Study Title: Effect of Low Volume Sprint Interval Training on Cardiorespiratory Fitness

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Informed Consent— Effect of Low Volume Sprint Interval Training on Cardiorespiratory Fitness; A Randomized Controlled Trial

Dear Prospective Participant:

KEY INFORMATION OF THIS STUDY: Dr. Todd A. Astorino, Professor, Department of Kinesiology, is conducting a study to assess the efficacy of time efficient interval based exercise on your physical fitness and health. Interval exercise consists of short, intense bursts of exercise within a relatively brief exercise session lasting less than 10 minutes. Please read this form carefully and ask any questions you may have before agreeing to be in the study. You must be 18 or older to participate in the study. You were recruited for this study because:

1. you are physically inactive (< 75 minutes/week of vigorous or 150 minutes/week of moderate physical activity in the last 12 months) and live in the greater San Diego County region.

2. you are an adult who is healthy, non-obese (body mass index < 35 kg/m^2), and free from any lower extremity injury, and do not take any medication (beta-blockers, metformin, statins, GLP1s, etc.) which may affect your responses to exercise

3. you are a male or female ages 18 – 64 years old who is a non-smoker

4. you are weight stable, meaning no voluntary weight loss in the last 3 months

STUDY PURPOSE: This study will assess the physical response to a time efficient mode of physical activity, called reduced exertion high intensity interval training (REHIT). Many studies have shown the potential efficacy and feasibility of REHIT to increase fitness and health, yet no study has used an adequately large sample to validate the true effectiveness of REHIT.

NUMBER OF PARTICIPANTS: Approximately 120 men and women will partake in this study; 60 adults will undergo REHIT and another 60 will be recruited as non-exercising controls.

If you meet these criteria and choose to volunteer for this study, you will do the following:

STUDY METHODS: Initially, each prospective participant will receive a questionnaire regarding your health and physical activity status which will be used to determine your eligibility to participate. If you are eligible and choose to participate, you will arrive at Academic Hall 115 on the campus of CSU – San Marcos.

Testing of aerobic fitness: This study consists of 1 initial session requiring a total time commitment of about **45 minutes**. You must be well rested and hydrated before this session and you will be required to abstain from physical activity for 36 hours before all sessions. Also, you will be asked to not eat for 6 hours before this visit and be dressed in exercise attire such as shorts/tights and T-shirt. Initially, body fat percentage will be evaluated with BIA, which will require you to step onto a foot scale. Subsequently, you will perform a 10 minute bout of stationary cycling to fatigue to determine aerobic fitness (VO2max). During this bout, you will breathe into a valve and wear headgear and nose clips. During this bout, six electrodes will be placed on your neck, back, and trunk (one on your right chest below your clavicle and one on your left side below your heart). Men will be asked to shave these areas before this bout or have these areas shaved by a member of the Research Team. Women will be asked to wear a sports bra to enable placement of these electrodes. This procedure is done to measure your heart function.

Before completing the VO_2max test, you will be asked to sit quietly on the cycle ergometer while you breathe at rest for 3 minutes. Subsequently, you will complete 10 minutes of cycling at a low intensity equal to approximately 50-60% of your peak heart rate, which induces the highest rate of fat use. The bout will also serve as familiarization to acquisition of gas exchange data and provide a warm-up to the $\dot{V}O_2$max test.

Participant randomization: After baseline testing, you will be randomized in a 1:1 ratio to REHIT or control by a statistician who will use a computer-generated random sequence program. All research personnel will not have access to this randomization sequence. If you are randomized to the control group, you will be asked to maintain your inactive lifestyle and return to the laboratory about 12 weeks later and repeat this session of exercise, after which you will be able to initiate REHIT if you choose.

Description of REHIT: If you are randomized to the REHIT group, you will complete 12 weeks of training (2 days per week), since duration greater than 6 weeks is recommended to better portray the adaptive response to training. All sessions will be held in the lab, be supervised, and will be performed on the cycle ergometer. You will wear a plastic strap around your waist to record heart rate during all sessions to assess the physiological load of REHIT.

