APPENDICES

APPENDIX 1

Informed Consent and Subject Information Pack

INFORMED CONSENT

THE EFFECTS OF AGING AND TRAINING ON PULMONARY AND MUSCULAR OXYGEN KINETICS DURING MODERATE-, HEAVY- AND SEVERE-INTENSITY CYCLING EXERCISE

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School of Health and Human Performance
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North Rockhampton, Qld. 4702
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Dear Sir,

The purpose of this study is to examine the effects of training and aging on pulmonary and muscle oxygen uptake during different intensity cycling exercise. The following pages will provide you with information outlining the background of the study, the procedures you will undertake and list any possible risks or side effects associated with the study. The present study is being administrated through The School of Health and Human Performance, Central Queensland University.

Introduction

Gas analysis is a commonly performed measurement in sports and exercise, for both the monitoring of performance and metabolic purposes. The rate at which oxygen consumption changes with respect to work intensity has also been of interest as the quicker the metabolic transition, the improved performance at the start of exercise. Previously it has been unknown how well the changes in pulmonary oxygen consumption relate to changes in the oxygen capacity of the muscle.

The introduction of Near-Infrared spectroscopy (NIRS) has allowed the continual monitoring of muscle oxygenation and regional blood flow using non-invasive techniques, which has allowed the relationship between pulmonary and muscle oxygen consumption to be compared. To date, however, very few investigations have investigated this relationship using these technologies particularly with reference to muscle fibre type, age or training status. The implications for such research may be to help identify any limitations which occur with aging that slow the change in oxygen consumption after changes in work intensity. This has potential implications for aging individuals who struggle to complete daily tasks without suffering metabolic fatigue or athletes who wish to 'turn on' quicker at the start of a race.

Purpose of the Study

The purpose of the proposed research project is to determine:

- The effect of aging and training status on pulmonary and muscle oxygenation kinetics during moderate, heavy and severe intensity exercise.
- The effect of aging and training on the relationship between oxygenation kinetics and muscle characteristics during moderate, heavy and severe intensity exercise.

Significance of the Study

The present study is the first research investigation to describe the effects of aging muscle on its ability to consume oxygen. It is well established that with aging the composition of muscle changes, and that this is can changed further through physical training. In addition, limited research has described both the pulmonary and muscle oxygen kinetics in response to work transitions of various intensities in different populations. Therefore, the findings of the study have both clinical and exercise applications in order to describe what factors help to allow a quick transition on oxygen consumption between work intensities.

Methods

Session #1: Health Screening and Familiarisation (total time = 1 hour)

The initial visit to the Health and Human Performance laboratory will be used to screen you for any medical conditions that may prevent you doing heavy exercise. This will be performed through the answering of questionnaires and discussion with the chief investigator, Ben Dascombe. If you exhibit any medical conditions you will be asked to visit a general practitioner. A detailed explanation and demonstration of the testing techniques will also be given throughout this session. During this visit, the cycle ergometer will also be adjusted to your correct handlebar and seat positions to be used throughout the duration of the study. During this visit your body composition will also be assessed.

Session #2: Ramp Test (total time = 1 hour)

The second visit to the lab will require you to perform a cycling test to exhaustion (lasts around 6-8 min). The purpose of the test is to determine your aerobic fitness and familiarise you with a number of the methods to be used later in the investigation.

During the exercise test, you will have a number of physiological measures being performed including:

1. *Heart Rate*: heart rate will be recorded by a Polar heart rate monitor attached to your chest throughout testing.
2. *Gas Analysis*: gas analysis will be performed using a Medgraphics CPX/D metabolic cart. Gas analysis is performed by analysing expired pulmonary gases which are collected through a mouthpiece and sampled each breath. A noseclip must also be worn throughout the test.
3. *Blood analysis*: the analysis of blood will consist of a collection of a capillary sample from the subject's fingertip. A 100µL capillary blood sample (4-5 drops) will be collected by a trained sports scientist into a capillary tube for storage and analysis both before and after the completion of the test. Blood samples will then be inserted into iSTAT CG_{4+} cartridges which will then be analysed using the iSTAT clinical blood analyser.

