UNIVERSITY of TASMANIA
MENZIES
Institute for Medical Research

PARTICIPANT INFORMATION SHEET

The BALSA Trial: Targeted care for chronic plantar heel pain: shockwave treatment for bone marrow lesions in the heel.

Invitation

You are invited to participate in a research study investigating the effect of a physical therapy treatment known as 'shockwave' for chronic heel pain.
The study is being conducted by:

- Dr Jason Rogers, Postdoctoral Research Fellow, Menzies Institute for Medical Research, University of Tasmania
- Professor Tania Winzenberg, Professor of Chronic Disease Management, Menzies Institute for Medical Research, University of Tasmania
- Professor Graeme Jones, Professor of Rheumatology, Menzies Institute for Medical Research, University of Tasmania
- Associate Professor Dawn Aitken, Senior Research Fellow, Menzies Institute for Medical Research, University of Tasmania
- Dr Andrew Halliday, Staff Specialist Radiologist, Royal Hobart Hospital
- Dr Karen Wills, Statistician, Menzies Institute for Medical Research, University of Tasmania
- Associate Professor Barbara de Graaff, Health Economist, Menzies Institute for Medical Research
- Mr Stan Drummen, Physiotherapist and PhD candidate, Menzies Institute for Medical Research, University of Tasmania
- Ms Wardah Malick, PhD candidate, Menzies Institute for Medical Research, University of Tasmania
- Ms Jane Barrett, Volunteer

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 it with others if you wish.

1. 'What is the purpose of this study?'

The purpose of this study is to determine if the application of a bone targeting treatment known as shockwave is effective in improving pain in people with chronic plantar heel pain who also have a type of bone stress response in the heel known as a 'bone marrow lesion'. Up to 50% of people with chronic plantar heel pain have a bone marrow lesion, which is diagnosed by having a type of scan known as a magnetic resonance imaging (MRI). A secondary aim is to determine if the mechanism of change in pain is related to change in size of a bone marrow lesion.

Shockwave is an approved treatment for chronic plantar heel pain in Australia. However, the specific effectiveness of shockwave in people whose heel pain may be related to having a bone marrow lesion, has not been determined.

2. 'Why have I been invited to participate in this study?'

You have been invited to participate in this study because you have symptoms of chronic plantar heel pain (i.e. pain under your heel > 3 months), with evidence of a bone marrow lesion on an MRI. The study is open to persons of any gender aged 18 and over who are willing to commit to a free 3-week course of treatment at the Menzies Institute. To enter the study, participants must not currently be receiving treatment for their heel pain by a healthcare professional.

3. '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 wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

Screening and baseline assessment.

After a phone call from a research assistant to confirm eligibility and to answer any questions you may have, you will next be asked to have an MRI scan on the study foot to confirm the presence of a 'bone marrow lesion'. Actual scan time is approximately 20 minutes and will be conducted at a private radiology clinic in Hobart. MRI is a very safe imaging modality with no known harmful effects. It uses magnetic fields and radio waves to image the body's internal structures.

Participants will also be asked to fill out questionnaires which ask you about your pain, general wellbeing, and activity levels as well as your medical history and medication intake. The initial questionnaires will take approximately 30 minutes to fill out, using an electronic format.

Those who meet the eligibility criteria and agree to participate in this trial will then attend the Menzies Institute in person to have their height, weight and foot size

measured, before being allocated to a treatment group. Treatment will commence on the same day.

Treatment phase

In the treatment phase, participants will be allocated by chance to either an active shockwave treatment group or a 'sham' (inert) group. Participants in both groups will need to commit to 3 treatment sessions of no more than 30 minutes each, one week apart. Shockwave treatment is a physical treatment applied to the underside of the heel using gel and a hand-held device, similar to ultrasound.

The shockwave units in both groups will sound and appear to operate similarly over the same treatment duration, but no energy is delivered by the sham handpiece.
Note that during the term of the study we will not reveal what treatment group participants are in. We will inform participants once the study is complete, after the final 12-month review.

Other treatments

To understand the effectiveness of shockwave treatment in isolation, you will be asked *not* to start any new treatments between having your baseline assessment and the follow-up at 4-month. This includes visiting a healthcare professional for treatment of your heel pain during this period. It does not include continuing on with self-administered treatments that you were using in the 6 weeks prior to starting the trial (e.g. if you were already exercising or wearing shoe inserts before the study started).
If you are uncertain, we ask that you discuss your need for treatment with the study co-ordinator, Mr Jason Rogers (03 6220 8525).

Follow up.

We will follow-up on your participation at 4- and 12-months.

