



Assessment of Low Intensity Pulsed Ultrasound for Lower Limb  
STress Fractures in Athletes: A RRandomised Controlled Study

## PLAIN LANGUAGE STATEMENT AND CONSENT FORM

### Plain Language Statement

<b>Date:</b>	5 August 2009
<b>Full Project Title:</b>	Assessment of Low Intensity Pulsed Ultrasound for Lower Limb Stress Fractures in Athletes: A Randomised Controlled Study
<b>Main Researcher:</b>	Dr Thomas Gan
<b>Associate Researcher(s):</b>	Professor William Walsh, Dr Donald Kuah, Kenneth Graham

This Plain Language Statement and Consent Form is 6 pages long. Please make sure you have all the pages.

### 1. Your Consent

You are invited to take part in this research project.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Plain Language Statement and Consent Form to keep as a record.

### 2. Purpose and Background

This study is being undertaken in collaboration with the New South Wales Institute of Sport, the University of New South Wales, the Prince of Wales Hospital, Sydney Sports Medicine Centre and Narrabeen Sports Medicine Centre.

Lower limb stress fractures are common injuries in athletes. The usual treatment involves a period of relative rest, usually for 6-8 weeks sometimes combined with activity modification, physiotherapy guided rehabilitation and a walker boot if pain is experienced in everyday activities. Stress fractures occur when there is increased load and damage on the bones beyond the ability of the body to repair itself. This often occurs during periods before important competitions when the athlete may increase their training volume and intensity. The current standard treatment of enforced rest presents obvious frustration to the athlete as they are not able to train and may even miss an important competition due to their injury.

The purpose of this study is to determine if the use of low intensity pulsed ultrasound in stress fractures of the lower limb when compared to placebo is able to return athletes to their sport or activity quicker when used in addition to standard therapy as outlined above. The speed of return to your sport or activity will be measured and MRI scans will be performed at diagnosis and follow up to determine the amount of healing that has occurred.

Previous experience has shown that low intensity pulsed ultrasound is effective for the healing of acute fractures and also for fractures where healing has been delayed. There has so far been one study looking at stress fractures in military recruits which showed no difference in healing times when low intensity pulsed ultrasound was used. There has been no study looking specifically at an athletic population or MRI scans.

You are invited to participate in this research project because you are an athlete who has sustained a lower limb stress fracture. Approximately 30 people will be recruited for this project.

Low intensity pulsed ultrasound, also known as bone growth stimulators, has marketing approval in Australia and is already used by some sports medicine practitioners.

This study is being funded by the Australian Sports Commission. Products and services will be provided by Surgical Synergies, the I-Med Radiology Network and the Surgical & Orthopaedic Research Laboratories at the Prince of Wales Hospital.

The results of this research may be used to help researcher Dr Thomas Gan obtain fellowship for the Australasian College of Sports Physicians.

### **3. Procedures**

Participation in this project will involve:

#### Low Intensity Pulsed Ultrasound

- As this is a clinical trial, you have an even chance of receiving either the new treatment or a mimic device that does not emit low intensity pulsed ultrasound
- You will be expected to use this equipment for **20 minutes a day** for **4 weeks**
- You will be instructed on how to use it at your first appointment
- Usage will be **free of charge**

#### MRI scans

- You will be expected to have **2 MRI scans**
  - The first being after your first appointment
  - The second at 3 months
- Both scans will be **free of charge**

#### Walker Boot

- If you have a metatarsal stress fracture, you will be required to wear a walker boot.
  - A new boot will be provided **free of charge**
  - You will be instructed on its usage at your first appointment

#### Medical Appointments

- You may choose to have your appointments at either location listed below:
  - Sydney Sports Medicine Centre, Sydney Olympic Park
  - Narrabeen Sports Medicine Centre
- Your schedule of medical appointments is as follows:
  - Initial, 4 weeks, 6 weeks, 8 weeks, 10 weeks and 12 weeks.
  - Please book these in advance after your initial appointment
- You may be reminded by our reception staff with either a phone call or text message
- The initial appointment will be half an hour in duration
- Subsequent appointments will be 15 minutes in duration unless otherwise specified
- All appointments will be **bulk billed (no charge to yourself)**
  - **Please bring your Medicare card to each appointment**

#### 4. Possible Benefits

Possible benefits include

##### The Subject (You)

- **Faster return to training and competition**
- Shorter period of enforced rest
- Confirmation of diagnosis by MRI scan

