



Participant Information Sheet

POST COVID-19

In response to the changes of COVID-19 pandemic placing restrictions on social interaction Western Sydney University, NICM Health Research Institute and the Western Sydney University Human Research Ethics Committee are restricting face-to-face contact between researchers and trial participants. These restrictions are in line with government and health agency recommendations to protect the safety of our research participants and researchers, which is of paramount importance.

In order to continue the important work of our clinical trials we will continue the study remotely using techniques such as video-call, telephone, email and post instead of in person visits. These new methods will be in place while the COVID-19 pandemic persists.

Project Title: The effectiveness and safety of a herbal formulation for the management of osteoarthritis of the knee (ACTRN12619000320156)

Project Summary:

You are invited to participate in a research study being conducted by Ms Christine Murray, PhD candidate, NICM Health Research Institute, Western Sydney University.

If you are 40 to 75 and have a diagnosis of osteoarthritis of the knee and experiencing pain of the knee you may be eligible for this study.

This clinical research study will assess the effectiveness and safety of a herbal formulation containing *Curcuma longa* (Turmeric), *Zingiber officinale* (Ginger) and *Boswellia serrata* (Indian Frankincense) for the management of osteoarthritis of the knee. The study will examine if taking this formulation reduces pain from osteoarthritis of the knee and improves function, physical movement and well-being.

Currently there is no cure or intervention to stop the progression of osteoarthritis. Pharmaceutical interventions such as non-steroidal anti-inflammatory drugs, although they can be effective for pain management, can only be used in the short-term. This is because they can pose serious side-effects when used long term, such as renal impairment and gastrointestinal complications. There is a lack of safe options to manage the symptoms of osteoarthritis, so there is an urgent need for new interventions that are safe and effective and can be used long term to manage osteoarthritis symptoms.

This research is important to be able to offer a new clinically validated formulation for the management of osteoarthritis of the knee.

How is the study being paid for?

The study is being funded by NICM Health Research Institute, Western Sydney University, an Australian postgraduate award, Western Sydney University and through a PhD scholarship provided by the Blackmore's Institute.

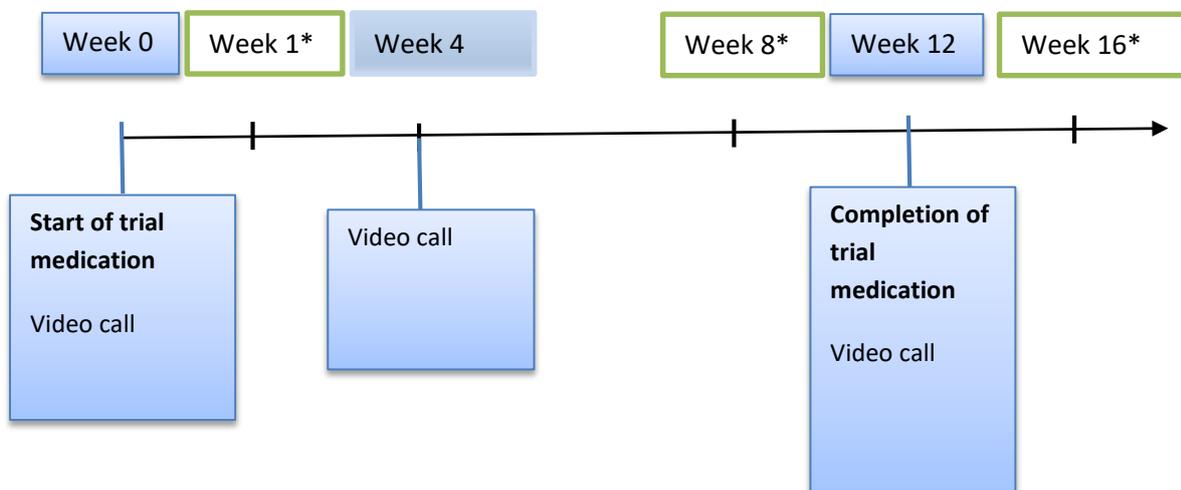
What will I be asked to do?

