Research proposal

The effect of wearing three different types of face masks during exercise on oxygen saturation

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Other co-investigators may be added

Participating Research Institutions
Research Office, Faculty of Health Sciences, University of Pretoria
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EXECUTIVE SUMMARY

Given the current COVID-19 pandemic and the growing number of jurisdictions stipulating that face masks must be worn in public, there is growing confusion and concern as to whether it is safe to wear face masks during exercise. Indeed, despite Prof Janse van Rensburg's blog post in the British Journal of Sports Medicine https://blogs.bmj.com/bjsm/2020/06/12/should-people-wear-a-face-mask-during-exercise-what-should-clinicians-advise/ as well as numerous media appearances, opponents of wearing face masks claim masks reduces blood oxygen saturation, and often cite the sad case of a person residing in China who passed away from a pneumothorax after going for a 5km run whilst wearing a face mask (although it has since been uncovered that this person was suffering from other medical conditions).

Unfortunately, the lack of any empirical evidence in this area allows for such opposition opinions to remain. Thus, a study needs to be undertaken to determine whether wearing masks during exercise affects blood oxygen saturation. We want to examine any changes in peripheral oxygen saturation during exercise at 60% of maximal power output [POmax]. Further aims of this study will examine whether exercising whilst wearing a masks increases the perceived effort of exercise (as in, whether exercise becomes harder), whether a person needs to breath harder during exercise, and whether there is any carbon dioxide (CO_2) build up in the area between the mouth and the mask (CO_2 is what is normally breathed out, however, there is concern that masks may 'store' the CO_2)

Participants will exercise whilst not wearing a mask, and whilst wearing a mask (cloth mask; moisture-wicking mask/buff; N95 mask), in a randomised, cross-over design. SpO_2% will be measured by the Apnealink, a device regularly used to examine for oxygen desaturations whilst sleeping. Statistical analysis will examine for within-participant changes in SpO_2% during the increased intensity of exercise, as well as between-condition (mask vs no mask) for SpO_2%.

Currently, the study is planned to be undertaken at Flinders University in Adelaide, South Australia and the University of Pretoria, South Africa. Given the importance of physical activity to health, but also mindful of the need to stop the spread of COVID-19, we believe this study will be met with great interest and will add value to the health of the general public.

Approval from the Ethics Committee of the Faculty of Health Science at the University of Pretoria and Flinders University will be obtained before the start of this study.

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1. DEFINING THE RESEARCH PROBLEM

Given the current COVID-19 pandemic many jurisdictions around the world have legally mandated the wearing of masks, which cover the mouth and nose. Yet there is concern, and even opposition, to wearing masks, partly due to concerns of hypoxemia. Furthermore, while many jurisdictions have allowed, and even encouraged, outdoor exercise as a respite for house quarantine, there is uncertainty as to whether facemasks should be worn during outdoor exercise, and whether it is safe to do so. Opponents of wearing facemasks claim masks reduces blood oxygen saturation, however, there is no evidence to either support or refute their concerns.

Therefore, this study will examine whether different versions of facemasks cause reductions in oxygen saturation whilst exercising. Further aims of this study will examine whether exercising whilst wearing a masks increases the perceived effort of exercise (as in, whether exercise becomes harder), whether a person needs to breath harder during exercise, and whether there is any carbon dioxide (CO_2) build up in the area between the mouth and the mask (CO_2 is what is normally breathed out, however, there is concern that masks may 'store' the CO_2).

2. LITERATURE OVERVIEW

The coronavirus disease 2019 (COVID-19) is a worldwide pandemic. The lockdown levels were recently changed in South Africa and the period for outdoor exercises, such as cycling and jogging, is presently from 4am to 9pm. Exercise is currently restricted to individual activities only and is not permitted in groups. Even so, people choosing to exercise still have the potential of exposure to COVID-19-containing droplets from those around them. While exercising, one must observe the behaviour of others in order to protect oneself, especially from those exercising nearby, to ultimately stop the spread of the virus.