4. *Surface EMG*: will also be recorded from the thigh to measure muscle electrical activity. EMG is performed through the placement of two electrodes being placed over the belly of the muscle whilst connected to a computer. The electrode area is to be shaven, and lightly sandpapered to ensure that adequate contact is made.
5. *Near Infrared Spectroscopy (NIRS)*: the testing procedure for NIRS comprises of the application of a device over the belly of the working thigh muscle, where it is firmly secured by a bandage. The device shines light into the muscle, and light detectors measure the light intensity which is reflected back out of the muscle. This device is used to measure the oxygen content of the blood which is located within the working muscle.

Sessions #3-5 (total time = 1 ½ hours)

During these visits, you will perform a number of 6 minute bike rides at moderate, heavy and severe intensities as shown below in Figure 1. Each 6 min test will be preceded and followed by 3 minutes of unloaded cycling. Repeated transitions are required to ensure that the results are accurate. Throughout each exercise bout you will have the following techniques monitoring a number of physiological factors, including:
During the exercise test, you will have a number of physiological measures being performed including:

1. *Heart Rate*: similar to visit 2.
2. *Gas Analysis*: similar to visit 2.
3. *Blood analysis*: A 100µL capillary blood sample (4-5 drops) will be collected at pre-, mid and post transition by a trained sports scientist into a capillary tube for storage and analysis. Blood samples will then be inserted into iSTAT CG_{4+} cartridges which will then be analysed using the iSTAT clinical blood analyser.
4. *Surface EMG*: similar to visit 2.
5. *Near Infrared Spectroscopy (NIRS)*: similar to visit 2.

Session #6

The last visit will take place at the Rockhampton Base Hospital where you will have a resting muscle biopsy on your right thigh. An orthopaedic surgeon, Dr. Eric Hohmann will preform the biopsy procedure. A quantity of local anaesthetic will be used to numb a small area of skin, where the doctor will make a small incision and insert the biopsy needle. During the biopsy procedure you may feel somewhat of a pressure or pulling sensation as a result of the needle insertion, but no pain. Two biopsy samples will be taken for analysis from the same incision during the visit. The wound will then be cleaned and bandaged for the next 48 hours as to minimise infection. You will be given comprehensive post-operative care instructions for management of the incision. The muscle biopsy will cause minimal interference with short-term performance, and will pose no long-term loss of function.

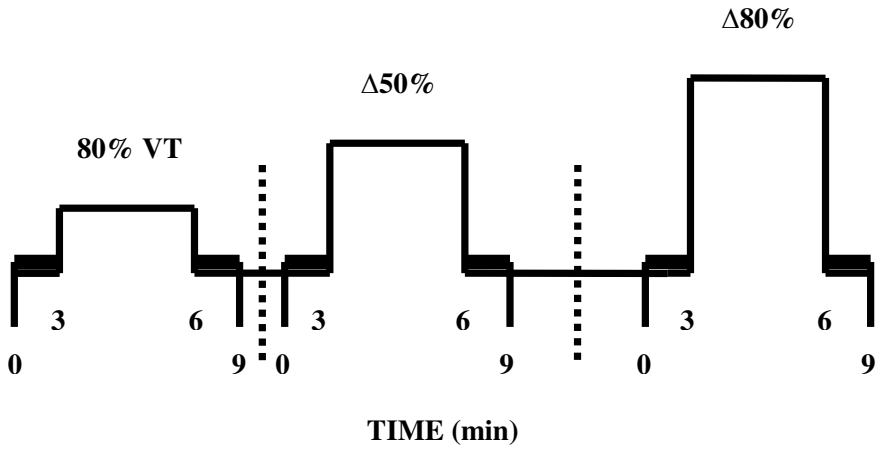

Figure 1: Demonstration of exercise bouts during a square-wave transition visit.

Analysis

A written report will be sent to you detailing and explaining your individual results and their implications. A verbal explanation of the results will also be provided after the completion of testing to inform you as to how the results relate to your training and performance. You will be asked to strictly maintain your normal diet and training load for at least the two days prior to testing. These measures will ensure that you are fresh for the test, and that diet and fatigue do not influence results.

