultrasound	✓	✓	✓	✓	x
Strength tests	Dynamometer strength test	✓	✓	✓	✓	x
	Chair stand	✓	✓	✓	✓	x
	Vertical jump	✓	✓	✓	✓	x
	Single leg balance	✓	✓	✓	✓	x
Descriptive characteristics	Actigraphy	✓	✓	✓	✓	x
	Body mass / height	✓	x	x	✓	x
Aerobic capacity	Peak aerobic power test	✓	x	x	✓	x
Resistive backwards cycling	Familiarisation	✓	x	x	x	x
Perception	QOL	✓	x	x	✓	x
	RPE	x	x	x	x	✓
	TLX	x	x	x	x	✓
	Nutrition survey	✓			✓	x

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RISKS

3.3 Resistive backwards cycling

3.3.1 Emergency stop on the recumbent ergometer

During the resistive backwards cycle protocols, the bike pedal cranks will be driven by a motor. If the participant's foot slips off the pedal, the bike has been designed with a large clearance between the cycle seat and the pedal cranks, the participant will not get hit with the rotating cranks. In addition, a safety stop button has been installed on the bike, similar to that on most commercially available treadmills, so that the motor can be disengaged to stop

3.3.2 Muscle soreness

Resistive backwards cycling exercise is commonly associated with muscle soreness for a period of time following exercise. However, this has been found to reduce following repeated exposures to this form of cycling (Penailillo et al., 2015). Therefore, it is anticipated that you may only experience minimal muscle soreness in the lower limbs, if any, for several days following exercise. Furthermore, this muscle soreness should not be dissimilar to that experienced following typical resistance training in a gym setting, and it is recommended that gentle exercise; walking, and stretching, even massage, or application of a heated wheat pack to the site, can reduce these symptoms.

3.3.3 Joint-loading

Additionally, because resistive backwards cycling involves resisting the backwards moving pedals, and thus a load not dissimilar to resistance training in a gym, you will experience some light to moderate joint loading, correlated to the respective exercise intensities you will be prescribed. This loading will be similar to walking down a flight of stairs holding a light-moderately loaded backpack. Furthermore, it is anticipated that any joint loading will be light to moderate in intensity, given that resistive backwards cycling will be performed on a recumbent bike, further minimizing joint loading (*i.e.* body weight will not add significantly to the exercising load).

3.4 Contraindications to exercise

If you become aware of the development of any of the following symptoms, even if you believe that they can be explained by your level of physical activity at the time, or any other mechanism, we highly recommend that you report this to the research team and if after leaving the laboratory, urgently seek medical assistance.

- Chest pain
- Increasing fatigue
- Gastrointestinal symptoms (indigestion, heart burn)
- Excessive breathlessness
- Generalised discomfort for no apparent reason

- Dizziness and palpitation
- Severe headache

Every participant will be screened (using a questionnaire) to eliminate those at greater risk of inappropriate physiological strain; musculoskeletal problems, prior to commencing experimentation: the *Par-Q questionnaire*. In this questionnaire, we will also seek to identify and exclude participants with a medical history that would indicate that you should not participate in this experiment. We will also collect exercise and medical history information.

Experiments will be terminated if any of the following occur:

- The participant wishes to terminate the trial.
- The participant is displaying any signs of discomfort or distress.
- The exercise protocol cannot be successfully achieved.

3.5 Dual dual-energy x-ray absorptiometry (DEXA)

You will receive a DEXA scan at four time points throughout this study (weeks 0, 4, 8, and 12) to assess changes to the muscle as a result of the training stimulus. To perform this scan, you will be exposed to a small amount of radiation in the form of X-rays. This form of radiation is much lower than that received from a standard x-ray, and is equivalent to less than one days ' exposure to natural background radiation (similar to sunlight). The PhD student; Miss Amelia Harrison, has certification from the Australian Society of Medical Imaging and Radiation Therapy in Radiation Safety and Training (Certificate No. IMS3155).

4 FUNDING

There is no financial cost of this project beyond the working hours provided by each member of the research team. All equipment for data collection and lab space is being provided by the supervisors. Equally there is no financial interests with relation to the outcomes of this project for any members of the research team.

5 BENEFITS

As a result of participating in this research the participant will likely benefit by:

- Improving both heart and muscle health and overall well-being, whilst increasing physical activity participation and achieving the minimum physical activity guidelines for this age group.
- Receiving detailed analysis and understanding of their bone health and whole body composition, including percentage of visceral fat deposits and muscle mass.
- Receiving exposure to a new and novel form of exercise that is commercially available but expensive and not yet widely adopted in gym settings, and that may also be preferential to some conventional forms of exercise.

The researchers will not receive any form of payment for conducting this project. It is anticipated that the researchers will publish the results of this study which will contribute to the scientific literature.

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6 DISSEMINATION OF RESULTS

It is anticipated that the results of this research project will be published in an international research journal, presented at a research conference, and form a part of Miss Harrison's PhD thesis. In any publication, presentation, and / or thesis writing of Miss Harrison, information will be provided in such a way that the participant cannot be identified, except with your permission. The data that we will collect from you will be de-identified at the first stage of analysis and this, along with a careful approach to data analysis and presentation, will ensure that your data will remain anonymous in any publications, presentations and / or thesis writing.

7 CONFIDENTIALITY

All data collected will be stored in a locked filing cabinet within the School of Medicine, University of Wollongong (Room 41.307). Results will be published within the scientific literature however you will not be identifiable by your name or initials.

8 PAYMENTS TO PARTICIPANTS

As this study is entirely voluntary, participants will not receive any form of payment for participating in the research project.

9 FREEDOM OF CONSENT

You will be required to provide your written informed consent prior to participating in this study. Before doing so it is highly recommended that you are fully aware of what you will be required to do as a participant. Please ensure that you speak with the research staff to answer any questions you may have. You may withdraw your consent at any time during the study. In order to do this, you should inform a researcher as soon as possible. This can happen via direct conversation with the research team or if you prefer in writing (for example email). Withdrawing from the study will mean that all your data will be deleted from analysis and not carried for any research presentation or publication, should you so choose. We will keep your file for records that you have commenced the study and withdrawn (located as mentioned in 'Confidentially'). The PhD student, Miss Amelia Harrison, will view all data collected up until the withdrawal date, and if requested by the participant, remove hard and electronic files to a new file named 'withdrawn from study – do not included in analysis'. This will not impact on your relationship with the University of Wollongong in any way, nor will it affect any future involvement in research projects with the University of Wollongong.

10 ETHICS AND COMPLAINTS

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Research Ethics Unit on 4221-3386 or rso-ethics@uow.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

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If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.
This study has been approved by the University of Wollongong Human Research Ethics Committee. The Approval number is *[enter approval number once the project has been approved]*.

11 CONTACT INFORMATION

You are free to tell other people about the study and your involvement in it. If any of these people would like to be involved, at the first step they should make contact with PhD student Miss Amelia Harrison, or chief investigator Dr Gregory Peoples (See contact details below). We will meet with each participant who expresses some interest in the study to discuss the research with them and before they decide to participate. If, after this meeting, you require additional information or need to discuss your involvement please make contact with PhD Student Miss Amelia Harrison by email: ajh976@uowmail.edu.au.

Questions concerning the procedures or rationale used in this investigation are welcome at any time. Please ask for clarification of any point which you feel is not explained to your satisfaction.

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12 REFERENCES:

PENAILILLO, L., BLAZEVICH, A. J. & NOSAKA, K. 2015. Muscle fascicle behavior during eccentric cycling and its relation to muscle soreness. *Medicine & Science in Sports & Exercise,* 47**,** 708-717.