Does Intermittent Pneumatic Compression improve symptoms of Delayed Onset Muscle Soreness in Healthy Adults: a study protocol of a randomized controlled trial.

Final project

Student: Arnaud Gras

Mentor: Professor Tony Donegan

Degree: Physiotherapy EUSES University Barcelona

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Abstract

Background

Delayed Onset Muscle Soreness (DOMS) is a frequent post-exercise condition characterized by micro-lesions, inflammation or metabolite accumulation within the skeletal muscles and the surrounding tissues. Intermittent Pneumatic Compression (IPC) is often used to treat DOMS and the benefits of this device remain unclear. The main aim of this study will be to evaluate the effectiveness of intermittent pneumatic compression related to strength in lower limb delayed onset muscle soreness in healthy adults.

Methods

The study will be a two-arm double blind parallel randomized controlled trial (RCT) with one intervention group and one control group in a single-centre in Spain. Voluntary male and female healthy adults will be enrolled into the study for 5 days. Only the researcher dedicated to the randomization and the physiotherapist in charge of the IPC treatment will not be blinded. After the randomization process, the interventional group will receive a massage therapy session followed by an IPC session whereas the control group will receive a massage therapy session followed by a sham IPC session. Following baseline measurement, DOMS induction and treatment for each group, strength will be measured using an isokinetic dynamometry device as well as a Visual Analogue Scale (VAS) for soreness scoring. The primary outcome of this study will be strength measured with an isokinetic dynamometry device and the secondary outcome will be perceived soreness in healthy adult lower limb DOMS at 24, 48, 72 and 96 hours. Data will be analyzed using a one-way repeated measures analysis of variance (ANOVA) with Dunnett's multiple comparison tests to compare post-treatment values to the baseline value.

Discussion: The results of this study will demonstrate the effectiveness of IPC in improving the symptoms of DOMS.

Keywords: Intermittent pneumatic compression, Delayed onset muscle soreness, eccentric exercise, muscle damage, strength.

Introduction

Delayed Onset Muscle Soreness is a frequent post-exercise condition characterized by micro-lesions, inflammation or metabolite accumulation within the skeletal muscles and the surrounding tissues [1]. The mechanism of injury is thought to be an exercise activity with eccentric pattern, high frequency and high intensity movement. Decrease range of motion, decrease in muscle strength and pain are the current symptoms one can experience particularly when returning to training after a period of reduced activity [2].

According to the Munich Consensus Statement on muscle injury classification, DOMS is classified as an overexertion-related muscle disorder (Type 1B). Despite the lack of sub-classifications into grades, DOMS are classified into functional muscle disorder in comparison with structural muscle injury. DOMS is an acute indirect muscle disorder without macroscopic evidence of a muscle tear (on US or MRI). Type 1 injuries (overexertion-related muscle disorder) have two subgroups important to differentiate. Type 1A is characterized as fatigue-induced muscle disorder and type 1B is defined as generalized muscle pain following unaccustomed eccentric deceleration with symptoms of acute inflammatory pain, pain at rest and pain hours after the activity. Despite the high variability of the clinical signs, the consensus stated that oedematous swelling, muscular stiffness, limited range of motion of adjacent joints and pain on isometric contraction are the main ones. According to the previous classification, the location of DOMS is mostly the entire muscle or muscle group and the diagnostic imaging tends to be negative or with oedema only on ultrasound and MRI [3]. MRI remains essential to assess the severity of muscle damage in general. MRI provides detailed image analysis that helps to characterize the type of muscular lesion. In the case of DOMS that are exercise induced muscle disorders, MRI performed directly after the exercise may reveal negative results as oedema signal intensity increases during the inflammatory response. On the other side, an MRI performed at the peak inflammatory muscle level may lead to an overestimation of this kind of lesion [3, 4]. The British Athletics Muscle Injury Classification (BAMIC) system is another grading system that claims a clear diagnostic framework to assist in the muscle injury classification [5]. Ekstrand et al, conclude that functional disorders are often underestimated clinically and show less prognostic relevance than structural injuries [6]. The BAMIC classification claims

to be more precise on functional disorders and recognizes that there may be clinical suspicion of a neural component related to DOMS. In the literature, grade 0b refers to the classification of DOMS using the BAMIC system [5]. The previous classifications have the purpose of providing prognostic and therapeutic direction for health professionals [3, 5].

Epidemiological data are lacking regarding DOMS due to unassessed cases and the difficulty to diagnose them [4].

