



Protocol Title	Effects of face coverings during physical activity
IRB Number	020-353
Sample Size	100
Sponsor	BSW Foundation
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BACKGROUND AND SIGNIFICANCE

Phase I: Due to the coronavirus disease 2019 global pandemic (COVID-19), conversations surrounding the return to physical activity and sports are in the beginning stages. However, recommendations and guidelines for wearing face coverings during physical activity are conflicting among gyms, schools, and collegiate and professional sports.

The Centers for Disease Control and Prevention (CDC) recommends that all people over the age of 2 wear a cloth face covering in public settings, especially when social distancing measures are difficult to maintain.¹ Conversely, the World Health Organization (WHO) states that people should not wear face coverings when exercising, as masks may reduce the ability to breathe comfortably and that sweat can make the face coverings become wet more quickly which makes it difficult to breathe and promotes the growth of microorganisms.²

In accordance with Executive Order GA-29, the University Interscholastic League (UIL) of Texas requires students, staff, and visitors to wear face coverings when entering and exiting facilities and practice areas, and when not actively exercising. Schools may, for example, allow students who are actively exercising to remove face coverings as long as they maintain at least six feet of distance from other students and staff who are not wearing face coverings. However, schools must require students and staff to wear face coverings as they get into positions that allow them to maintain safe distancing.³ The NCAA has similar recommendations for collegiate athletics including universal masking when physical distancing is not possible.⁴ The National Football League (NFL) is currently investigating the use of modified face coverings and helmets, though specific regulations have yet to be unveiled.

There is no scientific evidence available on the impact of wearing a face covering on sports performance (exercise capacity) during this pandemic.⁵

Phase II: Previous research has found that more than 40% of patients with COVID showed neurologic manifestations at the outset, and more than 30% of those had impaired cognition.⁶ Impaired cognitive performance and reaction time during mask wearing could negatively impact. Thus, in order to investigate the possible relationship between cognitive performance during physical activity and COVID-19, Phase II will consist of a prospective, randomized crossover trial of 50 eligible participants. Investigators will compare VO2 max during two maximal

cardiopulmonary stress exercise tests (CPET) on a cycle ergometer, seven to ten days apart, and examine differences in cognitive performance. ECG monitoring will take place during exercise testing among individuals with history of COVID-19. Previous research regarding cognitive performance includes private studies completed between Sports Academy Cognition Lab (SACL) and GlaxoSmithKline Human Performance Lab (GSK-HPL) to investigate the relationship between cognitive performance and sports performance training. As part of this research, international-level cricket athletes completed daily cognitive performance assessments using the *SACL Cognition* application on iPad as part of their sport performance training. The results showed that performance on a simple reaction time (SRT) task was statistically significantly correlated to a variety of physiological sports performance measures, including heart rate, sleep quality, self-assessment of motivation, self-assessment of physical soreness. When SRT was higher (i.e., slower), heart rate, sleep quality, motivation, soreness, and freshness were measured/rated lower. Among professional rugby players, SRT was correlated with body weight, mood, sleep quality, training performance, and distance covered in training. When SRT was higher, body weight, mood, sleep quality, training performance, and training distance covered all tended to be lower. The correlations were relatively small but reached statistical significance over large samples and across a wide variety of physiological output measures, suggesting that the relationship between cognitive and physical performance is broad even if not deep. These results are relevant to the current research as they support the inclusion of a cognitive performance metric (e.g., SRT) when evaluating the effect of face coverings on overall sport performance.

Therefore, in order to investigate the impact of face coverings on exercise capacity, research will take place in two phases:

Phase I: Participants will be randomized and complete 2 treadmill trials including (1) cardiopulmonary exercise tests (CPET) with face covering, and (2) CPET without face covering.

Phase II: Participants will be randomized and will complete 2 cycle ergometer trials including (1) cardiopulmonary exercise tests (CPET) with face covering, and (2) CPET without face covering. Cognitive testing will occur incrementally as exertion increases.

SPECIFIC AIMS & OUTCOMES

Phase I:

The proposed study consists of 4 specific aims:

Specific Aim 1: Describe the primary and secondary outcomes of athletes during a Cardiopulmonary Exercise Test (CPET) on a treadmill with (arm 1) and without (arm 2) the use of a face covering.

Specific Aim 2: Conduct a randomized crossover trial to determine if there is a significant difference in maximal and submaximal aerobic exercise capacity (VO₂ max; assessed during the CPET) in athletes with (arm 1) and without (arm 2) the use of a face covering.

