

Participant Information Sheet

Investigating the effect of inspiratory muscle training on breathing patterns in healthy subjects and individuals with a breathing pattern disorder.

We would like to invite you to take part in our research study being conducted by researchers from Sport, Exercise and Rehabilitation Sciences at the University of Kent. Before you decide if you would like to participate in the study, we want you to understand why the research is being done, and what we will ask you to do. Please take your time to read this leaflet. It is a good idea to talk to your friends or family about whether you should take part. One of our team will go through the participant information sheet with you and answer any questions you have.

What is the purpose of the research?

This study will investigate the effect of breathing training on breathing patterns.

Why have I been invited to take part in this study?

You have been invited to take part in this study because we are looking for volunteers aged over 18 years, who feel that their activity and performance is limited by their breathing. We are particularly interested in people who have a breathing pattern disorder, and we will test for this. We will complete an assessment with you before you start the study. This is to make sure that you are suitable to participate in the study. This study may not be suitable for you, and we will discuss potential exclusion criteria with you individually.

How long am I expected to be part of the study?

The testing will require a total of four visits to the University of Kent, Canterbury Campus. Each visit is expected to last around three hours. This study will also require you to perform breathing training at home, using a breathing training device. This will require you to perform 2 sets of 30 breaths daily for 6 weeks, each set should take no longer than 5 minutes.

Do I have to take part in the study?

No, taking part is voluntary. It is up to you whether you want to join the study, and we do not want to influence you in any way. If you agree to take part, we will ask you to sign an informed consent form and we will give you a copy of this form. However, you are free to withdraw from the study at any time without giving a reason and there will be no consequence at all.

What will I be asked to do if I agree to take part?

If you agree to take part in the study, you will be asked to attend two testing sessions. You will then perform a 6-week daily breathing training programme at home and then re-attend for two final testing sessions. Testing sessions will take place in a research laboratory and a biomechanics laboratory located within Sport, Exercise and Rehabilitation Sciences at the University of Kent on the Canterbury Campus. During the 6-week home programme, study researchers will review your progress weekly via a video call.

Visit one

Your first visit will be for a breathing assessment. You will be asked to fill in some short health and symptom questionnaires. This will let us check that you do not suffer from any medical conditions that would stop you from participating in the study. We will check that you understand what is involved in this research study and we will ask you to sign the consent form. We will then take a measurement of your height and weight and record your age, gender, and ethnicity.

We will measure the pressure that you generate from your nose by asking you to breathe in quickly through your nose via a small facemask. The level of nitric oxide in your breath will be

recorded by asking you to breathe out slowly into a machine. You will be asked to perform a breathing test, known as spirometry. This measures the maximum volume of air that you can breathe in and out with a maximal effort. From a sitting position, you will breathe in until your lungs are full. You will then breathe out as hard and as fast as you can via a mouthpiece until your lungs are empty. It is likely that we will measure this approximately 3 times. We will then measure your breathing strength. This will involve a fast and strong breath in via a mouthpiece followed by a relaxed slow breath out. You will repeat this around 10 times.

You will be asked to perform a maximal effort exercise test on a stationary bicycle. This test will measure your oxygen requirements during exercise. This will involve a steady warm up cycle for around 10 minutes and then a continuous cycle with increasing workload until you are no longer able to keep cycling. We will measure the air that you breathe out via a facemask, which you will wear throughout the whole test. We will monitor your heart rate and oxygen levels throughout the test. After you have completed the cycle test, we will monitor your breathing for 20 to 30 minutes and ask you to repeat the spirometry test at regular intervals.

Visit two

On your second visit we will attach 90 non-invasive self-adhesive small reflective markers on your torso - that is the area usually covered by a t-shirt. You will therefore need to be chest bare if you are male and wear a bra or sports bra if you are female. We may need to shave your chest where the markers attach if hair prevents adequate marker contact. Please speak to the research team if you identify as a gender that would make this difficult for you. We will make every effort to ensure you feel comfortable and are happy to participate in the study.

You will be asked to perform a sub-maximal exercise test on a stationary cycle, cycling at low, moderate and high intensity. The level that you will cycle at will be determined following the exercise test at visit one. Before you start the test, during and after we will be recording your chest movement with 3D-motion capture cameras mounted on the wall and around the room. The cameras will record the movement of the reflective markers on your chest. We will also record a video of your breathing with a mobile phone immediately after you have completed the exercise test.

A breathing training device is a small handheld device that will provide some resistance to your "in" breath. Once you have recovered from the cycle test, we will instruct you on how to use the breathing training device and give you time to become familiar with it. Once you are happy with the correct technique, we will repeat the submaximal exercise test and chest wall recordings.

You will then be given a breathing training device to use daily at home for 6 weeks. This will require two sets of 30 breaths daily. Each set should not take more than 5 minutes to complete. A member of the research team will contact you weekly to review your progress.

Visit three

Will be a repeat of visit one. You will not be required to perform post-exercise spirometry.

Visit four

Will be a repeat of visit two.

What are the possible side effects of taking part?