To safeguard the health of all, the key steps to prevent the spread of the disease include the frequent washing of hands with soap, social distancing and covering the face with a mask/buff to limit virus-laden droplets being transmitted. Indeed the government has imposed regulations about wearing masks in public spaces. Guidelines from the National Institute for Communicable Diseases (NICD)[1] and the Department of Health (DoH) refer to general public health with nothing specifically related to exercise. No real evidence exists for the prevention of COVID-19 during exercise and most of the recommendations to date are deductions from other areas of study, specifying how these can be clinically and practically applied.

2.1. How do these protective behaviours impact exercise?

- The highly transmissible COVID-19 disease is a pathogenic viral infection and caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Human-to-human spreading of the virus occurs with infected individual contact, and mainly via small respiratory droplets or aerosols distributed through coughing, sneezing or even exhaling. Droplets enter the lungs via inhalation through the nose or mouth.[2]
- During aerobic exercise, the rate and depth of breathing increases to ensure that more oxygen is absorbed into the blood and CO_2 are removed. Since COVID-19 penetrates the lungs via inhalation through the nose or mouth, it is necessary to be extra cautious during exercise. Human interaction during periods of activities such as running is also worth considering. A recent simulation study by Blocken et al. (Eindhoven University of Technology) using wind tunnel computer imaging, showed that the potential aerodynamic effect of respiratory droplet transfer is greatest when running in a straight line with one person following behind another. In this scenario, it is the person directly behind the others who is more exposed.[3] While this was a simulation study, the authors suggested: 1) running side by side with a two-meter distance between runners; however, this is virtually impossible on public roads; 2) running at least five meters (cycling 10 meters) behind the person in front– which may become a problem if there are many people nearby; 3) running with a mask or buff on as this will reduce the droplets that are aerolised by the virus; and 4) staggered running/cycling, especially when passing someone.

2.2 Available literature

Fikenzer et al.[4] only evaluated wearing no mask, a surgical mask and an FFP2/N95 mask during exercise. They measured pulmonary function, blood lactate and cardiac output in a small sample size of 12 male participants. They performed an incremental exertion test (IET) on a semi-recumbent ergometer (GE eBike, GE Healthcare GmbH, Solingen, Germany, Germany) at a constant speed of 60–70 revolutions per minute (rpm). The test began at a workload of 50W with an increase of 50W within 3min (as a ramp) until voluntary exhaustion occurred. Each subject continued for an additional 10min, and a recovery period at a workload of 25 W. They concluded ventilation, cardiopulmonary exercise capacity and comfort are reduced by surgical masks and highly impaired by FFP2/N95 face masks in healthy individuals.

Pifarré et al.[5] assessed 8 subjects (2 women) at baseline with and without a mask (type of mask not mentioned). The Ruffier protocol (21 push-ups in ambient air in a public park) was performed with a mask. HR (heart rate), O_2 and CO_2 concentration inside the mask and the Saturation O_2 were determined. They concluded that the use of masks during short exercise (6-8 METS intensity) decreases O_2 by 3.7% and increases CO_2 concentration by 20%. During exercise, a 20000ppm CO_2 (2%) was reached and wearing a mask may be uncomfortable and symptomatic for some individuals.

Chandrasekaran and Fernandes[6] warned against exercise with a tight face mask due to the possibility of inducing a hypercapnic hypoxia environment [inadequate Oxygen (O_2) and Carbon dioxide (CO_2) exchange]. They cite a study by Roberge et.al.[7] performed in 2010 on healthcare workers. This acidic environment at the alveolar and blood vessels level may induce physiological alterations when exercising with facemasks: 1) Metabolic shift; 2) cardiorespiratory stress; 3) excretory system altercations; 4) Immune mechanism; 5) Brain and nervous system.