If you are interested in this study, you will be asked to answer some questions on the NICM trial webpage and submit your interest. A trial research team member will contact you to let you know you may/may not be eligible and will provide you with details and requirements of the trial. If you are interested in participating and wish to proceed with screening we will arrange a remote screening day via video call. We will collect any recent blood tests and knee x-rays via email or post, however if you do not have these, we can refer you to get these or a letter of introduction about the trial can be arranged to be sent to your GP. This will inform your GP of your interest in the trial and request this information. There will be no cost to you should you need current X-rays. If your managing GP deems it appropriate to get current X-rays, they will either be covered by Medicare or, if not, then reimbursed by the study. If the study is suitable for you, we will ask that you record your daily pain scores for 7 days and if eligible a trial start time will be arranged.

In order for the study to assess the effectiveness of the herbal formulation, the use of analgesics or non-steroidal anti-inflammatory drugs will not be allowed during the trial, nor any other supplement for osteoarthritis such as chondroitin, fish oils, omega 3 and 6, joint repair formulations or avocado soybean unsaponables. You will however be allowed to use paracetamol if required.

This is a randomised trial meaning that study participants will be randomly allocated to receive the herbal formulation or the placebo (dummy tablet). You will not know which group you are in and neither will the research team members. This is done to ensure that the results of the study cannot be unfairly influenced by anyone.

The timeline below illustrates the weeks required to meet via video call from the start of the trial through to completion of the trial medication. On the weeks marked with an asterisk * you will be contacted by phone.



Trial start (baseline)

- Prior to trial commencement we will ask that you complete a daily recording of your knee pain for 7 days and we ask that during this time you do not take any non-steroidal anti-inflammatory drugs, but you are able to use paracetamol if required. We ask you don't take any non-steroidal anti-inflammatory drugs for at least 3 days, or paracetamol 24 hours prior to the first meeting or any supplements for osteoarthritis for 2 weeks.
- You will receive a study pack via email or post with a diary to record use of medications and any potential adverse events
- You will receive 12 weeks of either the herbal or placebo formulation in the post.
- You will have physical measures taken for safety (blood pressure, height and weight) either at home or a pharmacy/doctor

- You will be asked to complete 3 questionnaires on pain and function, 2 questionnaires on health and well-being and do a timed physical performance -30 second sit to stand test.
- You will have a basic blood test, including a test to assess the anti-inflammatory marker C-reactive protein.

The trial start meeting will take approximately 1 hour.

Week 1 Phone call

For the first 7 days of taking the formulation you will be asked to answer 5 questions related to pain and function daily. This can be completed either online or in paper format which can be provided.

At the completion of week 1, a research team member will phone you to see how you are going with the trial and to check your compliance and eligibility, this will take 5-10mins.

- Any illness or other adverse experiences over the week will be noted, as will any changes to the medications you are taking.
- You will be asked to complete 2 questionnaires on pain and function either online or on paper format which can be provided and if so post these and daily questions back to the research team in pre-paid envelopes.

Week 4 Video call

You will be asked to meet via video call with a research team member to see how you are progressing with the trial. This meeting will take 30mins.

- Any illness or other adverse experiences over the last 3 weeks will be noted, as will any changes to the medications you are taking.
- You will be asked to complete 3 questionnaires on pain and function and do a physical performance test

Week 8 Phone call

A research team member will phone you to see how you are going with the trial. This will take 5-10mins.

- Any illness or other adverse experiences over the last 4-weeks will be noted, as will any changes to the medications you are taking.
- You will be asked to complete 3 questionnaires on pain and function either online or on paper which can be provided, and if so post these back to the research team in pre-paid envelopes.

Week 12 Video call

The final of the trial. You will be asked to meet via video call with a research team member at the completion of the trial. This meeting will take 30-45mins.