Specific Aim 3: Describe participants' experiences' while wearing a face covering during exercise.

Specific Aim 4: Determine reliability of the Attitudes Toward Face Coverings Questionnaire

Primary Outcomes:

- VO₂ max during treadmill Cardiopulmonary Exercise Testing (CPET)
- Test duration (time) on a CPET

Secondary Outcomes

- Minute ventilation (VE) at max during CPET

- Subjective dyspnea rating (Borg) at max during CPET
- Subjective exertion rating (Borg) at max during CPET
- O₂ saturation at baseline, each stage, and recovery during CPET
- Blood pressure at baseline, each stage, and recovery during CPET
- Max heart rate during CPET
- Respiratory quotient at max during CPET
- Attitudes Toward Face Coverings Questionnaire
- Scale of Measuring Subjective Perceptions Questionnaire

Phase II:

Specific Aim 1: Describe the primary and secondary outcomes of participants during a Cardiopulmonary Exercise Test (CPET) on a cycle ergometer with (arm 1) and without (arm 2) the use of a face covering.

Specific Aim 2: Conduct a randomized crossover trial to determine if there is a significant differences in cognitive performance outcomes in participants with (arm 1) and without (arm 2) the use of a face covering. Cognitive performance will be measured by simple reaction time and accuracy on the SRT task.

Specific Aim 3: Describe differences in outcomes between participants with and without previous history of COVID-19 diagnosis

Primary Outcomes:

- VO₂ max during CPET
- Test duration (time) on a CPET
- Reaction time (measured in milliseconds) and percentage accuracy on the SRT task

Secondary Outcomes:

- Minute ventilation (VE) at max during CPET
- Subjective dyspnea rating (Borg) during CPET
- Subjective exertion rating (Borg) during CPET
- O₂ saturation at baseline, each stage, and recovery during CPET
- Blood pressure at baseline, each stage, and recovery during CPET
- Max heart rate during CPET
- Respiratory quotient at max during CPET
- Blood lactate during CPET

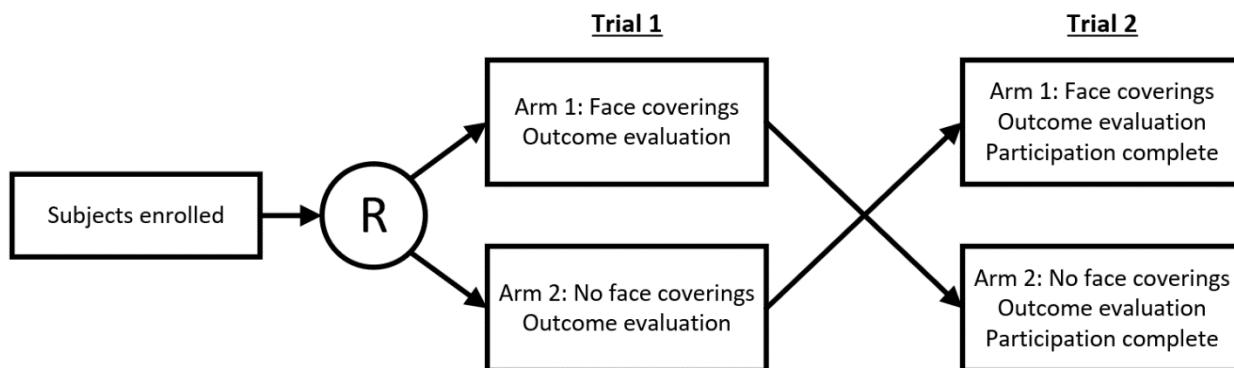
INVESTIGATIONAL PLAN

Research Design and Methodology

Phase I:

In this prospective, randomized crossover trial of eligible athletes, we will compare VO₂ max during two maximal cardiopulmonary stress exercise tests (CPET), seven to ten days apart. Subjects will be randomized into either the face covering or non-face covering group using a 1:1 randomization scheme, stratified by sex, and will serve as their own control in the subsequent test seven to ten days later (see Figure 1. Randomization diagram, below). A within-subjects analysis will be performed stratified by sex.

