Risks and benefits of running for your knees: The trajectory of knee osteoarthritis in runners with a history of knee surgery

The research is being carried out by the following researchers:		
Role	**Name**	**Organisation**
Lead investigator	Dr Richard Johnston	La Trobe Sport and Exercise Medicine Research Centre, La Trobe University
Chief investigator	Prof Kay Crossley	La Trobe Sport and Exercise Medicine Research Centre, La Trobe University
Researcher	Dr Adam Culvenor	La Trobe Sport and Exercise Medicine Research Centre, La Trobe University
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Researcher	Prof Stuart Warden	La Trobe Sport and Exercise Medicine Research Centre, La Trobe University
Researcher	Dr Danilo De Olivera Silva	La Trobe Sport and Exercise Medicine Research Centre, La Trobe University
Researcher	Mr James Alexander	La Trobe Sport and Exercise Medicine Research Centre, La Trobe University
Researcher	Dr Sean Docking	La Trobe Sport and Exercise Medicine Research Centre, La Trobe University
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1. **What is the study about?**
   This study is being conducted to explore the impact of running on knee joint health in people with and without a history of knee surgery. Specifically, the study will establish the relationship between running biomechanics, running load (e.g. frequency, duration, speed) and muscle strength, and changes in knee joint health on magnetic resonance imaging (MRI) and knee symptoms over a two-year period.

2. **Do I have to participate?**
   Being part of this study is voluntary. If you want to be part of the study, we ask that you read the information below carefully and ask us any questions.

   After you have read the information, and had your questions answered, you can decide if you do or do not want to participate. If you decide not to participate, this won't affect your relationship with La Trobe University or any other listed organisation. If you are a student at La Trobe University, your decision to take part or not will not affect your relationship with the university in anyway.

3. **Who is being asked to participate?**
   You have been asked to participate because you:
   - Have run on average more than 10 kilometres per week in the past 6 months
   - Have run at least 3 times per week in the last 6 months
   - Are between 18-50 years of age

- Either have had previous knee surgery OR never had a serious knee injury or knee surgery

You are not eligible and cannot participate in this study if you meet any of the following:

- Have contraindications for MRI [magnetic resonance imaging] (e.g. claustrophobia, pacemaker, a history of metallic foreign body in the eye, previous surgery for cerebral aneurysm, implanted metal material other than an ACL graft)
- Currently pregnant
- Planning on relocating interstate or overseas in the next 2 years or unable to commit to the various study assessments over the next 2 years (as detailed below)
- Unable to understand written and/or spoken English

4. What will I be asked to do?

If you wish to take part in the study, you will be asked to complete and sign a consent form to participate. For this project you will not be asked to change any of your normal activities. There are three parts to the study:

Part One:

The first part of the study involves using an electronic app to complete electronic questionnaires (time to complete 60 minutes) at five time points (baseline, 6, 12, 18, and 24 months). During the 2-year study period, your weekly running data (the distance and speed at which you run) will be collected through your own GPS-watch or an application for Android- or iOS-based smartphones. You can choose the device used to collect these data, as long as it can measure running distance (kilometers), duration (time), pace (minutes/kilometre) and heart rate (beats per minute). If needed, we may supply you with a Global Positioning System (GPS) watch (GARMIN). All running data will be automatically uploaded to the Fusion sport smartabase electronic platform developed specifically for this study. You will have visual access to all off your uploaded running data, and you will be able to track your weekly running load over the study period via the Fusion sport smartabase app. During the 2-year data collection period you will be asked to complete two monthly questions about running related knee and Achilles pain, this will be sent via the Fusion sport smartabase platform app (this will take 2-3 minutes). The online data stored on the Fusion sport smartabase platform is hosted through a secure, password protected, online data collection system Amazon Web Services (AWS) which, once set up, will be only accessible by you and the La Trobe University research team. At the end of the TRAIL study, your running load data (distance, duration, running speed and heart rate) will be accessed by the research team for data retrieval and statistical analyses.