Valle et al, summarized data regarding the timing of DOMS. Signs and symptoms usually begin between 6-12h post-exercise and increase progressively to reach a peak of pain between 48-72h to disappear between 5-7 days [7]. These findings confirm the heterogeneity of DOMS clinical signs and symptoms and by consequence the difficulty to diagnose, prevent and treat them.

Taking into consideration the latest research on the structure involved in DOMS, it is possible to exclude the lactic acid component as the main cause of DOMS as it disappears quickly after a physical activity and is mainly produced by concentric contraction instead of eccentric ones [1, 2, 8]. These findings have influenced treatment options for DOMS. White et al, highlighted studies covering two leading possible causes for DOMS. The first one is the ultrastructural muscle damage that involves Z-disc damage. The second one is more recent and involves an inflammatory process of the muscle fibers and the connective tissues surrounding it [1]. Biopsy analysis have shown a loss of myofibrillar integrity with Z-band streaming and a disruption of sarcomeres in the myofibrils, which leads to further protein degradation, autophagy and local inflammatory response. DOMS have shown to be associated with pro-inflammatory cells such as cytokines, electrolytes imbalances and leukocyte accumulation in the area [4].

Agten et al, have shown the potential implication of the fascia surrounding tissue in DOMS [9]. Despite the limitations of this study, further studies related to DOMS may consider deep fascia morphological and mechanical changes [1, 9, 10]. These findings on the potential ultrastructural muscle damage, inflammatory process and connective tissue involvement reveal the complexity of DOMS pathogenesis and the full understanding of this condition that still needs to be studied.

As seen previously, DOMS are associated with pain, potential tissue damage, inflammatory process and impaired function which are responsible for loss of training or competition days especially in sports activities. Active recovery (AR), cold water immersion (CWI), compression garments (CG), massage therapy, foam rolling (FR) or stretching have been proposed as a treatment option with heterogeneous results. Some of them may control inflammation and/or act on the cardiovascular clearance of the area affected by DOMS [11, 12].

AR is often used as a first line treatment for recovery in general by increasing blood flow, thus blood lactate clearance [13]. There is not any defined protocol but it is usually applied as a 10-20 min session of low intensity exercises at 80% of lactate threshold straight after a physical activity [14, 15]. It is a low cost technique and easy to set in a group but results remain inconsistent. AR may improve recovery objectively while subjectively AR may be less relevant. However AR has not demonstrated strong scientific evidence for DOMS treatment [4, 13]. CWI has shown promising results on attenuating the effects of exercises induced muscle damage by reducing the body temperature and inducing vasoconstriction. Vasoconstriction aims to facilitate the removal of metabolites from peripheral to central circulation [12]. Machado et al, demonstrated a dose-response relationship indicating that parameters such as temperature, time spent into the water and the frequency of immersion are components influencing the results positively or negatively [16]. CWI is supported in short-term management of DOMS for subjective outcomes mainly [17, 18]. Compression garments have shown little effect on recovery and performance but disparities concerning DOMS management. Most of the studies have heterogeneous results, influenced by the quality of the design, compression parameters such as textile type or the area being compressed [7, 12, 19, 20]. Massage therapy has shown promising results on subjective outcomes and inflammatory markers in recent studies. Some studies found that massage therapy is the most powerful treatment for DOMS in comparison to other techniques [21, 22, 23]. Foam rolling has shown to have a little positive impact on perceived pain from DOMS but did not enhance recovery in athletes [12, 24]. Also, all stretching methods did not show positive consistent results for DOMS management [12, 25, 26].

Intermittent Pneumatic Compression (IPC) is a new tool of the last decade used in the physiotherapy field and shown in **Figure 1**. The mechanism of action may have similarities to

a massage treatment [12, 27]. IPC recovery boots (NormaTec, Newton Center, MA) claims to accelerate recovery and drain metabolites from muscles that will reduce DOMS and pain after training [28].

Figure 1: IPC recovery boots (NormaTec Pulse 2.0).

Martin et al, conducted a study with the support of NormaTec medical, found that IPC improves conduit artery endothelial function systemically, but only improves reactive hyperemia blood flow locally [29]. According to Haun et al, IPC reduced skeletal muscle oxidative stress and proteolysis markers during recovery from heavy resistance exercise [30]. Also, IPC may decrease exercise-induced inflammatory signalling as it may reproduce some of the massage characteristics, but studies are lacking to demonstrate this similarity [12, 27]. There is a lack of high quality studies to demonstrate the effectiveness of IPC in the treatment of DOMS.