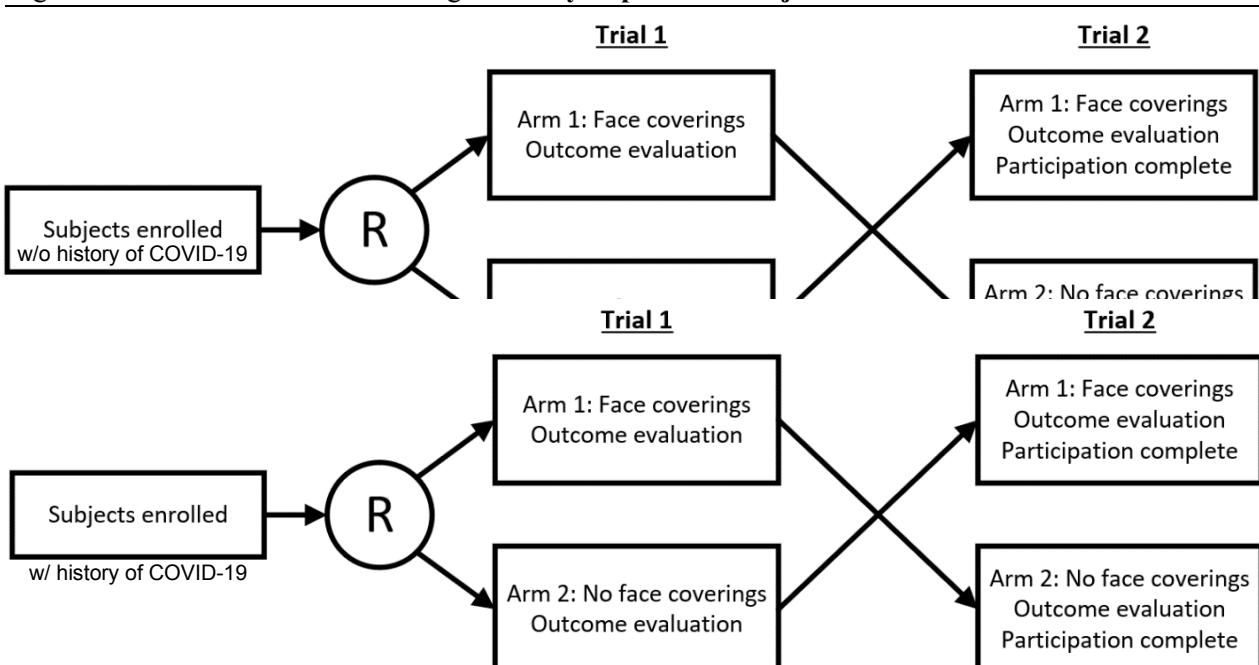
Figure 1. Phase I Randomization diagram

**Phase II:**

In this prospective, randomized crossover trial of 50 eligible participants, we will compare two maximal cardiopulmonary stress exercise tests (CPET) on a cycle ergometer, seven to ten days apart, and the impact on cognitive performance. ECG monitoring will take place during exercise testing among individuals with history of COVID-19. Subjects will be randomized into either the face covering or non-face covering group using a 1:1 randomization scheme, stratified by prior COVID-19 diagnosis, and will serve as their own control in the subsequent test (see Figure 2. Randomization diagram, below). A within-subjects analysis will be performed stratified by sex.

Cognitive testing will take place at the end of each stage of the CPET. Cognitive testing using the SACL Cognition application on iPad will include a baseline SRT measurement and additional measurements at the end of each stage of the CPET. The baseline will include a 30s session of SRT for familiarization and then a 30s session will be scored. SRT will then be administered for 30s at the end of each stage of the CPET. The SRT task includes a visual stimulus presented on the touchscreen. Subjects will be instructed to press the stimulus on-screen as quickly as possible. Reaction time and accuracy will be measured on the SRT task. Reaction time is calculated as the average amount of time in seconds between stimulus presentation and user response within a session. Accuracy is calculated as the total number of correct responses to stimuli divided by the total number of stimuli presented during a session (presented as a percentage).

Figure 2. Phase II Randomization diagram



Phase I: Eligibility Criteria

Inclusion Criteria	Rationale
18-29 years of age	Younger and older individuals are excluded to reduce variability of lung volume outcomes. <i>Herdy, A. H. & Uhlendorf, D. (2010) Reference values for cardiopulmonary exercise testing for sedentary and active men and women. Sociedade Brasileira de Cardiologia.</i>