Risks

During testing you will be asked to perform maximal intensity exercise which may cause some discomfort. You will have been pre-screened to ensure that you do not have any existing medical conditions that may indicate that you should not undertake maximal exercise. If health risk factors are found to exist which may affect your health or contra-indicate exercise participation, then you will be referred to a medical doctor to obtain approval to participate or be excluded for the study. Some slight skin irritation may also be encountered due to the skin preparation required for the surface EMG.

Additionally, there are a number of risks associated with the use of cuff ischemia with NIRS. Whilst the likelihood of these risks is minimal it is important to be aware of these complications prior to the commencement of the study. These risks include pulmonary embolus (blockage of blood vessel in lung), skin trauma, metabolic acidosis, tourniquet pain or hypertension, arterial injury or muscle damage, or neurologic disturbance. Whilst this list may seem excessive, these complications rarely occur, and are mostly associated with cuff ischemia lasting greater than 30-60 minutes. This timeframe is

considerably longer than the expected duration of cuff ischemia proposed for the present study (~15 min). The associated risk of these complications is exceptionally low, such as only 1:13 000 people have suffered neurologic disturbance as a result of prolonged cuff ischemia of the leg. However, less serious complications such as tourniquet pain have been reported in up to 66% of patients, but only after 30-60 min of tourniquet application. Therefore, whilst arterial occlusion is associated with a number of potentially dangerous complications, the likelihood of them occurring is low, particularly with the selected use and time frame proposed to be employed in the present study.

As the muscle biopsy is a considerably invasive technique, it carries a number of risks to the subject including haematoma, skin infection, denervation of a small area of the vastus lateralis and 'delayed muscle soreness' (similar to those following unaccustomed intense exercise). The minimal risk of each complication with all required precautions taken detailed below: haematoma 2:1300, skin infection: 1:1300; minor denervation: 1:1300. Note that the instances of haematoma and skin infection were noted after four serial biopsies were taken. The delayed muscle soreness is a typical response which may last up to 48 hours which should have minimal effect on the short-term functional capacity and no long-term side effects. The risk of post-sampling infection from the instruments and post-operative care will be minimised through the taking of samples in a hygienic setting with sterilised instruments. After the biopsy is taken, the incision will be cleaned and closed by a butterfly clip, with a sterile elastic surgical stocking placed on the site for a period of 24 hours to minimise bleeding and bruising. To minimise the soreness of the biopsy, the wound will be treated with an icepack for 10-20 minutes post-sampling to aid the initial healing process. You will be given instructions on how to manage the incision to protect against infection. You will be contacted by phone after 12 and 48 hours after the procedure to check how the biopsy site is healing. After 24 hours, the incision will be inspected and a new bandage applied. The biopsy should have minimal short-term effect on your exercise capacities, and no long-term consequences.

Anonymity

The confidentiality of the results of this study is assured. Under no circumstances will your name appear in publications associated with this research. Your results will be provided to you both in written and verbal form with no one else being given your results unless you request it. Hard copies of your results shall be stored in a locked filing cabinet. The information will be backed up on CD, and this will also be stored in the locked filing cabinet.

THROUGHOUT THE COURSE OF THE RESEARCH, YOU ARE FREE TO WITHDRAW AT ANY TIME FOR WHATEVER REASON WITHOUT QUESTIONS BEING ASKED OR PENALTIES INCURRED

Enquiries

Any enquiries or concerns regarding the nature and/or conduct of the proposed research can be directed to the Central Queensland University's Office of Research at (07) 4923 2607. Alternatively the researchers may be contacted to discuss any concerns or queries at the contact details below:

- Ben Dascombe
  - Phone: (07) 4930 9763
  - Mobile: 0417 712 381
  - Email: b.dascombe@cqu.edu.au

- Dr. Peter Reaburn
  - Phone: (07) 4930 9813
  - Email: p.reaburn@cqu.edu.au

Freedom to Withdraw

I have read the above information. The nature, the demands, risks and benefits of the project have been explained to me. I knowingly assume the risks involved, and understand that I may withdraw my consent and discontinue participation at any time without penalty or loss of benefit to myself. In signing this consent form I am not waiving my legal claims, rights or remedies. A copy of the consent form will be given to me.