As seen above, massage therapy has shown little to moderate effect in the management of DOMS in comparison to other techniques that showed heterogeneous results [21, 22, 23]. Massage therapy will be provided in both groups in this study.

Hypothesis

Null hypothesis:

IPC is not superior to sham IPC at improving strength in healthy adults DOMS.

Alternative hypothesis:

IPC is superior to sham IPC at improving strength in healthy adults DOMS.

Objectives

The primary objective of this study will be to determine the effectiveness of IPC related to strength using an isokinetic dynamometry device.

The secondary objective will be to evaluate perceived soreness using a VAS scoring in lower limb Delayed Onset Muscle Soreness in healthy adults.

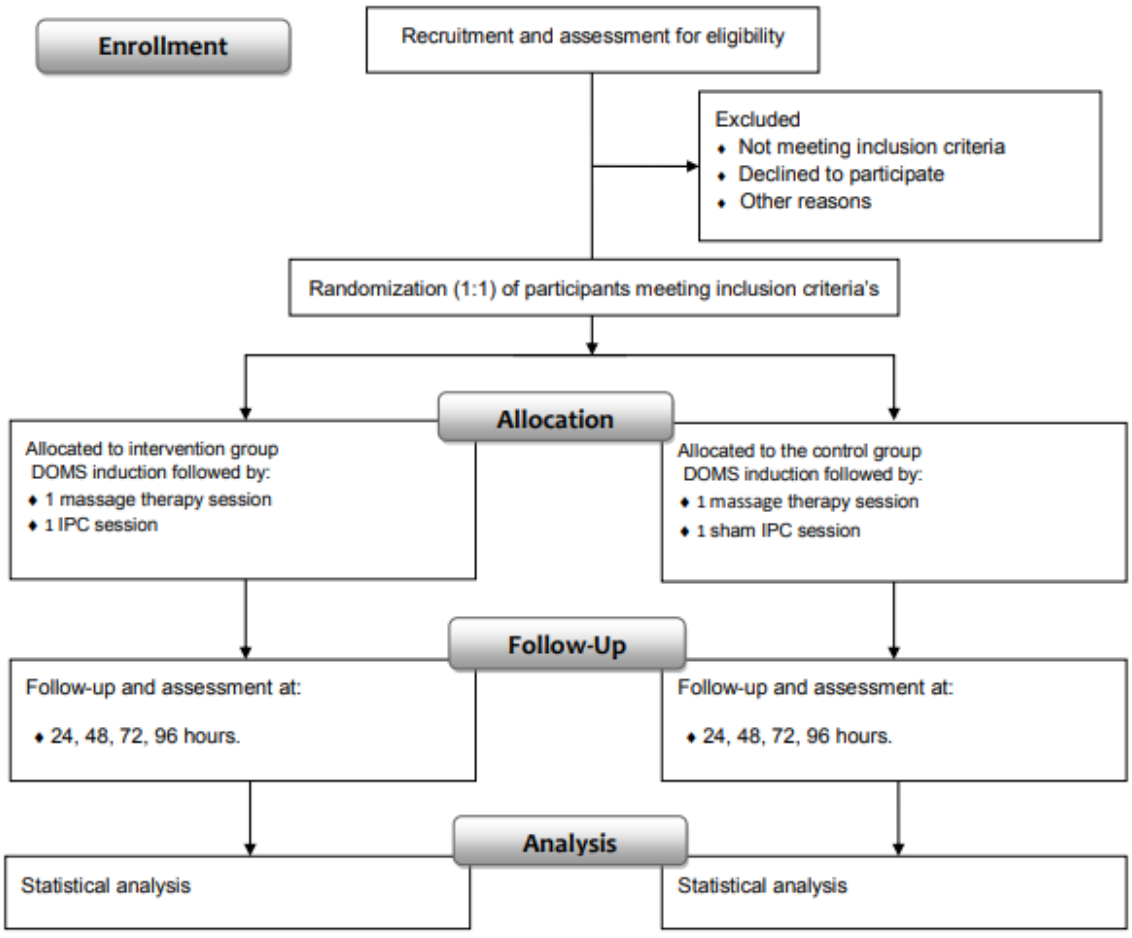
Methods

Study design and settings

The study will be a two-arm double blind parallel randomized controlled trial (RCT) with one intervention group and one control group that will follow the SPIRIT checklist recommendation for interventional trials. A single-centre will conduct this study in Spain.

The protocol will include two groups. The interventional group will receive a treatment composed of a massage therapy session followed by an IPC session. At the same time, the control group will receive a massage therapy session followed by a sham IPC session.

