**Participants information sheet**

**Study title: The influence of aerobic exercise on conditioned pain modulation and manipulation induced pain modulation effects in participants with tennis elbow.**

**Investigators**

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**Invitation statement**

This is an invitation to participate in a research study that will contribute to a PhD. Please take your time to read and understand the following information about why the study is conducted and what it will involve. Do not hesitate to ask us if you need any clarification or if you would like more details. This information sheet will help you decide whether or not to take part in the study.

**What is the research study about?**

My name is Ahmad Muhsen, and I am a PhD physiotherapy student supervised by Professor Tony Wright, Dr Penny Moss (School of Physiotherapy and Exercise Science at Curtin University) and Dr Will Gibson (School of Physiotherapy, University of Notre Dame, Australia). I am investigating 2 natural responses that our nervous system uses to relieve pain called conditioned pain modulation (CPM) and manual therapy-induced pain modulation (MIPM). CPM refers to the capability of our body to inhibit the painfulness of one stimulus when another painful stimulus is also felt. For example, if you have a headache but then you stub your toe, the headache is forgotten. MIPM is the pain relieving effect you get following a manual therapy treatment.

In this study, we are exploring the effect that a period of aerobic cycling exercise has on CPM and MIPM responses in people with tennis elbow. If we find that both CPM and MIPM responses behave in the same way, then this may potentially indicate that they share similar pain processes in the nervous system. This will broaden our knowledge about the way in which aerobic exercise influences natural pain relieving effects in the body.

**Why am I being asked to take part?**

You have been invited to participate in the study because you have had elbow pain for more than 6 weeks and have been diagnosed with tennis elbow.

**Do I have to take part in this research study?**

Taking part however is completely voluntary. It is your choice to take part or not. If you decide to take part and then change your mind, that is okay, you can withdraw from the project at any time, even once it is underway. You do not have to give us a reason for withdrawing; just tell us that you want to stop. Whether you choose to take part or not, it will not affect your relationship with the University or your ongoing treatment. There will be no financial costs to you in taking part and we will provide you with a $20 voucher to help pay for travel or parking.

**What will I have to do if I take part?**

If you choose to participate in the study, you will be asked to attend the Physiotherapy Clinic at the School of Physiotherapy and Exercise Science at the Bentley campus of Curtin University for 3 test sessions, with a rest period of 3 days in between. Each test session will each take approximately one and half hours. We will ask you to avoid taking pain medications 24 hours before each test occasion although you can continue to take them during the course of the experiment. We will also ask you to avoid any additional physiotherapy treatment and other physical treatments (e.g. chiropractic or acupuncture) on testing days.

**Test session 1**

We will initially assess you through questioning and physical assessment to confirm that you have tennis elbow. This will include testing your muscle strength and, and examining the nerve mobility of your arm. We will also ask you general information about your age and present and previous medical conditions. The physical tests may reproduce some of your symptoms but we will stop any test that makes you become too uncomfortable. This assessment is a standard clinical procedure performed in physiotherapy practice to assess people with tennis elbow. Once we have confirmed that you have tennis elbow, you will be asked to sign a consent form for the study. You will then undergo CPM testing followed by MIPM assessment on the same assessment day, with 15mins rest period in between.

**CPM testing:** For this testing you will be comfortably sitting on a chair with your forearm resting on a table. The assessor will use a device with a small rounded tip called a pressure algometer to apply a pressure stimulus over an area of 1 cm² in the wrist and elbow of your tennis elbow arm. The pressure will gradually increase and you will need to press a control button at the moment you feel the sensation of pressure begins to become painful. This point refers to the threshold of your pain or pressure pain threshold (PPT). When you press the button, the pressure immediately stops. We are only seeking to measure your pain threshold so there is no sustained pain. Three PPT measurements will be taken at each site on the symptomatic side with 10-15s intervals between each. The assessor will initially carry out the PPT testing on your unaffected wrist to allow you to become familiar with the process. Then, you will place your other hand in a cold water bath (5°-7°C) for a period of 2mins. The water will be cold and you may experience some discomfort but this should not be excessive. While your hand is in the water, we will repeat PPT testing on your sore elbow and wrist. After 2mins, you will remove your hand from the water and the assessor will immediately take PPT measurements one final time. If you find the cold water too unpleasant, you can withdraw your hand at any stage and we will stop the experiment.

**MIPM assessment**: 15mins after completing the CPM testing we will test you for MIPM. You will lie on your back on a treatment couch and the assessor will complete 3 tests. First he will repeat the PPT measurements on your sore elbow and wrist, as described above. The assessor will also assess the strength of your grip before you get pain and the mobility of the nerves in your arm. This test involves the assessor in slowly moving your arm away from your body until you start to feel a slight pulling sensation. The angle is then measured. You will then receive a gentle mobilisation treatment for your neck while comfortably lying on your back. Using one hand the assessor will stabilize your shoulder blade, while other hand will rhythmically move your neck towards your unaffected elbow using very small movements. The mobilisation should be painless. If you feel any discomfort during the mobilisation we will stop. The neck mobilisation will be performed for 60s, and will be repeated three times, with 60-s rest periods in between (5 min total). After the neck mobilisation, the assessor will immediately repeat the measurements of PPT, grip strength and nerve mobility as previously described. This is the end of the test session.

After completing CPM and MIPM testing, we will ask you to complete a pre-exercise screening tool to ensure your eligibility for exercise testing. If you are eligible, you will then be asked to fill in a questionnaire about your general physical activity level (the questionnaires will take approximately 30min to complete).