Part Two:

You will be asked to attend La Trobe University at the start of the study to have a comprehensive knee assessment, which will take about 2 hours. You will need to bring a pair of running shorts, a crop top (women) or running singlet (men), and your regular running shoes. If this face-to-face assessment and knee MRI scan (details below) are not possible due to restrictions related to the Coronavirus pandemic that is ok, and instead you will be asked to complete remote online questionnaires only. These will be sent to you via a link provided by e-mail. Once the Coronavirus restrictions are over, you may be asked to attend La Trobe University to complete the comprehensive knee assessment and undergo a knee MRI scan. Specific tests are:

- *Strength of your leg muscles (quadriceps and hamstrings).* This will be assessed using a special chair and you will be asked to push up and down a few times as hard as you can against an ankle pad. We will also measure and record your height, weight and waist circumference.
- *Physical performance.* We will test the performance of both of your legs on three hopping tasks.
- *Movement quality.* We will video your performance during some clinical tests (e.g. hop tests). These videos will not include your face, so you cannot be identified from the footage. If any of your face (or other identifying features) is inadvertently videoed, this will be masked (by electronically blurring the area) prior to data analysis.
- *3D running biomechanics.* You will have a 3D biomechanics assessment at the La Trobe University gait laboratory to assess the movement and forces in your knees during walking, running and hopping. Small reflective skin markers will be attached with tape to the skin on your arms, pelvis, torso, and legs, and tracked with infrared cameras when you walk, run and perform hopping tasks.
- *Achilles tendon ultrasound.* You will have a 3D ultrasound image captured of both your Achilles tendons using Ultrasound Tissue Characterisation to assess the size and structure of your Achilles tendon. Water-

based ultrasound gel will be applied on the skin over the Achilles and the ultrasound probe will automatically scan the tendon to create a 3D image. Ultrasound is safe as it emits no radiation or cause any discomfort.

- *Questionnaires*. You will be asked to complete a series of questionnaires related to pain, physical f

Part Three:
The final part of the study involves repeating the Part One measures 2-years after the start of the study: lower limb strength, functional performance, movement quality, ultrasound scan of the Achilles tendon questionnaires and running biomechanics at La Trobe University, and another free MRI at Lake Imaging Specialist and Research Centre, North Melbourne. These final assessments are vital to assess how your running biomechanics, knee structure and pain have changed over time.

What are the benefits?
The benefit to you is that you will obtain information regarding your quadricep and hamstring muscle strength, running biomechanics, and get a free knee MRI, which we can provide you with a copy of. The research benefits are a better understanding of the impact of running on knee joint health over time.

What are the risks?
With any study there are: (1) risks we know about, (2) risks we don't know about, and (3) risks we don't expect. If you experience something that you aren't sure about, please contact us immediately so we can discuss the best way to manage your concerns. If you do suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible. You will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. In the first instance the study research team who are all musculoskeletal physiotherapists will evaluate your condition and then discuss treatment with both you and your regular health practitioner. In the event of loss or injury, any question about compensation must initially be directed to the research team who will advise the university insurer of the matter.

Name/Organisation	Position	Telephone	Email
Richard Johnston/La Trobe University	Research Fellow	+61 394791428	R.Johnston@latrobe.edu.au

We have listed the risks we know about below. This will help you decide if you want to be part of the study.

1. Pain or discomfort during testing
The physical and muscle strength tests represent usual examination by a physiotherapist. You may experience a small amount of discomfort in the joints or muscles. Please report to the researcher any discomfort or pain experienced during the testing or exercises. If the pain or discomfort is deemed to be excessive by yourself or the investigators, the testing/treatment will cease.

2. Delayed onset muscle and joint soreness
You may experience a small amount of discomfort in the joints or muscles 24-48 hours following testing. Please report to the researcher any significant discomfort or pain experienced following the testing or exercises.

3. Injury or Re-injury
There is an extremely low risk of falling and injury during the hopping tasks. You will be given adequate time to warm up and practice the tasks prior to testing.

4. MRI examination
When you lie in the MRI machine, the MRI team will make sure you are in a comfortable position so you can keep still. The scanner is very noisy, and they can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan,

you will be able to alert staff by pressing on a call button provided to you. There are no proven long-term risks related to MRI scans. MRI is considered safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room. The MRI team will examine you to make sure there is no reason for you not to have the scan. You must tell them if you have metal implanted in your body, such as a pacemaker or metal pins.

The MRI scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a musculoskeletal condition. A specialist will look at your MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you and/or your health practitioner to talk about the findings. We cannot guarantee that we will find any/all unusual features. The MRI team will provide you with a copy of your MRI scans and a report. International specialists who we work with overseas may also analyse your scans for the purposes of the research project – all identifying information (name, date of birth etc) will be removed from your MRI scans prior to analysis so that you will not be able to be identified. MRI equipment is standard clinical equipment used in everyday clinical settings. MRI does not use x-rays or radiation and is not known to cause harmful effects.