Study Flow chart:



Eligibility criteria

The inclusion criteria will include:

- Male and female healthy adults aged equal over 18 years to 30 years old;
- Subjects that already experienced DOMS in the past;
- Non-professional sports participant;
- Subject willing to abstain from exercise and alcohol a week before and during the study intervention;
- Subject willing to abstain from caffeine during the study.

The exclusion criteria will include:

- Metabolic disease (such as inflammatory disease), cardiovascular disease that may affect the performance of the subjects;
- Contraindications to IPC such as history of:
    - Acute pulmonary oedema;
    - Acute thrombophlebitis;
    - Acute congestive cardiac failure;
    - Acute infections;
    - Deep vein thrombosis;
    - Episodes of pulmonary embolism;
    - Wounds, lesions;
    - Infection or tumors at or near the site of application;
    - Impaired venous and lymphatic return;
    - Bone fractures or dislocations at or near the site of application (NormaTec Manual, Pulse 2.0) [31];
- Other treatments (pharmacological treatments, physiotherapy for other conditions...);
- History of ACL and/or PCL rupture or tear, quadriceps tendon tear, medial and/or lateral knee ligaments tear or rupture;
- Subjects with previous experience of IPC;
- Non-attendance to the protocol sessions and treatments during the study.

Intervention (both groups)

After the baseline measurement, the intervention will start by inducing muscle damage to the non-dominant leg knee extensors muscles to the voluntary healthy adult enrolled in the study.

1. Muscle damage induction

1.1 Parameters

In each group DOMS will be provoked in healthy volunteers using an isokinetic dynamometry device. Eccentric muscle contractions will be performed following the protocol detailed by Deyhle et al and highlighted below [32].

After the baseline measurement, the computer dynamometer will be set as follow:

1. A new protocol will be created and the following selected: “Exercise”, “Isokinetic”, “Knee”, “Extension/Flexion”.

2. Program 10 sets of 10 repetitions at speeds of 180°/sec away and 120°/sec towards with 60 seconds rest between sets. Torque will be comprise between 200 to 600 Newton-meter (N.m) anticipating the strength of the subject. These steps might need to be repeated for each set depending on the device.

3. The “Anatomical Reference” for the subject knee position will be 90°.

4. Range of motion limits will be 40° away and 110° towards (0°= full extension, 135°= full flexion). It will be important that the subject provide resistance through the entire range of motion otherwise the dynamometer will stop as a safety precaution. The range of motion might need to be slightly adjusted to fit the abilities from one individual to another.

1.2 Induction

1. The subject will perform first a warm up session on a cycle ergometer for 10 min at 50 to 150 Watts.

2. The subject will be instructed how to perform the exercise: The goal will be to contract against the shaft arm as forcefully as possible and the instructor will verbally encourage the subject and tell to breathe.

3. The instructor will guide the subject during the 10 sets of 10 repetitions with 1 min rest between sets. A rest period of 1 min to 5 min every 10 sets will be given until the total of 300 eccentric contractions will be performed.

2. Treatment

The treatment will start 15 minutes after the muscle damage induction for both groups. The interventional group will receive the massage protocol directly followed by a single bout of the IPC protocol. The control group will receive at the same time the massage protocol directly followed by a single bout of the sham IPC protocol.

2.1 Massage protocol (both groups)

Due to the heterogeneous treatment options and absence of establish protocol or clinical guideline in the treatment of DOMS, this study will follow the systematic review with meta-analysis of Dupuy et al, highlighting the different treatment options also supported by Guo et al and Torres et al, that defined massage therapy as the most powerful treatment for DOMS [21, 22, 23].

Nelson, in the review concerning massage techniques related to DOMS noted that massage cannot be precisely duplicated influenced by the therapist's intention, speed of stroke or depth of pressure. These components are difficult to quantify, control and measure as each therapist develops a unique massage strokes method. Studies highlighted by Nelson, tend to reproduce a 30 minutes massage combining effleurage and petrissage technique [33]. The same physiotherapist will perform the massage treatment in both groups with the purpose to reduce the differences seen above between subjects.

A neutral cream will be used by the therapist that will be allowed to perform effleurage and petrissage technique to the patient anteriorly and posteriorly on the entire affected limb with distal to proximal strokes without causing pain to the patient. The therapist will provide the massage treatment for 30 minutes using a massage table.

