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Exploring the effects of different cold therapy treatments on pain, movement, and strength in healthy participants with induced pain

Submission date 06/03/2020	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 12/03/2020	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 05/02/2021	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and Study Aims
Tissue cooling is a popular and widely used treatment applied by medical professionals and the general public before, during and after sports participation in preventing injury and promoting recovery. Swellaway have developed a new portable, controlled device which can control temperature and compression levels, applied to the surface of the skin within safe parameters. This allows healthcare professionals and researchers to explore the effect of a range of compressive-cryotherapy and thermotherapy protocols in a controlled, safe and easy manner, to identify possible effective protocols to use on different conditions and soft tissue injuries.

This pilot study aims to explore the efficacy of three cooling interventions on healthy participants with induced pain caused by capsaicin cream (0.075%) which causes a short term, mild, burning sensation when applied to the skin.

Who can participate?
Healthy volunteers aged 18 to 65

What does the study involve?
Participants will be required to attend three separate sessions, lasting up to 75 minutes each session. In each session, participants will receive all three of the following 20-minute treatments in a random order.
1. Swellaway - set to 6°C with medium compression
2. Wetted ice- 400ml water, 400g ice
3. Swellaway - contrast therapy alternating from low compression with 40°C to medium compression with 6°C

Participants will be asked to shave a 2 cm by 2 cm area on the medial aspect of their non-dominant (non-kicking foot) knee 24 hours prior to the study session.

The researcher will apply a small amount of capsaicin cream 0.075% (Axsain®) on to these prepared areas. Capsaicin cream (Axsain®, 0.075%) will be used in accordance with the

manufacturer's guidance and is commonly used in experimental pain model studies. Body measurements will be taken including height and weight. Measurements on levels of pain, muscle strength and joint position sense will be collected before, immediately after and 20 minutes after each treatment.

What are the possible benefits and risks of participating?
To ensure that we do not take on anyone with any conditions that may be made worse by the intervention, participants will not be allowed to take part if they have a musculoskeletal lower limb injury or any known reactions to cold or pressure applications or capsaicin cream.

Due to the nature of the study, there is minimal risk of injury. However, pain may be felt following the application of the capsaicin cream, albeit it is anticipated to be a mild pain. Participants will be advised to inform the researchers as soon as they feel any discomfort for further advice.

Participants will be given a £20 'One4all' gift card per session of data collection they attend.

Also, although it is not a direct benefit to taking part, the data collected may benefit the development of this device and its use in soft tissue injury management in the future.

Where is the study run from?
Manchester Movement Unit (UK)

When is the study running from and to?
February 2020 to October 2020 (updated 08/07/2020, previously: June 2020)

Funding information
This study is funded by Swellaway Ltd (UK).

This research has been carried out as part of a Knowledge Transfer Partnership between Manchester Metropolitan University (UK), University of Central Lancashire (UK) and Swellaway Ltd (UK).

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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EthOS 10731

Study information

Scientific Title
A pilot study exploring the efficacy of cryotherapy modalities, on pain, joint position sense and muscle strength in healthy subjects with experimentally induced pain

Acronym
Swellaway Phase II

Study objectives
Intervention 1 and 2 will be more effective at reducing perceived pain than intervention 3

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/07/2019, HPSC Research Ethics and Governance Committee, Manchester Metropolitan University (Brooks Building, 53 Bonsall St, Hulme, Manchester M15 6GX; +44 0161 247 2282; HPSCEthics@mmu.ac.uk), ref: EthOS number 10731

Study design
Pilot crossover randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Induced Pain

Interventions
The study will include three, 20-minute cryotherapy interventions.
1. 10°C with 50mmHg compression using the Swellaway Handheld Unit V3
2. Wetted ice (400ml water, 400g ice)
3. 10°C with 50mmHg compression and 40°C with 25mmHg, alternating every 3 minutes, using the Swellaway Handheld Unit V3

The order in which participants will receive the interventions is randomized by a randomization plan created on Randomization.com. The participants will each attend three sessions each lasting 75 mins and in each session will receive all three treatments.

