INFORMATION and CONSENT to PARTICIPATE in RESEARCH

The Effects of Functional Overreaching on Cardiovascular and Autonomic Nervous System Function in Endurance Athletes

Investigators

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Introduction

You are being asked to participate in a research study conducted in the Department of Human Health and Nutritional Sciences at the University of Guelph.

In an effort to see improvements in performance, endurance athletes often train to a state of fatigue, commonly termed 'Functional Overreaching', in which performance is temporarily decreased. Following a week of recovery, athletes often see an increase in performance, termed 'Supercompensation'.

While Functional Overreaching is a fairly normal part of the overload-recovery cycle, the effects on cardiovascular and nervous system functioning during this period of fatigue are not fully understood. The aim of this research is to investigate how Functional Overreaching affects arterial compliance, which is a marker of cardiovascular health. Furthermore, as autonomic nervous system activity may affect cardiovascular function, we will be looking at various measures of parasympathetic and sympathetic nervous system activity including using heart rate variability, cardiac vagal tone, and muscle sympathetic nerve activity, in order to further investigate this phenomenon.

This study is a 3-week overload training study on cyclists, triathletes, or endurance athletes who cycle regularly. There will be **two groups**: a **control group** who

perform their training as usual, and the **overload group** who will have an additional 3 hard bike workouts per week on top of their regular training. Both groups will be required to have recovery weeks before and after the 3 week block, and come in to the Human Health and Performance Lab for testing three times. We are looking for recreational endurance athletes, who are currently training, to participate in this study.

This research is funded by an NSERC Discovery Grant through Dr. Jamie Burr.

Inclusion Criteria

- Recreational endurance athlete currently training for cycling, triathlon or an endurance athlete in a different sport who cycles frequently
- Ages 18-45yr
- Healthy, with no known diseases or active use of medications known to influence cardiovascular function
- Willingness and Motivation to do a 3-week overload training protocol, and track your training daily for 5 weeks

Procedure

This study will take approximately 5 weeks from start to finish. Testing and some training will take place in the Animal Nutrition (ANNU) building 314 and 383, and other workouts and training logs will be expected to occur at home.

Introductory visit (approximately 30-45 minutes): Prior to beginning the study you will be asked to thoroughly read and sign this consent form. You will also be asked to fill out a general health questionnaire to ensure your health status and eligibility to participate. In the introductory visit, we will lend you a heart rate monitor if you do not have your own, in order to track your daily training. We will also set you up with a personal Polar Flow account, so that you can track your daily training, and upload your heart rate data (10 minutes/day). We will then ask you all about your current training, so that we can plan out your next few weeks accordingly (and in accordance with your coach's wishes if you have a coach). We will then determine an optimal start date for the training block. Females will aim to start the 3-week overload or controlled training during day 17-21 of their menstrual cycle. Once a start date is determined, we will ask you to go on a week of training that is **reduced in volume by 50%** (which Alexandra Coates will help you to plan out). This will ensure you begin the training block fully recovered.

Session 2 Baseline Testing: (approximately 90 minutes)

This testing will take place both in Jamie Burr's Exercise Lab (ANNU 383) and Philip Millar's Cardiovascular Physiology Lab (ANNU 314). Before testing, we will ask that you refrain from any drugs or alcohol for 12 hours, or intense exercise or caffeine for 24 hours prior.

Order of Tests:

- **Height/Weight/Resting Blood Pressure**
- **Pulse Wave Velocity and Heart Rate Variability**
- **Muscle Sympathetic Nerve Activity and Cardiac Vagal Tone**
- **Profile of Mood States-2 Questionnaire**
- **Food Log from the night prior and that morning**
- **VO_2 peak test on the Velotron bike with Impedance Cardiography**
- **Blood Lactate**

Resting Blood Pressure: Using an automated blood pressure cuff while seated.

Pulse Wave Velocity, Heart Rate Variability and Cardiac Vagal Tone: Pulse wave velocity requires you to wear loose fitting shorts, and either a sports bra (for females), or loose shirt/no shirt for males. You will be lying down, and have a 3 electrode ECG on the torso. A tonometer (pen-like structure) will be placed against two sites to get a reading. The sites are at your neck (carotid pulse), and inner thigh (femoral pulse). Heart rate variability will be analyzed later via the ECG treading. Lastly, while you are lying down and resting for MSNA (see below), we will take a cardiac vagal tone reading with little device called a Neurozoid. This is done similarly to HRV, and simply requires you to be laying down, and perform another ECG reading while the Neurozoid takes a reading.