Exclusion Criteria	Rationale
Orthopedic or neurologic, or other limitations	Individuals with limitations that would not allow for exercise testing on a treadmill are excluded.
Previous or current diagnoses for cardiopulmonary conditions	Individuals with conditions for which a healthcare provider has discouraged high-intensity exercise are excluded (e.g., arrhythmia, pacemakers, Wolfe Parkinson White syndrome).
Medical diagnosis of diabetes and/or currently on medications for diabetes (e.g., insulin)	Individuals with a diagnosis of diabetes and/or individuals currently taking medications for diabetes will be excluded, as the results from their VO2max tests would not be comparable to the testing sample.
Uncontrolled asthma	Individuals with conditions for which a healthcare provider has discouraged high-intensity exercise are excluded.
Inmates	Protected population.
Pregnancy	Protected population.
History of previous positive COVID-19 test	Individuals who have previously tested positive for COVID-19 will be excluded from the current study due to possible cardiopulmonary implications.
Presence of beards	Beards interfere with the fit of the Vo2 mask. Therefore, participants with beards will be asked to shave prior to their visit. If they are unwilling to shave, they will not be eligible for the study.
Claustrophobia	Participants who have been diagnosed or treated for claustrophobia will be excluded. Claustrophobia is a contraindication of the CPET test.

Phase II: Eligibility Criteria

Inclusion Criteria	Rationale
18-39 years of age	Younger and older individuals are excluded to reduce variability of lung volume outcomes. <i>Herdy, A. H. & Uhlendorf, D. (2010) Reference values for cardiopulmonary exercise testing for sedentary and active men and women. Sociedade Brasileira de Cardiologia.</i>

Exclusion Criteria	Rationale
Orthopedic or neurologic, or other limitations	Individuals with limitations that would not allow for exercise testing on a treadmill are excluded.
Previous or current diagnoses for cardiopulmonary conditions	Individuals with conditions for which a healthcare provider has discouraged high-intensity exercise are excluded (e.g., arrhythmia, pacemakers, Wolfe Parkinson White syndrome).

Medical diagnosis of diabetes and/or currently on medications for diabetes (e.g., insulin)	Individuals with a diagnosis of diabetes and/or individuals currently taking medications for diabetes will be excluded, as the results from their VO2max tests would not be comparable to the testing sample.
Uncontrolled asthma	Individuals with conditions for which a healthcare provider has discouraged high-intensity exercise are excluded.
Inmates	Protected population.
Pregnancy	Protected population.
Presence of beards	Beards interfere with the fit of the Vo2 mask. Therefore, participants with beards will be asked to shave prior to their visit. If they are unwilling to shave, they will not be eligible for the study.
Claustrophobia	Participants who have been diagnosed or treated for claustrophobia will be excluded. Claustrophobia is a contraindication of the CPET test.
Currently experiencing symptoms of COVID-19 or < 7 days since last symptoms	Participants will be screened for COVID-19 symptoms using the BSW COVID-19 screener; if participants have past history of COVID-19 based on laboratory testing, participants will be ineligible if <7 number of days since last symptoms

Study Procedures

Phase I & II Subject Recruitment

Up to 100 participants (50 for each phase) will be recruited from Baylor Scott & White Sports Therapy and Research at The Star in Frisco, Texas through approved fliers, calls, emails, and social media, as well as through local community organizations, healthcare clinics, and collaborating centers and organizations, including but not limited to the Sports Academy and the University of North Texas. IRB-approved fliers will be posted at BSW The Star and at affiliated organizations and collaborators in the DFW Metroplex and surrounding areas. In addition, members of the study team will attend meetings with local clinicians and community partners to inform them of the purpose of the study. The study flier will contain information on the study and methods to contact the study team including (1) a QR code linked to the eligibility screener which will be stored in a REDcap, a HIPAA-compliant (21 CFR Part 11) secure web application, (2) a phone number, and (3) an email address of the study coordinator. Interested individuals may contact the study team by phone or email to learn more about the study and undergo a telephone screener or follow the QR code to complete the eligibility screener electronically. A snowball sampling technique will be used for further recruitment whereby interested participants will be invited to ask other athletes they know to contact the study team about participation. Eligible individuals will be contacted by a member of the study team to schedule their first study visit. It is anticipated that recruitment will take 2-4 weeks during each phase to achieve our desired sample size.

Subject Information and Screening

Eligible individuals will be screened by trained study coordinators via telephone using the Eligibility Script. If a participant is ineligible based on the screening tool, they will be thanked for their time and informed that they are not able to participate further. If a participant is eligible based on the screening tool, they will be asked to schedule a baseline assessment appointment where informed consent will be obtained. All individuals will be given a screening ID number and all screening information will be input into a password-protected subject tracking database.

