

Participant Information Form

Project title: The effect of cleat wedges on pain, function and comfort in experienced male cyclists with anterior knee pain - A randomised double-blind controlled trial

Name of Researchers:

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This research is a master's level student project at the University of Western Australia under the supervision of Dr Sarah Carter, PhD Candidate (Podiatry/Dance Biomechanics), BPodM (UWA), MSc (Motion Analysis) (Dund) (sarah.carter@uwa.edu.au).

Invitation:

You are invited to take part in this clinical trial because:

- You are a male cyclist who has been cycling for at least 6 months, and cycles between 140 and 480 km a week; and
- You have been experiencing pain at the front of the knee, during or after cycling and in the absence of trauma, for more than 6 weeks.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please read through the following information carefully, and feel free to discuss it with others. Take time to decide whether or not you wish to participate. Ask us if you have any questions or if you would like to have more information.

If you agree to take part in this study, you will be asked to sign the Participant Consent Form, and be given a copy of both the Participant Information Sheet and your signed Participant Consent Form to keep.

Aim of the Study (What is the project about?)

This study aims to find out and compare the effects of two types of cleat wedges in reducing pain at the front of the knee (anterior knee pain) and improving function and comfort in experienced male cyclists. Participants will be randomly allocated into two groups, each trialing one of the two types of cleat wedges. The study will also be looking to see if there are any subgroups in these cyclists, based on general demographics, measures of musculoskeletal alignment, flexibility and strength, as well as other factors that may be identified during the study. In doing so, we aim to see if there are any prognostic factors with the success or failure of cleat wedge treatment in the reduction of anterior knee pain.

What does participation involve?

Participation will involve:

- A telephone or email interview to confirm participant eligibility;
- Providing a signed Participant Consent Form;
- An initial visit to the UWA Podiatry Clinic for physical screening of knee pain and collection of baseline data through a physical examination and video cycling analysis;
- A random allocation of one of the two types of cleat wedges after physical screening;
- Fitting of cleat wedges to the bottom of your cycling shoes;
- Completing an online survey at 2 weeks, 12 weeks and 24 weeks after commencement of the trial (will be sent to you via email and should take approximately 5-10 minutes to complete); and
- A second visit to the UWA Podiatry Clinic in 12 weeks' time after commencement of the trial for a follow-up video cycling analysis.

As this is a double-blind study, neither you nor the data analysts will know which type of wedge is given. This helps to reduce bias in the study findings. In order to assist in this blinding process, you will be asked to keep your wedge allocation confidential. You will also be asked not to remove the cleat wedges from your shoes throughout the course of the study.

The initial visit and 12 week follow-up session will involve you being recorded cycling on a stationary bike with the cleat wedges on. This is to observe overall changes in body alignment during cycling that may impact on the knee joint complex.

Voluntary Participation and Withdrawal from the Study

Your participation in this study is completely voluntary. You may choose to withdraw from the study with no consequences at any time and without reason. You may also choose not to answer any of the questions asked of you.

Your Privacy

Your participation in this study and any information you provide will be treated as confidential. Data will be kept safe in a de-identified, password protected format on a portable drive for the minimum required duration of seven years. Your data will be destroyed upon withdrawal, unless otherwise agreed. Your name and identifying information will not be published or released in any form without your consent.

Possible Benefits

The cleat wedges in this trial may provide relief of anterior knee pain and improved function and comfort. However, we cannot guarantee that the cleat wedges will eliminate or reduce your knee pain, nor promise that they will provide improved function and/or comfort. We hope information gained from this study can be used to offer better insights and recommendations for male cyclists in the future. Results from the study may also lead to further research regarding the use of cleat wedges in the treatment of anterior knee pain.

Possible Risks and Risk Management Plan

There are no foreseeable risks associated with the use of cleat wedges and no adverse effects have been shown in previous studies that looked at similar devices. However, there may be side effects that we do not expect or do not know about. Please let us know if you do experience any new or unusual symptoms.

Immediately discontinue use of the cleat wedges if you:

- Experience any level of discomfort or worsening of symptoms with use of the cleat wedges; or
- Have any medical conditions or injuries that require you to stop cycling.

It is your responsibility to see your health professional and follow any medical advice. Provision of medical assistance is outside the scope of this study.

Contacts

If you would like to participate or discuss any aspect of this study, please do not hesitate to contact us via:

Phone: 0438521551 (Elena), 0478837477 (Matthew), 0416880181 (Truong); or

Email: anterior.knee.pain@gmail.com.

Sincerely,

Sarah Carter (Supervisor)

Lena Chen

Mengyuan Huang

Elena Penkova

Matthew Storer

Truong Truong

Approval to conduct this research has been provided by the University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics Office at the University of Western Australia on (08) 6488 3703 or by emailing to humanethics@uwa.edu.au. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.