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The effect of compression heat and cold therapy on the recovery of athletes

Submission date	**Recruitment status**	[_] Prospectively registered
15/05/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/05/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2024	Other	

Plain English summary of protocol

Background and study aims
Impaired regeneration in sports reduces the sports form of an athlete and increases the risk of injury and overtraining. Previous studies describe regenerative methods using cold and heat stimuli, but data on the effect of therapy combining both of these stimuli on the muscular system and research on optimizing the duration of stimuli seem innovative and still little recognized in the light of scientific reports. There is insufficient evidence analyzing the duration of heat, cold and contrast therapy. This study is an evaluation of the impact of contrast therapy on changes in elasticity, stiffness, pain threshold and muscle power level in a group of people with different levels of physical preparation. The project aims to assess the impact of different times of contrast therapy on muscle biomechanical parameters and tissue perfusion.

Who can participate?
Male mixed martial arts fighters aged between 18 and 40 years old with a minimum of 3 years of training experience in MMA, training at least 4 times a week

What does the study involve?
The research is a crossover trial on MMA training volunteers randomly selected into different groups. The tests will be conducted at the Provita Medical Center, Poland. The research will last 2 weeks. The duration of a particular experiment for one participant is from 1 to 3 days and about 2 hours for one therapeutic and measurement session, depending on the group. The measurements are non-invasive, painless and, together with regenerative methods, will be performed on the muscles of the forearms and quadriceps of the thigh. The following device will be used for contrast therapy: GameReady Med4 Elite (GR). Volunteers will be divided into several groups:
1. Cryocompression GR (n=40) 2 minutes and 5 minutes stimulation time
2. Heat compression GP (n=40) stimulation time 5 and 10 minutes
3. Contrast therapy GR (n=40) hot-cold, pacing duration 10 and 20 minutes
4. Sham therapy GR (n=40) stimulation time 10 and 20 minutes
Measurements will be taken at rest, after therapy, 5 minutes after therapy 24 h and 48 h
GR therapy consists of application through a compression cuff with a pressure of 15 to 75 mmHg on the muscles of local contrast therapy or monotherapy with a temperature of 4 to 45 °C. The total time of the procedure is on average 10 to 30 minutes. The tests are conducted according to

standardized protocols. The devices used for the tests have proper safety certificates and are approved by the relevant regulations for conducting physiotherapy in EU countries. Analyzed variables: muscle tone, stiffness, flexibility, relaxation, "creep", muscle pain threshold, and power. Measuring devices used: Myoton (Myoton AS, MyotonLtd, Estonia 2021) inclinometer (Baseline USA 2020), body composition analyzer (Accuniq BC720, Korea), algometer (FPIX 5.2021 USA), Measuring platform Force Decks (Vald Performance Australia 2012), Tendo Sports (Czech Republic 2015).

What are the possible benefits and risks of participating?
The research results obtained as part of the proposed project should allow for the creation of an optimal contrast therapy protocol, which will significantly increase knowledge in the field of prevention, public health and optimization of recovery protocols in sports.

During the experiment, the subjects will undergo therapy during which there is a risk of non-specific responses to heat/cold stimuli (hypo/hyper with a scale of 4 to 45 ° C) from the skin and subcutaneous tissue of the thigh and lower limb muscles. This exclusion will also occur in the event of illness, extreme exhaustion, or malaise of the examined person or at his explicit request.

Where is the study run from?
Provita Medical Center (Poland)

When is the study starting and how long is it expected to run for?
June 2023 to September 2023

Who is funding the study?
Provita Medical Center (Poland)

Who is the main contact?
Robert Trybulski (PI), rtrybulski@o2.pl (Poland)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The immediate effect of contrast therapy on muscle biomechanical properties and tissue perfusion in mixed martial arts (MMA) fighters

Acronym
GRT

Study objectives
Evaluation of the effect of contrast therapy on changes inelasticity, stiffness, pain threshold and muscle power level in a group of people with different levels of physical preparation .

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2022, Council of Physiotherapists Poland (al. Jerozolimskie 93, 02-001 Warsaw, Poland; +48 22 230 23 80; komisjaetykibadan@kif.info.pl), ref: No. 9 / 2022

Study design
Interventional randomized crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other therapist office

Study type(s)
Efficacy

Participant information sheet

See trial outputs table

Health condition(s) or problem(s) studied
Optimization of recovery in sports

Interventions
Current interventions as of 10/07/2023:
The experiment will be conducted according to a randomized crossover design where each participant performs the familiarization intervention and receives a 3-minute Game Ready (GR) stimulation 3 days prior to the study. The volunteers submitted by MMA trainers according to the inclusion and exclusion criteria will be randomly divided into 4 groups and subjected to different GR stimulations in the cross-match design. Simple randomization methods will be used to assign MMA fighters to groups of subsequent MMA volunteers by flipping a coin, where drawing the obverse will mean assigning the next participants to group 1 and the reverse - to group 2. The implementation of the intervention is planned in the Provita Medical Center, which is a clinical facility registered with the relevant authorities and subject to National regulations. The GR therapy described in the study scheme to be used during the study on the health of the participants is controlled by a paramedic, the measurements will be made by appropriately trained students, and the entire application of the intervention is managed by the project manager, Robert Trybulski PhD, PT. The other project participants at the stage of data preparation and publication are:
Prof. dr hab. Aleksandra Żebrowska – head of the Department of Physiological and Medical Sciences of the Academy of Physical Education in Katowice
Dr. kf - physiotherapist Robert Trybulski - assistant professor at the Medical Faculty of GWSH Katowice
Grzegorz Biolik, MD, PhD – Department of Vascular Surgery , Phlebology and Angiology of the Upper Silesian Medical Center in Katowice

