ISRCTN15418049 https://doi.org/10.1186/ISRCTN15418049

The influence of strength training and occlusion on tissue congestion, muscle strength and power, and muscle stiffness

Submission date
10/04/2024

Recruitment status
No longer recruiting

Registration date
18/04/2024

Overall study status
Completed

Last Edited
29/07/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Muscle pain in the upper and lower torso is an increasingly common social problem. A sedentary lifestyle and low physical activity predispose to excessive strain on less efficient muscles. Such pain occurs very often throughout life, affecting up to 90% of the population. Because there is significant variability in the clinical presentation and dysfunction of back muscles in the population of people with back pain, the potential role of these muscle dysfunctions in the persistence of low back or neck pain varies among individuals. Therefore, the study team decided to evaluate strength training interventions to change pain and improve mobility, quality of life, and biomechanical parameters of muscles. Plyometric training, a widely used jumping training in various sports disciplines, enhances neuromuscular coordination by training the nervous system, enabling the cycle of muscle stretching and shortening. For soccer players and strength and conditioning coaches, plyometric training to improve kicking performance holds significant practical implications. Therefore, our project aims to evaluate the impact of plyometric training and its correlation with biomechanical properties (muscle tension, flexibility, muscle stiffness), providing valuable insights for sports performance enhancement. Occlusive training, also described as blood flow restriction (BFR), is receiving more and more attention in scientific literature and sports practice. As its importance in the physiotherapy and sports industry increases, reports of its effectiveness appear. There is a gap in the scientific literature describing reperfusion and reperfusion parameters for 60%, 80%, and 100% arterial occlusion pressure (AOP) based on laser Doppler flowmetry (LDF; allows continuous real-time measurement of local microcirculatory blood flow), which is why this study aims to develop an occlusive protocol and assess the reperfusion most favorable for physical exercise.

Who can participate?
Volunteer participants aged 18 to 60 years old, individuals with non-radicular pain in the lumbar spine (L/S) and cervical spine (C) who reported muscle pain at least twice within the previous 12 months, fourth-league football players aged between 18 and 38 years old, martial arts practitioners with a minimum of three years of experience training at least three times per week aged between 18 and 40 years old, as well as healthy volunteers aged between 18 and 60 years old, all of whom will be required to complete a health questionnaire before participation.

What does the study involve?
In this study, volunteers will be randomly assigned to 3 groups (strength training, plyometric training, and occlusion training). Individual training strategies will be undertaken and the following will be investigated: muscle biomechanical parameters, hyperemia, and pain to determine optimal training protocols and improve quality of life.

What are the possible benefits and risks of participating?
The research results obtained as part of these studies should allow the creation of an optimal strength training protocol for people with diseases of the cervical and lumbar musculoskeletal system and plyometric system in football players. In addition, the research should be beneficial for occlusion training in determining the most favorable AOP values and the changes occurring during different periods of occlusion use. The above data may expand prevention, public health, and competitive sports knowledge. During the tests, subjects may experience increased physical fatigue. The risk for participants may be related to the low probability of injury during exercise.

Where is the study run from?
The study will be a multicenter study conducted at the indicated universities with the main medical facility - Provita.

When is the study starting and how long is it expected to run for?
March 2024 to May 2025. The estimated start date of the research is as follows: recruitment from May 2024 to July 2024 and implementation of the intervention evaluation within 3 months from the end of recruitment.

Who is funding the study?
Provita Medical Center

Who is the main contact?
Dr. Robert Trybulski - Director of the Provita Medical Center, rtrybulski@o2.pl

Contact information

Type(s)
Public, Principal Investigator

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Scientific

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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
Assessment of the impact of a strength training protocol, plyometric and occlusion on the biomechanical parameters of muscles in people with various physical activity level

Acronym
TOB

Study objectives
1. Plyometric training influences changes in biomechanical properties, improving muscle strength and power
2. Strength training influences pain suffering and changes biomechanical physical properties in patients with cervical and lumbar muscle pain
3. Occlusion with a value of 60, 80, and 100 AOP affects the change in network perfusion and biomechanical parameters of the muscles

(added 18/12/2024)
4. Four weeks of BFR training significantly improves individual parameters of post-neurovascular hyperemia reactions in patients with type 2 diabetes
5. Four-week BFR training combined with Bemer magnetic therapy significantly changes hyperemic reactions in patients with type 2 diabetes

(added 28/01/2025)
6. Supporting the strength training group with Tecar therapy and dry clay therapy will have a beneficial effect on pain modulation, RoM, biomechanical properties and balance control

