



Document date: 2/26/22
NCT number: NCT05143801

Official Title:
Facemask use during High Intensity Interval Exercise in temperate and hot environments

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Consent to Participate in Research

11/02/20

Purpose of the research: You are being asked to participate in a research project that is being done by Dr. Christine Mermier and Andrew Wells, from the Health, Exercise, and Sport Science (HESS) department and their associates. The purpose of this research is to compare changes in heart function and perceived difficulty during high intensity interval exercise (HIE) while wearing a mask in both a normal room temperature and a hot environment. You are being asked to join because you are a regular exerciser (including high intensity exercise), English speaking, 18 years or older, have no serious medical conditions, do not smoke, or have quit smoking for at least 6 months, and do not use an inhaler to control for exercise induced asthma. You should not have symptoms of COVID-19 nor have been exposed to anyone who has tested positive for the disease for at least two weeks.

This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research is voluntary.

Key information for you to consider:

- After reading the consent form and discussing the details with a research team member, you will be asked to sign this consent form only if you decide to take part in the study.
- Three visits will take place at the Exercise Physiology Lab in Johnson Center (Room #B143) where you will be tested for your aerobic fitness and perform four high intensity interval exercise sessions.
- The first visit will take about a 1.5 hour and will include paperwork and the assessment of your aerobic fitness.
- The second and third visits will take about 4 hours. During each visit you will perform two high intensity interval exercise sessions with a long rest between sessions. Two of the four exercise bouts will be in a hot room (95-99°F)
- Risks include discomfort, stress, nausea, dizziness, lightheadedness, fainting, muscle soreness, and fatigue from exercise as well as an increased risk of exposure to COVID-19.
- Time commitment for participation in this project will take a total of 10 of hours over a period of three visits.

What you will do in the project:

After reading the consent form and discussing the details with a research team member over the phone, email, or Zoom, if you decide to participate, you will be asked to fill out a health history questionnaire and a University of New Mexico COVID-19 Symptoms Screening Checklist that will be sent to you via email. You will send them back to the research team via email the day before your first visit. You will sign the consent form during your first visit. If you never come to Visit 1 or do not sign the informed consent, your completed health history questionnaire and COVID-19 Symptoms Screening Checklist will be deleted permanently within 4 weeks of receipt.

For each visit, a research team member will call you and inquire whether you have any COVID-19 symptoms using the COVID-19 symptoms checklist for the final two visits. You will also be asked if you have been exposed to anyone with suspected or known COVID-19. You will be approved to come to

the laboratory if you have no signs and symptoms of COVID-19, haven't traveled outside the state, and if you have not been exposed to anyone who has COVID-19 symptoms or has tested positive for the virus within the past 14 days. Before entering the lab, a no-touch forehead thermometer will be used to measure your body temperature. If your temperature is over 37.5 °C (99.5 °Fahrenheit) you will not be allowed to continue with the visit and will be provided information on COVID-19 testing. Following a negative COVID-19 test you will be able to continue the study if you wish to do so and your visit will be rescheduled. The information you provide from your COVID-19 test will not be kept on file. During each visit, all research team members will wear a N95 mask, a face shield, and a lab coat. You will be provided and asked to wear a surgical mask at all times with the exception of two of the HIIE sessions and for five minutes following each HIIE session. You have the right to withdraw from the study at any time and are not required to provide a reason. If you withdraw, all the data gathered from your visits will be promptly destroyed.

Visit 1

You will report to the Exercise Physiology Lab in the University of New Mexico in Johnson Center after being asked to: (a) avoid eating a filling meal within 1 hour, (b) avoid having caffeine for 4 hours, (c) avoid performing vigorous exercise for 24 hours before your first visit, and (d) wear exercise attire (women will be required to wear a sports bra underneath a workout shirt). Upon arrival, your temperature will be measured with a no-touch thermometer. If is below 37.5°C (99.5° Fahrenheit), you will be able to continue. You will be asked to complete the consent form, and a state trait anxiety index questionnaire.

(Female participants only) Before beginning testing, if you are of childbearing potential, you will be asked to complete a pregnancy test. You will have access to a private bathroom. After a research team member reads the test result, if the test is negative you will be able to continue with the research study. If the test is positive, you will be thanked for your time, withdrawn from the study, and will be advised to see your health care provider. Results will be to you provided privately.

