UNIVERSITY of TASMANIA | MENZIES Institute for Medical Research

PATIENT CONSENT FORM

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

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1. I acknowledge that the nature, purpose and contemplated effects of the project so far as it affects me, have been fully explained to my satisfaction by the research worker and my consent is given voluntarily.

2. The details of the procedure proposed have also been explained to me, including the anticipated length of time it will take, the frequency with which the procedure will be performed, and an indication of any discomfort, which may be expected.

3. I understand that my involvement includes the following <u>compulsory</u> components:

   a. Providing researchers with my sex, date of birth and Medicare number.

   b. Having a physical assessment by a study doctor during screening to confirm I have clinically diagnosed osteoarthritis.

   c. Collection of a small amount of blood at screening, week 12 and 24 by a qualified venepuncturist.

   d. I understand that the blood and urine samples collected during the study at baseline, 12, and 24 weeks will be retained for future biomarker analysis by other authorized researchers after the completion of the study.

   e. 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 required by law.

   f. I understand I will be asked to wear an accelerometers for a week before the start of intervention, 12 weeks and 24 weeks.

g. Measurement of height, weight and leg strength at baseline, 12 and 24 weeks.

h. Gait characteristics (assessed using GAITRite system) at baseline, 12 and 24 weeks.

i. Body composition assessed using bioelectrical impedance analysis (BIA) analyser at baseline, 12 and 24 weeks.

j. Questionnaires about my knee symptoms, medical history, osteoarthritis treatments used, and medication usage at screening, baseline, weeks 4, 8, 12, 16, 20 and 24.

k. Questionnaires about treatment side-effects and overall satisfaction with the study treatment at weeks 4, 8, 12, 16, 20 and 24.

l. Questionnaires about my general well-being, how my symptoms impact on my life, quality of life, neuropathic pain, smoking and alcohol consumption, use of orthotic devices, occupation, and depressive and anxiety symptoms at baseline, weeks 12 and 24.

m. Questionnaires about my employment, use of health services and the costs I have incurred due to medications, medical appointments, scans, transport, and specialised equipment purchased for my knee pain, and my concession/health care card and private health insurance status at baseline, week 12 and 24.

n. I understand I will need to take part in either the *group-based yoga program* or the *group-based strengthening exercise* for 24 weeks.

o. If I am woman of childbearing age and there is a possibility that I may be pregnant, I will need to do a urine test before I can start in the study.

4. I understand that if I am randomised to the *yoga group* or the *strengthening exercise* group I will be required to take part in a 24 weeks *group-based yoga program* or *strengthening exercise* that involves attending <u>3 days/week</u> group-based supervised *yoga*

program or *strengthening exercise* for 12 weeks and I will be instructed to continue the yoga or the *strengthening exercise* at home for another 12 weeks, based on the group I am randomised to. Further to this I understand that:

a. I will have to arrange my own travel to the supervised *yoga/ strengthening exercise* classes and travel costs will not be reimbursed as part of this study.

b. I will be contacted directly by the researchers if I miss any sessions.

c. If I use a smart phone or smart device, I will be asked to use the mobile app called “Heja” through which I will receive the reminder/communication about the schedules of yoga or exercise classes.

d. I cannot participate in this study if I have a planned absence (e.g. trips away) that will last more than 2 weeks during the study period.

5. I understand that there are the following risks or possible discomfort:

a. I understand that there are the following risks associated with exercise: an increase in knee pain or pain at other sites, temporary muscle stiffness, falls or other injuries due to the exercise, and a very rare chance of heart attack or case sudden death. I understand that the research team has a number of precautions in place to try and minimise these risks.

6. I give consent for my medical records to be made available from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) for the purpose of checking on any knee joint replacement surgery following study completion.

7. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

8. I understand that the research gathered in this study may be published. I am informed that no information regarding any medical

history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

9. I understand that my involvement in the project will not affect my relationship with my medical advisers in their management of my health. I also understand that I am free to withdraw from the project at any stage and any of my data/scans/videorecording that have been collected. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.

10. I understand that I will be given a signed copy of this patient information sheet and consent form. I am not giving up my legal rights by signing this consent form.

11. I understand that the trial will be conducted in accordance with the latest versions of the *National Statement on Ethical Conduct in Human Research 2007* and applicable privacy laws.

CONSENT

Name of patient _____

Signature of patient _____ Date _____

I have explained this project and the implications of participation in it to this patient and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator _____

Signature of investigator _____ Date _____