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/03/2024, Ethics Committee of the Polish Physiotherapy Association (Zygmunta Modzelewskiego 37, Warszawa, 02-679, Poland; +48 601719721 ; biuro@fizjoterapeuci.org), ref: No. 3/03/2024

Study design
Randomized parallel controlled crossover multicenter study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Fitness/sport facility, Other therapist office, University/medical school/dental school

Study type(s)
Diagnostic, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Patients with non-radicular pain in the cervical and lumbar spine as well as athletes and healthy volunteers with various levels of motor preparation

Interventions
Current interventions as of 28/01/2025:

The study is based on several separate protocols, and participants were randomly assigned to several groups. Group allocation was achieved by simple 1:1 randomization using a random sequence generated on the randomizer.org website. The randomization process was independent of treatment duration and study personnel.

Group A (n=30) myofascial cervical pain syndromes. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). e.g., will undergo strength training of the neck muscles according to the training protocol. Observation and measurement time was rest (before the study) 7 days after the start of the intervention, two months, and three months after the start of the intervention.In this group, Tecar therapy and dry needling will be additionally used to compare the effectiveness of combining these therapies with strength training.

Group B (n=30) lumbar myofascial pain syndromes. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). e.g., will be devoted to strength training of the back muscles according to the training protocol. Observation and measurement time was rest (before the examination) 7 days after the start of the intervention, two months, and three months after the start of the intervention.In this group, Tecar therapy and dry needling will be additionally used to compare the effectiveness of combining these therapies with strength training.

Group C (n=30) plyometric training for football players. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). For example, they will be subjected to plyometric training, while cG will implement the current training plan, which does not include plyometric training. Observation and measurement time was rest (before the study) 7 days after the start of the intervention, two months, and three months after the start of the intervention.

Group D (n= 20) analysis of perfusion and reperfusion parameters in occlusion training for people with different levels of motor preparation. The group will be randomly divided into three subgroups: G60% (n=40), G80%(n=40) and G100%(n=40). The cuff is placed on the thigh in the supine resting position at 60% and 80% 100% AOP (total arterial occlusion pressure) for 1, 3, and 5 minutes. There will be a week break between 1, 3, and 5-minute measurements for individual groups, after which the groups will be changed and measured on the dominant leg and arm with simultaneous measurement of the other lower limb as a control measurement. All test subjects will undergo familiarization sessions before the trials. Observation and measurement time was rest (before the test) immediately after the intervention, 1 hour after the intervention, 24 hours, 48 hours after the intervention, and seven days after the intervention.

Measuring devices used for primary research:
Myoton (Myoton AS, Myoton Ltd, Estonia 2021), inclinometer (Baseline USA 2020), body composition analyzer (Accuniq BC720, Korea), algometer (FPIX 5.2021 USA), Force Decks measurement platform (Vald Performance Australia)), photocell (Sectro TS-F7- 2021), electric SONOMED DOPPLER MD4 (China 2020) with 8 MHz head, 10 cm wide FitCuffs (Denmark 2019), Perimed Laser Flowmeter (Sweden 2004) with a laser amplifier with a wavelength of 670 nm (near infrared). Used for 20 Hz sampling with a perfusion range of up to 10 V, Sonoscape P20 ultrasound device with a 5-20 Hz linear head (China 2022). Measurements taken on the muscles: longissimus dorsi, sternocleidomastoids, quadriceps femoris, trapezius biceps femoris and at the top of the big toes (tips for LDF) in places and resting positions. Used with the textbook in the scientific literature and practising methods. Physiotherapists and students will appropriately train the measurements and training.

The secondary measures look at muscle thickness (MT), subjective Borg fatigue scale, running speed (m/s) and other perfusion parameters TR (time of recovery) - time from the moment of cessation of occlusion until the blood supply returns to the value up to; BZ (biological zero) - biological zero - whether it occurs during occlusion and its time BZ(t)time; BZ/RF index - an index expressing the ratio of the zero flow value to the rest flow.

roup E analysis of the effect of four-week BFR training on the post-occlusive hyperemic reaction in patients with type 2 diabetes. Random division into the control group (n=20) and the experimental group (n=20).
The control group will undergo sham therapy, consisting of inflating the cuff 2 times a day for 4 weeks at a pressure of 40 mmHg for 3 minutes with a 3-minute break. The number of repetitions in the series is 3. The experimental group will similarly, however, with pressure of AOP ranging from 80 to 100% AOP. Measurements will be taken at rest before the therapy and after 4 weeks.