A short communication by Ting and Villanueva[8] indicated that wearing surgical face masks while jogging did not decrease oxygenation in 10 healthy participants. They measured oxygen saturation using a pulse oximeter at 4 intervals: before jogging, and at the 10th, 20th and 30th minute (end) of their jog. However, they did recommend a bigger formal study to provide stronger evidence before making final conclusions.

In order to help us better understand whether wearing a face mask during exercise causes any changes in blood oxygenation saturation, we plan to do a number of exercise tests on a cycle ergometer, separated by several days, whilst wearing different types of masks and no mask. The aim and objectives are based around the masks' multilayered design, along with a buildup of moisture on the inner layer of the mask, restricting the free movement of air.

3. AIM, OBJECTIVES and HYPOTHESIS

3.1. Aim

This research study will aim to examine the wearing of different types of face masks during exercise and its effect on the gas composition of inhaled air, blood oxygenation levels, perceived exertion, objective inspiratory effort and metabolic response of the athlete.

3.2. Objectives

Specific objectives will include the quantification of the influence of 3 types of face masks (of different material i.e. N95 medical-grade vs cotton vs elastane), during a standardized cycle exercise, on:

1. **gas composition of inhaled air** by measuring the CO_2 concentration between the mouth and the inner layer of the masks.
2. **blood oxygen** saturation levels by utilizing Apnealink
3. **perceived exertion** as measured by the Borg Rating of Perceived Effort scale
4. **objectively measured inspiratory effort** with the aid of the Apnealink,
5. **metabolic response** as measured by serum lactate levels

3.3. Hypotheses

We hypothesize that depending on mask type, the different masks will:

1. result in the accumulation of different concentrations of CO_2 between the mouth and the inner layer of the mask
2. reduce blood oxygenation levels
3. increase the rating of perceived exertion of undertaking exercise,
4. increase inspiratory effort
5. result in different metabolic response rates

4. METHODS

4.1. Research Program

The compilation of this research will be conducted in collaboration from both:

i. **The University of Pretoria.** Site lead will be Prof Christa Janse van Rensburg, Head of Sports Medicine within the Faculty of Health Sciences, a clinical sports physician and rheumatologist. The University of Pretoria is equipped to undertake this research.

ii. **The Flinders University**, Flinders Health and Medical Research Institute, College of Medicine and Public Health, Adelaide. Site lead will be Dr Stevens [B.App.Sc (Exercise and Sport Science) Honours, PhD] who has extensive experience in both exercise and respiratory physiology. Dr Stevens has undertaken research examining exercise-induced changes in cerebral oxygenation, which is caused by an exercise-induced hyperventilation response. Since moving into sleep research, Dr Stevens specialised in studying the aetiology, outcomes, and alternative treatments for nocturnal respiratory disorders.

iii. This **research is supported** by the office of the British Journal of Sports Medicine. (Annexure A).

iv. This research will be undertaken in the exercise science laboratories of:
   a. The University of Pretoria - Sports, Exercise Medicine, and Lifestyle Institute (SEMLI), Hillcrest Campus.
   b. Flinders University - Adelaide Institute for Sleep Health (Mark Oliphant Building)

   Both laboratories are equipped to perform the methodology and have infection control guidelines in place to commence research during the COVID-19 pandemic.

v. Research will not proceed until ethical approval is received by the University of Pretoria’s and Flinders University`s Research Ethics Committees. Approval provided by the University of Pretoria will be forwarded to the Flinders HREC and vice versa.

vi. The recruitment, methodology, and data storage (described later) will be replicated at both sites.

4.2. Initial Study Setting

Initial recruitment for participants will occur through advertisements posted around both Universities. Likewise, social media accounts affiliated with both universities will be used to advertise.

The advertisements, and social media posts, will have contact information for the study. After a potential participant has expressed interest, a member of the investigator team will send the potential participant the Participant Information Sheet, as well as ask for their contact number, and a time several days ahead to contact them to discuss the study.

