



Patient Information Sheet

A randomised comparative effectiveness trial of yoga and strengthening exercise for knee osteoarthritis (YOGA trial)

Invitation

You are invited to participate in a research study investigating the effect of yoga for knee osteoarthritis. The study is being conducted by:

Dr Benny Antony (Menziess Institute for Medical Research, University of Tasmania)
Dr Steffany Moonaz (Maryland University of Integrative Health, USA)
Prof Kim Bennell (University of Melbourne)
Prof Graeme Jones (Menziess Institute for Medical Research, University of Tasmania)
Assoc Prof Dawn Aitkens (Menziess Institute for Medical Research, University of Tasmania)
Prof Andrew Palmer (Menziess Institute for Medical Research, University of Tasmania)
Prof Leigh Blizzard, (Menziess Institute for Medical Research, University of Tasmania)

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss your intention to participate with someone who is able to support you in making your decision, if you wish.

What is the purpose of this study?

Yoga is a mind-body exercise intervention that can provide increased flexibility, muscle strength, physical balancing, improved fitness, and has demonstrated pain-relieving properties. Although current guidelines for the treatment of knee osteoarthritis suggest yoga as an adjunctive form of exercise, guidelines highlight the lack of evidence about the effect of yoga as compared to strengthening exercise. Therefore, this study aims to investigate the impact of a 6 month yoga program compared to strengthening exercise on the knee pain in knee osteoarthritis patients.

Who is being asked to participate?

We will be studying up to 126 patients. Patients can be included in the study if they:

- ✓ Are male and female ≥ 40 years;
- ✓ Knee pain on most days for at least 6 months
- ✓ VAS knee pain intensity of ≥ 40 mm in the last month.



- ✓ Meet American College of Rheumatology clinical criteria for the diagnosis of knee osteoarthritis
- ✓ Be willing to participate in a group-based yoga program or group-based strengthening exercise program three times per week for 12-weeks and can attend on the days/times of the week that scheduled classes are running.
- ✓ Be willing to continue the yoga or the strengthening exercise at home for another 12 weeks

What does this study involve?

If you agree to participate in this study, you will be asked to sign the Patient Consent Form. Once you are enrolled in the study (following a screening visit), it will go for 6 months and you will have to attend three study visits during the 6 months (baseline, month 3 and 6).

You will also have to participate three times a week for 12 weeks either in a group-based yoga program or a group-based strengthening exercise program. You will be instructed to continue your yoga or strengthening exercise program at home for another 12 weeks. All the visits will be done at the Menzies Institute for Medical Research. The group-based yoga program and group-based strengthening exercise program will occur at the at the Menzies Institute for Medical Research.

Who will have to participate in the yoga program?

In this study one half of participants will participate in a 6-month group-based yoga program and the other half will participate in group-based strengthening exercise program. This is a '*randomised trial*' which means you will be allocated to one of the two groups randomly, like the flip of a coin. You will have equal chance of ending up in either group and neither the researcher nor yourself can decide which group you will be in. Control groups are required in medical research to determine whether an intervention (in this case, yoga) is effective.

Detailed information about what will be involved

Screening visit

You will be asked to complete questionnaires related to your age, sex, marital status, Medicare number and educational status. You will also be asked questions to assess the amount of knee pain you have, medications you use, and information about whether you have had a previous knee injury or knee surgery. One of our researchers will

perform a clinical exam on your knee to confirm you have osteoarthritis. At this visit, we will also perform a safety check to make sure it is safe for you to commence an exercise program. If you satisfy all the inclusion criteria, you will then be included in for the trial participation.

Baseline visit

At this visit we will assess the amount of pain that you have, your leg muscle strength, weight and height. At this visit you will be randomised into one of two groups (*yoga program* or *strengthening exercise program*). Randomisation means you will be allocated to one of these groups randomly, like the flip of a coin. You will have equal chance of ending up in either group and neither the researcher nor yourself can decide which treatment the participant receives. This is a single-blind trial, which means you will be told which treatment group you are in but the researchers who will perform measurements on you during the study will not know which group you are in.