Group F analysis of the effect of combined Bemer and BFR magnetotherapy on post-occlusive hyperemic reactions in patients with type 2 diabetes. Random division into the BEMER experimental group (n=20), the BEMER&BFR experimental group (n=20), and the control group with sham BFR&BEMER therapy (n=20). The experimental groups will be subjected to x 1 daily for four weeks of BEMER magnetotherapy lasting 30 to 1 hour and BFR training x 2 daily with a cuff pressure of 80 to 100% AOP. The sham therapy will consist of applying BFR cuff pressure of 40% AOP and imitation of BEMER electromagnet therapy application. Measurements will be taken at rest before and after 4 weeks of therapy.

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Previous interventions as of 18/12/2024 to 28/01/2025:

The study is based on several separate protocols, and participants were randomly assigned to several groups. Group allocation was achieved by simple 1:1 randomization using a random sequence generated on the randomizer.org website. The randomization process was independent of treatment duration and study personnel.

Group A (n=30) myofascial cervical pain syndromes. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). e.g., will undergo strength training of the neck muscles according to the training protocol. Observation and measurement time was rest (before the study) 7 days after the start of the intervention, two months, and three months after the start of the intervention.

Group B (n=30) lumbar myofascial pain syndromes. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). e.g., will be devoted to strength training of the back muscles according to the training protocol. Observation and measurement time was rest (before the examination) 7 days after the start of the intervention, two months, and three months after the start of the intervention.

Group C (n=30) plyometric training for football players. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). For example, they will be subjected to plyometric training, while cG will implement the current training plan, which does not include plyometric training. Observation and measurement time was rest (before the study) 7 days after the start of the intervention, two months, and three months after the start of the intervention.

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measurement platform (Vald Performance Australia)), photocell (Sectro TS-F7- 2021), electric SONOMED DOPPLER MD4 (China 2020) with 8 MHz head, 10 cm wide FitCuffs (Denmark 2019), Perimed Laser Flowmeter (Sweden 2004) with a laser amplifier with a wavelength of 670 nm (near infrared). Used for 20 Hz sampling with a perfusion range of up to 10 V, Sonoscape P20 ultrasound device with a 5-20 Hz linear head (China 2022). Measurements taken on the muscles: longissimus dorsi, sternocleidomastoids, quadriceps femoris, trapezius biceps femoris and at the top of the big toes (tips for LDF) in places and resting positions. Used with the textbook in the scientific literature and practising methods. Physiotherapists and students will appropriately train the measurements and training.

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Group F analysis of the effect of combined Bemer and BFR magnetotherapy on post-occlusive hyperemic reactions in patients with type 2 diabetes. Random division into the BEMER experimental group (n=20), the BEMER&BFR experimental group (n=20), and the control group with sham BFR&BEMER therapy (n=20). The experimental groups will be subjected to x 1 daily for four weeks of BEMER magnetotherapy lasting 30 to 1 hour and BFR training x 2 daily with a cuff pressure of 80 to 100% AOP. The sham therapy will consist of applying BFR cuff pressure of 40% AOP and imitation of BEMER electromagnet therapy application. Measurements will be taken at rest before and after 4 weeks of therapy.

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Previous interventions:

The study is based on several separate protocols randomly assigned to 4 groups. Group allocation was achieved by simple 1:1 randomization using a random sequence generated on the randomizer.org website. The randomization process was independent of treatment duration and study personnel.

Group A (n=30) myofascial cervical pain syndromes. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). e.g., will undergo strength training of the neck muscles according to the training protocol. Observation and measurement time was rest (before the study) 7 days after the start of the intervention, two months, and three months after the start of the intervention.

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of the back muscles according to the training protocol. Observation and measurement time was rest (before the examination) 7 days after the start of the intervention, two months, and three months after the start of the intervention.

Group C (n=30) plyometric training for football players. The group will be randomly divided into subgroups: experimental (eG=15) and control (cG=15). For example, they will be subjected to plyometric training, while cG will implement the current training plan, which does not include plyometric training. Observation and measurement time was rest (before the study) 7 days after the start of the intervention, two months, and three months after the start of the intervention.

Group D (n= 20) analysis of perfusion and reperfusion parameters in occlusion training for people with different levels of motor preparation. The group will be randomly divided into three subgroups: G60% (n=40), G80%(n=40) and G100%(n=40). The cuff is placed on the thigh in the supine resting position at 60% and 80% 100% AOP (total arterial occlusion pressure) for 1, 3, and 5 minutes. There will be a week break between 1, 3, and 5-minute measurements for individual groups, after which the groups will be changed and measured on the dominant leg and arm with simultaneous measurement of the other lower limb as a control measurement. All test subjects will undergo familiarization sessions before the trials. Observation and measurement time was rest (before the test) immediately after the intervention, 1 hour after the intervention, 24 hours, 48 hours after the intervention, and seven days after the intervention.

