PARTICIPANT INFORMATION SHEET V2: 6/1/17

Title of study: A technical evaluation of the Swellaway cooling and heating device
Researchers: Professor James Selfe, Jill Alexander, Karen May and Professor Jim Richards.

Invitation: You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please do not hesitate to ask if there are any areas of the study you are unclear about or if you would like more information. Take time to decide whether or not you wish to take part.

Who is funding the research?
Swellaway are the designers and manufacturers of the device. They have commissioned us to conduct this independent research. Swellaway are providing funding for staff time and are supplying a quantity of devices to trial in the study. Swellaway are the creators and owners of the Copyright, IP and patents for the device. No Swellaway personnel are involved in the design, conduct or analysis of the results. Our results will be presented in the form of an independent report. There are no conflicts of interest.

What is the purpose of the study?
The purpose of the study is to investigate whether the application of the Swellaway device reduces skin surface temperature to within the desired therapeutic range in order to successfully cool soft tissues in the event of managing musculoskeletal injuries. The Swellaway therapy wrap is a patented device that combines thermal, control and compression, to provide treatment for common musculoskeletal injuries. The Swellaway electronic cooling device claims to cool or heat an area without the need of water or ice.

Aims of the study
The aim of the study is to assess the effectiveness of the Swellaway device on the cooling of skin temperature of the knee in healthy subjects.

Do I have to take part?
No. It is up to you to decide whether or not you take part. If you do wish to participate, you will be given this information sheet to keep and given the opportunity to ask the researchers any questions you have regarding the study. During the study, if there is any aspect you are unhappy with, you have the right to withdraw at any point without giving any reasons and without any negative consequences.

What we will ask you to do?
If having read this information sheet you wish to participate in this study you will be asked to sign a consent form. The consent form will provide your consent and eligibility for the study. During testing general sports clothing is appropriate and you will be required to wear shorts so that the device can be applied to your knee.

Where will the data collection take place?
All data for this project will be collected in one of the physiotherapy practical rooms on the 4th Floor of Brooks Building.

What are the possible disadvantages or risks of taking part?

There are minimal chances of an adverse reaction, but if at any point during the study you show signs of an adverse reaction to the cold temperature the researchers will immediately stop the data collection.

Am I eligible to participate?

If you answer YES to any of the **exclusion criteria** you will be **ineligible** to take part in the study.

EXCLUSION CRITERIA
Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
Have you had unusual chest pain when you were not doing physical activity?
Is your doctor currently prescribing drugs for your blood pressure or heart condition or are you taking any type of anti-inflammatory medication?
Have you had any condition or disease which will affect your muscles functioning or repairing?
Do you have any condition or disease that affects heart function?
Do you know of any other reasons why you should not undergo cooling treatments? This might include severe asthma, diabetes, a recent injury, serious illness, high / low blood pressure, Raynaud's Syndrome, Cancer, cold allergies.
Do you have any condition that effects blood clotting?

If you answer YES to any of the **inclusion criteria** below you will be **eligible** to take part in the study.

INCLUSION CRITERIA
No current musculoskeletal injuries to the knee.
Between the ages of 18-65

What will happen to me if I take part?

On arrival you will be asked to get changed into a pair of shorts and a consent form will be collected from you. Pre-intervention data collection will consist of a thermal sensation and a thermal comfort questionnaire followed by an Infra-Red thermal image recording of your knee. This method is non-invasive and you will not be recognised in the image after data collection. The Swellaway device will then be applied to your knee (Figure 1).

Figure 1: Prototype Swellaway device.

Once the exposure time of the device is complete the same data will be recorded immediately post removal of the device. The study has two phases. Phase 1 will measure your knee skin temperature once immediately on removal of the Swellaway device and requires you to attend a one off session of cooling at approximately 10^{o}C for either 2, 5, 10 or 15 minutes (random allocation will occur). This session will last for approximately 0.5 hours. Phase 2 will compare Skin Surface Temperature (Figure 2), Thermal Comfort and Sensation Questionnaires following a 10 minute application immediately and repeatedly at 5 minute intervals up to 20 mins following removal of the Swellaway device at 10^{o}C. This requires you to attend on 1 occasion of approximately 1 hour. You can choose which phase you would prefer to take part in and you will be free to take part in both phases if you wish.

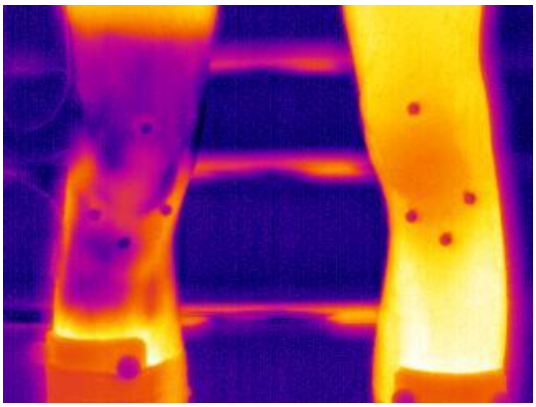

Figure 2: Example thermal image of a knee that has just been cooled (NB. not with a Swellaway device)

What are the possible benefits of taking part?

Although there are no direct benefits of taking part, the data collected may benefit the development of this device and its use in soft tissue injury management in the future.

What happens when the research study stops?

You will not be contacted or required to complete any further assessments regarding this study. Data will be stored for 5 years from the end of the project and then destroyed.

Will information about me be kept confidential?

All the information that we collect about you during the course of this research will be kept strictly confidential on a password protected computer to which only the researchers of the study will have access to. If we write about the results of the study your name and details will be removed completely. Data will be stored for 5 years from the end of the project on a password protected computer and then destroyed.

What will happen to the results of the research study?

The findings of the study will be used to provide an independent report to Swellaway (the funders of the study and the suppliers of the Swellaway device), we may also write peer reviewed journal publications and submit the findings to relevant conferences. The final report is a public document and will be available from the researchers on completion of the study. Should you wish to know the results of the study on completion

please email the researchers Jill Alexander (JAlexander3@uclan.ac.uk) / Karen May KAMay@uclan.ac.uk / Prof. James Selfe JSelfe@mmu.co.uk.

What will happen to my data if I withdraw from the study?

You are free to withdraw from the study at any point, however, once you leave the testing laboratory, we will not be able to identify your data and it will still be used.

Who is organising the research?

Manchester Metropolitan University and The University of Central Lancashire (UCLan) are organising the research.

Are there any conflicts of interest for the project?

There are no conflicts of interest from the funding party. No Swellaway personnel will be involved in the research process.

Who has reviewed the study?

The Faculty of Health, Psychology and Social Care Ethics committee of Manchester Metropolitan University have reviewed and approved this study.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any complaints about the study or how you have been treated in the study, please in the first instance contact the researchers using the details provided below, they will do their best to answer your questions. If you do not receive a satisfactory response, concerns should be addressed to Cate Lawton, Research Administrator, Brooks Building, Birley, 53 Bonsall St, Manchester, M15 6GX (cate.lawton@mmu.ac.uk). Information provided should include the study name or description (so that it can be identified), the principal investigator and the substance of the complaint.

Thank you for taking the time to read about the study, if you have any questions please do not hesitate to ask.

Research Team

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