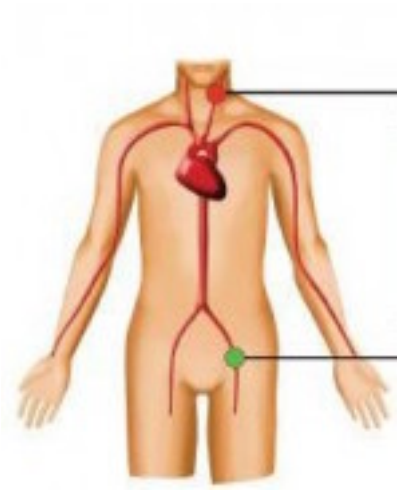


Figure 1. Sites for Pulse Wave Velocity

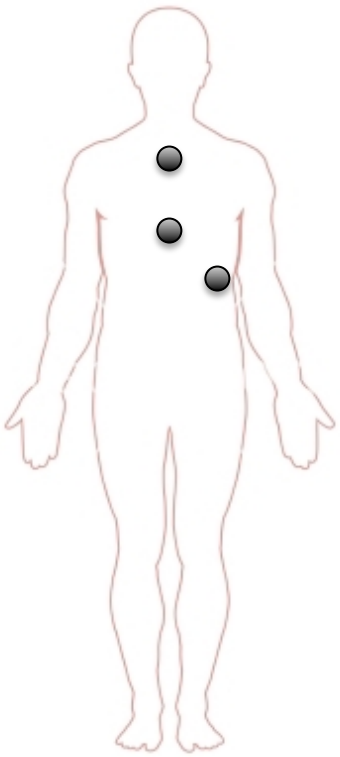


Figure 2. Electrode placement for ECG for Heart Rate Variability

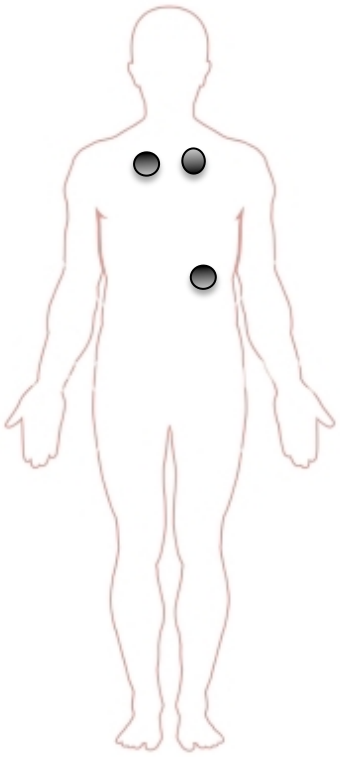


Figure 3. Electrode placement for Neurozoid

Muscle Sympathetic Nerve Activity: To locate the fibular nerve, we will palpate the surface of the outside part of the knee. We will next touch a small stimulating pen to your leg and look for a muscle twitch. This will be a strange feeling as your leg will twitch on its own, but it is not painful. We will mark with a pen the position of the nerve on your leg. Once the nerve is located, we will then proceed to place the microelectrode into the nerve. Proper placement in the nerve will be determined by listening for specific sounds while we move the microelectrode. Placement may take up to 60 minutes.

Profile of Mood States 2- Questionnaire and Food Log: This is a simple questionnaire that assesses your current mood state, and should take about 10 minutes. This will be performed after the other tests. The food log will just require you to write down what you ate the night before and the morning of testing. This is so we can give you a copy and try to standardize your meals on the other two testing days. **You may want to eat a small snack at this time**. Following this paper work, you may desire to take a short 10-15 minute break.

VO_2 peak test: You will be asked to ride a cycle ergometer to determine your maximal oxygen uptake (VO_2max). This test will take approximately 10-14 minutes. The exercise will be progressive, consisting of stepwise increases in resistance (typically between 25-50 watts) that occur every 2-4 minutes. The test is concluded when your oxygen consumption plateaus despite increases in intensity or you have reached volitional exhaustion (i.e. you feel you cannot continue). During the test you will be wearing a nose plug to ensure you will breathe through a mouthpiece. You will breathe in normal room air but when you exhale air our equipment will determine the volume of air and the concentrations of oxygen and carbon dioxide. This will permit us to determine how much oxygen your body is using to complete the exercise task.

Impedance Cardiography (ICG): ICG will take place during the **VO_2** peak test. ICG is a non-invasive technique that measures total electrical conductivity of the thorax and its changes in time to determine parameters, such as Stroke Volume, Heart Rate, Cardiac Output. Surface electrodes placed at the base of the neck, at the level of the diaphragm, and on the left ribcage, are used to detect the impedance changes of blood flowing through the thorax. The impedance signal will be unnoticeable to you and functions in the same way that an off-the-shelf bathroom scale capable of measuring body fat does. The electrodes placed on the body look feel and act like the ECG electrodes commonly used in a doctor's office or for monitoring heart activity during exercise (such as during a stress test).