**Test session 2 & 3**

Three days following Test session 1 we will assign you into one of 2 groups. Group 1 will receive a 15min session of low intensity stationary cycling and group 2 will receive a 15min session of moderate intensity stationary cycling. Before starting the cycling session, each group will be tested for their pain threshold. Both groups will then undergo CPM testing and MIPM testing immediately after cycling in 2 different sessions in 2 days, with 3 days-rest in between. Your assignment into one of the 2 cycling groups and CPM testing and MIPM assessment will be done by chance, like tossing a coin. For the length of the study neither you nor the researcher will know what exercise group you are in. The cycling activity will be monitored by a physiotherapy student and their clinical supervisor.

**Pressure pain threshold (PPT):** This part involves measuring pressure pain threshold by using the pressure algometer in the same way described above in the CPM testing, but without cold water immersion. Again, we are only seeking to measure your pain threshold so there is no sustained pain. The test will be initially carried out on your opposite wrist to allow you to become familiar with the process. Three PPT measurements will be taken at each site on the symptomatic side with 10-15s intervals between each.

**Stationary cycling exercise**: After taking PPT measurements, you will receive a 15min session of low or moderate intensity stationary cycling, depending on the group you are allocated into. Both groups will follow the same experimental procedure, but each will undergo different exercise intensity. You will be fitted with a heart rate monitor to observe and monitor your heart rate at rest and during cycling. To determine the desired cycling intensities, we will initially measure your heart rate at rest. You will ride a stationary bike and start warming up to gradually reach the target intensity within 5mins. You will then continue cycling at the required intensity level for the next 10mins. Your heart rate will be continuously monitored to ensure that you maintain the target exercise intensity. A physiotherapy student, who is under the close supervision of senior physiotherapy staff member at Curtin University Physiotherapy Clinic will accompany you throughout the cycling session. After the 15-mins cycling session, the physiotherapy student will guide you into the examination room, where the assessor will assess you for the CPM and MIPM testing.

**CPM testing:** Following the cycling session, you will sit on a chair with your affected forearm resting on a table for PPT measurements in the way described above before cycling. Then, you will place your other hand in a cold water bath (7°C) for a period of 2mins. The water will be cold and you may experience some discomfort but this should not be excessive. While this hand is in the water, we will repeat PPT testing on your sore elbow and wrist. We will also ask you to rate the intensity of any discomfort you feel in the cold water. After 2mins, you will remove your hand from the water and the assessor will immediately take PPT measurements one final time. If you find the cold water too unpleasant, you can withdraw your hand at any stage and we will stop the experiment.

**MIPM assessment**: Immediately following the cycling session we will also test MIPM. You will lie on your back on a bed and the assessor will complete 3 tests. First he will repeat the PPT measurements on your sore elbow and wrist, as described above. The assessor will also assess the strength of your grip before you get pain and the mobility of the nerves in your arm. This test involves the assessor in slowly moving your arm away from your body until you start to feel a slight pulling sensation. The angle is then measured. You will then receive a gentle mobilisation treatment for your neck while comfortably lying on your back. Using one hand the assessor will stabilize your shoulder blade, while other hand will rhythmically move your neck towards your unaffected elbow using very small movements. The mobilisation should be painless. If you feel any discomfort during the mobilisation we will stop. The neck mobilisation will be performed for 60s, and will be repeated three times, with 60-s rest periods in between (5 min total). After the neck mobilisation, the assessor will immediately repeat the measurements of PPT, grip strength and nerve mobility as previously described. This is the end of the baseline test session.

**What are the possible risks, inconveniences, and discomforts?**

The testing will take a total of approximately4 and a half hours. When your hand is in the cold water, you may experience discomfort but there will be no sustained pain after the immersion. You can withdraw from any of the testing at any time. Apart from this, we do not expect that there will be any risks or inconveniences associated with taking part in this study. The exercise will be moderately vigorous and you may experience some fatigue and muscle soreness after the exercise if you are not accustomed to regular exercise. Any muscle soreness should settle within 2-3 days.

**What are the possible benefits of taking part?**

There may be no direct benefit to you from participating in this research. We will give you feedback at the end of the study as to whether aerobic exercise is effective for you in terms of changing your CPM or MIA response. If it is effective and if you wish to continue to use aerobic exercise to control you pain, we will advise you of the best intensity level for your condition. Alternatively, you can be referred to the Curtin Physiotherapy Clinic for ongoing treatment. However, this will incur a small standard cost. Further, we hope the results of this research will allow us to enhance the effect of manual therapy in clinical practice, and add to the knowledge we have about the relieving effect of manual therapy. This information may also help lead the direction of future research into assessment and treatment of chronic pain disorders.

**Will my taking part in this study be kept confidential?**

We will remove any identifying information from your data and replace it with a numbered code. All information we collect will be treated as confidential and used only in this project unless otherwise specified. The following people will have access to the information we collect in this research: the research team listed above and the Curtin University Ethics Committee. All data will be stored electronically and will be password-protected on the Curtin server. All paper data will be in locked storage. The information we collect in this study will be kept under secure conditions at Curtin University for 7 years after the research has ended and then it will be destroyed. You have the right to access your information in accordance with relevant privacy laws.

**What will happen to the results of the research study?**

The results of this research may be presented at conferences or published in professional journals. You will not be identified in any results that are published or presented. We will email or write to you on your request at the end of the research to let you know of a summary of the results from the research. Results will not be individual but based on all the information we collect and review as part of the research.

**What happens next and who can I contact about the research?**

If you decide to take part in this research, we will ask you to sign the consent form. By signing it you are telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the consent form to keep for reference. If you require any further information you can contact:

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**Ethics review and complaints**

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number XX/XXXX). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

Thank you for your interest in this study.