COVID-19 Screening

Participants will be instructed to wear face coverings from the parking lot and inside the building. Prior to participation in the CPET, subjects will complete the BSWH COVID-19 screening (procedure outlined in supplementary materials) and a temperature check with a TIR-1 thermometer (procedure outlined in supplementary materials) outside of testing environment. If the subject screens positive or has a temperature of over 100 degrees, subject will not be able to participate in the study and instructed to leave the facility and

comply with current state and local recommendations. If the subject screens negative on both assessments, subject will be taken into testing area for CPET testing.

Informed Consent

Informed consent will be obtained by study staff in person at the beginning of their study visit and prior to any study related procedures taking place. Informed consent will be conducted in a private location using similar procedures as described above by trained study staff to minimize coercion. Participants will be informed about the study, have sufficient time to review the consent form, and all study questions will be answered prior to signature. Participants will be given sufficient opportunity to decide whether or not they want to participate. If the participant elects to enroll in the study, they will be instructed on how to sign the consent form and a copy will be given to them prior to the initiation of any study procedures.

Randomization

Phase I & II: Participants meeting the inclusion and exclusion criteria will be approached, screened, consented, and enrolled into the study. After obtaining informed consent, participants will be randomized to either complete their first test with no face covering or with a face covering in a 1:1 randomization ratio stratified by sex. A random number generator will be used to pre-determine the randomization group for each participant ID number. The group assignment will be not be revealed to either the participant or the study staff until informed consent is complete.

Cardiopulmonary Exercise Testing (CPET)

During the screening process, subjects will be encouraged to abstain from nicotine and caffeine prior to the test. Subjects will be scheduled to perform a CPET on a treadmill with (arm 1) and without (arm 2) a face covering (with testing for each arm seven to ten days apart). A face covering will be provided to participants randomized into the face covering group, with the option for participants to keep their face covering at the end of the assessment. Subjects will be fitted for metabolic testing (K5 CPET, COSMED, Concord, CA) equipment according to factory requirements. <https://www.cosmed.com/en/products/cardio-pulmonary-exercise-test/k5>

The use of new cloth face coverings beneath the K5 mask will be standardized, with face coverings consisting of the same material and cut/design for each participant (which the participant then keeps or discards). The correct fitting and leak tightness will be confirmed before each test for each subject. This will be achieved through (a) inspiration and (b) expiration with maximal force. During both maneuvers, the valve of the mask is closed leading to abrupt stop of the air flow. The fitting is carefully checked for the absence of any acoustic, sensory or visual indication of leakage (e.g., lifting of the mask, whistling or lateral airflow) by the investigators and the test person.

Phase I CPET Procedures:

The CPET will be performed in an area with immediate access to an automated external defibrillator (AED). Resting blood pressure, heart rate, pulse oxygenation and will be measured and recorded. Explanation of the Borg dyspnea and exertion scales will occur by an Exercise Physiologist prior to beginning test. Each subject will be asked to perform the exercise test to the best of their abilities. At the beginning of the test, subjects will be instructed to perform a walking warm up of 3 minutes at 1.7 speed and 0% incline.

- The Borg Rating of Perceived Exertion (6-20) scale will be used during the test to assess subjective exertion
- The Modified Borg Dyspnea Scale (0-10) will be used to assess subjective shortness of breath.
- Intermittent blood pressure measurements and pulse oximeter measurements will be taken by an exercise physiologist and heart rate will be monitored constantly.

Testing will be terminated if any of the following occurs: (a) subject becomes symptomatic; (b) pain is reported; (c) subject wishes to terminate test; (d) unsafe drop in blood pressure or hypertension over 250/120 mmHg reported; or (e) subject reports a “20” on Borg RPE scale or “10” on Dyspnea scale. Other termination of the test is reserved for the clinical judgment of research staff to ensure safety of the subject. After termination

of the test, subject will be instructed to perform a walking cool-down of 3 to 5 minutes. After subject has completed cool-down, recovery blood pressure, heart rate and pulse oxygenation will be measured and recorded. After completion of the first test, subject will be scheduled for second CPET 7-10 days later to allow for adequate recovery. When data collection is complete, CPET data will be gathered from metabolic cart and matched with subject testing materials.

Phase II CPET Procedures:

Among individuals with history of COVID-19, an ECG will be performed prior to CPET procedures and will be monitored throughout the CPET.

The CPET will be performed in an area with immediate access to an automated external defibrillator (AED). Resting ECG (among individuals with history of COVID-19), blood pressure, heart rate, pulse oxygenation, and blood lactate will be measured and recorded. Explanation of the Borg dyspnea and exertion scales will occur by an Exercise Physiologist prior to beginning test. Each subject will be asked to perform the exercise test to the best of their abilities.

