Effects of a High-intensity Interval Training (HIIT) Exercise Intervention on Sleep in Women Exposed to Trauma: A Randomized Controlled Trial

9/16/2021

UNIVERSITY OF GEORGIA
CONSENT FORM
Effects of a short-term exercise intervention on sleep in women exposed to trauma: A randomized controlled trial

Researcher's Statement
You are being asked to take part in a research study. The information in this form will help you decide if you want to be in the study. Please ask the researcher(s) below if there is anything that is not clear or if you need more information.

Principal Investigator: **Patrick J. O'Connor**
University of Georgia,
Ramsey Center, Room 115-L,
Department of Kinesiology,
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706-461-0930 poconnor@uga.edu

- The primary purpose of the research is to learn about the effect of short-term exercise training on sleep in women who have been exposed to a traumatic event.
- Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled.
- The total time commitment is about 11.25 hours. The first lab session will be 1 hour and 20 minutes. Afterward, you will be randomly assigned to either a high-intensity interval training (HIIT) or waitlist control group.
- If assigned to the HIIT group you will complete 25 minutes of HIIT exercise three times a week for 6 weeks.
- If assigned to the waitlist control group you will complete biweekly questionnaires. After 6 weeks, you will be given the opportunity to complete the HIIT exercise training program.
- The final lab session will require about 1 hour and 10 minutes.
- The lab sessions consist of completing questionnaires, providing a saliva sample, having your height and weight measured, completing a body composition scan, wearing a heart rate monitor, and completing a mental arithmetic task. Lastly, you will complete a peak exercise test involving leg cycling.
- Risks include potential discomfort from answering questions about your exposure to trauma and mental health history. The high-intensity exercise periods will cause you to breathe hard and your heart rate to increase.
- In order to make this study a valid one, some information about the study will be withheld until completion of your participation.
- You may experience improved fitness from completing the HIIT exercises during the study. You may benefit from knowing your current body composition. Society ultimately may benefit by learning new information about the extent to which HIIT does, or does not, influence physical and psychological health outcomes.

Study Procedures
Today and following the 6-week intervention period, you will be tested in a lab in the Ramsey Center which will include:

1. Completing questions about your: general health status, medication or supplement use, menstrual status, sleep, trauma symptoms, depression symptoms, anxiety symptoms, bodily pain, quality of life, expectations, and alcohol use.
2. You will be asked to rinse your mouth with water and ten minutes later, you will be asked to provide a saliva sample.
3. Your height and weight will be measured on a medical scale and body composition will be assessed using a Dual X-Ray absorptiometry (DXA) scan.
4. In a private room and after we demonstrate proper placement, you will put a heart rate monitor strap on the lower part of your chest. You will be asked to sit and rest for 5 minutes. Then, you will complete a mental arithmetic task for 10 minutes. After the task, you will recover for 5 minutes.
5. You will then perform a peak oxygen uptake test (VO_2peak; a measure of the fitness of the cardiovascular system), which will be completed on a stationary bicycle. This test will begin at a low intensity, and the intensity will increase until you can no longer continue. The test is designed to last ~6-12 minutes.

6. You will be given a sleep diary and an ActiGraph wristwatch to be worn the week before starting the exercise training or waitlist. You will randomly be assigned into one of the two groups below:

Exercise Intervention

You will be asked to complete three leg cycle ergometer bouts a week in the laboratory. These sessions will start with a three-minute warm-up and end with a two-minute cool-down on the cycle. For the first two weeks, you will complete 13, 30-second high-intensity exercise intervals at a pedal resistance prescribed to elicit 67% of peak power output. After each 30-second interval, you will go into a 1-minute active recovery interval at 30% of peak power output. Then, for each week, the prescribed resistance will be increased by 4% of peak power output. At the third week, exercise duration will increase to 10, 60-second high-intensity intervals. Additionally, bi-weekly assessments will be taken in the laboratory, where you will answer questionnaires about mood, trauma symptoms, and health behaviors.

OR

Waitlist control

You will be asked to maintain your current lifestyle as well as come into the laboratory to complete your baseline, bi-weekly assessments, and post-assessments. You will also be given the choice of receiving a six-week supervised HIIT training program after the waitlist participation.

7. After 6 weeks, you will return to the lab within 3-7 days of the end of the 6 week period and complete steps 1-5 above.

Risks and discomforts

The high-intensity exercise periods will cause you to breathe hard and your heart rate to increase. You will also feel hot, sweat, discomfort, and pain in your upper thigh muscles. High-intensity exercise has inherent risks of musculoskeletal and cardiac injuries that, while low among younger adults, are higher than for low-intensity exercise. Our prescreening questions about physical activity and health were designed in part to rule out individuals who are at higher risk of injury while performing high-intensity exercise. For adults who have passed our pre-screening, the typical risks of high-intensity exercise are minor (e.g., muscle strain, soreness). Nevertheless, by participating in this research you are assuming the inherent risks of participating in high-intensity exercise, including the unlikely, but theoretically possible, risks of a major injury (e.g., broken bone) or a life-threatening event (e.g., heart attack).