The health and symptom questionnaires are designed to make sure that you are suitable to participate in the study and to help avoid side effects. However, as with all exercise tests, there is a risk of general fatigue, muscle/joint soreness and shortness of breath. If these are experienced, symptoms will be short-lived and will resolve. As the cycle tests involve maximal

and sub-maximal exertion, there are some cardiac risks, such as irregular heartbeat and sudden heart attack. This is no different to any 'normal' exercise that you may do. You will undergo a warm-up as part of the exercise protocol to minimise these risks. Your heart rate, oxygen levels and perceived breathlessness will also be monitored throughout exercise testing. The test will be stopped at any point if it is considered that you are having difficulty breathing or are incurring any other form of distress. You are in control of the exercise tests and can stop the test at any point.

If your resting lung function appears reduced (less than 70% of your predicted) you will not be able to participate in the study. Your lung function will be closely monitored during and after the first exercise test and if it falls below 10% of your baseline level, you will be offered inhaled medication (Salbutamol) to reverse the reduction in lung function. This will be given via a standard inhaler. Alternatively, you can use your own reliever inhaler if you have one. You will be advised to remain in the laboratory until your lung function is within 10% of your baseline reading.

Because we are looking at breathing against resistance, you may experience some shortness of breath during testing or some breathing muscle fatigue. This should not last long and will improve on stopping the test. The research team can show you positioning and breathing exercises to settle your breathing if this is required. The study will involve repeated deep breathing which could result in some light-headedness. We will instruct you on a correct breathing technique to help to avoid this. You can, of course, stop the study at any time without reason at any point during the study.

There may also be a risk of skin irritation from the hypo-allergenic tape that secures the markers onto your torso. Advice on how to manage this, should it occur, will be given by the research team.

What are the possible benefits from taking part?

We can offer you £30 to pay you for your time and to reimburse you for travel expenses. This will be payable via bank transfer on full completion of the study. We will also inform you of your breathing assessment and exercise test results. This will give you a better understanding of your breathing. You will also receive some training on how to improve your breathing pattern. Your participation may inform the future use of breathing training devices in people with inefficient breathing patterns.

Will my taking part be confidential?

Yes, the records obtained while you are in this study will always remain strictly confidential, including your payment details. We will take steps to protect your personal information and will not include your name on any reports or publications.

The consent form is the only form that will contain information that can identify you (e.g. name and contact details) and this will be stored within Sport, Exercise and Rehabilitation Sciences' premises in accordance with the Data Protection Act 2018 and the University's own data protection procedures. The consent form includes space for an anonymous code that will be written against your test scores and the questionnaires you complete. So, no one will be able to see what your test scores and questionnaire answers are except for the research team who have the consent form with both your code and your name. The consent forms are kept for up to 12 months after testing so that we can show our ethics committee that you gave written informed consent and are then securely destroyed. Anonymous data such as your test scores and questionnaires will be stored for up to 5 years after the study. No personal data will be passed on to any third party.

You can access the University of Kent's privacy notice related to research here:

[10 GDPR Privacy Notice - Research.pdf](#)

What will happen to the results of the research?

We will analyse the anonymous results to help us understand if using a breathing training device improves breathing patterns. The anonymous results may also be used by the company that is providing the breathing training device. This company is called POWERbreathe International Ltd, and they may use the results to develop enhanced feedback programmes that will be provided to users. Your anonymised data may also be used in future research projects.

The results may be published in scientific journals and/or conferences, but all data will be anonymous or presented as overall group summaries of all data combined. We will also report group results to funding organisations and may present the data at national and international meetings. You will not be identified in any report or publication.

Who is organising and funding the study?

The study is organised and part-funded by Sport, Exercise and Rehabilitation Sciences at the University of Kent. The study is also supported by POWERbreathe International Ltd, a privately own company that makes and sells breathing training devices. Support is via a signature research theme scholarship.

Who has reviewed this study?

The Sport, Exercise and Rehabilitation Sciences Ethics and Advisory Group at the University of Kent has approved this study.

Who can I contact if I need to ask more questions about the study?

You can contact the research team at any time using the contact details below. If you have any concerns or wish to complain about any aspect of the study or in the way that you have been approached or treated during the study, you may contact Dr Katrina Taylor, Chair of the Sport, Exercise and Rehabilitation Sciences Research Ethics Advisory Group (K.Taylor-399@kent.ac.uk).

What should I do now?

If you are happy to participate in the research, then please contact Kris Bahadur on the contact details below to book into a testing session.

Prior to visit one, please ensure that:

- You do not consume food within 2 hours of testing or alcohol within 24 hours of testing
- You avoid sports drinks and caffeine intake 4 hours before testing
- You are allowed to drink water
- You avoid eating green leafy vegetables or foods high in nitrates for at least three hours before visit one and three
- You are free from illness or infection in the two weeks before testing
- You avoid high intensity exercise within 24 hours of testing
- You avoid smoking for at least an hour before testing

Thank you for taking the time to read this information sheet.

Research Team Information:

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