The follow-up phone call will allow the potential participant to ask any questions they may have, where after a data sampling appointment will be arranged. Consent will occur during the first exercise test, after the participant has seen the masks and the exercise equipment, and had one final chance to ask questions prior to signing consent.

4.3. Selection of participants

A population of 30 participants (in total between the 2 sites) that will include anyone over the age of 18 years (due to Covid-19 precautions there are capacity restrictions at the University of Pretoria, and only 12 participants will be assessed at the University of Pretoria site).
We will only include participants who did not have a recent COVID-19 infection. Participants with chronic respiratory condition (e.g., asthma, chronic obstructive pulmonary disease), known cardiovascular problems (e.g., congestive heart failure, atrial fibrillation), known orthopaedic conditions that will be exacerbated by exercise (e.g., rheumatoid arthritis), or musculoskeletal injuries, nor takes any medications that may affect respiration (for example, opioids and physician recommended), will be excluded.

4.3.1. Informed Consent

All potential volunteers will be informed regarding the study and will be asked to sign an Participants Information Leaflet and Informed Consent Form at registration (Annexure B).

4.4. Data collection and procedures

Data will be collected as follows:
Prior to any exercise participants will complete the Physical Activity Readiness Questionnaire (PAR-Q), which is the standard questionnaire to ensure participants are safe to partake in exercise (Annexure C). All participants will undertake five separate exercise sessions separated by at least 48 hours.

4.4.1. Test 1 (baseline)

The first cycle exercise test will be to determine maximal power output (POmax) during cycling, as well as maximal heart rate (heart rate monitor), ventilatory threshold (VO2max test) and metabolic threshold (serum lactate levels). This data will be used to prescribe the exercise intensity for the next 4 exercise sessions.

A. Measurement of maximum power output (POmax)

At the start of the incremental exertion test, participants will cycle at a workload of 50W (very light workload) for three minutes. From minute four, the workload is increased by 20W every 3 minutes until the participant reaches volitional fatigue. The last completed minute of cycling is the POmax. Incremental exertion tests are extremely common both in research and clinical practice.

B. Measurement of HR and VO2max

Participants will be fitted with a Polar Team Pro sensor and chest strap (Polar Electro Oy, Kempele, Finland) for continuous online recording of heart rate (HR). A METAMAX 3B (Cortex, Germany) portable metabolic analyser, prepared and calibrated as per manufacturer instructions, will be used for continuous online sampling of expired air for the measurement of pulmonary gas exchange and metabolic parameters (oxygen uptake VO2, carbon dioxide expulsion VCO2, minute ventilation VE, respiratory exchange ratio RER). This will be done during submaximal steady-state, progressive incremental, and/or maximal exercise intensities on ergometers simulating a sport-specific exercise modality (e.g. Wattbikes), and will permit measurement of maximum oxygen uptake (VO2max) and mechanical efficiency (ME) during exercise.[9]

C. Measurement of lactate

A small blood sample (0.3µl) will be collected by means of lancet prick of the earlobe to determine the blood lactate concentration (mmol/l) of all participants. Blood lactate concentration will be measured using a LactatePro2 (Arkray Inc. Shiga, Japan) portable analyser and test strips. This will permit the derivation of exercise intensity transition thresholds (lactate and anaerobic thresholds). Lactate will be sampled at rest and then every 3 minutes until the participant reaches volitional fatigue (threshold reached).[9]

4.4.2. Test 2-5 (mask testing)

In the next 4 submaximal exercise sessions, participants will be asked to exercise whilst wearing three different types of masks, or not wearing a mask as a control. The order in which participants wear a mask will be randomised. All masks will be worn only once. The masks tested are:

a) N95 surgical mask – the gold standard medical grade mask used to stop transmission of airborne and droplet pathogens
b) Cotton mask – this mask is regularly available at retailers and is a popular choice for non-medical workers
c) Sports Mask of elastane (spandex, moisture-wicking buff) – these masks are popular with people who exercise regularly as they block dirt and insects from the airway, whilst claiming not to reduce airflow

