Participant Information Sheet/Consent Form

Interventional study - *Adult providing own consent*

Title	Optimising outcomes for people with knee pain through food: FEAST randomised controlled trial
Short Title	The FEAST trial
Ethics Reference Number	HEC22044
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Dr Adam Culvenor (School of Allied Health, Human Services and Sport (SAHHSS), La Trobe University)
Associate Investigator(s)	Dr Brooke Devlin (School of Human Movement and Nutrition Sciences, University of Queensland) Prof. Peter Brukner (SAHHSS, La Trobe University) Ass. Prof. Joanne Kemp (SAHHSS, La Trobe University) Prof. Kay Crossley (SAHHSS, La Trobe University) Dr Andrea Mosler (SAHHSS, La Trobe University) Dr Josh Heerey (SAHHSS, La Trobe University) Ms Lynette Law (PhD student, SAHHSS, La Trobe University) Ms Amanda Attanayake (SAHHSS, La Trobe University)
Location	La Trobe University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project because you have knee pain. This research project aims to assess the effectiveness of two different programs provided through advice and education by a qualified dietitian to improve your knee pain, function and quality of life.

This information sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the project. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Your participation is voluntary

Participation in this research is completely voluntary and there will be no cost to you. If you don't wish to take part, you don't have to. If you decide you want to take part, you will be given a copy of this Participant Information Sheet and asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participation Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

As you may be aware, knee pain is very common and is often associated with knee osteoarthritis. Osteoarthritis is the most common form of arthritis and is a leading cause of disability in Australia. Currently, there is no cure for osteoarthritis, therefore it is important to investigate treatments that can improve the main symptoms associated with osteoarthritis: pain, swelling, stiffness and movement difficulties. We will recruit 140 adults who have knee pain.

This study is being conducted by researchers at La Trobe University and is partly funded by the National Health and Medical Research Council (NHMRC) of Australia and Dr Peter Brukner. All assessments and consultations will be at **no cost** to you.

3 Who can participate?

You can participate in this study if you meet all the following:

- Between 45-85 years of age and understand written and spoken English
- Activity-related knee pain on most days of the past month
- Knee pain for at least 3 months
- No morning knee stiffness, or morning stiffness that lasts less than 30mins
- Willing to complete the assigned 12-week eating program and attend all appointments (detailed below)

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

- Knee pain not primarily due to osteoarthritis (e.g., fibromyalgia, referred pain)
- Bilateral knee replacement
- Already strictly following a specific diet (e.g., low-carb, paleo, Mediterranean, Vegan)
- Received treatment from a dietitian, or knee injection, in the past 3 months
- Experienced ≥5kg weight loss in the past 3 months or body weight ≥200kg
- Planning to have knee surgery in the next 6 months
- Pregnant or breastfeeding
- History of psychiatric or eating disorder (excluding anxiety/depression) or bariatric surgery

4 What does participation in this research involve?

This study will be conducted over 6 months in total (see flowchart on next page).

Pre-baseline (online/phone) appointment

You will be asked to attend a 30-minute Zoom/telephone appointment prior to your first face-to-face appointment. At this appointment, we will discuss the consent form, outline the fasting process needed to complete your blood test and DEXA scan, and answer any questions you might have. We will also explain how to complete a 3-day food diary, which will be done using a smart phone application or paper-based food diary (personal preference).

Baseline (first) appointment

This appointment will be arranged at a convenient time for you at La Trobe University, Bundoora and will take approximately 2 hours. You will be asked to not eat/drink anything or conduct any exercise in the morning of your appointment (i.e., fasting for 12-hours) for the purpose of a blood test. At the appointment, we will assess your:

- Height, weight, waist circumference and blood pressure
- Body composition measured via a Dual-energy X-ray Absorptiometry Scan (DEXA).
  This involves laying on the scanner bed for ~7 mins. The machine uses small doses (<1% yearly dose) of radiation to assess tissue density (how much muscle and adipose tissue you have). The total effective dose of radiation has been calculated by a Medical Physicist (see risks below). Light clothing with no metal (e.g., zips, clips, underwire) should be worn (gown provided if needed). All measures will be taken by trained

researchers who hold Victorian Government radiation licenses and comply to the Code of Practice set out by the Australian Radiation Protection and Nuclear Safety Agency.

- Blood test: A trained researcher qualified to take blood will collect a small amount of blood (~25 mL, equivalent to ~4 teaspoons) from a forearm vein to assess inflammation levels.
- Questionnaires assessing your pain, activity level and quality of life and food intake
- Functional tests: i) how many times you can stand from a chair in 30 secs; and ii) how fast you can walk 40 metres.