2.2 Intermittent Pneumatic Compression protocol

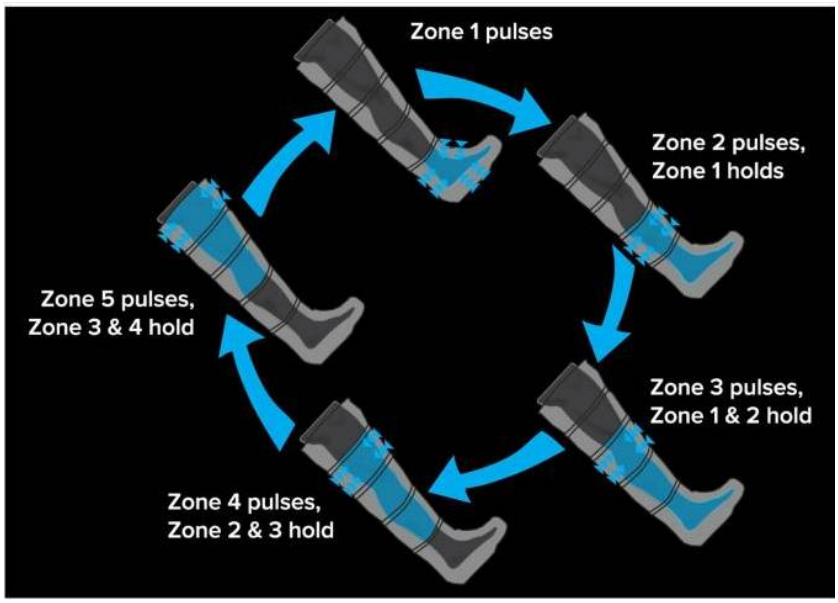
Intervention group

The IPC will be used in 'peristaltic' pulse dynamic mode (NormaTec PULSE 2.0 recovery system device). The protocol for IPC treatment will follow the recommendation of NormaTec for the device PULSE 2.0 and previous studies on IPC [27, 29, 30, 34].

The study of Martin et al, described the device as two separated "leg sleeves" which contain five circumferential inflatable chambers connected to an automated pneumatic pump that control the cycle. The first chamber is located at the foot level and the last one at the thigh (as shown in **Figure 2**) [29]. The manufacturer proposes different pressure levels (Level 1 (30mmHg) to Level 7 (110mmHg). Level 1 to 3 (low pressures) claims to promote warm-up, blood flow and gentle treatment sessions. Level 4 to 7 (medium to high pressures) claims to help speed up muscle recovery, decrease muscle soreness, reduce oedema and increase circulation [34].

Pressures of ±70mmHg for each chamber will be used in this study as the recovery protocol recommended by NormaTech. During one complete brand preprogrammed cycle, the first chamber will inflate for ± 1 min ('pulsed') and the pressure will be held at ±70mmHg. Then, the same process will occur in the chamber above (calves' level). As shown in **Figure 2**, a maximum of two distal chambers will be inflated at the same time. The purpose of this maneuver is to prevent backflow. After one minute, the first chamber will deflate completely while pressure will be held in the second chamber (calves). This process is repeated until the last chamber (thigh). At this point, all zones will be deflated completely for 30 seconds [29]. The previous complete cycle will be repeated continuously during the entire treatment session lasting 30 minutes [34].

Figure 2: Illustration of an IPC complete cycle.



2.3 Sham IPC protocol

Control group

The sham IPC treatment will follow the protocol detailed by Martin et al who noted that a low pressure (Level 1-3) sham treatment is likely to provide an effect on the study outcome as seen previously [29, 34]. The sham IPC treatment will consist of applying the 'leg sleeves' connected to the automated pneumatic pump devoid of compression for 30 minutes. Before the IPC session in each group, the subject will remove shoes, empty pockets and remove trousers. A towel will be used to remove the excess of massage cream. The physiotherapist will make sure that the subject can comfortably straighten their limbs on the table. Interruptions during the IPC session will exclude the subject from the study.

To improve adherence, the study aims to reduce the complexity of the intervention by gathering the baseline measurement, DOMS induction and treatment during the same session.

Outcome measurement

The primary aim of this study will be to determine the effectiveness of IPC related to strength (quantitative variable). Isokinetic dynamometry is considered the "gold standard" to measure strength. The outcome measurement will follow the protocol detailed by Deyhle et al and highlighted below [32].

Isokinetic strength parameters:

The computer dynamometer will be set as follow:

1. A new protocol will be created and the following selected: "Isokinetic", "Knee", "Extension/Flexion", "Concentric contraction" for extension and flexion movements, "End by" reps.