A standard cycle ergometry ramp protocol⁷ will be designed for each participant as used in previous masking study.⁸ The initial workloads and incremental increases will be determined based on the subject's age and weight. The protocol consists of 1 minute of unloaded cycling, followed by a 2-minute warmup at 25 W. The exercise phase consists of continuous progressive increases in power output (25 W · min⁻¹) every three minutes until the subject is unable to maintain 50 rpm. This is followed by 4 min of active recovery at 20 W.

- The Borg Rating of Perceived Exertion (6-20) scale will be used during the test to assess subjective exertion
- The Modified Borg Dyspnea Scale (0-10) will be used to assess subjective shortness of breath.
- Intermittent blood pressure measurements and pulse oximeter measurements will be taken by an exercise physiologist and heart rate will be monitored constantly.
- Blood lactate will be measured pre and post-CPET using a Nova Medical Lactate Plus: Blood Lactate Measuring Meter-Version 2 device.

Testing will be terminated if any of the following occurs: (a) subject becomes symptomatic; (b) pain is reported; (c) subject wishes to terminate test; (d) unsafe drop in blood pressure or hypertension over 250/120 mmHg reported; or (e) subject reports a “20” on Borg RPE scale or “10” on Dyspnea scale. Other termination of the test is reserved for the clinical judgment of research staff to ensure safety of the subject. After termination of the test, subject will be instructed to perform a cycling cool-down of 3 to 5 minutes. After subject has completed cool-down, recovery blood pressure, heart rate and pulse oxygenation will be measured and recorded. After completion of the first test, subject will be scheduled for second CPET 7-10 days later to allow for adequate recovery. When data collection is complete, CPET data will be gathered from metabolic cart and matched with subject testing materials.

Disinfection Procedures

All equipment will be disinfected between each subject contact using BSWH approved disinfectant wipes (sani cloths AF3) using Cidezyme and Cidex OPA with testing strips as per factory requirements. This process will take place in a designated “dirty room” to perform high level disinfecting (e.g., sink and proper ventilation) and has been approved by BSWH Infection Prevention and is effective against COVID-19 spread in addition to other high-consequence infectious diseases (procedure provided in supplementary procedures).

Data Collection Details

All data will be collected during each study visit on paper case report forms or via direct data entry in the study's REDCap database. Complete paper case report forms will be entered in the REDCap database within 3 days of collection. Sources for data include patient reported data and objective results from CPET evaluation.

Staff Training

All study staff will be trained on study procedures at the project launch meeting and subsequent support meetings.

Venue

In-person sessions will take place at BSW Sports Therapy and Research at The Star in Frisco, Texas.

Communication

To facilitate appointment scheduling and timely ongoing communication between study staff and participants, study staff will communicate with participants via their preferred methods of communication (established during screening), whether phone, email, or text message. All communication will be documented on communication logs that will be kept in patient files or in electronic communication logs stored in Excel. Participants will be asked not to transmit sensitive health information via text message, but will be given a secure email message that they can reply to when communicating sensitive health information digitally. Participants will be informed that they may be responsible for charges incurred by text messages.

Study Testing Visits

Participants will be asked to come in at two time points for measurements, surveys, and testing.

Schedule of Assessments**Phase I:**

Study Visit	Visit Details
Initial visit/Visit 1	<ul style="list-style-type: none"> • COVID-19 screening and temperature check is performed • Demographic information (age, race, ethnicity, sex, income, insurance, work history, sport) • Clinical and physical activity information (Physical activity readiness questionnaire, physical activity history, tobacco use, marijuana use, vaping, history of asthma, height, weight, use of beta-blockers) • Attitudes Towards Face Coverings Questionnaire • Cardiopulmonary exercise testing (CPET) <ul style="list-style-type: none"> ◦ Dyspnea scores ◦ Exertion scores ◦ Pulse ox measurements ◦ Blood pressure measurements • Scale of Measuring Subjective Perceptions • Participant will be scheduled for 2nd CPET
Visit 2	<ul style="list-style-type: none"> • COVID-19 screening and temperature check is performed • Attitudes Towards Face Coverings Questionnaire • Cardiopulmonary exercise testing (CPET) <ul style="list-style-type: none"> ◦ Dyspnea scores ◦ Exertion scores ◦ Pulse ox measurements ◦ Blood pressure measurements • <i>If subject is randomized to face covering:</i> Qualitative question describing experience • Quantitative and qualitative questions about difficulty of wearing face coverings during CPET and differences completing the CPET with and without a face covering. • Scale of Measuring Subjective Perceptions

