# Informed Consent to Participate in a Research Study

**Study Title:** Upper- and lower-body resistance exercise with and without blood flow restriction on pulse wave reflection and autonomic function

**Principal Investigator:** J. Derek Kingsley, PhD, Yu Lun Tai, M.S., Erica Marshall, M.S.

You are being invited to participate in a research study. This consent form will provide you with information on the research project, what you will need to do, and the associated risks and benefits of the research. Your participation is voluntary. Please read this form carefully. It is important that you ask questions and fully understand the research in order to make an informed decision. You will receive a copy of this document to take with you.

## Purpose

The purpose of this study is to compare the effects of upper- and lower-body resistance exercise with and without blood flow restriction on heart rate, blood pressure, and forearm blood flow using weight machines, specifically the chest press, latissimus dorsi pulldown, knee extension, and knee flexion. These results may be used to better understand how to prescribe exercise, and to understand the acute responses that resistance exercise with blood flow restriction has on the heart rate, blood pressure, and forearm blood flow. For this particular study, we are recruiting 30 healthy, college-aged (15 in upper-body resistance exercise group, 15 in lower-body resistance exercise group) between 18-30 years of age.

## Procedures

If you decide to take part in this study, you will be asked to come to the Applied Exercise Physiology Laboratory at the Kent State University campus (MACC Annex 167) 5 times. First time will be an orientation, and the other 4 days will be for data collection. Exclusion criteria include a smoking history (< 6 months), obesity (defined as a body mass index $\geq$ 30 kg/m$^2$), skeletal or orthopedic injuries, cancer, metabolic disease, known cardiovascular disease open wounds, history of blood clots, uncontrolled hypertension (resting brachial blood pressure $\geq$ 140/90 mmHg), pregnancy, planning to be pregnant, or vascular function as assessed via Physical Activity Readiness Questionnaire (PAR-Q) and Health Participant Questionnaire. Also, participants will be excluded if their circumferences of limbs above 70.8 cm due to the limited size of cuffs.

*Orientation.* During the orientation, you will read and sign the informed consent form (provided you wish to participate), and fill out PAR-Q and Health Participant Questionnaire that will ask about your health history. The investigator will sit down and thoroughly explain each testing day and the methods utilized on those test days. The investigator will encourage questions during this time. This should take 15 minutes.

*Test days.* There are 4 days of testing. On your first day of testing at the Kent State Applied Exercise Physiology Laboratory, you will have your height, weight, body composition (7-site skinfold), arterial occlusion pressure which is a pressure needed to block blood flow (Doppler device (ultrasound) on the arm or leg and a nylon cuff at the upper end of right arm or right leg then we will inflate the cuff to 50 mmHg. From there we will increase the pressure by 1 mmHg per second until the doppler device cannot detect blood flow), and maximal strength on the chest press and latissimus dorsi pulldown or knee extension and knee flexion assessed. A pregnancy test will be given to all women participants prior to any testing using the bathroom attached to the Applied Exercise Physiology Laboratory. This test day will take 30 minutes. Forty-eight hours later on day 2 will be verification of your arterial occlusion pressure and maximal strength. The final arterial occlusion pressure used for testing will be averaged between two days. An Ankle-brachial Pressure Index, in which we assess the blood pressure in the ankle and the brachial (upper arm) arteries, will be performed to make sure you are not at risk for a blood clot. This test day should take 15 minutes. Days 3 and 4 will be separated by 4-7 days. It will measure the function of your heart and your arteries after an acute bout of upper- or lower-body resistance exercise with or without blood flow restriction. Each test day will take 100 minutes. Total time for testing is then 4 hours and 20 minutes scattered over 2-3 weeks.

- Maximal Strength. Maximal strength of chest press and latissimus dorsi pulldown or knee extension and knee flexion will consist of your 1-repetition maximum which you will move the maximum amount of weight one time through a full range of motion. Proper breathing and technique will be enforced through this testing and the verification.
- General Testing Procedure. Before each testing day you will be asked to wear shorts and a t-shirt before lying down on the gurney for 10 minutes to allow pulse wave analysis (PWA, heart rate and blood pressure), pulse wave velocity (PWV), blood flow (BF), and electrocardiogram (ECG) to come down to resting levels (Table 1).

Table 1. Timeline of acute resistance exercise testing.