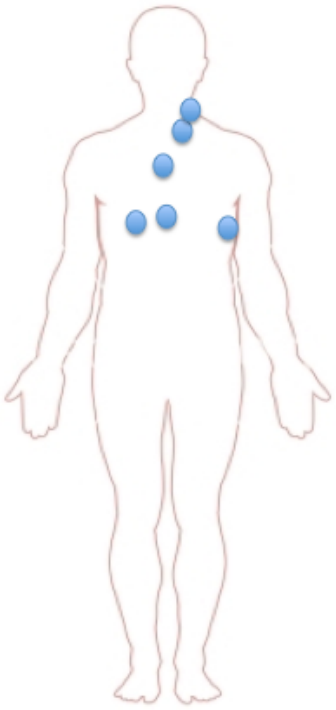


Figure 3. electrode placement for Impedance Cardiography

Blood Lactate: Following the maximal cycling test, we will use a small finger prick to get a drop or two of blood in order to get a **maximal blood lactate reading**. Lactate will be read every 90 seconds until a peak is reached, however, it likely will not require more than one finger prick.

Session 3 Training Protocol: You will be randomized into either the control group or the overload protocol following the VO_2peak test (in order to fitness-match the groups).

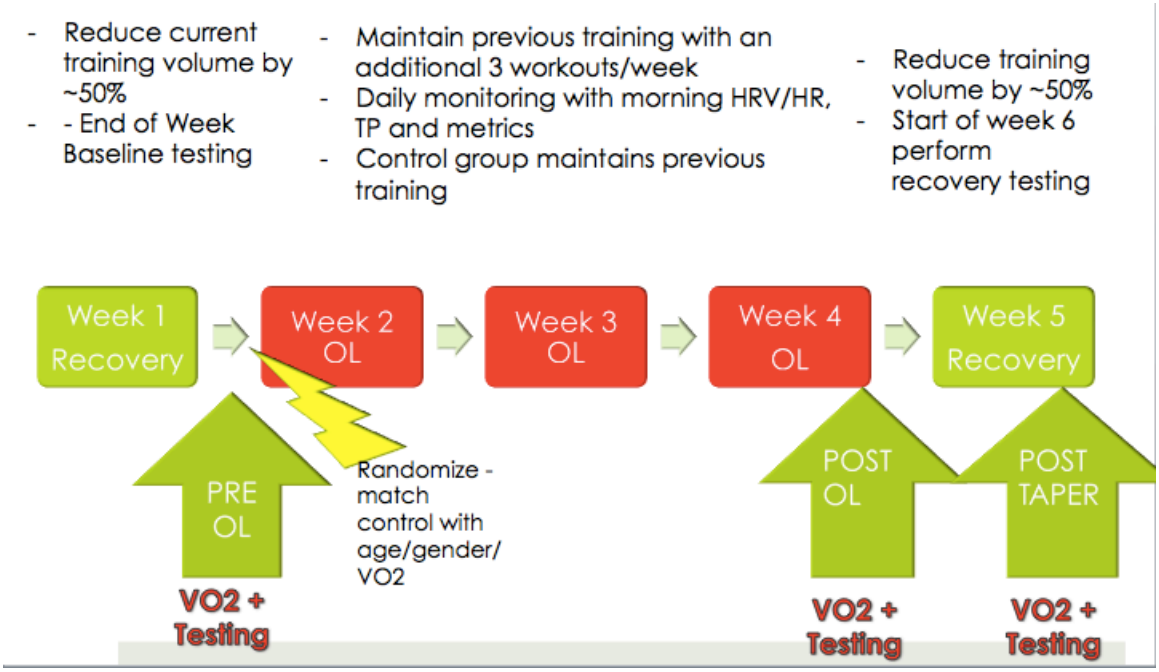
Control Group: You will be asked to maintain your previous training for 3 weeks. You will also performs the POMS-2 questionnaire online once per week, and uploads training with heart rate data into your Polar Flow account daily.

Overload Group: You will be asked to maintain your previous training for 3 weeks. You will also performs the POMS-2 questionnaire online once per week, and uploads training with heart rate data into your training peaks account daily. In addition to this, you will be asked to do 3 additional bike workouts per week, 2 of which take place in the lab on the Velotron. The first is a high-intensity workout consisting of 4x30second Wingate tests (supramaximal effort) with 4 minutes recovery. This session will be 20 minutes of biking, and may take up to an hour of your time in the lab. The second is a 15km time trial on the Velotron. This should take under 30 minutes, with up to an hour of your time spent in the lab. The third is a two hour steady ride on your own time (or option to come in to the lab).