- *Resting Measurements*

If needed, a private room with an interior door lock for additional privacy will be provided to change into workout clothes. After, your height and weight will be measured in workout clothes with empty pockets and your shoes removed. You will then be asked to rest in a seated position for five minutes followed by resting heart rate and blood pressure measurements. Next you will be asked to fill out an anxiety questionnaire. Before the maximal effort exercise test on a stationary bike, you will be provided a heart rate monitor strap to wear around your chest. The resting measurements and questionnaire should take between 10 and 15 minutes to complete.

- Maximal effort exercise test (aerobic fitness test)

*All equipment will be sanitized before and after this test. All research team members administering this test will wear an N95 mask, lab coat, and face shield at all times.

Up until the time you are hooked up to our equipment, you are required to wear a surgical facemask at all times. Before the test you will be permitted to temporarily adjust your surgical facemask to drink water. You will be asked to perform a 5-minute warm-up on a stationary bike at a self-selected difficulty. After completion of the warm-up you will be fitted with head gear where you will breathe through a device with a mouthpiece (like a snorkel mask) and a nose clip at rest for approximately 1 minute. At the start of this test, you will be asked to achieve and then maintain a pedaling rate between 60 and

100 revolutions per minute throughout the test. The pedaling rate will be displayed on the stationary bike. As the exercise continues, it will become more difficult until you cannot maintain this pedaling rate and the test will end. The exercise portion of the test typically takes 8-12 minutes. As this is a maximal effort test, you will be instructed to try to exercise as hard as you can. Following this test, we will remove the mask and nose clip, you may drink water before you put your surgical facemask back on. You will stay on the bike for a 5 to 10-minute cool-down at a self-selected difficulty. This maximal effort exercise test will take between 18 and 30 minutes to complete accounting for set-up and any questions you may have before the test.

*As this study requires high intensity exercise sessions, if you are categorized below the 50th percentile for aerobic fitness for your age and sex based on this test, you will be thanked for your time and withdrawn from the study. We will give you your results of the maximal test and your results will not be kept on file.

- *Number of sessions and conditions*

After the first visit, to complete the study you will perform high intensity interval exercise (HIEE) four times, two times each visit. One HIEE session will be in a room temperature environment (68-72°F) wearing a disposable surgical facemask provided to you, one HIEE session in a room temperature environment without a surgical facemask, one HIEE session in a hot temperature environment (95-99°F) with a disposable surgical facemask provided to you, and one HIEE session in a hot temperature environment without a surgical facemask. The order of these high intensity interval exercise sessions will be randomly selected, meaning the order will be chosen based on chance, like flipping a coin.

Visits 2 and 3

Prior to arrival to the Johnson Center Exercise Physiology Lab you will be instructed to avoid a filling meal 1 hour and vigorous exercise 24 hours before the HIEE sessions. You will also be reminded to bring workout attire (females will be required to wear a sports bra underneath a workout shirt). Before each HIEE session, you will be asked to take a 20 question anxiety questionnaire. The two visits will be separated by at least 72 hours. During each visit you will have a three-hour rest period between the two HIEE sessions where you will be provided with water and a small 350 calorie meal*. You may remain in the lab for the entire duration of your visit and will be provided a room for you to read or work on your computer. Your mask will stay on the entire rest period except when eating or drinking. However, you are free to leave and return to the lab during the three-hour rest period. If you decide to leave, you will be asked to abstain from any exercise and food and beverage other than water outside the lab. Each of the HIEE sessions will take 20 minutes to perform.

*Please alert the research team members to any food allergies.

- *Hydration measurements and core temperature measurement setup*

Before performing any exercise, if needed, a private room will be available for you to change into workout clothing for all visits. After, you will be asked to use the private restroom to provide a small urine sample to test to see if you are hydrated. If you are dehydrated, you will be provided with 500 ml of water to consume. After consuming the 500 ml of water you will be asked to rest for 30 minutes and provide another urine sample to test to see if you are hydrated. If you are still dehydrated after the second urine sample, you will be provided with another 500 ml of water to consume asked to rest for another 30 minutes followed by a third urine sample to test for hydration. If after the third urine sample you are still dehydrated, you will be asked to reschedule and instructed to drink plenty of water the day

before the rescheduled visit. During this portion of your visit you will be required to wear a surgical facemask at all times with the exception to drink water. Next, in a locking private room you will be provided lubricant gel to insert a rectal thermistor approximately 10 cm into the rectum. This rectal thermistor will remain in place during the exercise to continuously measure your body temperature. After the first high intensity interval exercise bout, you will be able to remove this thermistor in a private room. You will be provided gloves, disinfectant (70% alcohol) and paper towels to disinfect the thermistor and then asked to place it in a plastic bag. After the three-hour rest period, you will be asked to re-insert the thermistor before the next HIEE session. This portion of the visit will take a minimum of 15 minutes and a maximum of 80 minutes to complete depending on hydration status.