Yoga program

If you are randomised to the *yoga program group* you will be asked to take part in a 12 weeks group-based yoga program. This will involve attending 3 days/week a group-based supervised yoga program for 12 weeks. Group yoga sessions will be tailored to individual fitness levels and led by a physiotherapists/exercise physiologists or yoga and exercise teachers with experience in prescribing exercise for osteoarthritis patients. Trainers will lead a group of up to 10 participants. You will be instructed to continue your yoga program at home for another 12 weeks. The structure of our yoga program will involve:

- 5 minutes of yoga poses consisting centering and chanting
- 10 minutes of warmup yoga poses involving body scan, focus, pranayama, and joint mobilization
- 10 minutes of sun salutations
- 10 minutes of various standing asanas
- 10 minutes of various floor asanas
- 10 minutes of Savasana consisting of tense and release, progressive body scan, and breath and mind relaxation
- 5 minutes of closing asanas consisting awareness and movement, side lying, return to sitting, chanting, meditation

The yoga classes will occur at the Menzies Institute for Medical Research. You will be required to arrange your own travel to the supervised yoga classes and travel costs will not be reimbursed as part of this study. Below



is an example of the timetable you will receive if you are randomised to the intervention group. We will provide you with travel directions and exact meeting points for each yoga program session. c. If you use a smart phone or smart device, we will also ask you to use the app called “Heja” through which you will receive the reminder/communication about the schedules of yoga classes. No clinical information will be collected and the use of the app is strongly advised however it is not compulsory.

***Example only: Will be updated once yoga day/time are finalised.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			7:00 am Location C			
		9:00 am Location B			9:00 am Location B	
11:00 am Location A				11:00 am Location A		
	2:00 pm Location B					2:00 pm Location C
			5:30 pm Location A			

Our research assistant, Name Name, will be in regular contact with you to monitor your attendance at the group-based sessions and also monitor your home sessions. If you miss a scheduled group yoga session, Name Name will contact you directly to re-schedule.

Strengthening exercise program

If you are randomised to the *strengthening exercise group* then you are in the **control group** of this study and you will be asked to take part in a 12 weeks group-based strengthening exercise program. This will involve attending 3 days/week a group-based strengthening exercise program for 12 weeks. Group strengthening exercise sessions will be tailored to individual fitness levels and led by a physiotherapists/exercise physiologists or yoga and exercise teachers with experience in prescribing exercise for osteoarthritis patients. Trainers will lead a group of up to 10 participants. You will be instructed to continue your strengthening exercise at home for another 12 weeks. Each group session will be 60 minutes and will comprise:

1. Assessment – 5 mins
2. Warm up – 5 mins

3. Lower limb strengthening exercises run as a circuit class – 45 mins
4. Cool down – 5 mins

The strengthening exercise classes will occur at the Menzies Institute for Medical Research. You will be required to arrange your own travel to the supervised strengthening exercise classes and travel costs will not be reimbursed as part of this study. Below is an example of the timetable you will receive if you are randomised to the control group. We will provide you with travel directions and exact meeting points for each strengthening exercise session. If you use a smart phone or smart device, we will also ask you to use the app called “Heja” through which you will receive the reminder/communication about the schedules of exercise classes. No clinical information will be collected and the use of the app is strongly advised however it is not compulsory.

***Example only: Will be updated once strengthening exercise day/time are finalised.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			7:00 am Location C			
		9:00 am Location B			9:00 am Location B	
11:00 am Location A				11:00 am Location A		
	2:00 pm Location B					2:00 pm Location C
			5:30 pm Location A			

Our research assistant, Name Name, will be in regular contact with you to monitor your attendance at the group-based sessions and also monitor your home sessions. If you miss a scheduled group strengthening exercise session, Name Name will contact you directly to re-schedule.

These procedures/measures will also be performed as part of this study:

- Questionnaires about knee pain, knee function, and pain at other sites, occur at screening, baseline, 4, 8, 12, 16, 20, and 24 weeks;
- Questionnaires about quality of life, neuropathic pain, depressive symptoms, smoking and alcohol consumption, use of orthotic devices, satisfaction with intervention, change in concomitant

medication general well-being, health service utilization, days off work, medication cost, transport and any specialized equipment costs will occur at baseline, 12 and 24 weeks;

- Height, weight, waist and hip circumference and leg strength will be measured at baseline, 12 and 24 weeks;
- Blood and urine sample will be taken at baseline, 12 and 24 weeks and retained for the future biomarker analysis after the completion of the study.
- We will measure your gait characteristics using a device called GAITRite system. You will be asked to walk on a mat placed on floor for the assessment of gait characteristics at baseline, 12 and 24 weeks
- We will measure your body composition using a device called bioelectrical impedance analysis (BIA) analyser at baseline, 12 and 24 weeks
- We will videorecord you walking to assess the alignment of your lower leg (unless you opt out of the videorecording in which case we will perform this assessment by watching you walk instead).
- Physical performance measures which include 30s Chair Stand Test, 40m Fast-paced Walk Test, 6-minute walk test, Time up and Go test and Stair Climb. These tests will assess your ability to walk over long and short distances, ascend and descent stairs, how quickly you can change your body position from sitting to standing as well as how well you transition between these activities. The test will be performed at baseline, 12 and 24 weeks;
- You will be asked to give consent to have your medical records made available to us from the National Joint Registry for the purpose of checking on any knee joint replacement surgery following study completion.
- I understand about the possible secondary use of de-identified data for individual patient based meta-analyses. However, no identifiable information will be passed on for any analyses unless the circumstances mentioned below

Are there any risks in this study?

