**PARTICIPANT EXPLANATORY FORM**

**PROJECT TITLE:** A bike pedalling based protocol after total knee replacement surgery compared to a standard multi-exercise physiotherapy program: a randomised control trial.

**BUHREC PROTOCOL NUMBER: 0000015631**

My name is Larissa Sattler and I am the Senior Orthopaedic Physiotherapist at Pindara Private Hospital currently completing a Research Masters at Bond University under the supervision of both Professor Wayne Hing (Head of the Physiotherapy Program at Bond University) and your Orthopaedic Surgeon, Dr. Christopher Vertullo.

I am conducting a research investigation into physiotherapy treatment after Total Knee Replacement surgery. I am specifically interested in comparing different types of physiotherapy exercises to evaluate whether they provide equal benefit to patients in regards to both physical measures and patient reported satisfaction.

Although we would appreciate your willingness to participate in this study your consent is completely voluntary and you may withdraw at any time without risking any negative consequences. If you do choose to withdraw you will still be entitled to the standard practice of post-operative physiotherapy care at Pindara Private Hospital.

If you choose to participate, the frequency and duration of your physiotherapy sessions following your Total Knee Replacement will be no different to what is normally prescribed at the Hospital, which is twice daily for approximately 20 minutes’ duration.

You will be randomly allocated to one of two physiotherapy treatment groups, which although different in exercise prescription, will both still consist of standard physiotherapy care. Your treating physiotherapist will help you to start walking normally again, they will prescribe and supervise knee bending exercises for your operated leg which may include: lying in bed and bending your knee up towards you, sitting on the side of your bed and letting your foot gently dangle down with your knee bent, sliding your heel back underneath you once seated in a chair, and using a set of stationary bike pedals to assist knee bend. Your physiotherapist may also prescribe you with other exercises to help strengthen the muscles around the knee these may be performed in the bed, in a chair or in a standing position, and may include thigh muscle setting then lifting your foot up against gravity to make your thigh muscle work harder, straightening your knee out with the help of a stretchy band, heel raises and mini squats. Your physiotherapist will supervise all your walking and other exercises until they think it is safe for you to perform these by yourself. The risks and benefits of participating in this study are no different than what are normally experienced by a patient receiving post-operative physiotherapy care. Risks such as increased pain and swelling in the knee following a physiotherapy session are offset by the experience of the supervising physiotherapist ensuring you work within what is comfortable to you during the treatment session. Although you will not be prescribed all of the above exercises depending on the physiotherapy group you are allocated to, both exercise groups consist of standard exercises commonly already being prescribed to patients post total knee replacement. It is expected that you will continue with a prescribed independent home exercise program based on your hospital exercises twice daily on discharge from hospital.

As an inpatient you will be also be asked to complete two surveys about how you feel about your knee pain and function and complete some physical tests as described below prior to your discharge from hospital. You will also be asked to return to the Pindara Private Hospital Physiotherapy Gym following your post-operative review with your Orthopaedic Surgeon at 12 days and 4 months post-operatively to record the same surveys and physical measures.

The two surveys you will be asked to complete are the Lower Limb Outcomes Assessment consisting of seven items addressing pain, stiffness and swelling, and function; and the EQ-5D™ which is used to measure health outcomes with questions across 5 areas: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each of these two questionnaires should only take a few minutes to complete. There are four physical measures being recorded: A Timed Up and Go (TUG) test which involves raising from a chair walking 3 metres and returning, a timed 10 metre walk test which times how long it takes you to walk 10 metres, a 6-minute walk test which measures the distance you can walk in 6 minutes and your knee bend will also be measured. The first two walking tests will take you less than a minute each to complete whereas the longer walk test runs for 6 minutes as indicated.

All the data collected in this study will be treated with complete confidentiality and not made accessible to any person outside of the researchers working on this project. The information I obtain from you will be dealt with in a manner that ensures you remain anonymous. Data will be stored in a secured location at Bond University for a period of 5 years in accordance with the guidelines set out by the Bond University Human Research Ethics Committee.

It is anticipated that the results of this study will assist us in better understanding the effects of physiotherapy treatment and exercise prescription in patients after Total Knee Replacement surgery of which there is little current evidence for differing methods.

If you choose to withdrawal from the study, please contact:

**Research Masters Student:**

Larissa Sattler

Phone: 0406 537 395

Email: larissa.sattler@student.bond.edu.au

Or

**Orthopaedic Surgeon:**

Dr Christopher Vertullo

MBBS FRACS FAOrth A

Phone: 0418877685

Email: chris.vertullo@icloud.com

Or

**Research Masters Supervisor:**

Professor Wayne Hing

Professor of Physiotherapy, Head of Department

Bond Institute of Health and Sport

Faculty of Health Sciences and Medicine

Phone: +61 7 5595 3055

Fax: +61 7 5595 3524

Email: whing@bond.edu.au

Should you have any complaints concerning the manner in which this research is being conducted please make contact with:

**Bond University Human Research Ethics Committee,**

**c/o Bond University Office of Research Services.**

**Bond University, Gold Coast, 4229**

**Tel: +61 7 5595 4194**

**Fax: +61 7 5595 1120**

**Email: buhrec@bond.edu.au**