Exercise-therapy and education for knee osteoarthritis: a randomised clinical trial		
Role	**Name**	**Organisation**
Lead Chief Investigator	Dr Christian Barton	La Trobe Sports and exercise medicine research centre (LASEM)
Chief Investigator	Prof. Kay Crossley	La Trobe Sports and exercise medicine research centre (LASEM)
Chief Investigator	Prof Trevor Russell	Centre for Research in Telerehabilitation, University of Queensland
Chief Investigator	Dr Joanne Kemp	La Trobe Sports and exercise medicine research centre (LASEM)
Chief Investigator	Dr Paul O'Halloran	La Trobe University, School of Public Health
Research funder	This research is in part being funded by Arthritis Australia National Research Program and in kind support by La Trobe University.	

1. **What is the study about?**
   You are invited to participate in a study focusing on the management of knee osteoarthritis. We hope to learn the most effective ways of delivering evidence based osteoarthritic active management techniques. There will be 110 people who will be part of this study.

   Your contact details were obtained from you responding to a promotional flyer or through the Musculoskeletal Australia help line (https://www.msk.org.au/).

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.

   If you decide you do not want to participate this won't affect the treatment you are currently receiving. You can read the information below and decide at the end if you 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.

3. **Who is being asked to participate?**
   You have been asked to participate because:
   - You are 40 years or older and suffer from ongoing knee pain.

4. **What will I be asked to do?**
   If you want to take part in this study, we will ask you to fill out a questionnaire in regard to your knee pain, perform two simple activity tests (30 second chair stand test, 40 metre fast paced walk test) and participate in an 8 week supervised exercise program specifically tailored to knee osteoarthritis. It will take 1 hour per week for 8 weeks of your time to be part of this study.

   Participants will be randomised into two groups which differ in how the same program is delivered.

Study procedures	Assessment/task	Screening Time: 2 hours	Follow-up (3 months) Time: 30 mins
	Informed consent	x	
	Demographic information	x	
	Weight	x	x
	Questionnaire	x	x
	Physical tests (x2)	x	x

The program commitments: Exercise therapy and education

Exercise therapy				Education		
Procedure	**Time/visit**	**Dosage**		**Procedure**	**Time/visit**	**Dosage/volume**
Exercise therapy	**1 hour/visit**	**x2/week for 6 weeks**		**Education**	**1hour/visit**	**x2**

You may also be asked to participate in an interview about your experiences with the program. This interview will take place on the same day as your 3 month follow up or at another time and location convenient to you. If you do participate in the interview component, this is expected to take approximately 40 minutes.

5. What are the benefits?

The benefit of you taking part in this study is that you may experience a reduction in knee pain and the use of pain medication, improve knee related quality of life and you may increase your physical activities levels and confidence in your knee. The expected benefits to society in general are reduction in the healthcare costs associated with knee osteoarthritis and an increase in community engagement with improvements in quality of life (QoL), and physical-activity levels.

6. What are the risks?

With any medical treatment 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.

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

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Increase knee pain	You may experience increase in knee pain after exercise	Mild to moderate	Increases in knee pain are expected to be short lived (1-2 days)
Muscle soreness	You may experience some muscle soreness following the exercise therapy sessions (particularly at the start of treatment if uncustomed to regular exercise).		Muscle soreness could last for a few days and is a normal common occurrence after muscle strengthening

7. Will I be paid to be part of this study?

It will not cost you to be part of this study. We will reimburse you for your time by the way of a gift voucher ($50).

8. What will happen to information about me?

We will collect and store information about you in ways that only we will know who you are. Any information that reveals your identity will be kept confidential, and will only be disclosed with your permission, unless we are required by law to reveal this information. The Human Research Ethics Committee, monitors and regulatory bodies may also access information about you, if possible, these people will not know who you are.

The way we store and find out the results of the study means you cannot be identified in any type of publication from this study.

We will keep your information for 15 years after the project is completed. After this time, data from the study will be destroyed.

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 Privacy and Date Protection Act 2014 (Vic). You and your child 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 complaint about a breach of the Information Protection Principles as contained in the Information Privacy Act.

9. Will I hear about the results of the study?

If you wish to receive the results of the study, you may request an email summary to be sent to you upon completion of the study.

10. What if I change my mind?

At any time you can choose to no longer be part of the study. You can let us know 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.

11. What happens if the study needs to be stopped?

The study may be stopped if we find out:

- The risks from side effects outweigh any benefits to you;
- The treatment you are receiving doesn't give you any benefits

12. What happens if I suffer an injury or complications because being part of this study?

Treatment Available

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Compensation

In the event of loss or injury, the university have agreed to cover the costs of any medical treatment required.

13. What happens if you find out new information about the study?

To ensure your safety we will make sure we look at the information we collect about this study. This may mean that we find out new information that you should know about. If this happens we will contact you and discuss what it means for you. New information may mean that we recommend you withdraw from the study, or that you may choose to withdraw.

14. 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
Zuzana Machotka/LaTrobe Sports & Exercise Medicine Research centre	Research assistant	0407828863	z.machotka@latrobe.edu.au

15. 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
HEC18500	Senior Research Ethics Officer	+61 3 9479 1443	humanethics@latrobe.edu.au