During the four submaximal exercise sessions, participants will be asked to;

- Sit quietly for 5 minutes whilst wearing the mask
- Cycle at 30% of POmax for 5 minutes as a warm-up
- Cycle at 60% of POmax for 30 minutes
- Cycle at 30% of POmax for 5 minutes as a cool down

A. Measurement of Carbon dioxide (CO_2)

CO_2 build-up between the mouth and the inner layer of the mask will be measured by a very fine catheter placed inside the mask (the opening sealed with Prestik), which will be connected to a CO_2 analyser. *This will address hypothesis 1.*

B. Measurement of blood oxygen saturation levels

Blood oxygen saturation levels will be measured by respiratory polygraphy (Apnealink, Resmed Inc). The Apnealink has a fingertip blood oxygenation measurement device (exactly the same as those in hospitals), which measures peripheral oxygenation at 1Hz. The device is routinely used to determine hypoxemia in people with suspected obstructive sleep apnea, and chronic obstructive pulmonary disease. *This will address hypothesis 2.*

C. Measurement of perceived exertion

Every 5 minutes during exercise, participants will be asked to indicate their perceived exertion, by pointing to a number on a sheet. Increases in the perceived effort of exercise - measured by Borg Rating of Perceived Effort scale, is on a 6-20 Likert scale (each number is meant to represent heart rate levels). (Annexure D) Participants will merely point to the number that best represents their perceived exertion. *This will address hypothesis 3.*

D. Measurement of inspiratory effort

The Apnealink measure respiratory effort via a waveform (200Hz), from base to peak in inspiration. It is possible to measure inspiratory effort by measuring the area under the curve for the first half of each 'wave'. A Matlab based analysis tool, which is capable of performing this measurement, will be employed. This will address hypothesis 4.

E. Blood lactate concentration

As explained in 4.4.1.C above, a small blood sample (0.3µl) will be collected by means of lancet prick of the earlobe to determine the blood lactate concentration (mmol/l) of all participants. Lactate will be sampled at rest before warm-up, after warm-up, in the middle of the exercise session and directly after the exercise session.[9] *This will address hypothesis 5.*

4.5. General precautions

For COVID-19 infection control reasons, each mask will be used only once.

At both the University of Pretoria and Flinders, trained exercise physiologists/scientists will administer the tests. Participants will wear a heart rate monitor during the whole test for safety purposes. The total time wearing a mask is 45 minutes

Participants will be provided with a bottle of water to consume prior to and after exercise. However will be informed they cannot drink water whilst wearing the mask, therefore, will need to be well hydrated before commencing exercise. It is normal to exercise for over an hour without drinking.

4.5.1. COVID-19 PRECAUTION

Whilst small, there is the chance of being exposed to COVID-19 if a participant is an asymptomatic carrier. To mitigate this risk, all investigators involved in the exercise data collection will wear N95 face masks. All participants will be health screened for COVID-19 (health questions on potential exposure, temperature screening) which is commonplace at both sites. The test area will be sanitised before and after each test.

This research will be undertaken in the exercise science laboratories of both Flinders University, Adelaide Institute for Sleep Health (Mark Oliphant Building), and The University of Pretoria, Sport Exercise Medicine, and Lifestyle Institute (SEMLI), Hillcrest Campus. Both laboratories are equipped to perform the methodology and have infection control guidelines in place to commence research during the COVID-19 pandemic.

4.6. Data Management and Analysis

Tanita Cronje, from The University of Pretoria, will conduct the statistical data analysis. (Annexure E)

The participants will consist of a convenience sample of 30 participants who will take part in a randomized cross-over design. Each participant will have an initial round where all baseline characteristics will be collected after which they will take part in 4 rounds, each time wearing a different type of mask or no mask. The order in which the participants will or will not be wearing the masks will be randomized. The data analysis will consist of descriptive statistics such as mean, median, standard deviations, frequencies, proportions, etc. to describe the results, and graphical representations can be made where applicable to assist in visualizing aspects of the data. Inferential tests may include tests like the ANOVA test, followed by Tukey's post hoc analysis or the non-parametric alternative Friedman test followed by Dunn's post hoc test for those instances where the data was not normally distributed.