2. Program 1 set of 3 repetitions at a speed of 60°/sec for away and toward movements.

3. Select 90° for the "Anatomical reference" of the lever arm and 10° away / 110° towards, for the range of motion.

Isometric strength parameters:

Isometric strength will also be recorded as DOMS symptoms may also be present during isometric contractions [3].

The computer dynamometer will be set as follow:

1. A new protocol will be created and the following selected: "Isometric", "Knee", "Extension/Flexion", "Contraction direction away" and "End by" reps.

2. 1 set of 3 isometric contractions of 5 sec each at 70° angle will be performed by the subject.

3. Select 90° for the "Anatomical reference" of the lever arm and an away limit of 70°.

The secondary objective will be to evaluate perceived soreness (quantitative variable) from the participants.

VAS scoring for muscle soreness will be set as the commonly used method and detailed in previous studies [26, 32, 35, 36, 37]. A 100 mm line will be drawn horizontally across a page, on a left hand limit the scale will indicate “No soreness” and on the right opposite limit “Extreme soreness” as seen in **[Annex 1]**. After performing two body-weight squats, the subject will be asked to indicate the intensity of the soreness in the *quadriceps femoris* muscle during the squat on the scale. Quantification of the score is done by measuring the distance in mm from 0 to 100 mm [32].

Assessment

The primary outcome will be assessed as below:

Knee extensors isometric and isokinetic strength measurement will be performed at 24, 48, 72 and 96 hours on the participant non-dominant leg in both groups. Following the previous parameters on the isokinetic dynamometry device, measurements will be done following the protocol of Deyhle et al [32].

1. A warm up session at 50 to 150 Watts for 10 min on a bicycle ergometer will be performed by the participant.

2. The seat of the dynamometry device will be adjusted to the subject.

3. The physiotherapist will instruct the subject how to perform the isometric test (breathing, hand placement). The subject will have to contract against the lever arm that will remain stationary. The subject will have to follow the screen contraction indication (1 set of 3 repetitions for 5 seconds at maximal effort). The subject will be allowed to perform the test at submaximal effort 2 to 3 times to understand the process beforehand.

4. Once the test has started, torque (Nm), power (W) and work (J) will be recorded from the software. A coefficient of variance exceeding 15% will lead to repeating the

test up to 4 times if necessary. After 4 attempts data from the set with the lowest coefficient of variance will be used.

5. After 3 minutes of rest, isokinetic data will be obtained.

6. The physiotherapist will explain to the subject to perform a forceful contraction against the lever arm that will move at fixed rate in extension and flexion.

7. Once the test has started, torque (Nm), power (W) and work (J) will be recorded from the software. A coefficient of variance exceeding 15% will lead to repeating the test up to 4 times if necessary. After 4 attempts data from the set with the lowest coefficient of variance will be used.

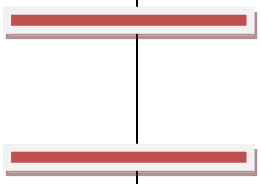
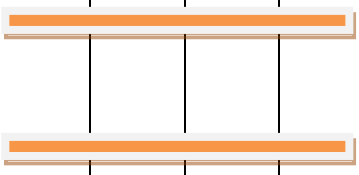
From the previous process, isometric strength (Newton) and isokinetic strength (Newton-meter) will be recorded by the physiotherapist.

The secondary outcome will be assessed as below:

Perceived soreness will be evaluated from the participants at 24, 48, 72 and 96 hours in both groups following the previous parameters (secondary outcome measurement section) on VAS scoring for muscle soreness.

Participant timeline

	Study Period								
	Enrollment	Allocation	Baseline	DOMS induction	Treatment intervention	Follow-up & assessment			
Timepoint	-Day 10	Day 1	Day 1	Day 1	Day 1	Day 2 (24h)	Day 3 (48h)	Day 4 (72h)	Day 5 (96h)
Enrollment Eligibility Screen									
Informed Consent									
Allocation									

Interventions Intervention Group Control Group									
Assessments Baseline Primary outcome Secondary outcome									

Sample size

A minimal clinical important difference (MCID) is not available in the literature; therefore the sample size will be taken from studies which explored similar main outcome [38, 39].

Recruitment

Participants will be recruited at the Bellvitge campus of the University of Barcelona through advertisement to participate in this study at the university entrance.