GR therapy consists of applying a pressure of 15 to 75 mmHg to the muscles through a compression cuff, local contrast therapy or monotherapy with a temperature of 4 to 45°C. The total treatment time is on average 10 to 30 minutes. Tests are performed according to standardized protocols.

Intervention groups:
1. CGR cryocompression (n=40) - 2 minutes and 5 minutes stimulation time
2. Heat compression GP (n=40) stimulation time 5 and 10 minutes
3. Contrast therapy GR (n=40) hot-cold, pacing duration 10 and 20 minutes
4. Sham therapy GR (n=40) stimulation time 10 and 20 minutes

For all subjects, the analysis of specific primary variables will be carried out in the following periods, assuming the measurement times:
– rest value (Rest)
– value after GR therapy (Post 5 min, 24 h and 48 h)

Variables analyzed: muscle tone (F = Hz), stiffness (S = N/m), elasticity, relaxation (ms), "creep", muscle pain threshold (PT-kG or N), muscle power (W), PU perfusion Unit

For the secondary outcomes, the following measurements were taken in all participants of the study: muscle tone (T - [Na Hz]), stiffness (S - [N/m]), elasticity (E- [NaN]), pressure pain threshold (PPT - [N/cm]) microcirculation response described in non-reference units (PU) and maximum isometric force (Fmax [kgf]). All participants were tested in these time conditions (between 10 a. m. and 12 p.m.) in a standardized resting position, sitting in a medical chair with elbows bent at

60 degrees and leaning against the chair. The project was carried out in the Provita Medical Center. All measurements were taken at rest (r)-rest), 2 minutes before GR stimulation and 2 minutes after GR (p)-post 5min, 24h, 48 h). Properly trained students and physiotherapists participated in the measurements. The order of measurements was as follows: PU, T, S, E, PPT, Fmax.

Measuring devices used: Myoton (Myoton AS, MyotonLtd, Estonia 2021) inclinometer (Baseline USA 2020), body composition analyzer (Accuniq BC720, Korea), algometer (FPIX 5.2021 USA), Measuring platform Force Decks (Vald Performance Australia 2012), Tendo Sports (Czech Republic 2015).

Previous interventions:
The experiment will be conducted according to a randomized crossover design where each participant performs the familiarization intervention and receives a 3-minute Game Ready (GR) stimulation 3 days prior to the study. The 40 volunteers submitted by MMA trainers according to the inclusion and exclusion criteria will be randomly divided into 2 groups and subjected to different GR stimulations in the cross-match design. Simple randomization methods will be used to assign MMA fighters to groups of subsequent MMA volunteers by flipping a coin, where drawing the obverse will mean assigning the next participants to group A and the reverse - to group B. The implementation of the intervention is planned in the Provita Medical Center, which is a clinical facility registered with the relevant authorities and subject to National regulations. The GR therapy described in the study scheme to be used during the study on the health of the participants is controlled by a paramedic, the measurements will be made by appropriately trained students, and the entire application of the intervention is managed by the project manager, Robert Trybulski PhD, PT. The other project participants at the stage of data preparation and publication are:
Prof. dr hab. Aleksandra Żebrowska – head of the Department of Physiological and Medical Sciences of the Academy of Physical Education in Katowice
Dr. kf - physiotherapist Robert Trybulski - assistant professor at the Medical Faculty of GWSH Katowice
Grzegorz Biolik, MD, PhD – Department of Vascular Surgery , Phlebology and Angiology of the Upper Silesian Medical Center in Katowice

GR therapy consists of applying a pressure of 15 to 75 mmHg to the muscles through a compression cuff, local contrast therapy or monotherapy with a temperature of 4 to 45°C. The total treatment time is on average 10 to 30 minutes. Tests are performed according to standardized protocols.