Phase II:

Study Visit	Visit Details
Initial visit/Visit 1	<ul style="list-style-type: none"> COVID-19 screening and temperature check is performed Demographic information (age, race, ethnicity, sex, income, insurance, work history, sport) <i>If subject reports a previous COVID-19 diagnosis:</i> information regarding symptoms, severity, hospitalization, health changes, experience while exercising, and vaccinations will be collected. Clinical and physical activity information (Physical activity readiness questionnaire, physical activity history, tobacco use, marijuana use, vaping, history of asthma, height, weight, use of beta-blockers) Attitudes Towards Face Coverings Questionnaire ECG among individuals with history of COVID-19 Cardiopulmonary exercise testing (CPET) <ul style="list-style-type: none"> Heart rate Dyspnea scores Exertion scores Pulse oximetry measurements Blood pressure measurements Lactate measurements (pre and post-CPET) Scale of Measuring Subjective Perceptions Participant will be scheduled for 2nd CPET
Visit 2	<ul style="list-style-type: none"> COVID-19 screening and temperature check is performed Attitudes Towards Face Coverings Questionnaire ECG among individuals with history of COVID-19 Cardiopulmonary exercise testing (CPET) <ul style="list-style-type: none"> Heart rate Dyspnea scores Exertion scores Pulse oximetry measurements Blood pressure measurements Lactate measurements (pre and post-CPET) <i>When subject is randomized to face covering:</i> Qualitative question describing experience Quantitative and qualitative questions about difficulty of wearing face coverings during CPET and differences completing the CPET with and without a face covering. Scale of Measuring Subjective Perceptions

Compensation and Costs

While we will not pay participants for taking part, participants will be reimbursed a \$50 Visa gift card for their time/effort to attend each of the assessments (two) which are required for research for a total of \$100. Participants will be given the option to keep their face covering that was given to them during CPET testing. Participants will not incur any additional research-related costs due to study participation.

Data Protection & Confidentiality

In order to assure participant confidentiality, all participants will be assigned a unique study identification number. Only one master list will be maintained by the PI and the study coordinator on a secure network drive in a password protected file. All case report forms and databases will use the subject ID number rather than names or other private health information and entered into REDCap. All paper documentation, including

signed paper consent forms and case report forms will be maintained by the PI behind a locked door in a locked file cabinet.

All participants that are screened will be given a screening identification number. Screening reports will not use private health information and will only refer to patients using the screening identification number. After consent, participants will be given a unique subject ID. All documents thereafter will refer to the participant by subject ID. All screening and enrollment data will be tracked on a password protected enrollment tracking spreadsheet which will also contain the link to identifiers. Only authorized study personnel will have access to this database. All data will be shared on the secured Baylor Network Onedrive server.

Subject IDs will be recorded on all pages of case report forms. Protected health information will not be used during data analysis or dissemination. Subjects will only be referred to by their unique Subject IDs.

Data Entry in Database

All subject tracking information will be maintained in a password-protected Excel spreadsheet and REDcap, a HIPAA-compliant (21 CFR Part 11) secure web application on a BSWH computer by trained study staff.

All case report forms and outcomes data will be input into REDcap, a HIPAA-compliant (21 CFR Part 11) secure web application on a BSWH computer by trained study staff.

Data Quality Assurance

Data management functions will occur on a monthly basis and will include data quality checks and verification, as well as internal edit and logic checks (e.g., out of range values, internal inconsistencies). Ten percent of charts will be audited for source document and data entry review. Cross tabulation checks using SAS will also be used. Data will be stored and backed-up periodically on the biostatistician's space on the secure server. Descriptive statistics will be calculated and included into quarterly reports to ensure the quality of data and progress of the study.

Record Retention

All paper source documents will be kept in a double locked storage cabinet in the BSW research office at The Star. All electronic data will be kept on a secure server per federal guidelines. All data will be maintained for two years after study termination per federal guidelines and will be disposed of in accordance to current BSWRI policy.