5. GPS wearable device
You will be asked to wear a GPS watch during each run you complete during each week over the 2-year study period. At the beginning of the study your GPS watch will be set up to sync with an electronic application which will store your running data. The extraction of running data will be done on a weekly basis through a secure, password protected, online data collection system Amazon Web Services (AWS). This data will be de-identifiable and will not be available to other participants within the study. The data that is gathered will be solely used for project analysis. GPS watches are commercially available, safe and secure for tracking daily physical activity levels within running populations. There are no risks in wearing a GPS watch.

What will happen to information about me?
We will store information about you in ways that will NOT reveal who you are. This means you CANNOT be identified in any type of publication from this study. The anonymity of your participation is assured with our procedure in which a code number and not your name will identify you. Data will be kept securely at La Trobe University in a locked filing cabinet and password protected research computer.

All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The principal investigator (Dr Richard Johnston) is responsible for maintaining this confidentiality.

We will keep your information for 7 years after the project is completed. After this time, we will destroy all of your identifiable data.

We will collect, store and destroy your data in accordance with La Trobe Universities Research Data Management Policy which can be viewed online using the following link: https://policies.latrobe.edu.au/document/view.php?id=106/.

The information you provide is personal information for the purposes of the Information Privacy Act 2000 (Vic). You have the right to access personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the Information Privacy Act.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums and may be used by research higher degree students to obtain a research degree. In any publication, presentation or data files shared with other researchers, information will be provided in such a way that you cannot be identified, except with your permission. Any personal information that could identify you will be removed or changed before files are shared with other researchers. We, or other researchers, may also use non-identifiable information (completely anonymous) collected for this research study in future related studies. If you consent (tick the box on the consent form) to be contacted for future related research, we will store your contact details (name, address, phone number, email) on the

secure La Trobe University research drive, only accessible to members of the research team, and may contact you about future related research projects.

Will I hear about the results of the study?
We will let you know about your individual results after the baseline and follow-up testing time points. Results of the overall study will be published in medical journals in due course, and you can request a copy of these by contacting a member of the research team.

What if I change my mind?
If you choose to no longer be part of the study. You can let us know at any time during the study by:
1. Completing the 'Withdrawal of Consent Form' (provided at the end of this document)
2. Calling us
3. Emailing us

Your decision to withdraw at any point will **not** affect your relationship with La Trobe University or any other organisation listed.

When you withdraw we will stop asking you for information. Any identifiable information about you will be withdrawn from the research study. However, once the results have been analysed (4 weeks after testing completion), we can only withdraw information, such as your name and contact details. If results haven't been analysed, you can choose if we use those results or not.

Who can I contact for questions or want more information?
If you would like to speak to us, please use the contact details below:

Name/Organisation	Position	Telephone	Email
Richard Johnston/ La Trobe University	Research Fellow	+61 3 94791428	R.Johnston@latrobe.edu.au

What if I have a complaint?
If you have a complaint about any part of this study, please contact:

Ethics Reference Number	Position	Telephone	Email
HEC19524	Senior Research Ethics Officer	+61 3 9479 1443	humanethics@latrobe.edu.au

Electronic Consent Form – Declaration by Participant

I (the participant) have read (or, where appropriate, have had read to me) and understood the participant information statement, and any questions have been answered to my satisfaction. I agree to participate in the study, I know I can withdraw at any time. I agree information provided by me or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that I cannot be identified. Please use the electronic link below to complete the declaration of consent for the study.

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* All parties must sign and date the electronic consent form

Withdrawal of Consent

I wish to withdraw my consent to participate in this study. I understand withdrawal will not affect my relationship with La Trobe University of any other organisation or professionals listed in the Participant Information Statement. I understand the researchers cannot withdraw my information once it has been analysed, and/or collected as part of a focus group.

I understand my information will be withdrawn as outlined below:

- ✓ Any identifiable information about me will be withdrawn from the study
- ✓ The researchers will withdraw my contact details so I cannot be contacted by them in the future studies unless I have given separate consent for my details to be kept in a participant registry.
- ✓ The researchers cannot withdraw my information once it has been analysed, and/or collected as part of a focus group

***if you have consented for your contact details to be included in a participant registry you will need to contact the registry staff directly to withdraw your details.*

I would like my already collected and unanalysed data

☐ Destroyed and not used for any analysis

☐ Used for analysis

Participant Signature

Participant's printed name	
Participant's signature	
Date	

Please forward this form to:

CI Name	Dr Richard Johnston
Email	R.Johnston@latrobe.edu.au
Phone	+61 3 9479 1443
Postal Address	La Trobe Sport and Exercise Medicine Research Centre School of Allied Health, Human Services and Sport College of Science, Health and Engineering La Trobe University Victoria 3086 Australia