At 4-months after your baseline assessment we will electronically send you out the same questionnaires to re-assess your responses. Questionnaires will also ask your opinion on what effect treatment had on your foot symptoms, if you were satisfied with the treatment, if there were any side effects, and whether you used any other treatments within the study period. You don't need to physically re-attend at Menzies but you will need to re-attend the radiology clinic for another MRI.

Between completing the trial treatment and the month 4 follow-up, we will send you an email at month 2 and month 3 to ask you to report your ongoing level of heel pain (a single question), to help us understand how symptoms change over time.

The follow-up at 12-months will only require you to fill out the same questionnaires sent at 4-months. You do not need to attend Menzies at this time, nor have another scan.

To understand the personal experience of people who participated in this study and their heel pain journey, at the end of the study we have an open-ended request for qualitative feedback. If you agree, we may seek your advice as a 'consumer and community' representative to better understand how we align research to the needs of people with plantar heel pain. We may also approach you to ask if you are willing to be contacted for future studies. This component of the study is not compulsory, and there is no obligation to participate. You do not need to provide a reason if you do not wish to participate further.

5. 'How is this study being paid for?'

The project is being funded by external grant funds from the Royal Hobart Hospital Research Foundation, and by internal Menzies funds. This funding will be managed by the University and applied towards direct costs associated with the research (such as imaging)- no money is paid to the researchers. The shockwave unit used in the study is on loan from the Australian distributor EMS Australia and New Zealand. EMS are not involved in the design or conductance of the study, nor the analysis of results and their distribution.

6. 'Are there risks to me in taking part in this study?'

The risks of participating in this study are low. Risks associated with the use of shockwave include:

- you might experience some increased discomfort during or after treatment, minor bruising, swelling, redness or numbness at the site where shockwave is applied.

To minimize this risk the treatment will be provided by a registered and experienced physiotherapist according to manufacturer guidelines.

You will be provided instructions for managing these potential low level side effects, and we will actively encourage you to monitor and report these.

The study involves having a scan known as an MRI. MRI does not involve ionising radiation and there are no known risks from MRI in pregnancy. However, it is still important that women participating in this study are not pregnant at the time of their assessment to avoid unnecessary exposure of an unborn baby to MRI. If there is uncertainty regarding pregnancy status, we will ask you to take a pregnancy test. You

must also inform the researchers or the MRI team if you have metallic implants from past surgery or a pacemaker. Metal cannot go in or near the MRI scanner. If you are unsure, we may need to get your permission to access your medical records.

7. 'What should I do if I am uncomfortable with some of the questions in the Questionnaires or they cause me distress or worry?'

Some of the surveys ask very personal questions about your health, feelings and thoughts. If any question causes you to worry, become upset or feel distressed you should contact the study co-ordinator or a member of the research team who will assist you. We may recommend that you contact your GP to discuss these issues further.

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

As discussed above, the risks associated with this study are low. However if you suffer any injuries or complications as a result of this study, you should contact the study co-ordinator or a member of the research team as soon as possible, who will assist you in arranging appropriate medical treatment.

9. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future treatment of plantar fasciitis/ plantar heel pain, however it may not be of direct benefit to you. We will take imaging scans of your foot however these will not be reported on as they are for research/ measurement purposes only, and are not diagnostic.

If the treatment is effective, participants in the active treatment group may experience reduced heel pain.

10. 'Will taking part in this study cost me anything, and will I be paid?

There are no direct costs associated with participation in this study. There are indirect costs related to transporting yourself to Menzies, with free participant parking available underneath Menzies for study participants.

Tea and coffee will be available during the study visit.

12. 'How will my confidentiality be protected?'

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above, or staff working directly on the study under their supervision will have access to your details and results, and these will be held securely at the Menzies Institute for Medical Research.

13. 'What happens with the results?'
If you give us your permission by signing the consent document, we plan to discuss/ publish the results in peer reviewed journals and at professional conferences.

In any publication, information will be provided in such a way that you cannot be identified. We may also use some of the scan images for educational or descriptive purposes such as in lectures, conferences, academic papers, grants or posters. These images will have all identifying data removed by specialised software, and won't be re-identifiable. Results of the study will be provided to you if you wish.

14. 'What should I do if I want to discuss this study further before I decide?'
When you have read this information, one of the research team will discuss it with you and clarify any queries you may have.
If you would like to know more at any stage, please do not hesitate to contact Dr Jason Rogers on 03 6220 8525 (jason.rogers@utas.edu.au) or Professor Tania Winzenberg on 6226 7770 (tania.winzenberg@utas.edu.au).

15. 'Who should I contact if I have concerns about the conduct of this study?'
This study has been approved by the University of Tasmania Human Research Ethics Committee (HREC). If you have concerns or complaints about the conduct of this study, you can contact the Executive Officer of the HREC on +61 3 6226 6254 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote H0029837.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.