We will provide a snack/drink as soon as you complete the DEXA and blood tests.

Random assignment to one of two different treatments

At the end of the first appointment at La Trobe University, you will be randomly assigned (50:50 chance, like a coin toss) to receive a program (from qualified dietitians) to either:

i) minimise processed foods that are known to promote inflammation and optimise foods shown to reduce inflammation; or
ii) minimise foods that are known to be high in fat content.

This means neither you nor the researchers will be able to choose which group you are assigned to. We do not know which treatment is best; to find out we need to compare the two programs. Although the two programs involve modifying some types of food that you eat, you can eat as much as you like of these foods. **You do not need to restrict the amount of food that you eat**.

Irrespective of which group you are assigned to, you will receive specific education and advice from an Accredited Practising Dietitian (APD) in a dietary consultation at the start of the study (at the end of your first appointment at La Trobe University). Your dietitian will also work with you to develop a personalised management plan to support you throughout the study. You will be asked to follow the program for 12 weeks (but you can continue for as long as you like). We will ask you to record your food intake for 3 days at up to six different times throughout the study.

Support phone calls

To support you throughout the study and answer any questions you have, we will arrange up to four follow-up consultations to be conducted over the phone/online during the 12 weeks. This phone call will take approximately 15-20 minutes. At these times, we will also ask you to complete some of the same questionnaires online (via a secure link provided by e-mail).

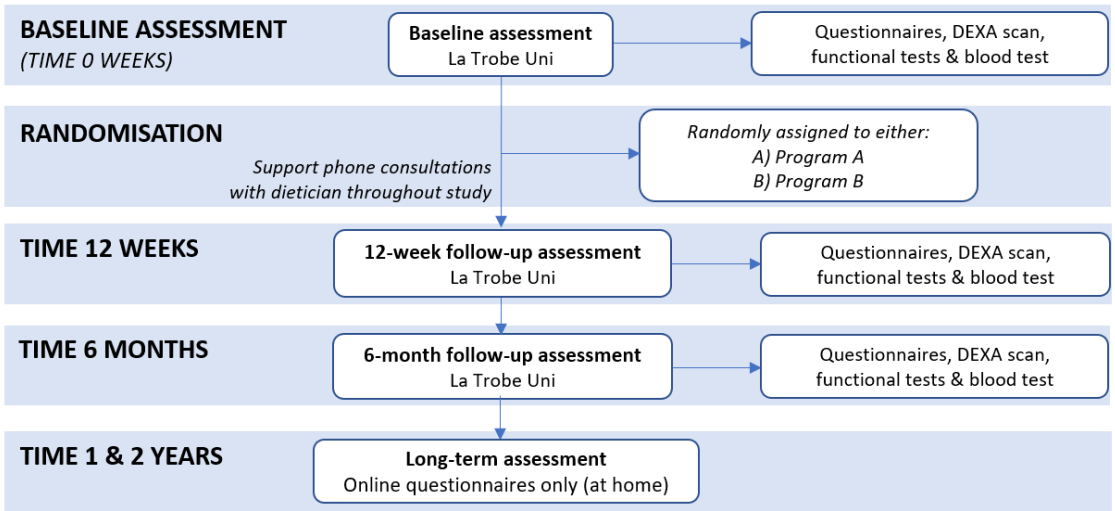

Figure 1. Flowchart of study assessments

Follow-up appointments

So that we can assess the results of the program you have been assigned, we will ask you to return for face-to-face appointments at La Trobe University at **12 weeks and 6 months after your first appointment.** These follow-up appointments will be like the first appointment where

we will do all the same tests and questionnaires. You will need to fast (not eat/drink anything) the morning of your appointment for the blood test. You will have another dietary consultation with the study dietitian who will provide support for you to continue with the program you have been assigned. You should allow about 2 hours for these appointments. To assess longer-term results, we will ask you to complete the same online questionnaires at 1 and 2 years after your first appointment. The total time commitment for participating will be approximately 6-8 hours.

There are no additional costs associated with participating in this research project. All medical care and tests (i.e., dietitian consultations, DEXA scan, blood tests) required as part of the research project will be provided free of charge. The results of the DEXA scan and blood tests will not be used to diagnose health conditions, but only to evaluate the effects of the intervention. We will provide you with your individual results when the DEXA and blood analyses are completed at the end of the study. Your travel costs to attend the assessments will be reimbursed up to $100.

