TITLE: Combined cryotherapy and intermittent dynamic compression compared with conventional ice and static compression in post-operative anterior cruciate ligament reconstructions: A randomised controlled trial

Patient Information Sheet

INVESTIGATORS: Dr Abay Sundaram, Dr Mira Marinova, Ms Katie Holtham, Dr Jay Ebert, Mr Ross Radic

Thank you for taking the time to read about this study being conducted by the Perth Orthopaedic and Sports Medicine Centre. You are being invited to take part in this trial. Before you make your decision, it is important for you to understand why the research is being done and what it would involve. Please take as much time as you need to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Ask us if there is anything that is not clear or if you require more information.

Anterior cruciate ligament (ACL) injuries are common injuries in the athletic population. An ACL reconstruction is a well-established surgical treatment for a knee without an intact ACL, regardless of how old your injury is. You may already feel that your knee is unstable or it may even give way on you. We understand that your decision to go ahead with the surgery takes a lot of thought and planning; and it is our role as your team to ensure we make your recovery and rehabilitation as smooth and as safe as possible to get you back to the activities you enjoy.

Unfortunately, like any major operations of the knee, you will experience pain and swelling caused by normal post-operative inflammation. You may also find it difficult to bend or straighten your knee and you may find that your muscles are weaker. These side-effects (i.e. pain and swelling) of knee surgery are currently managed by conservative treatments such as icing the knee and providing compression. Therefore, we are currently conducting a study to see if applying a device called Game Ready, which provides a combination of continuous compression and cold therapy, can improve outcomes above and beyond the routine application of knee icing and compression, for patients undergoing ACL reconstruction.

NATURE AND PURPOSE OF THIS STUDY

If you decide to be involved in this study, in addition to standard post-operative rehabilitation you will either be assigned to the conventional protocol of knee icing and compression over the first two post-operative weeks, or to the icing protocol provided by the Game Ready system. The outcomes of each ice/compression intervention will be evaluated via validated subjective (asking you about your pain and symptoms) and clinical scores (assessing your knee function

and mobility), as well as your perceived satisfaction with your outcome. This information will be of benefit to you in your return to full function, as well as other patients who require such treatment in the future.

EXPECTED STUDY DURATION AND NUMBER OF PARTICIPANTS

We hope to continue to see you for 2 years following your operation. A total of 66 patients will be recruited for this study.

STUDY PROCEDURES

What will happen in this clinical trial?

This is a randomised controlled trial (RCT) investigating two different post-operative interventions. All patients who are undergoing ACL reconstruction surgery with any of Perth Orthopaedic and Sports Medicine Centre's surgeons will be invited to participate in this trial. If you meet our inclusion criteria and consent to participate in this RCT, you will be randomised to either one of two groups (Game Ready ice/compression or conventional treatment with elastic knee wraps and ice packs).

In addition to following the designated intervention that you are randomised to, you will be required to complete a pre-surgery evaluation and undertake post-operative evaluations at day 1 and 2 post-surgery, at 2 and 6 weeks, and at 3, 6, 12 and 24 months post-surgery. This will include validated self-reported questionnaires, and a series of strength/functional, knee girth and range of movement measurements. These are all measures that are employed routinely in the follow up evaluation of patients undergoing ACL reconstruction.

POTENTIAL BENEFITS

- As a participant in this study you will be provided with a comprehensive evaluation of your post-operative lower limb range of movement, strength and function throughout the trial.
- Potential benefit of decreased pain, inflammation and generally improved post-operative recovery.
- Potential benefit of a quicker return to your pre-injury level of activity.

POTENTIAL RISKS

- There are no expected risks/discomforts expected through participation in this study. You may experience a feeling of cooling on your knee and surrounding area, but this should not cause any pain or adverse reactions.
- Although using the Game Ready system is a minimally investigated protocol, we anticipate no adverse complications as a result of its use.

WITHDRAWAL FROM STUDY

If at any time you wish to withdraw from this study, you are free to do so without prejudice and it will not affect your current or future medical care.

WHAT HAPPENS IF THERE IS AN ADVERSE MEDICAL EVENT

If you experience an adverse medical event or injury arising from your participation in this study, the investigating team will arrange for you to receive the appropriate medical treatment. Your usual rights under Australian law in relation to an adverse medical event or injury will not be affected by your agreeing to participate in this research study or by signing the consent form. If you do have any concerns or questions, please do not hesitate to contact us.

CONFIDENTIALITY - Who will see my study records?

Your privacy is important to us. We will keep any paper records under lock and key in a metal filling cabinet at the Perth Orthopaedic and Sports Medicine Centre. Any computer records will be stored in the assessor database and will be password protected. Personal data, which may be sensitive, (eg. date of birth) will be collected and processed but only for research purposes in connection with this study and will not be shared with any third party. Your surgeon and the principal investigators will only have access to patient study records. Records will be kept for 15 years in keeping with Australian Law; after which, paper records will be shredded and computer records will be permanently deleted including back-up copies.

The result of the research will be made available through medical journals or meetings, but all patient information will be de-identified and no private information will be identified outside the investigator office. Your rights under any applicable data protection laws are not affected.

STUDY COSTS

There are no additional costs to you, outside of the normal standard of care. While most of the assessments will be conducted at times where you would normally be assessed by your surgeon as per ACL reconstruction protocol, some later stage clinical reviews (i.e. 6, 12 and 24 months) are required and we ask that you travel for these reviews. Unfortunately, we can't reimburse your cost of travel to and from the venue for these assessments. If you are randomised to the Game Ready intervention, the device will be provided for your usage free of charge for the full intervention period of 2 weeks.

ETHICAL APPROVAL OF THE STUDY

This study has been approved by the Hollywood Private Hospital Human Research Ethics Committee, and will be carried out in a manner conforming to the principles set out by the "National Statement on Ethical Conduct in Research involving Humans" and according to the Good Clinical Practice Guidelines and the International Conference of Harmonisation.

"If you have any concerns about this study or your rights as a participant please do not hesitate to contact Dr Terry Bayliss, Chairperson, Research Ethics Committee Hollywood Private Hospital, Monash Avenue, NEDLANDS WA 6009 telephone (08) 9346 6345".

FURTHER INFORMATION

If you have any questions, please ask the Research Coordinator as outlined below.

Research Coordinator: Dr Abay Sundaram Phone: (08) 9481 3792

Advising Your Family Doctor about your Participation in the Study

Please provide your family doctor's details below, we will keep him/her informed of your participation in the study as well as any other study relevant information.

Your GP's name: _____

Telephone: _____

Address: _____

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To be completed by the Participant (parent/guardian if under 18 years) of the study:

1. Have you read the information sheet about this study? Yes ☐ No ☐
2. Have you had opportunity to ask questions and discuss this study? Yes ☐ No ☐
3. Have you received satisfactory answers to all your questions? Yes ☐ No ☐
4. Have you received enough information about this study? Yes ☐ No ☐
5. Which Doctor (or other researcher) has spoken to you about this study? _____
6. Do you understand that you are free to withdraw from this study at any time without giving a reason and without affecting your current or future medical care? Yes ☐ No ☐
7. Do you agree to take part in this study? Yes ☐ No ☐
8. Have you received a copy of the information sheet & consent form? Yes ☐ No ☐

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM

_____	_____	_____
Participant's Name	Participant's Signature	Date
_____	_____	_____
Parent / Guardian Name	Parent / Guardian Signature	Date
_____	_____	_____
Person Obtaining Consent	Signature	Date