Session 4 Post-testing: At the end of the three weeks of overload or control training, you will come in to the lab and repeat the procedures for baseline testing.

Session 5 Post-recovery testing: You will then take a week of reduced training (50% normal volume), and come in one more time for post-recovery testing (following the same procedures as baseline testing, however MSNA will not occur as it may only be performed once per month).

Timeline of Events



<u>Potential Benefits</u>

Participants who are part of the overload group may potentially see increases in their performance following a week of recovery. Participants in the control group may also have increases in fitness simply from participating in the VO_2peak exercise tests and following through with their regular training plan. All participants will receive exercise test data that may help them to customize their training, including heart rate zones and maximal blood lactate information. Participants may also learn more about their individual autonomic nervous system responses to training and recovery.

This research will help to researchers and coaches understand how the human body functions during periods of intense training, and what is causing the decreases in performance that we see during functional overreaching. There is no easy way to identify athletes who are in a state of functional overreaching, and therefore this research has the potential to fill in that gap. Furthermore, research hasn't looked into

the particular mechanisms we are looking at, including arterial stiffness and muscle sympathetic nerve activity. This research may help personal trainers and coaches to better prescribe training in terms in order to prevent potentially unnecessary decrements to health and maximize performance. Furthermore, this research will help us to better understand states of fatigue, which may be caused by other stressors affecting the autonomic nervous system.

Data

You may also request to receive a form of aggregate results of the study. Every effort will be made to ensure confidentiality of personal information that is obtained in connection with this study. Confidentiality will be secured by the use of participant ID Codes on all correspondence. Data will be kept on a password-protected computer and all written material secured indefinitely in a locked cabinet on site.

Data will be retained for 5 years for possible use for future analysis for the lab group in the case the project may be expanded upon (i.e. the student investigator may pursue a 4 year PhD expanding on this project). All data will be stored electronically in databases with access only granted to investigators involved in the use of the data: Alexandra Coates, Dr. Jamie Burr, and Dr. Philip Millar. All personal identifiers will be destroyed following the participants study completion. Jamie Burr, PhD, Assistant Professor will be in charge of data stewardship.

Potential Risks and Discomforts

There are always some risks to exercise, however they are usually benign and may include feeling tired and short of breath for a period of time. Functional Overreaching is a state of fatigue in which there is a decrease in mood states due to fatigue, and you will feel quite tired with likely increased muscle soreness, and decreased ability to perform during maximal exercise. This state occurs regularly in elite athletes, and is not usually worrisome. In the literature, following and a period of recovery, there is often super compensation and fitness actually increases.

Signs and Symptoms of Non-Functional Overreaching or Overtraining Syndrome will be assessed as well, and should you appear to be excessively fatigued, we will stop the training protocol, and complete the final testing early. While there is currently no easy way to distinguish between functional overreaching and non-functional overreaching, signs and symptoms of non-functional overreaching will include severe depression or loss of motivation, abnormal muscle/joint pain independent from the normal soreness from training, and hormonal disturbances. **Please inform the researcher should you feel any of these symptoms**. If you feel like the training is too hard, we encourage you to first talk to us before deciding to quit. In this situation we will end the training

program early, but possibly still get post-training data. You are also always free to withdraw from the study at any time.

The VO_2 peak exercise test and training visits may cause discomfort as a result of fatigue. This may also result in leg muscle soreness and/or soreness in the legs for one to two days after. These feelings are completely normal and should not harm you. These tests can also be associated with shortness of breath or breathing difficulty and light-headedness due to the requirement to breathe through your mouth using a special tube. Exercise is associated with an increase in breathing rate and perspiration (sweating). Any lasting discomfort should be reported immediately to the researchers.

Microneurography is used in research to directly measure nerve activity. The sterilized microelectrode will be inserted into one your fibular (peroneal) nerve on the outside part of your knee. The microelectrode is very tiny in diameter and will very rarely draw blood upon insertion. During the placement of the electrode, there may be tingling sensations in parts of the leg. This is normal and will subside once we stop moving the electrode. In order to find the best recording site, we will move the electrode to different sites in the nerve. This movement may cause mechanical microdamage to the nerve and surrounding tissue. The damage is minor and nerves in the periphery are able to repair themselves. There are no reported cases of permanent nerve injury as a result of microneurography. In addition, the principle investigator, Dr. Philip Millar, has 4 years' experience (in over 200 people) with this procedure with no complications. Dr. Philip Millar will be extensively training and supervising student investigator, Anthony Incognito, in this procedure to ensure that it is conducted in a safe and effective manner. To minimize risk, we will limit the time of search for the nerve fibre (electrode manipulation) to 1 hour. If the nerve is not found by this time then the experiment will be end and we will invite you back to complete the experiment at a later date. To further reduce risk, we do not record from the same nerve more than once a month.