One of the risks of being involved in this study is that there is a chance that the yoga or the strengthening exercise involved in this study will increase your knee pain, or pain you may experience at other body sites. To minimise this risk, a trainers will lead groups of 8-10 participants to ensure yoga/strengthening exercise intensity is tailored to individuals and provide close contact and supervision to enhance motivation and

ensure safety. Physiotherapists and exercise physiologists are qualified to advise patients about recognising an “unsafe” symptom exacerbation. If symptoms rise above unsafe levels, participants will be advised to rest and the intensity will be reduced appropriately.

The yoga/strengthening exercise involved in this study may result in temporary muscle stiffness. There is also a risk that you may fall or injure yourself while doing yoga or strengthening exercise. The classes will be supervised by physiotherapists/exercise physiologists or yoga and exercise teachers to minimise these risks.

There are reports that exercise may induce a heart attack or cause sudden death, but this is very rare. As part of this study, we will perform a safety check to make sure it is safe for you to commence an exercise program. If any risks are identified during our safety assessment, you will be required to get clearance from your GP before you can participate in our study.

What happens if I suffer injury or complications as a result of the study?

If you suffer any injuries or complications as a result of this study, you should contact the investigators as soon as possible, and they will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

Will patients receive any reward for participating in this study?



All participants in this study will receive a yoga mat and elastic band as may be required for performing the yoga or strengthening exercise. You will be provided with yoga mat and elastic band at the start of the study. Also, the tests, yoga, and the strengthening exercise program provided as part of the trial will be provided at no cost.

What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you decide to take part in the study you can withdraw (including your data, scans, and video recording) at any time without effect. New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

Likewise, if your doctor feels that it is in your best interest to withdraw study therapy, he/she will do so immediately without your consent.

How is this study being paid for?

The study is being funded by the Rebecca L Cooper Medical Research Foundation. All of the money being paid by the sponsor to run the trial will be deposited into an account managed by the Menzies Institute for Medical Research Tasmania. No money is paid directly to individual researchers.

Will I benefit from the study?

This study aims to further medical knowledge about treating knee osteoarthritis. If the treatment is effective, then the patients in the treatment groups may experience reduced knee pain. However, it is possible that you may not directly benefit.

How will my confidentiality be protected?

Your identity as a participant in this study is confidential. Your information will be maintained on confidential password protected databases or in locked filing cabinets with restricted access to only the researchers and support staff of this study.

Unless required by law, only your doctor, the study team, and its authorized agents, other genuine researchers who agree to preserve the confidentiality of your information and the responsible Human Research Ethics Committee will have access to data which identifies you by name or from which your identity is otherwise apparent or can be reasonably ascertained. All such personal information will be used only for the purpose of administering your participation in this Study, and in accordance with the laws governing protection and privacy of personal information under the Privacy Act 1988 (Cth).

What happens to the study results?

If you give us your permission by signing the consent document, we plan to discuss/publish these study results with the study sponsor, the ethics committee for monitoring purposes, peer-reviewed journals, presentations at conferences and/or other professional forums. You will not be personally identified in any reports or publications resulting from this study. Any patient, who wishes, may ask their doctor to receive a copy of these results.

What happens to my treatment when the study is finished?

The yoga or the exercise program provided as part of this study is not funded to continue when the study finishes. Therefore, the group based yoga sessions and strengthening exercise session will cease. If you want to continue yoga or strengthening exercise as part of your treatment for knee osteoarthritis, you can do so at your own expense and discretion.

What should I do if I want to discuss this study further before I decide?

When you have read this information, the Research Assistant, NameName is available to discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact his/her on 03 XXXX XXXX (Monday to

Wednesday). You may also contact the Chief Investigator, Dr Benny Antony, on 03XXXX XXXX.

Concerns or complaints?

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 6254 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research patients. You will need to quote HREC Reference # H0017108.

Thank you for taking the time to consider this study.

This information sheet is for you to keep.