NAME: _____

SIGNATURE: _____

DATE: _____

CONTACT DETAILS:

Address: _____

_____

Phone: (H)_____

(W)_____

(Mobile) _____

Email: _____

INVESTIGATORS SIGNATURE: _____

DATE: _____

SPECIAL CONSIDERATIONS:

_____

_____

_____

_____

_____

_____

I also agree to participate in a 30 minute time trial using the same testing techniques as those described above, which include gas analysis, blood collection, near infrared spectroscopy, electromyography and a muscle biopsy. I agree for the data gained from the 30 minute time trial to be used in collaboration with the data collected during my previous visits for publications and a doctoral thesis.

NAME: _____

SIGNATURE: _____

DATE: _____

INVESTIGATORS SIGNATURE: _____

DATE: _____

I also agree that any images of myself collected through the 30 minute time trial can be used for presentation purposes and any publications arising from the research investigation. I will receive no remuneration for such.

_____ _____

Signature Date

APPENDIX 2

Revised Physical Activity Readiness Questionnaire

THE EFFECTS OF TRAINING AND AGING ON PULMONARY AND MUSCULAR OXYGEN KINETICS

PHYSICAL ACTIVITY READINESS QUESTIONNAIRE (PAR-Q)

Name: _____ Date: _____/_____/_____

Date of birth: _____/_____/_____ Sex: M F (Circle one)

Address: _____

Phone (H): _____ (W): _____ (M): _____

Email: _____

1. When was the last time you had a physical examination?

2. Has any member of your family been treated for or suspected to have any of the following conditions? Please identify their relationship to you (eg. Mother, father, etc)
    a. Diabetes YES NO _____
    b. Heart disease/attack YES NO _____
    c. Stroke YES NO _____
    d. High blood pressure YES NO _____
    e. Peripheral Artery Disease YES NO _____

3. Do you Smoke? YES NO

If no, have you quit within the last 6 months? YES NO

4. Do you know your blood fat content? YES NO

Please list:

Cholesterol:	_____	mmol/L
VLDL:	_____	mmol/L
LDL:	_____	mmol/L
HDL:	_____	mmol/L

5. Have you ever been told you have abnormal blood pressure? YES NO

Was it high or low? (please circle)

6. Are you currently taking any medication? If so what are they? (Please list)

7. If you are allergic to any foods, medications or other substances, please list them here.

8. If you have been told that you have any chronic disease or serious illness, please name them here.

9. Have you been hospitalised in the past three (3) years? Please give details.

10. During the past twelve (12) months;	YES	NO
Has a physician prescribed any medication for you?	☐	☐
Has your weight fluctuated more than a few kilograms?	☐	☐
If yes, did you attempt to control this weight change by diet and/or exercise?	☐	☐
Have you experienced faintness, light headiness or blackouts?	☐	☐
Have you experienced unusual heartbeats such as skipped beats or palpitations?	☐	☐
Have you experienced periods in which you heart felt as though it was racing for no apparent reason?	☐	☐

11. At present, do you:	YES	NO
1. Experience shortness or loss of breath when walking?	☐	☐
2. Experience sudden tingling, numbness or loss of feeling in your arms, hands, legs, feet or face?	☐	☐
3. Experience swelling in your feet or ankles?	☐	☐
4. Experience pains or cramps in your legs?	☐	☐
5. Experience any pain or discomfort in your chest?	☐	☐
6. Experience any pressure or heaviness in your chest?	☐	☐
7. Suffer from diabetes?	☐	☐

If yes, how is it controlled (circle)?