After the second of the two HIEE sessions you will be asked to remove, disinfect, and place the thermometer in a plastic bag identified with your study participant number to be stored for the next visit. If you ask, or if the thermistor is damaged, we will provide you with a new thermistor. After your final HIEE session on your last visit, you will be asked to place the thermistor in the plastic bag and discard it.

- *Cardiovascular measurements*

In a private room a research team member will ask you to remove your shirt in order to apply electrodes to several spots on the upper body. If you are male, a research team may provide you with a disposable razor and may ask you to shave hair from your chest at the site of electrode placement before using an abrading gel and alcohol pad to clean the sites for electrode placement. If you are female, a research team member may ask you to adjust your sports bra to use an abrading gel and alcohol pad to clean the sites for electrode placement. Two electrodes will be placed on the left side of the neck, two on the back, one near the left armpit, and one on the chest. You may put your shirt back on after being hooked up to the equipment. After all the electrodes are placed and connected, you will be asked to sit and rest for 5-minutes. Next your resting blood pressure will be measured, and you will be fitted with a small finger cuff that will inflate with a small amount of pressure to continuously measure your blood pressure, and a finger clamp that will measure your blood oxygen saturation (how much oxygen in your blood) will be attached. Finally, on your dominant leg you will be fitted with a near infrared spectrometry device. This device uses infra-red light to measure your blood oxygen saturation during the HIEE sessions. This setup should take about 30 minutes to complete.

*You will be able to request a male or female research team member to apply electrodes.

- *Rated perceived exertion, thermal sensation, and dyspnea scale measurements*

Before each HIEE session, you will also be instructed or reminded on how to use a rating of perceived exertion (RPE) scale and asked to report the difficulty of exercise rated from 6 (resting) to 20 (maximal effort). You will be asked to report your RPE (exercise difficulty) after every 4 minutes of HIEE. Additionally, you will also be asked to rate how cold or hot you are on a scale of 1 (very cold) to 7 (very hot) after every 4 minutes of the HIEE session. Finally, before, mid-way through, and immediately after the HIEE you will be asked to place a mark on a line that indicates how difficult it is for you to breathe.

- *Sweat rate estimation*

Before and after each HIEE session, before putting in the thermistor and after taking out the thermistor you will be asked to measure your nude body weight (in the locking private room). After each HIEE session, you will be asked to dry off as much as possible and measure another nude body weight in the private room. If you need to urinate before the second body weight measurement, a research team member will provide you with a container and asked to empty your bladder into the container in the

restroom so we may measure the urine volume. These measurements should take about 15 minutes to complete.

- *Blood Lactate and exercise gas exchange recovery measurements*

Before, immediately after, and 5-minutes after each high intensity exercise session, your ear lobe will be cleaned using an alcohol wipe. Then a sterile lancet will be used to poke your ear lobe so a small drop of blood for lactate can be measured. Additionally, after exercising (at rest) you will be asked to breathe into a mouthpiece with a nose clip (like you did for the maximal test) for 5-minutes to measure gas-exchange during exercise recovery.

- *High Intensity Interval Exercise Sessions*

*All equipment will be sanitized before and after high intensity interval exercise session. All research team members administering this test will wear an N95 mask, lab coat, and face shield at all times.

Before exercising you will perform a 5-minute warm-up on the stationary bike. Next you will be asked to perform 10 separate bouts of HIE. Each high intensity bout will last 30 seconds with 90 seconds of light intensity exercise in between bouts. The high intensity bout will be at 85% of your maximum power output generated during your $VO_{2\text{max}}$ test. The light intensity exercise in between high intensity bouts will be 30% of your maximum power output generated by your $VO_{2\text{max}}$ test. Following the ten bouts, you will remove your surgical facemask (if applicable) and will breathe into a mouthpiece with a nose clip to measure gas exchange for five minutes. After removal of the mouthpiece and nose clip you will be required to immediately put your surgical facemask back on. Including warm-up and gas exchange measurements, each HIE session will take a total of 30 minutes. You will be able to remove or adjust your surgical facemask to drink water during the HIE session. After taking a drink of water you will put your surgical facemask back on or adjust your surgical facemask to cover both your nose and mouth.