At the end of the first 12 weeks, or after 6-12 months, we may also ask if you are willing to have a separate interview with one of the study researchers (this interview is optional and you can take part in the study without needing to complete the interview). The purpose of this interview is to seek feedback on the study treatments, satisfaction with the process received and whether there are any suggestions for improvement. The interview will take approximately 30 minutes, but you can cease the interview at any time. To ensure responses are correctly interpreted, responses to questions will be audio recorded and transcribed. Audio recording transcriptions will be completed by 'Transcription Australia' on their secure, encrypted Australian-based software. Although voice in your audio recording could lead to your identification, this file will not be used during analysis. Instead, a re-identifiable transcription, which you will have the opportunity to check for accuracy, will be used for analysis. Re-identifiable means that we will use a code number and not your name on data collected to ensure your anonymity. Following the completion of analysis of this transcription, the audio file associated with your interview will be deleted. After analysis, overall findings and conclusions from all interviews will also be sent to you, to allow an opportunity to make any further comments. We will seek around 40 participants to be interviewed. It is your decision or not whether you wish to be interviewed.

5 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for your knee. Other options are available; these include seeing a physiotherapist or dietitian (e.g., private or public health centre). The research team will discuss these options with you before you decide to take part in this project. You can also discuss the options with your doctor, dietitian or physiotherapist.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, possible benefits may include improvement of pain, function, quality of life, physical activity, and confidence in your knee. You may gain valuable insight into how to manage your food intake and specific anti-inflammatory and low-fat foods, nutrients and eating habits. The expected benefit to society is the development of a drug-free and non-invasive treatment option to help manage pain and disability associated with osteoarthritis. This will give doctors and patients alternative ways to manage knee pain, which in turn may lead to improvements in the quality of life for patients.

7 What are the possible risks and disadvantages of taking part?

With any medical treatment there are: (i) risks we know about; (ii) risks we don't know about; and (iii) risks we don't expect. We have listed the risks we know about below. You may have none, some or all the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with the study coordinator.

Possible Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Emotional distress due to involvement in research and completion of questionnaires	Rarely; although can occur when completing study questionnaires	Minimal	While completing the study questionnaires
Emotional distress due to diet assessment	Rarely; although can occur when assessing food intake prior to, or during, appointments	Minimal	While completing the food diary or assessment
Discomfort due to body measurements	Can occur while measurements are done by your dietitian or researcher	Minimal Mild	During appointment only
Discomfort due to blood test	Rarely; while blood is being collected	Mild	Bruising or swelling may last 1-3 days
Exposure to ionising radiation	1x 7-minute scan at initial, 12-week and 6-month appointment	Minimal	Effect too small to measure
Tiredness/change in bowel patterns with change in diet	Any change in diet can make you feel tired or have different bowel patterns	Minimal	1-2 weeks
Contraction of COVID-19	Can occur during the face-to-face assessments	Minimal Moderate	1-2 weeks

If you become upset or distressed because of your participation in the research, the study coordinator together with the qualified dietitian will assist you with appropriate support. We can also provide you information about services you can access to seek help for emotional distress.

Risks associated with completing study questionnaires and diet assessment
Completing questionnaires about your knee pain, function, quality of life and dietary intake may cause emotional distress. If you begin to feel upset or distressed when completing your questionnaires or dietary assessment, please let a member of the research team know. We will provide you with the appropriate support, including a document outlining services you can access to help with your emotional distress.

Risks associated with blood test
Having a blood sample taken may cause some discomfort or bruising. On very rare occasions, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which blood is taken could become inflamed. Some people may feel light-headed when having blood taken and may occasionally faint. Very rarely, there could be a minor infection or bleeding. A qualified person will take a very small amount of your blood (max 30mL each appointment (normal blood donation is 500mL)) using stringent infection control procedures. If you notice increased redness, swelling or other signs of infection in the days following your assessment, tell us immediately.

Risks associated with eating low-inflammatory foods or low-fat foods
As you adjust to the eating program you are assigned to, you may experience feelings of tiredness and/or changes in bowel habits and patterns. The researchers will assess your diet and ensure you are meeting your energy and nutrient needs throughout the study intervention. This eating program may be different than your normal diet and therefore influence your usual weekly shopping bill and expenses. As part of the consultations, you will be provided with some advice on how to follow the diet on a budget if required to ensure there is minimal financial burden.