Dietary means

Insulin injection

Oral medication

Uncontrolled

12. Have you ever had asthma? YES NO

13. How often would you characterise your stress levels as being high?

1. Occasionally
2. Frequently
3. Constantly

14. Tick the appropriate box indicating whether or not you have previous suffered from any of the following conditions?

	YES	NO
1. Myocardial Infarction	☐	☐
2. Arteriosclerosis	☐	☐
3. Heart Disease	☐	☐
4. Heart Block	☐	☐
5. Coronary Thrombosis	☐	☐
6. Rheumatic Heart Complications	☐	☐
7. Heart Attack	☐	☐
8. Aneurism	☐	☐
9. Coronary Occlusion	☐	☐
10. Angina	☐	☐
11. Heart Failure	☐	☐
12. Heart Murmur	☐	☐
13. Neuromuscular Disorder	☐	☐
14. Peripheral Artery Disease	☐	☐
15. Pulmonary Embolism	☐	☐
16. Deep Vein Thrombosis	☐	☐
17. Compartment Syndrome	☐	☐
18. Oedema	☐	☐

SCREENING CHECKLIST:

- ☐ Apparently healthy individual
- ☐ Medical examination required
- ☐ Submaximal $\dot{V}O_2$ test required
- ☐ Diagnostic testing required
- ☐ Inadequate information given
- ☐ Exclusion from study
- ☐ Special conditions for inclusion:

Participant: _____ Date: _____/_____/_____

Exercise Physiologist: _____ Date: _____/_____/_____

Exercise recommendations/considerations

APPENDIX 3

Institutional Ethics Approval

MEMORANDUM

From the Office of Research

Secretary, Human Research Ethics Committee

Ph: 07 4923 2603

Fax: 07 4923 2600

Email: n.turner@cqu.edu.au

19 August 2004

Mr Ben Dascombe
Faculty of Arts, Health and Science
Building 77, Central Queensland University
ROCKHAMPTON QLD 4702

Dear Mr Dascombe,

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL FOR PROJECT
H04/07-83, *THE EFFECTS OF AGING AND TRAINING ON PULMONARY AND MUSCULAR OXYGEN KINETICS DURING MODERATE, HEAVY AND SEVERE INTENSITY CYCLING EXERCISE.*

The Human Research Ethics Committee is an approved institutional ethics committee constituted in accord with guidelines formulated by the National Health and Medical Research Council (NHMRC) and governed by policies and procedures consistent with principles as contained in publications such as the joint Australian Vice-Chancellors' Committee and NHMRC *Statement and Guidelines on Research Practice.*

At its meeting on 10 August 2004, the Human Research Ethics Committee of the Central Queensland University granted ethics approval for the research activity, *The effects of aging and training on pulmonary and muscular oxygen kinetics during moderate, heavy and severe intensity cycling exercise.*(Project Number H04/07-83).

The period of ethics approval is 16 August 2004 to 20 November 2004.

The approval number is H04/07-83.

The conditions of approval for this research project are that you:

(a) liaise with Dr Joyner or Mr Fenlon regarding the resubmission of the procedure for the control group (45-60 years); and amend the hypertension figure to Stage 1, 160/100;

(b) amend the procedure for the biopsies to be performed by a medical practitioner in a medical facility;

(c) amend section 4.1 to provide counselling support to participants and include the details on the Information Sheet;

(d) conduct the research project strictly in accordance with the proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee;

(e) report immediately anything which may warrant review of ethics approval of the project, including:
   (i) serious or unexpected adverse effects on participants;
   (ii) proposed changes in the protocol;
   (iii) unforeseen events that might affect continued ethical acceptability of the project;

   (A written report of any adverse occurrence or unforeseen event that might affect the continued ethical acceptability of the research project must be submitted to the Chair of the Human Research Ethics Committee by no later than the next working day after recognition of an adverse occurrence/event.)

(f) provide the Human Research Ethics Committee with a written "Final Report" by no later than 31 December 2004;

(g) if the research project is discontinued, advise the Committee in writing within 5 working days of the discontinuation;

(h) comply with each and all of the above conditions of approval and any additional conditions or any modification of conditions which may be made subsequently by the Human Research Ethics Committee.

Please forward relevant information (via email or memo) and relevant documentation to the Human Research Ethics Committee Secretary within 30 working days from the date of this advice. Please note that failure to comply with the conditions of approval and the *National Statement on Ethical Conduct in Research Involving Humans* may result in withdrawal of approval for the project.