You then will go into a room to consume the provided meal and water, and may remain there until the second portion of the test, or you may leave and come back three hours after the end of the first session of exercise. We ask you to keep on the electrodes (unless they are coming off) to use for the next session. We will remove them at the end of the second exercise trial

Risks:

The risks associated with high intensity exercise both in the heat and in regular room temperature may include discomfort, stress, nausea, dizziness, lightheadedness, fainting, muscle soreness, muscle injury, and fatigue. You will be allowed to terminate the high intensity exercise at any point. You will perform a 5-minute warm-up at a self-selected intensity prior to exercise. If your body temperature gets too hot (at a pre-determined temperature) during exercise in the heat, you will be removed immediately from the heat and will be given wet towels to drape on your body and will sit in front of a fan until your body temperature drops. You will not resume the exercise trial.

There is also a risk of embarrassment with use of a rectal thermometer to measure your core temperature. One end of the thermistor will be exposed outside your clothing to hook up to a thermometer for core body temperature measurement.

There is a risk of exposure and infection of COVID-19 with the participation in this study. In order to minimize this risk, the room and all equipment will be disinfected before and after each high intensity

interval exercise session using whole-room disinfectant equipment (Clorox® Total 360®). The research team members will wear N95 masks, lab coats, and face shields at all times during your visit. They will keep at least 6 feet away from you except when necessary to place equipment or take measurements. They will complete a COVID-19 screening before they are allowed to work with you. You will also be asked to wear a surgical mask at all times during each visit with the exception of two of the high intensity interval exercise sessions. Hand sanitizer will be available at all times and used before any physical contact with you or the equipment used for the study.

Benefits:

The only benefit to you is that you will receive results of your aerobic fitness test. This information can be used to develop or adjust your workout program. Societal benefit from this study is that it will provide information for individual exercisers and to inform policy on performing high intensity exercise in both normal room temperature (68-72°F) and hot (95-99°F) environments while wearing a surgical facemask.

Confidentiality of your information:

The loss of confidentiality or privacy is a risk present with participation in research studies. Loss of privacy will be minimized as only you will have access to a restroom or a locker room offering a private environment. Privacy curtains are also available to section off testing rooms to maintain privacy upon your request. Further, the Laboratory has multiple rooms equipped with doors that can be closed for privacy during the consent process, state trait anxiety questionnaire screening, and all exercise testing. You will be given a participant number that will be used on all paperwork for the study to ensure confidentiality of your data. Only approved research team members will have access to your information through a password protected computer, with hard copies of any data sheets and questionnaires stored in a locked file cabinet. We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of your data. The University of New Mexico Institutional Review Board (IRB) that oversees human subject research may be permitted to access your records.

*You should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

Use of your information for future research:

All identifiable information (e.g., your name, date of birth) will be removed from the information or samples collected in this project. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

Payment: You will not be compensated for your participation in this study.

Right to withdraw from the research:

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without penalty. If you are a student at UNM, your standing will not be impacted by withdrawing from the study. When withdrawn from the study, you will be marked as withdrawn and will no longer be contacted in relation to this study. Any data collected will be excluded from analysis and will be destroyed. In addition, the research team will stop your

participation in the study if you are not willing to wear a mask when required or do not follow other COVID-safe practices.

If you have any questions, concerns, or complaints about the research study, or contract COVID-19 (including showing symptoms or testing positive) within 14 days of a visit to the lab please contact the principal investigator **immediately**: Christine Mermier, Ph.D., Department of Health, Exercise & Sport Sciences, 1 University of New Mexico, Albuquerque, NM, 87131. She may be reached Monday-Friday 8:00 a.m. – 5:00 p.m. at (505) 277-2658, or anytime via email at cmermier@unm.edu.

If you would like to speak with someone other than the research team to obtain information, offer input, or if you have questions regarding your rights as a research participant, please contact the IRB. The IRB is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving people: UNM Office of the IRB, (505) 277-2644, irbmaincampus@unm.edu. Website: <http://irb.unm.edu/>

CONSENT

You are making a decision whether to participate in this research. Your signature below indicates that you have read this form (or the form was read to you) and that all questions have been answered to your satisfaction. By signing this consent form, you are not waiving any of your legal rights as a research participant. An electronic copy of this consent form will be provided to you.

I agree to participate in this research.

Name of Adult Participant

Signature of Adult Participant

Date

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of their questions. I believe that they understand the information described in this consent form and freely consents to participate.

Name of Research Team Member

Signature of Research Team Member

Date