- Any illness or other adverse experiences over the last 4-weeks will be noted, as will any changes to the medications you are taking.
- You will have physical measurements taken at home or pharmacy/doctor (blood pressure, height and weight)
- You will be asked to complete 3 questionnaires on pain and function, 2 questionnaires on health and well-being, and a question on the trial and to do a physical performance test..
- You will post back any unused formulation.

- Your diary for recording any adverse events and the use of rescue medication will be collected via email or post.
- Safety final blood test will be required at a Pathologist

Week 16 phone call

A follow-up phone call will be made by a research team member to ask how you are and if you have any reports or adverse experiences. This will take 5-10mins.

- You will be asked to complete 3 questionnaires on pain and function and an overall assessment either online or in paper format which can be provided and if so post these back to the research team in pre-paid envelopes.

How much of my time will I need to give?

The study will involve 12 weeks of taking a tableted formulation, two tablets in the morning and two tablets at night with food for the first 4 weeks, then one tablet in the morning and one tablet at night, with food for the remaining 8 weeks

The initial meetings will take 1 ½ hours. Daily it may take 1-2mins to record any events and medications used. Week 1 will take 5-10mins of answering questionnaires. Week 1 a phone call by the study investigator will take 5-10mins of answering a questionnaire. Week 4 a video call will take 30-45 mins to complete questionnaires and physical tests. Week 8, will take 5-10mins of answering questionnaires. Week 12 via video call will take 1 hour to answer questionnaires, have physical tests and get a blood test.

What benefits will I, and/or the broader community, receive for participating?

There is potential that you may experience less pain from osteoarthritis of the knee and have functional improvement and better quality of life. However, there may be no benefit at all from the treatment as you will be randomly allocated to either the active group or placebo group and neither you nor the study investigator will know.

Your participation will allow us to assess if the herbal formulation is safe and effective for the management of osteoarthritis of the knee. The research may offer individuals with osteoarthritis of the knee, a clinically validated alternative to managing their pain.

You will be given reimbursement for your travel costs or parking (3 x \$30, excluding the screening) for participating in the study at the end of the trial.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

The ingredients in the herbal formulation are all considered safe for consumption and are already available over the counter. However, we will still record any potential side effect you may experience and in the case of serious adverse effect you will be withdrawn from the study and a medical examination by a qualified physician will be undertaken. The blood tests, will be taken at a commercial laboratory (Laverty) by a trained phlebotomist so any discomfort would be very minor, however you may experience pain, bruising, swelling from the needle puncture. During the sit to stand tests, you may feel some discomfort or pain from your osteoarthritis in the knee, however this test is completed at your own pace so you can minimise any discomfort by taking your time.

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research will be published in academic journals and presented at conferences. In any publication and/or presentation, only group information and trends will be presented. No reference will ever be made to individual participants.

Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to the raw data you provide. The data collected from you and other participants will be securely stored with a participant code and there will be no identifiable information recorded, apart from age and sex, to ensure your confidentiality is maintained. Data from your baseline and final blood testing and results may be used in future studies.

All aspects of the study, including results, will be confidential and only the researchers will have access to information on participants. Please note that the minimum retention period for data collection is 15 years.

Can I withdraw from the study?

Participation is entirely voluntary and you are not obliged to be involved. If you do participate you can withdraw at any time without giving reason. There will be no consequences from you withdrawing from the study and it will not affect your usual care with the clinician or physicians at any time. If you do choose to withdraw, any information that you have supplied will remain confidential and de-identified. However, any de-identified data collected up until that time will still be used as part of the study and final analysis. This is important as we are assessing the effectiveness and safety of the herbal formulation, so any data collected and reasons for withdrawal will be recorded.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with the investigator's contact details. They can contact the investigator to discuss their participation in the research project and obtain an information sheet.

What if I require further information?

Please contact Ms Christine Murray should you wish to discuss the research further before deciding whether or not to participate.

Ms Christine Murray phone: 0488-228-474 email: christine.murray@westernsydney.edu.au

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H13062.