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Intervention Type
Mixed

Primary outcome measure
The following primary outcome measures are assessed at rest (before intervention), immediately post-intervention at 5-30 minutes, and 1, 24 and 48 hours, and 1, 2, and 3 months:
1. Muscle tone (T [Hz]) measured using the Myoton device (Myoton AS, Myoton Ltd, Estonia 2021)
2. Elasticity (E [arb- relative arbitrary unit]) measured using the Myoton device (Myoton AS, Myoton Ltd, Estonia 2021)

3. Maximum isometric Force (Fmax [kgf]) measured using the Force Decks measurement platform (Vald Performance Australia)
4. Reactive Strength Index (RSI [m.s-1]) assessed using the Force Decks measurement platform (Vald Performance Australia)
5. The angle of Pennation Muscle (PA- [%]) measured using an ultrasound device (Sonoscape P20, China 2022)
6. Transcutaneous electromyographic examination, EMG device (Deymed TruScan 2022) (added 04/12/2024)
7. Measurement of the displacement of the center of gravity in(cm 2) measured using a pedobarographic platform (Pedobarograph MPS 120 Italy 2019)(added 28/01/2025)

Secondary outcome measures
1. Muscle Thickness (MT) measured using ultrasound imaging before the intervention, after the intervention and at 24 hours, 48 hours and 1 week after the intervention
2. Subjective fatigue level measured using the Borg fatigue scale questionnaire before the intervention, after the intervention and at 24 hours, 48 hours and 1 week after the intervention
3. Running Speed (m/s) measured using a stopwatch or timing device on a track before the intervention, after the intervention and at 24 hours, 48 hours and 1 week after the intervention
4. Perfusion Parameters (TR, BZ, BZ/RF Index) measured using a perfusion monitoring device (e. g., Laser Doppler flowmetry) before the intervention, during the intervention (for BZ), after the intervention and at 24 hours, 48 hours and 1 week after the intervention
5.Survey study of the perception of the role of regeneration and motor preparation in sports (added 04/12/2024)

Overall study start date
01/03/2024

Completion date
20/05/2025

Eligibility

Key inclusion criteria
1. Participants aged between 18 and 60 years old
2. Individuals experiencing non-radicular pain in the lumbar spine (L/S) and cervical spine (C), who have reported muscle pain at least twice within the 12 months before the study
3. Fourth-league football players aged between 18 and 38 years old for the plyometric exercise group
4. Volunteers practising martial arts for a minimum of three years, engaging in training sessions at least three times per week, aged between 18 and 40 years old, for the occlusive intervention group
5. Healthy volunteers aged between 18 and 60 years old
6. All volunteers must have completed a health questionnaire before the study to provide information about their health condition

Participant type(s)
Healthy volunteer, Patient, Learner/student, Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
100

Total final enrolment
28

Key exclusion criteria
1. Unregulated blood pressure (pressure > 140/90 mm Hg)
2. Heart and circulatory system diseases
3. Radicular pain in the spine
4. Other diseases disqualifying from physical exercise
5. Damaged skin areas at the measurement sites, i.e. back, leg and arm muscles

Date of first enrolment
25/05/2024

Date of final enrolment
20/07/2024

Locations

Countries of recruitment
Poland

Study participating centre
Medical Centre Provita
al.Zjednoczonej Europy 37
Żory
Poland
44-240

Study participating centre
The Jerzy Kukuczka Academy of Physical Education
Mikolowska str 72A
Katowice
Poland
40-065

Study participating centre
Academy of Physical Education and Sport in Gdansk
Kazimierza Górskiego str 1
Gdansk
Poland
80-336

Sponsor information

Organisation
Medical Centre Provita

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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 peer-reviewed high-impact journal

Intention to publish date

01/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the research director Robert Trybulski, rtrybulski.provita@gmail.com. The type of data that will be shared are data on measured variables and their changes during all interventions and data characterizing the anthropometric characteristics of study participants. Data will be available after the publishing process is completed. A consent form, which was attached to the application, was signed by each participant, indicating their agreement to share their data. The study was conducted following the Declaration of Helsinki with the consent of the ethics committee (consent attached to the application).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Polish		10/04/2024	No	Yes
Results article		28/07/2025	29/07/2025	Yes	No