Pulse Wave Velocity is a non-invasive method of assessing arterial stiffness, and will not be painful or risky in any way. However, you could feel some discomfort, as the femoral site is where the thigh creases at the pelvis, which may be a sensitive area for some participants. In order to reduce un-comfortable sensations, we recommend you wear loose fitting short which you can roll up to access the femoral artery (maintaining full clothing coverage of your groin) and we can arrange for a same-gender tester, if you would prefer. As pulse wave velocity is the gold standard method for testing central arterial stiffness and is a main outcome of our study, we cannot use an alternative method.

Electrodes used for heart rate variability, pulse wave velocity, for the Neurozoid, and for impedance cardiography may irritate the skin or has the potential to elicit allergic reactions on some individuals. Some individuals may be required, or may prefer, to shave their chest in order for the electrodes to stick. This will also aid in electrode removal.

For lactate testing, the finger prick may be uncomfortable. The skin will be broken so there is a possibility of infection afterwards, however the area will always be sterilized, and a band-aid will be given, and this risk will be very unlikely.

Participation and Withdrawal

You may choose whether to be involved with this study or not. As Alexandra Coates, the student investigator, is a coach for a local triathlon club (Loaring Personal Coaching), there is absolutely no obligation to participate if you are coached by her, and it will not affect the coach-athlete relationship in any way. If you volunteer, you may **withdraw at any time without consequence.** You may exercise the option of removing your data from the study up until the completion of data collection. At this point in time the master list will be destroyed, and we will be unable to separate your data from that of the other participants. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise that warrant doing so. Daily training will be logged through the Polar Flow website. Confidentiality cannot be guaranteed for the training and any identifying information that the participant chooses to include on this website, as it is over the Internet. If you are a coached athlete, please be advised that we will not be directly talking to coaches, but will only be working directly with the athlete. You may choose to share any/all information with your coach, but we will not alter the training/testing based on your coach's feedback.

The researchers wish to be inclusive in their recruitment process. This project requires:

- Daily logging of training
- Anticipated feelings of fatigue, and changes in mood
- The use of fine needle-electrodes (similar to acupuncture needles), and finger pricks
- Removal of articles of clothing
- Testing being performed by both male and female testers, although you may request same-gender investigators if desired.

If for any reason you may feel uncomfortable taking part, please contact the researcher to discuss these requirements and possible modifications to the procedure to address your concerns. If you feel like you are becoming too tired/over trained during the protocol, there is the possibility that you have reached Functional Overreaching faster than anticipated, and we can end the training protocol early. If you wish to have only male or only female testers, you may speak to the investigators.

Payment for Participation

All participants will receive a Human Health and Performance Lab T-shirt following

baseline testing Participants will be reimbursed for parking costs if required, however, this will not include any parking tickets incurred. We will keep a log of any parking payments, and at the completion of the study we will pay you. You will be required to sign a form indicating you have received the payments. Participants who have been randomized into the OL group will have the opportunity to compete for three $100 gift cards per sex to Speed River Bicycle Shop. This will be given to the best power/kg of body weight on the Wingates workout in week 1, and best improvement in time trials from week 1-2 and 2-3. It is anticipated that there will be 7 participants per group, so you will be competing against approximately 7 other athletes for these prizes on three occasions.

Rights of Research Participants

This project has been reviewed by the University of Guelph Research Ethics Board for compliance with federal guidelines for research involving human participants. If you have any questions regarding your rights and welfare as a research participant in this study (REB **#16MY023),** please contact: Director, Research Ethics; University of Guelph: reb@uoguelph.ca: 519-824-4120 ext. 56606. You do not waive any legal rights by agreeing to take part in this study.

SIGNATURE of RESEARCH PARTICIPANT

I have read the information provided for the study "**The Effects of Functional Overreaching on Cardiovascular and Autonomic Nervous System Function in Endurance Athletes** " as described herein. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____ Name of Participant (please print)

_____ _____

Signature of Participant Date

SIGNATURE OF WITNESS

_____

Name of Witness (please print)

_____ _____

Signature of Witness Date