Pre-exercise
0-10 min – Rest (no measurements)
10-15 min - Assessment of blood pressure, heart rate, central and peripheral arterial function
15-20 min – Stoppage of blood flow
20-23 min – Assessment of blood flow after the occlusion

Intervention
Upper- or lower-body resistance exercise with or without blood flow restriction

Post-exercise
0-10 – Recovery (no measurements)
10-15 min – Assessment of blood pressure, heart rate, central and peripheral arterial function
15-20 min – Stoppage of blood flow
20-25 min - Assessment of blood pressure, heart rate, central and peripheral arterial function
30-35 min - Assessment of blood pressure, heart rate, central arterial function
40-45 min - Assessment of blood pressure, heart rate, central arterial function
50-55 min - Assessment of blood pressure, heart rate, central and peripheral arterial function
55-60 min – Stoppage of blood flow
60-65 min - Assessment of blood pressure, heart rate, central and peripheral arterial function

- Preparation. During this 10-minute quiet rest period, 3 electrodes will be placed on your chest (Figure 2), to collect an ECG and a blood pressure cuffs will be placed on the middle finger of your right hand. Two cuffs will be placed on your right arm for PWA and right leg for PWV, and two cuffs will be placed on your left arm and left wrist for BF.
- Pre-exercise Testing. After the 10-minute quiet rest, blood pressure will be collected on your middle finger and we will measure PWA using a blood pressure cuff on your right arm, and central arterial function using a tonometer (Figure 3), a small pen-like device used to measure pressure and stiffness of the artery in your heart by placing it on your neck, and a blood pressure cuff wrapped around your thigh to measure function of your aorta. After these data are collected, a 5 minute ECG will be collected. During this 5-minute period you will be breathing with a metronome, set a 12 breaths/minute. Meanwhile, your peripheral artery function via blood flow in the forearm will be measured. To accomplish this, a blood pressure cuff will be placed on your wrist and one on the upper arm (Figure 4). A thin strain-gauge will be placed around the widest portion of your forearm, and the hand will be elevated. One minute before blood flow measurements, the wrist cuff will be inflated to 220 mmHg in order to prevent venous return. Three minutes of resting data will be then be collected. Once this is complete, the cuff on your upper arm will be inflated to 220 mmHg for 5 minutes to occlude blood flow. Once the 5 minutes is complete, the pressure in the cuff will be released and measurements of blood flow will be taken for the next 5 minutes with the wrist cuff inflated.

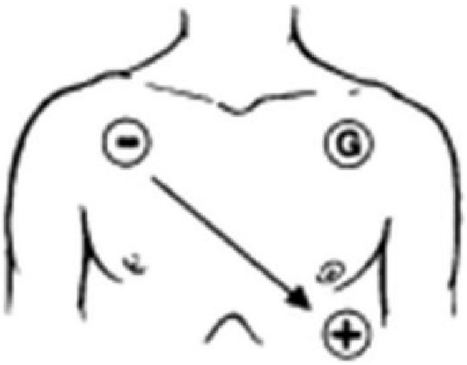

Figure 2. Electrode Placement

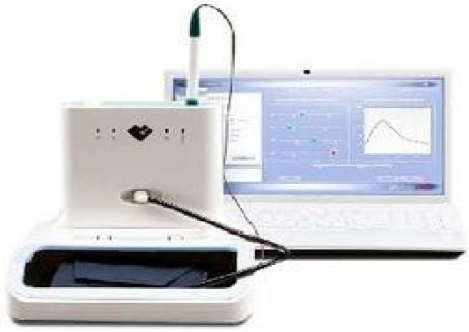

Figure 3. Tonometer

Figure 4. Forearm Blood Flow

- Upper- or lower-body Resistance Exercise with or without blood flow restriction. After this testing is complete you will undergo one of two randomly assigned research groups, upper-body resistance exercise with and without Blood flow restriction group or lower-body resistance exercise with and without blood flow restriction group. The upper-body (chest press and latissimus dorsi pulldown) or lower-body (knee extension and knee flexion) resistance exercise with blood flow restriction consist of 4 sets of 30, 15, 15, and 15 repetitions at 30% 1RM with 30 second rest between sets and 2 minutes rest between exercises while the upper- and lower-body resistance exercises without blood flow restriction will consist of 4 sets of 8 repetitions at 70% 1RM with 1 minute rest between sets and 2 minutes rest between exercises. Three minutes warm up and three minutes cool down will be given before and after upper- or lower-body resistance exercise with and without blood flow restriction.
- Post-exercise Testing. Immediately after completion of the upper- or lower-body resistance exercise with or without blood flow restriction, PWA and ECG measurements will be taken at 10, 20, 30, 40, 50, and 60 minutes post exercise while the BF measurements will be taken at 20, 30, 50, and 60 minutes post exercise.