Management of Subject Safety/ Adverse events

The study staff (PI, Co-Investigators, research coordinators and assistants) will be responsible for collecting and recording all clinical data. As results are collected, all Adverse Events will be identified, graded for severity and assigned causality, reported to the IRB, and compiled for periodic review. After assigning causality, the PI will decide the course of action for the study participant. The PI will evaluate all Adverse Events and determine whether the Adverse Event affects the risk/benefit ratio of the study and whether modifications to the protocol or informed consent form are required. An electronic regulatory binder in REDCap will be used to manage study logs and regulatory documentation. Throughout this process, the PI will inform and collaborate with the research team. The plan to monitor participant data and safety will specifically include the following: (1) Dr. Driver will inspect collected data; (2) The IRB offices will be contacted if there is an Adverse Event due to participation; (3) the research protocol will be revised if it is determined that the protocol or intervention presents an unforeseen risk to participants; (4) if an event occurs that requires immediate attention and Dr. Driver is unavailable, then members of the research team will follow the emergency procedures put in place by the research team, which may include calling emergency medical services; (5) an invitation to BSW Research Institute Quality Assurance will be delivered to conduct a site visit for internal auditing of procedures and documentation.

Study Withdrawal

Subjects may voluntarily discontinue participation in the study at any time, for any reason.

Protocol Deviations

All protocol deviations will be recorded in the participant's chart and electronic regulatory binder (REDCap) as they occur, and subsequently formally to the IRB at continuing review.

Data Analysis

Participant characteristics will be summarized with means and standard deviations or medians and interquartile ranges for numerical variables, and counts and percentages for categorical variables. The primary outcomes, VO₂ max and test duration, will first be assessed for normality using a Kolmogorov-Smirnov test prior to determining the analysis to be used. If the distribution meets the normality assumption, paired t-tests will be used to determine if there is a difference between participants when wearing and not wearing a face covering. If the distribution does not meet the normality assumption, Wilcoxon signed-rank tests will be used. All secondary outcomes will follow the same analysis plan of assessing the normal distribution assumption to determine the appropriate test for each outcome. Inter-rater reliability analysis will be conducted for the Attitudes for Face Coverings Questionnaire. All analysis will be performed using SAS 9.4 at a 0.05 significance level.

Risks & Benefits

- Physical risks: The potential risks include any and all risks associated with exercise including muscular injury, increased blood pressure and heart rate, and cardiac arrest. Other risks include hypoglycemia post-exercise and lightheadedness or syncope. Although some risks are unavoidable, the careful monitoring of signs and symptoms by the subject and clinical staff will minimize these risks.
- No psychological risks have been identified by participating in this study.
- No social risks have been identified by participating in this study.
- No economic risks have been identified by participating in this study.
- No legal risks have been identified by participating in this study.
- Potential benefits: Participants in this study may experience greater confidence in performing aerobic activities and may gain a better understanding of their personal functional exercise capacity at the time of testing. Participants may also better understand their body's response to exercise with and without a face covering which may impact training and performance in recreational and occupational ventures.

The risks posed to study are minimal in this cohort, while the intervention poses multiple substantial benefits to society, as it will shed light on the impact of face coverings on performance in a maximal exercise test. It is hoped that the information gained from this study will contribute to an evidence base regarding the use of face coverings in settings requiring maximal physical effort.

References

1. Centers for Disease Control and Prevention. Considerations for Wearing Cloth Face Coverings. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>. Published 2020. Accessed 7/15/20.
2. World Health Organization. Coronavirus disease (COVID-19) advice for the public: Mythbusters. 2020.
3. University Interscholastic League. COVID-19 Strength & Conditioning and Sport Specific Instruction. 2020.
4. NCAA. Resocialization of Collegiate Sport: Action Plan Considerations. 2020.
5. Ranasinghe C, Jayawardena R, Palihawadana V. Kick start training during the COVID-19 pandemic-Challenges of the sporting community. *Sri Lankan Journal of Sports and Exercise Medicine*. 2019;2(1).

6. Liotta EM, Batra A, Clark JR, et al. Frequent neurologic manifestations and encephalopathy-associated morbidity in Covid-19 patients. *Annals of clinical and translational neurology*. 2020;7(11):2221-2230.
7. GREIWE JS, KAMINSKY LA, WHALEY MH, DWYER GB. Evaluation of the ACSM submaximal ergometer test for estimating JOURNAL/mespex/04.02/00005768-199509000-00015/ENTITY_OV0312/v/2017-07-20T222452Z/r/image-pngO2max. *Medicine & Science in Sports & Exercise*. 1995;27(9):1315-1320.
8. Epstein D, Korytny A, Isenberg Y, et al. Return to training in the COVID-19 era: The physiological effects of face masks during exercise. *Scandinavian journal of medicine & science in sports*.