Randomization

Patients that will be eligible and asked to give their written consent will be allocated to either the intervention or the control group. Males and females will be separated in two lists to prevent potential imbalance between the interventional and control group. In those lists, each participant will be listed from 1 to n by alphabetical order of their name and then the researcher will generate a random number between 1 to n using the open access Google number generator to select each one of the participants. The first half of the participants in each list (males and females) randomly selected will be allocated to the intervention group; the second half will be allocated to the control group. By this process, the 1:1 ratio in the number of participant inter-groups and 1:1 sex ratio intra-groups will be preserved. One researcher will be dedicated exclusively to the allocation sequence and assignment.

Blinding

As blinding the participants will be possible due to the exclusion criteria ("subjects with previous experience of IPC") the study will be double-blinded by allowing one physiotherapist to the massage treatment in both groups and one physiotherapist to the IPC treatment in both groups. That way, only the researcher dedicated to the randomization and the physiotherapist in charge of the IPC treatment will know which participant is from the intervention or control group, making the patients, the physiotherapist providing massages, the physiotherapist that induce DOMS and assess the primary and secondary outcome and the statistician blinded.

Data collection, management and analysis

Baseline measurement

The baseline measurement of the participants will be performed on the first day before the muscle damage induction. The isokinetic dynamometry device will be set as seen in the primary outcome measurement section (see isokinetic strength parameters and isometric strength parameters). The process as in the primary outcome assessment section (step 1 to step 7) will be repeated.

From the previous process, isometric strength (Newton) and isokinetic strength (Newton-meter) will be recorded by the physiotherapist.

Data analysis

Data will be analyzed using a one-way repeated measures analysis of variance (ANOVA) with Dunnett's multiple comparison tests to compare post-treatment values to the baseline value. The difference between them will be considered significant if the p-value obtained with the ANOVA measurement is under 0.05.

Harms and interruption

The research team will report adverse events according to the Public Health Spanish law.

Participants will be removed from the study in case of serious adverse event (injury), participant desire to withdraw or absence during the protocol.

Limitations

There will not be a non-treatment control group as massage therapy has shown benefits; participants will receive this treatment for ethical preservation of this study.

Only one therapist will perform massage treatment in both groups. Massage cannot be duplicated and the therapist's intention, speed of stroke or depth of pressure may vary between participants.

Participants accustomed to eccentric exercise might show less muscle damage than unaccustomed individuals. Thus, levels of soreness might exist between groups initially.

Roles of investigators

One researcher will be dedicated to the enrolment and evaluation of eligibility criteria. One researcher will be in charge exclusively of the randomization. One physiotherapist will be dedicated to provide massage treatment and another physiotherapist the IPC treatment in both groups. One researcher will induce DOMS, assess the primary and secondary outcome and a statistician will be in charge of the study data analysis.

Resources

Fungible and non-fungible materials:

To achieve this study, an isokinetic dynamometry device, an IPC device (NormaTec Pulse 2.0), a neutral massage cream, a massage table, table towels and cleaning product will be needed.

Human resources:

- 3 researchers
- 2 physiotherapists
- 1 statistician

Ethics

This study will be conducted in accordance with the Declaration of Helsinki and its legal framework for good clinical practice. The study will also need to be approved by a Local Ethics Committee. All participants will be asked to sign an informed consent form **[Annex 2].**

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Annex 1:

Visual Analogue Scale for muscle soreness

Annex 2

INFORMED CONSENT FORM

INFORMED CONSENT FOR ALL STUDY PARTICIPANTS

The informed consent below asked to sign by men and women from the Bellvitge campus of the University of Barcelona who are invited in this study about the role of intermittent pneumatic compression in delayed onset muscle soreness symptoms. The title of the study project is "Does Intermittent Pneumatic Compression improve symptoms of Delayed Onset Muscle Soreness in Healthy Adults: a study protocol of a randomized controlled trial".

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Arnaud Gras, a student of the EUSES University in Barcelona. I am doing a research protocol about intermittent pneumatic compression and its effectiveness on the symptoms of delayed onset muscle soreness. I am going to give you information and invite you to be part of this research. Before you decide, you can talk to me about the research.

There may be some words or concepts that you do not understand. Please ask me to stop as we go through the information and we will take time to explain. If you have any questions later, you can ask me or anyone in the staff of the study.

Purpose of the research

Delayed onset muscle soreness (DOMS) is a frequent post-exercise condition that usually happens after a period of reduced activity. Adults may experience pain, swelling, soreness, and decrease in motion and strength in the area affected. Moreover, I think that intermittent pneumatic compression ("leg sleeves" with pneumatic compression) might improve symptoms of DOMS as it has shown interesting results in previous studies but not precise enough to be sure that intermittent pneumatic compression (IPC) improves symptoms of DOMS. The reason I am doing this research is to find out if IPC can have benefits to improve symptoms of DOMS.