Intervention groups:
1. Cryocompression GP (n=20) stimulation time - 2 minutes and 5 minutes
2. Heat compression GP (n=20) stimulation time 5 and 10 minutes
3. Contrast therapy GR (n=20) hot-cold, stimulation time 10 and 20 minutes

For all subjects, the analysis of specific primary variables will be carried out in the following periods, assuming the measurement times:
– rest value (Rest)
– value after GR therapy (Post 5 min, 24 h and 48 h)

Variables analyzed: muscle tone (F = Hz), stiffness (S = N/m), elasticity, relaxation (ms), "creep", muscle pain threshold (PT-kG or N), muscle power (W), PU perfusion Unit

For the secondary outcomes, the following measurements were taken in all participants of the study: muscle tone (T - [Na Hz]), stiffness (S - [N/m]), elasticity (E- [NaN]), pressure pain threshold (PPT - [N/cm]) microcirculation response described in non-reference units (PU) and maximum isometric force (Fmax [kgf]). All participants were tested in these time conditions (between 10 a. m. and 12 p.m.) in a standardized resting position, sitting in a medical chair with elbows bent at 60 degrees and leaning against the chair. The project was carried out in the Provita Medical Center. All measurements were taken at rest (r)-rest), 2 minutes before GR stimulation and 2 minutes after GR (p)-post 5min, 24h, 48 h). Properly trained students and physiotherapists participated in the measurements. The order of measurements was as follows: PU, T, S, E, PPT, Fmax.

Measuring devices used: Myoton (Myoton AS, MyotonLtd, Estonia 2021) inclinometer (Baseline USA 2020), body composition analyzer (Accuniq BC720, Korea), algometer (FPIX 5.2021 USA), Measuring platform Force Decks (Vald Performance Australia 2012), Tendo Sports (Czech Republic 2015).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GameReady Med4 Elite

Primary outcome measure
The following primary outcome measures are assessed at rest, 5 minutes and 24 and 48h after GR therapy:
1. Muscle tone (F = Hz), stiffness (S = N/m), flexibility, and relaxation (ms), are measured with a myotonometer (MyotonPRO AS, Myoton Ltd, Estonia 2021)
2. Muscle pain threshold (PT-kG or N) is measured with the FDIX algesimeter (Wagner Instruments, Greenwich, CT, USA 2013)
3. Muscle strength (W), is measured with a hand dynamometer (EH106 China 2020)
4. Perfusion units (PU) are measured using laser Doppler flowmetry (LDF), (Perimed, Sweden 2004)
5. Muscle power (RSI - relative strength index) is measured behind Measuring platform Force Decks (Vald Performance Australia 2012)

Secondary outcome measures
Muscle tone (Hz), stiffness (N/m), flexibility (NaN), pressure pain threshold (N/cm), microcirculatory response described in non-reference units (PU) and maximum isometric force (Fmax [kgf]) measured with LDF, myonometer, platform, algesimeter, dynamometer - as described in the primary outcome measures (between 10:00 and 12:00) at rest, 2 minutes before GR stimulation and 2 minutes after GR stimulation 5min, 24h, 48h.

Overall study start date
15/03/2022

Completion date
15/07/2023

Eligibility

Key inclusion criteria
1. Randomly selected MMA fighters with a minimum of 3 years of training experience in MMA, training at least 4 times a week
2. Age between 18-40 years old

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Male

Target number of participants
160

Key exclusion criteria
1. Elevated blood pressure before the study (blood pressure > 140/90 mm Hg)
2. Patients treated after injuries, injuries or unspecified skin and myofascial lesions of the musculoskeletal system
3. Tattoos at the measurement site
4. Extreme tiredness, fever, infection or at the explicit request of the subject
5. Study participants had to refrain from training for 48 hours and abstain from training for 24 hours during the study
6. Participants were asked to refrain from consuming ergogenic beverages for 4 hours prior to the study

Date of first enrolment
15/02/2023

Date of final enrolment
15/06/2023

Locations

Countries of recruitment
Poland

Study participating centre
Provita Medical Center
al. United Europe 37
Zory
Poland
44-240

Sponsor information

Organisation
Centrum Medyczne Provita

Sponsor details
Provita Medical Center
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44240
+48 696086912
provitazory@gmail.com

Sponsor type
Hospital/treatment centre

Website
https://rehabilitacja-provita.pl/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Provita Medical Center

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/09/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Robert Trybulski, rtrybulski@o2.pl. The type of data shared will be a personal survey containing personal data. The participants signed the informed consent in the study (please see attached).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		04/10/2021	22/05/2023	No	Yes
Results article		19/02/2024	23/02/2024	Yes	No
Results article	The Effects of Compression Contrast Therapy and Dry Needling	01/03/2024	07/08/2024	Yes	No
Results article	Assessment of the Impact of Heat-Compression Therapy Time on Muscle Biomechanical Properties and Forearm Tissue Perfusion in MMA Fighters—A Pilot Study	25/09/2024	18/12/2024	Yes	No
Results article	Optimal Duration of Cold and Heat Compression for Forearm Muscle Biomechanics in Mixed Martial Arts Athletes: A Comparative Study	28/05/2024	18/12/2024	Yes	No
Results article	Reliability of MyotonPro in measuring the biomechanical properties of the quadriceps femoris muscle in people with different levels and types of motor preparation	29/08/2024	18/12/2024	Yes	No
Results article	The Effects of Combined Contrast Heat Cold Pressure Therapy on Post-Exercise Muscle Recovery in MMA Fighters: A Randomized Controlled Trial		18/12/2024	Yes	No