Questions of a sensitive nature (i.e., traumatic events) may cause distress. Please remember you can stop at any point and the contact information for the University of Georgia's counseling department will be provided at the end of the visit.

Exposure to X-rays during the DXA body composition scan. DXA uses X-rays and thus can be dangerous. However, risks associated with DXA operation are limited by the regular maintenance and inspection of the device to ensure appropriate safe levels of radiation, and only study team members who have received the required radiation safety training from the University's Environmental Safety Division will use the machine. The degree of X-ray exposure is less than a typical doctor's X-ray exam (for broken bones). You cannot participate in this study if you are pregnant, planning to become pregnant, or think you might be pregnant. This is because the DXA X-rays may pose a health risk to the unborn child. To be included in the study, you must confirm to the research team that you are not pregnant. If you are unsure, a free urine pregnancy test will be provided prior to each DXA, and the results must be negative. If you wish to take the test privately, you do not have to tell the research team your test results. You can withdraw from the study at any time without having to give a reason. The results of any pregnancy test will be kept confidential along with any other information gathered as part of this study. Your participation in the DXA exam is voluntary. You can decide not to perform the exam.

Benefits

You may benefit from receiving information about your body composition and fitness level. You may obtain multiple physiological and psychological benefits of becoming more physically active and increases your cardiorespiratory fitness. Society ultimately may benefit by learning new information about the extent to which short-term exercise training may affect physical and mental health outcomes.

Incentives for participation
There is no payment for the online screening. If you complete all parts of the study, you will be paid a total of $40 in gift cards. You will receive $5 in Amazon gift cards for visit 1. You will receive $20 in gift cards for the final in-person testing session. You will receive up to an additional $15 in gift cards for completing the exercise sessions and/or the biweekly questionnaires. If you stop participating in the study or are removed from the study your visits will be prorated to $2.50 for visit 1 and $2.50 for the weeks you completed the questionnaires. You will receive payment at the end of your participation in the study. To receive payment, you will be required to provide a photo ID to the custodian of the gift cards, provide your email for the gift cards to be sent to, and sign your name in a log-book next to the number of the gift cards you received.

Confidentiality of records
No individually identifiable information about you that you provide (e.g., your name provided on the screening or the IP address of the computer you used) will be shared with others without your written permission unless otherwise required by law or for your safety in the case of a research-related injury or illness.

The consent form that you sign will be kept in a location separate from the information that will be obtained from you during this study. To safeguard your identity, you will be given a 4-digit code that the researcher will use on all forms. This code will not appear on the consent forms. The key code which links your name to the code will be destroyed immediately after data collection is complete.

Your identity will not be revealed in any publication of the results of this research. The individually identifiable results of your participation will be confidential. After identifiers are removed, the information may be shared with other researchers and/or used for future studies without additional consent. A copy of the study results will be made available to you if you request it. The project's research records may be reviewed by departments at the University of Georgia responsible for regulatory and research oversight.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

With your consent, de-identified saliva samples will be kept for a maximum of 10 years. Future analyses of these samples will be congruent with and within the scope of the purpose of the study, i.e. to determine the influence of HIIT exercise on health-related outcomes. Please check one of the boxes below to indicate whether you consent to this retention of your saliva samples.

□ Yes, I consent to storage of my saliva samples for up to 10 years.
□ No, I do not consent to storage of my saliva samples for up to 10 years.

Research Injuries or Illnesses
The researchers will exercise all reasonable care to protect you from harm as a result of your participation. In the event that any research-related activities result in injury or harm, the sole responsibility of the researcher will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Dr. Patrick J. O'Connor right away at 706-461-0930 (cell) or via email at poconnor@uga.edu or contact Melissa McGranahan at either 815-666-9006 or mmcg91@uga.edu. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

Taking part is voluntary

Your participation is voluntary. You can refuse to participate or withdraw your consent at any time without giving any reason, and without penalty or loss of benefits to which you are otherwise entitled. Your decision about participation will have no bearing on your grades or class standing.

The principal investigator may withdraw you from participating
Under some circumstances, you will be withdrawn from participating in the study, and these include: (i) if you are unwilling to follow the instructions and deviate from the required protocol, (ii) if you suffer an adverse response to the exercise, or (iii) for other unforeseen reasons that negatively impact the investigation.

If you have questions
The main researcher conducting this study is Melissa McGranahan, a doctoral student at the University of Georgia who is working under the supervision of Dr. Patrick O'Connor, a professor at the University of Georgia. Please ask any questions you have now. If you have questions later, you may contact Patrick O'Connor at poconnor@uga.edu. If you have any questions or concerns regarding your rights as a research participant in this study, you may contact the Institutional Review Board (IRB) Chairperson at 706-542-3199 or irb@uga.edu.

Research Subject's Consent to Participate in Research:
To voluntarily agree to take part in this study, you must sign on the line below. Your signature below indicates that you have read or had read to you this entire consent form and have had all of your questions answered.

_____	_____	_____
Name of Researcher	Signature	Date
_____	_____	_____
Name of Participant	Signature	Date

Please keep one copy and return the signed copy to the researcher.