A copy of the reporting pro formas may be obtained from the Human Research Ethics Committee Secretary, Nicole Turner please contact at the telephone or email given on the first page.

You are required to advise the Secretary in writing within 5 working days if this project does not proceed for any reason. In the event that you require an extension of ethics approval for this project, please make written application in advance of the end-date of this approval. The research cannot continue beyond the end date of approval unless the Committee has granted an extension of ethics approval. Extensions of approval cannot be granted retrospectively. Should you need an extension but not apply for this before the end-date of the approval then a full new application for approval must be submitted to the Secretary for the Committee to consider.

If you have any queries in relation to this approval or if you need any further information please contact the Secretary, Nicole Turner or myself.

Yours sincerely,

Associate Professor Ken Purnell
Chair, Human Research Ethics Committee

APPENDIX 4

Cuff Ischemia and Muscle Biopsy Pain Scale Results

MUSCLE BIOPSY PAIN AND FOLLOW-UP DATA

Subject Number	Date	Pain Rating (/10)	12 hr Follow Up	24 hr Follow Up	48 hr Follow Up	TIME BEFORE RESUMING ACTIVITY
BDMA01	**10/05/2004**	4	Severe cork	Major Cork	No problems	36
BDMA02	**19/10/2004**	1	Tender with limp - major cork	Mild soreness	No problems	48
BDMA03	**10/05/2004**	3	Tender with limp - major cork	Mild soreness	No problems	48
BDMA04	**10/12/2004**	1	Tender with limp - major cork	Tender with limp - major cork	Minor cork	3
BDMA05	**10/12/2004**	5	Severe cork	No problems	No problems	48
BDMA06	**10/11/2004**	3	Tender with limp - major cork	Minor cork	No problems	72
BDMA07	**19/10/2004**	1	Slight cork	No problems	No problems	36
	MEAN	**2.6**				
BDYT01	**27/09/04**	3	Throbbing pain	Slight cork	No problems	32
BDYT02	**28/09/04**	2	Slight cork	No problems	No problems	24
BDYT03	**10/04/2004**	3	Major Cork	Minor cork	No problems	48
BDYT04	**18/10/2004**	3	Major Cork	Slight Cork	No problems	24
BDYT05	**28/09/04**	3	Slight cork	No problems	No problems	48
BDYT06	**10/04/2004**	1	Minor ache	No problems	No problems	48
BDYT07	**16/11/2004**	5	Minor ache	Minor cork	No problems	32
	MEAN	**2.9**				

CUFF ISCHEMIA PAIN DATA

Subject Number	RAMP	SWT1	SWT2	SWT3
BDMA01	5	5	5	3
BDMA02	6	7	4	3
BDMA03	5	4	4	4
BDMA04	6	2	2	2
BDMA05	5	2	3	3
BDMA06	5	5	4	4
BDMA07	3	3	2	2
MA AVERAGE	**5.0**	**4.0**	**3.4**	**3.0**
BDYT01	4	5	4	3
BDYT02	4	5	5	4
BDYT03	3	3	2	3
BDYT04	4	2	2	2
BDYT05	7	4	5	5
BDYT06	6	7	6	5
BDYT07	8	8	8	9
YT AVERAGE	**5.1**	**4.9**	**4.6**	**4.4**
TOTAL AVERAGE	**5.1**	**4.4**	**4.0**	**3.7**

0	Pain Free
1	Very minor annoyance - occasional minor twinges.
2	Minor annoyance - occasional strong twinges.
3	Annoying enough to be distracting.
4	Can be ignored if you are really involved in your work, but still distracting.
5	Can't be ignored for more than 30 minutes.
6	Can't be ignored for any length of time, but you can still go to work and participate in social activities.
7	Makes it difficult to concentrate, interferes with sleep You can still function with effort.
8	Physical activity severely limited. You can read and converse with effort. Nausea and dizziness set in as factors of pain.
9	Unable to speak. Crying out or moaning uncontrollably - near delirium.
10	Unconscious. Pain makes you pass out.