**Benefits**

This research will not benefit you directly. However, your participation in this study will help us to better understand how to safely prescribe resistance exercise. These data will also contribute to the body of knowledge related to resistance exercise on cardiac function and blood flow. It has been suggested that training with blood flow restricted training may reduce the stress on the heart and cardiovascular system compared to traditional training methods, thus reducing the risk for a cardiovascular event such as a heart attack or stroke. In addition, the responses of different genders are currently unknown and by assisting with this project you are contributing the field of knowledge on this topic.

**Risks and Discomforts**

There is a possibility of a minimal level of risk involved if you agree to participate in this study. The risks will be minimized by using trained certified technicians as well as research participants that have experience with resistance exercise training.

The risk for the 1RM may include muscle soreness and possible injury. Proper form, technique and breathing must be followed to avoid injury. Trained technicians will adjust your form, spot your lifts, and provide feedback if needed.

Although participants do not to perform resistance exercise during the determination of arterial occlusion pressure, the risk includes pain and bruising. Proper breathing must be followed to avoid pain, and trained technicians will deflate the cuff once the arterial occlusion pressure is determined.

During testing, pre- and post-exercise, the risk for injury is low. However, while the blood pressure cuff is inflated to occlude blood flow during the measurement of blood flow you may experience some discomfort. To assist with our understanding of your pain we will use a Visual Analog Scale at 2-minute intervals throughout the occlusion.

If you reach an 8/10 during testing the test will be terminated. If you complete the 5 minutes of occlusion, once the cuff is released the discomfort should disappear.

In addition, blood flow restriction exercise may cause pain, bruising, lightheadedness, and blood clots such as pain, skin discoloration, and swelling during the acute of resistance exercise, and the symptoms should reduce after the elastic cuffs are removed from arms or legs. Please be aware that there is added risk for blood clots in women taking birth control independent of exercise. The effects of BFR in combination with birth control on blood clots is unknown.

The risk for injury during the acute bout of resistance exercise is low. This prescription is recommended by the American College of Sports Medicine, is individualized and you have been resistance exercise training for at least 1 year. However, it still has the risk of injury if proper form and technique are not utilized. Proper spotting and appropriate directions will be provided by trained technicians. After resistance exercise, muscle soreness may be present for the next 24-48 hours. If muscle soreness does not dissipate by the 72nd hour, please alert the primary investigator and suggestions to reduce the soreness includes heat, ice, and stretching. A follow-up email and information for symptoms of blood clot and muscle soreness will be sent 24 hours after completing either upper- or lower-body resistance exercise with or without blood flow restriction.

Medical treatment by the University Health Center is provided only to currently registered students. Please be advised that for all other injuries, emergency services will be called for those occurring on the Kent State University campus. You or your medical insurance will be billed for this service. No other medical treatment or financial compensation for injury from participation in this research project is available.

**Privacy and Confidentiality**

Any identifying information will be kept in a secure location (locked in a cabinet in a locked office) and only the primary investigator will have access to the data. All data electronic data will be collected on password protected computer. Research participants will not be identified in any publication or presentation of research results; only aggregate data will be used. All data will be destroyed 3 years after completion of the study.

**Termination**

You may also choose to withdraw from this study at any time.

**Voluntary Participation**

Taking part in this research study is entirely up to you. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. You will be informed of any new, relevant information that may affect your health, welfare, or willingness to continue your study participation.

**Contact Information**

If you have any questions or concerns about this research, you may contact the primary researcher, Dr. J. Derek Kingsley (jkingsle@kent.edu) at 330.672.0222 or Yu Lun Tai (ytai1@kent.edu) at 330-422-8830. This project has been approved by the Kent State University Institutional Review Board. If you have any questions about your rights as a research participant or complaints about the research, you may call the IRB at 330.672.2704.

**Consent Statement and Signature**

I have read this consent form and have had the opportunity to have my questions answered to my satisfaction. I voluntarily agree to participate in this study. I understand that a copy of this consent will be provided to me for future reference.


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**Participant Signature** **Date**