Each REHIT session will consist of 2 minutes of unloaded pedaling, followed by an all-out sprint, 3 minutes of unloaded pedaling, a second all-out sprint, and a further 4 minutes of unloaded pedaling. Sprint duration will increase from 10 seconds in Week 1, to 15 seconds in Week 2, and 20 seconds in the remaining 10 weeks. Pedal resistance will be set at a load equal to

5% of body mass. Each participant will be asked to increase the pedal speed to maximal ~2-3 s prior to applying the resistance at the start of the sprint. You will be required to maintain the highest pedal speed you can achieve during each sprint. A small drop of blood from a fingertip will be taken at the end of exercise every week to measure blood lactate concentration. Sessions will be spaced equally over each week whenever possible. **This exercise regimen, which requires only 10 minutes per day, has been shown to be safe, effective, and well-tolerated in inactive adults.**

Participants undergoing REHIT will repeat the baseline exercise session at the end of Week 6 to examine the early change in aerobic fitness. Three days after the final training session and at the same time of day within participants, $\dot{V}O_2$max and fat use will be re-measured using identical procedures.

Habitual physical activity can impact the $\dot{V}O_2$max response to exercise training, so your physical activity will be assessed before and after training using the International Physical Activity Questionnaire (IPAQ). You will be asked not to perform additional structured physical activity during the study or change your dietary habits. You will complete a 4-day food log with 2 weekend days (Diet Frequency Questionnaire III, National Cancer Institute) at baseline and in week 12 to assess dietary intake.

POTENTIAL RISKS AND INCONVENIENCES:

1. There is potential for fatigue resulting from the exercise bouts, as well as potential for nausea and/or dizziness as well as small onset of injury. Our prospective subjects are physically inactive yet healthy, and the risks of these items as well as any cardiac event are so small, so these risks are relatively minimal.

2. Loss of time.

3. Potential for coercion to participate in the study.

4. Potential for your identity to be revealed through participation in the study or breach of confidentiality of your data.

5. Chance of slight pain or bruising to be experienced during the finger stick blood samples.

6. Potential for embarrassment during the placement of the electrodes.

SAFEGUARDS:

1. Soreness, leg pain, nausea, and/or fatigue will be minimized by requiring you to complete a cool-down after each bout of exercise. Moreover, each participant is non-obese and healthy so any incidence of this will be brief and likely of minimal magnitude.

2. Members of the research team will strive to make these trials as time-efficient as possible—those performing REHIT will spend no more than 30 minutes per week for 12 weeks in the training group.

3. No one will be coerced to take part in this study, and you are free to withdraw participation at any time without penalty.

4. All trials will be conducted in our Laboratories, during which time the only people in the room will be members of the research team. As far as your data, it will be kept in a locked cabinet and only be accessed by the Investigators and his research team.

5. The research team will follow proper procedures for proper handling and acquisition of all blood samples, and any pain perceived will be short-lived.

6. All methods related to this study will be performed in a private lab space with only the members of the Research Team, all of whom are properly trained in Human Subjects Research Protections.

CONFIDENTIALITY: Participants' names will be coded and concealed by the Investigators, and all data will be reported without using your name or any other identifying information. Data-containing folders will be placed in a locked cabinet only accessible to the Investigators.

BENEFITS: There are no direct benefits to participating in this study; however, you may better understand your physical fitness and how you respond to exercise. Results will be used by clinicians to improve the effectiveness of exercise programs to enhance health and fitness.

PAYMENT & INCENTIVES: There is no cost for you to participate in this study. If you complete all requirements of REHIT, which include completing three (3) sessions of exercise testing and 12 weeks of training, you will receive a $250 payment, with $125 payable after testing is completed at week 6.

VOLUNTARY PARTICIPATION: Participation in this study is voluntary. You may withdraw at any time without penalty, and only the primary investigator will have knowledge of your choice to discontinue participation.

CONTACT INFORMATION: The Primary Investigator will gladly answer any questions that you have regarding this study. If you want more details, please contact the Primary Investigator Todd A. Astorino Ph.D. through email at astorino@csusm.edu. You will be given a copy of this form for your records. If you have any questions about your rights as a participant in this research or if you feel you have been placed at risk, you can contact the CSU—San Marcos IRB Office at irb@csusm.edu or (760) 750-4029.

☐ I agree to participate in this research study.

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Participant's Name Date

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Participant's Signature