A power analysis showed that for a parametric test like the ANOVA with a large effect size (calculated from previous studies considering similar variables), using G*Power 3.1.9.2, at an alpha level of 5% and a power of 80%, it can be seen that a sample of 24 would be required per group

5. ETHICAL CONSIDERATIONS

- The study will be performed in accordance with the principals of the Declaration of Helsinki.
- The research study will be submitted for ethical approval to the Research Ethics Committee of the Faculty of Health Science at the University, and approval will be obtained prior to the start of this study.
- Written informed consent will be obtained from all the participants who volunteer to take part in the study.
- The names of participants will remain anonymous.
- Feedback will be given to the participants on the outcome of the study.
- There will be no incentives for the participants in the study.
- Data will be stored securely for a period of 15 years post-study.

6. BUDGET

Item Description	**Cost**	**Units**	**TOTAL (SA Rand)**
Face masks: a. N95	R615.00 per mask	32	R 19 680.00
b. 2 ply cotton mask	R69.00 per mask	32	R 2 208.00
c. Moisture wicking Buff	R279.90 per unit	32	R 8 956.80
Paper Copies	R2.00 / page		R 500.00
COVID-19 precaution: Lab cleaning Sanitiser – Surgical Spirits	R100 / 100ml	10	R 1 000.00
Surface wipes (Tuffies)	$100.00AUD	6 x 150	R 1 249.80
Surface disinfectant spray	$12.00AUD	5	R 749.88
PPE - 3ply Surgical Face Mask	R499.00 / 50 pack	2	R 998.00
Latex/Nitrile gloves	$16.00AUD	9 (3x each size)	R 1799.82
Lactate Tests Lactate Pro2 analyser Lactate Pro2 test strips	€329.00 €44.90 / 25 pack	1 15 packs	R 7 238.00 R 14 850.00
GeoTech CO_2 analyser [G110 - CO_2 & O_2 100% range analyser] Import costs (20% duty, 15% VAT, insurance, transport)	GBP 1,226.82 GBP692.62	1 1	R 29 443.68 R 15 888.73
ApneaLink™ Plus (APP)	$2000.00AUD	3	R 74 997.18
Research Travel allowance		1	R 17 998.32
Total Project Cost			**R 197 558.21**

Funding: The research in Pretoria will be funded by Section Sports Medicine, University of Pretoria. No funding either in Adelaide or Pretoria is available at the time of submission.

7. TIME LINES AND PROJECT MANAGEMENT

	Protocol	**Ethics Submission & Approval**	**Data Collection**	**Data Analysis**	**Write-up/ Publish**
July 2020	✓				
August 2020		✓			
August 2020 - October 2020			✓		
October 2020 - November 2020				✓	
November 2020 - December 2020					✓

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In future, other co-authors may be added

9. REPORTING

The results of the study will be electronically available to all participants and will be published in accredited, peer-reviewed high impact scientific journals and presented at scientific conferences. Data reported in scientific journals will be analysed and presented anonymously, and will not include any information that will identify any participant.

10. REFERENCES

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11. ANNEXURE

ANNEXURE A: LETTER OF SUPPORT BY THE OFFICE OF THE BRITISH JOURNAL OF SPORTS MEDICINE

ANNEXURE B: PARTICIPANTS INFORMATION LEAFLET AND INFORMED CONSENT FORM

ANNEXURE C: PHYSICAL ACTIVITY READINESS QUESTIONNAIRE (PAR-Q) QUESTIONNAIRE

ANNEXURE D: BORG RATING OF PERCEIVED EFFORT SCALE

ANNEXURE E: LETTER OF STATISTICAL SUPPORT