##### Future Athletes & Coaches

- **Faster return to training and competition**
- Shorter period of enforced rest
- Improved treatment protocol for athletes with lower limb stress fractures
- Improved understanding of the association of clinical signs and symptoms with MRI images

#### 5. Possible Risks & Adverse Effects

##### Biological

- **Nil significant**
- There is no risk of ionising radiation with either low intensity pulsed ultrasound or MRI scans

##### Pregnancy & Lactation

The effects of low intensity pulsed ultrasound on the unborn child and on the newborn baby are not known. Because of this, it is important that study participants are not pregnant or breast-feeding and do not become pregnant during the course of the study. You must not participate in the study if you are pregnant or trying to become pregnant, or breast-feeding. If you do become pregnant whilst participating in the study you should advise your treating doctor immediately. He will withdraw you from the study and advise on further medical attention should this be necessary. You must not continue in the study if you become pregnant.

*Although all care will be taken during the study period, there may be additional unforeseen or unknown risks.*

#### 6. Other Treatments Whilst on Study

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies and any changes to these during your participation in the study.

#### 7. Privacy, Confidentiality and Disclosure of Information

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to publish the results with a major peer reviewed sports medicine journal and present at various scientific conferences and educational seminars. In any publication or presentation, information will be provided in such a way that you cannot be identified.

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the Australian Government's Therapeutic Goods Administration (TGA) and other national drug regulatory authorities such as the Food & Drug Administration (FDA) of the United States of America (USA). By signing the attached Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

In accordance with the *Freedom of Information Act* 1989 (NSW), you have the right to access and to request correction of information held about you.

## 8. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

## 9. Further Information or Any Problems

If you require further information or if you have any problems please the researcher responsible for this project:

- **Dr Thomas Gan**

- Sydney Sports Medicine Centre 02 9764 3131
- Narrabeen Sports Medicine Centre 02 9971 1188
- Mobile 0403 309 028

## 10. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the institutions involved with this study.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

## 11. Reimbursement for your costs

You will not be paid for your participation in this trial. However, as mentioned, all medical reviews, investigations and treatments will be available free of charge to you.

## 12. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Research Involving Humans* (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the University of New South Wales Human Research Ethics Advisory Panel.

## 15. Injury

In the event that you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you.

## 16. Termination of the Study

This research project may be stopped for a variety of reasons. These may include reasons such as: unacceptable side effects, the medical device being shown not to be effective or the medical device being shown to work and not need further investigation.



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Stress Fractures in Athletes: A Randomised Controlled Study

## PLAIN LANGUAGE STATEMENT AND CONSENT FORM

### Consent Form

**Date:** 5 August 2009

**Full Project Title:** Assessment of Low Intensity Pulsed Ultrasound for Lower Limb Stress Fractures  
in Athletes: A Randomised Controlled Study

I have read the Plain Language Statement.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate (or allow my child / ward to participate) in this project according to the conditions  
in the Plain Language Statement.

I will be given a copy of the Plain Language Statement and Consent Form to keep.

I understand that the researcher has agreed not to reveal my identity and personal details (or that of my  
participating child / ward) if information about this project is published or presented in any public form.

Participant's Name (printed) \_\_\_\_\_

Name of parent / guardian if under 16 (printed) \_\_\_\_\_

Signature

Date

Name of witness to signature (printed) \_\_\_\_\_

Signature

Date

**Declaration by researcher:** I have given a verbal explanation of the research project, its procedures and risks  
and I believe that the participant or parent / guardian has understood that explanation.

Researcher's Name (printed) \_\_\_\_\_

Signature

Date

*Note:* All parties signing the consent form must date their own signature.



Assessment of **L**ow Intensity Pulsed Ultrasound for **L**ower Limb  
**S**tress Fractures in **A**thletes: A **R**andomised Controlled Study

### PLAIN LANGUAGE STATEMENT AND CONSENT FORM

**Revocation of consent Form** *(To be used for participants who wish to withdraw from the project)*

**Date:** 5 August 2009

**Full Project Title:** Assessment of Low Intensity Pulsed Ultrasound for Lower Limb Stress Fractures  
in Athletes: A Randomised Controlled Study

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I hereby wish to WITHDRAW my consent (or that of my child / ward) to participate in the research proposal named above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the researcher or any of the institutions involved.

Participant's Name (printed) \_\_\_\_\_

Name of parent / guardian if under 16 (printed) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Name of witness to signature (printed) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

**Declaration by researcher:** I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant or parent / guardian has understood that explanation.

Researcher's Name (printed) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

*Note:* All parties signing the revocation of consent form must date their own signature.