Type of Research Intervention

This research will involve baseline strength measurement with an isokinetic dynamometry device followed by an induction of DOMS to the knee extensor muscles (knee and hip region) with the same device on the non-dominant leg. Then the participants will receive a massage therapy session followed by an IPC session. Strength assessment will be done at 24, 48, 72 and 96 hours using an isokinetic dynamometry device. Participants will also be assessed on the soreness level experienced during the study.

Participant selection

I am inviting adults from the Bellvitge campus of the University of Barcelona that already experience DOMS before and never receive an IPC treatment.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Technique [Intermittent Pneumatic Compression]

1) The technique I want to study is IPC and its effectiveness on the symptoms of DOMS. IPC is usually applied on both legs in the form of "leg sleeves" providing intermittent compression initiating at the foot level towards the thigh.
2) The reason I am doing this research is because previous studies gave promising results on different biological markers from blood tests after using IPC but I want to be more specific and test this technique on strength and soreness outcomes after DOMS. NormaTec Pulse 2.0 will be the IPC brand used during this study.
3) NormaTec 2.0 pulse will be used because they claim the benefits of this method on recovery and DOMS management.
4) The technique is safe and any negative effects have been reported.

Procedure and Protocol

After you will be selected and included in the study; a baseline measurement of your knee extensor muscles strength on your non-dominant leg will be performed with a device called isokinetic dynamometry. On the same day, DOMS will be induced with the same tool on the non-dominant leg using the same device. It consists of active forceful extension of your knee against a lever arm for 300 repetitions. 15 minutes after the DOMS induction you will receive a massage therapy session followed by an IPC session. Again, an isokinetic dynamometry device will be used to assess the strength of your knee extensor muscles at 24, 48, 72 and 96 hours and muscle soreness evaluated using a scale.

A. <u>Unfamiliar Procedures</u>

All participants of this study will receive a massage therapy session followed by an IPC session. Participants will be separated into two groups.

The healthcare workers will be looking after you and the other participants carefully during the study. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers.

If the DOMS induction or any procedure is not well supported by the participant at any time, the participant can ask for information or withdraw himself from the study. There is not any

established clinical guideline regarding the management of the symptoms of DOMS; this is why you will receive a massage therapy session which is a technique that has shown the highest benefits from recent studies.

B. Description of the Process

During the process you will make five visits to the centre where assessments, treatments and measurements will take place for a week period.

1) In the first visit baseline measure of your knee extensor muscles will be taken on your non-dominant leg followed by DOMS induction using an isokinetic dynamometry device. A massage therapy treatment and IPC session will be performed 15 minutes after the DOMS induction.
2) In the following visits at 24, 48, 72, 96 hours the strength assessment of your knee extensor muscles will be performed using an isokinetic dynamometry device. You will also be asked for muscle soreness level using a validated scale called Visual Analogue Scale.

Duration

The research will take place over 5 days. The week before and during the study you will need to abstain from exercise and alcohol consumption. You will also need to abstain from caffeine during the study only. During that time, it will be necessary for you to come to the centre for 5 days, 2 to 3 hours each day. In total you will be asked to come 5 times to the centre over 5 days. At the end of these 5 days the research will be finished.

Side effects

During the DOMS induction you might feel pain, decrease of strength and motion as well as potential signs of inflammation in the lower limb. Concerning the treatment, no side effects are involved.

Risks

Because we are researching on IPC and DOMS, you might experience unpleasant symptoms related to DOMS and exercise activity such as pain or soreness and decrease in strength.

But DOMS symptoms are not permanent and should disappear within 10 days.

Benefits

During the research you will benefit from physiotherapy care and if you suffer from something other than DOMS, you will be treated for anything that can be done with the physiotherapists.

Reimbursements

All travel fees for coming to the centre for the five sessions will be paid by our study staff. You will not be given any other money or gifts to take part in this research.

Confidentiality

We will not be sharing the identity of those participating in the research. The information that we collect from this research will be kept strictly confidential and no one but the researcher will be able to see it. Any information about you will have a number on it instead of your name and then information will be locked up and will not be shared with anyone except your therapist for research purposes.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is widely available to the public. Confidential information will not be shared. At the end of the process, we will publish the results of our study in order that other interested people may learn or benefit from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will be respected.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started.

If you wish to ask questions later, you may contact:

- Arnaud Gras: ag.paca@hotmail.fr

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the IRB, contact [name, address, and telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year