Exposure to ionising radiation
If you choose to take part in this research, you will undergo three 7-minute DEXA scans (first, 12-week and 6-month assessments). DEXA scans are a non-invasive, fast and simple procedure. This research study involves exposure to a very small amount of radiation from a DEXA scan that you would not normally receive. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose you will receive from all of these DEXA scans is approximately 0.03 mSv. At these

dose levels, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

The scans we are taking are for research purposes and are not intended to be used like scans taken for a full clinical examination or to be used to help diagnose, treat or manage a particular condition. The whole-body DEXA scan may identify participants with a low bone mineral density. However, a whole body DEXA scan is not the established method for detecting low bone mineral density. Therefore, as a precaution if you are identified as having a low bone mineral density you will be encouraged to make an appointment with your General Practitioner to discuss the results.

Have you been involved in any other research studies that involve radiation? If so, please tell us. Please keep information contained within this Patient Information Sheet about your exposure to radiation in this study, including the radiation dose, for at least 5 years. You will be required to provide this dose to researchers of any future research projects involving exposure to radiation.

Contraction of COVID-19
You may be at risk of contracting COVID-19 during one of the face-to-face appointments at La Trobe University. Prior to attending La Trobe University, you will be screened for signs and symptoms of COVID-19 by a member of the research team. You will also need to be fully vaccinated (or hold a valid medical exemption) to be able to attend La Trobe University for your assessments. The research team will put in place the appropriate control measures to reduce the risk of COVID 19 transmission. The risk is believed to be minimal.

8 What if I withdraw from this research project?

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons, and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. Information about you that has already been analysed (i.e., once you have been allocated to either program), may not be able to be destroyed to ensure accurate and unbiased study reporting. Personal details collected, such as your name and contact details, can be destroyed at any time upon study withdrawal.

9 What happens when the research project ends?

At the completion of the research project, you may continue to use the resources provided and to follow the eating program principles if you choose to. If requested, we will provide you with your individual results including your body composition (DEXA) assessment and whole study results. We, or other researchers, may also use coded information (so that you cannot be identified) 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.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

By signing the consent form you agree to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

Storage, retention and destruction

The anonymity of your participation is assured with our procedure, in which a code number (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. Identifiable data will be stored for 15 years, then destroyed (electronic records deleted, paper-files shredded). Data will be strictly handled confidentially under guidelines set out by the National Health and Medical Research Council. The principal investigator (Dr Adam Culvenor) is responsible for maintaining this confidentiality.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected.

The results of this project may be published and/or presented in a variety of forums and used by research 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.

11 Who is organising and funding the research?

This research project is being conducted by Dr Adam Culvenor and a team of researchers. It has been funded by the NHMRC (GNT2008523) and Dr Peter Brukner. Dr Peter Brukner is also an investigator on the project and has written a book and developed an app that will be used as part of the study. He will not be involved in data collection, analysis or the decision to publish results. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

12 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of La Trobe University Human Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13 Further information and who to contact

For all enquiries, you can contact the Clinical Trial Manager, during business hours:

Dr Adam Culvenor, Senior Research Fellow in Physiotherapy, La Trobe University
Telephone: 03 9479 5116; E-mail: a.culvenor@latrobe.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC: La Trobe University Human Research Ethics Committee
Complaints Contact: Senior Human Ethics Officer, Ethics and Integrity, Research Office
Telephone: 03 9479 1443 E-mail: humanethics@latrobe.edu.au
* Please quote the application reference number HEC22044

LA TROBE UNIVERSITY

Consent Form - *Adult providing own consent*

Title	Optimising outcomes for people with knee pain through food: FEAST randomised controlled trial
Short Title	The FEAST trial
Ethics Reference Number	HEC22044
Project Sponsor	La Trobe University
Coordinating Principal Investigator/ Principal Investigator	Dr Adam Culvenor (La Trobe University)
Associate Investigator(s)	Dr Brooke Devlin (University of Queensland) Prof. Peter Brukner (La Trobe University) Ass. Prof. Joanne Kemp (La Trobe University) Prof. Kay Crossley (La Trobe University) Dr Andrea Mosler (La Trobe University) Dr Josh Heerey (La Trobe University) Ms Lynette Law (PhD student, La Trobe University) Ms Amanda Attanayake (SAHHSS, La Trobe University)
Location	La Trobe University

Consent Agreement

I have read the Participant Information Sheet and I understand the purposes, procedures and risks of the research described in the project.

I understand that data files may be shared with other researchers, and that information will be provided in such a way that I cannot be identified, except with my permission.

I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. I agree that data gathered for the study may be published provided my name or other identifying information is not used.

☐ I wish… / ☐ do not wish… to receive results of the study
☐ I consent… / ☐ do not consent… to be contacted for future related research
☐ I consent… / ☐ do not consent…to have my interview responses audio-recorded/transcribed.
☐ I consent… / ☐ do not consent… to have my samples/data used in future research

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.