There will be a minimum of 24 hours, and a maximum of 7 days, between each of the three sessions. There is no further participant follow up involved in this study.

Intervention Type
Device

Phase
Phase II

Primary outcome measure
Perceived pain scores will be measured using a numeric pain rating scale (NPRS), at baseline (pre-intervention), immediately post-intervention, and 20 mins post-intervention

Secondary outcome measures
1. Pressure pain threshold (PPT) measured using a digital algometer (Wagner FPX, USA) and a numeric pain rating scale (NPRS) at baseline (pre-intervention), immediately post-intervention, and 20 mins post-intervention
2. Muscle strength measured using a handheld dynamometer (Microfet, Draper, UT) to obtain an isometric measure of quadriceps muscle performance of the non-dominant leg at baseline (pre-intervention), immediately post-intervention, and 20 mins post-intervention
3. Joint position sense (JPS) measured using a ten camera infra-red Oqus motion analysis system (Qualisys medical AB, Gothenburg, Sweden) collecting at 115 Hz at baseline (pre-intervention), immediately post-intervention, and 20 mins post-intervention. For this measurement, anatomical markers will be placed posterior superior iliac spine (PSIS), anterior superior iliac spine (ASIS), greater trochanter, medial and lateral epicondyle of the femur, medial and lateral malleolus, calcaneus, dorsal aspect of first and fifth metatarsal heads and the middle cuneiform, acromion, lateral epicondyle of the humerus and radial styloids. Clusters of four markers mounted on a thin sheath of lightweight carbon fibre will be applied to the anterolateral aspect of the femur and tibia. As carried out in Alexander et al. (2016), pre-testing familiarisation to the

small knee bend (SKB) protocol of 45° will be conducted measured by a goniometer, prior to kinematic data collection. The participant will be given three attempts to replicate the 45° SKB in order to familiarise themselves with the movement pattern. Following the 'practice' attempts participants will then complete five SKB using three-dimensional (3D) motion analysis to measure knee motion. No white noise or blindfold will be worn by the participants; as advised in Alexander et al. (2016).

Overall study start date
21/06/2019

Completion date
30/10/2020

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. No current musculoskeletal injuries to their lower limbs
3. No known reactions to cold, heat or pressure applications or capsaicin cream (0.075%).
4. Willing to participate including both shaving the region of interest on the knee (minimum 2 cm) on the medial aspect of their non-dominant knee, and avoiding alcohol and significant caffeine consumption for 24 hours prior to the study session

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Pregnancy or possibly pregnant
2. Broken or irritated skin in the region of interest on the knee
3. Respond 'yes' to any of the following:
a. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
b. Have you had unusual chest pain when you were not doing physical activity?
c. Is your doctor currently prescribing drugs for your blood pressure or heart condition?
d. Are you taking any type of anti-inflammatory medication?
e. Have you had any condition or disease which will affect your muscles functioning or repairing?
f. Do you have any condition or disease that affects heart function?
g. Do you know of any other reasons why you should not undergo physical activity or perform

cooling treatments? This might include severe asthma, diabetes, a recent injury, serious illness, high/low blood pressure, Raynaud's Syndrome, Cancer, cold or heat allergies.
h. Do you have any condition that affects blood clotting?

Date of first enrolment
04/02/2020

Date of final enrolment
10/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Movement Unit
Manchester Movement Unit
Manchester Metropolitan University
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Sponsor information

Organisation
Swellaway

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Sponsor type
Industry

Website

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Funder(s)

Funder type
Industry

Funder Name
Swellaway Ltd

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 05/02/2021:
1. Study final report to the funder is due by March 2021
2. Submission for publication of results in a peer-reviewed journal is planned for May 2021

Previous publication and dissemination plan:
1. Study final report to the funder is due May 2020
2. Submission for publication of results in a peer-reviewed journal is planned for June 2020

Intention to publish date
01/11/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Data sharing statement to be made available at a later date