ISRCTN51633853 https://doi.org/10.1186/ISRCTN51633853

Is low intensity resistance training combined with blood flow restriction beneficial to the rehabilitation of patients with knee osteoarthritis?

Submission date
12/05/2022

Recruitment status
No longer recruiting

Registration date
16/05/2022

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis causes the cartilage in your knee joint to thin and the surfaces of the joint to become rougher, which means that the knee doesn't move as smoothly as it should, and it might feel painful and stiff.
Older people with knee OA usually experience challenges in performing vital independence tasks compared to those without OA. Hence, improving muscle strength and promoting physical function recovery is an important goal of knee OA rehabilitation.
Resistance exercise is a traditional method to improve muscle mass and muscle strength, Nevertheless, the capacity to tolerate the high mechanical stresses directed onto the joints during heavy resistance training varies among individuals. A combination low load resistance training and blood flow restriction (BFR) could elicit parallel impacts as high load resistance training, which has recently led to its frequent use in the rehabilitation of knee OA. Additionally, a study revealed that single-leg BFR training effectively improved the muscle strength of the contralateral limb in healthy adults, known as the crossover effect. This event might result from the systemic circulation of myogenic-related hormones. This provides a new idea for sports rehabilitation of patients with unilateral knee OA. Nonetheless, the effect of unilateral limb exercise on serum myogenesis-related hormones in patients with knee OA remains unclear.
Our previous study demonstrated that BFR training promotes the production of muscle growth-related hormones in healthy adults. Therefore, this study aims to elucidate the effects of BFR with single-leg low load resistance exercise and high load resistance exercise on insulin-like growth factor-1, serum growth hormone, and testosterone in patients with unilateral knee OA. The findings will provide the theoretical basis to assist researchers and physical therapists in developing a more scientific exercise strategy.

Who can participate?
Female patients aged 40 - 70 years with knee OA in one knee.

What does the study involve?
The study included a survey of participants' maximum muscle strength and hormonal responses to three different exercises.

What are the possible benefits and risks of participating?
The benefits of participation can obtain more effective exercise rehabilitation prescriptions. The risk of participation is the possibility of muscle soreness after exercise.

Where is the study run from?
Qingdao Haici Hospital (China)

When is the study starting and how long is it expected to run for?
May 2022 to July 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Junguo Wang, wangjunguo7765@163.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of low load resistance training with blood flow restriction on serum growth hormone, insulin-like growth factor-1, and testosterone in patients with mild to moderate unilateral knee osteoarthritis (OA)

Acronym
BFRKOA

Study objectives
Myogenesis-related hormones in women with unilateral knee OA could be increased by high load resistance exercise and low load resistance exercise with BFR on unaffected limb.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/05/2022, The Medical Ethics Committee of The Affiliated Qingdao Hiser Hospital (Qingdao Hospital of Traditional Chinese Medicine, No. 4, Renmin Road, Qingdao, Shandong, China; +8615901569205; qdhaiciwenhua@126.com), ref: 2022-HYJ-247

Study design
Single-blind observational cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Female patients with unilateral knee osteoarthritis

Interventions
This study will recruit 18 female patients with mild to moderate unilateral knee OA, which was then followed by randomly conducting three resistance exercise tests by drawing lots:
1. A 30% 1-repetition maximum (1-RM) resistance exercise with BFR of 70% arterial occlusive pressure (AOP) (BFR group)
2. A 70% 1-RM resistance exercise without BFR (RES group)
3. A 30% 1-RM resistance exercise without BFR (CON group)

Intervention Type
Behavioural

Primary outcome(s)
Blood lactate (BLA), IGF-1, GH and testosterone levels will be tested at 4-time points using blood test: before exercise, immediately after exercise, 15 minutes after exercise, and 30 minutes after exercise.

Key secondary outcome(s))
Heart rate measured using heart rate band during exercise

Completion date
25/07/2022

Eligibility

Key inclusion criteria
1. Currently experiencing objective functional limitations
2. Female aged between 40 and 70 years old
3. Symptomatic unilateral knee OA
4. Not participating in any regular resistance training.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
18

Key exclusion criteria
1. Health status contradicted the use of a tourniquet
2. Currently suffering from peripheral vascular disorders or any condition contradicting subjecting them to exercise training
3. High blood pressure defined by a diastolic blood pressure >100 mm Hg or resting systolic blood pressure >160 or <100 mm Hg

Date of first enrolment
25/05/2022

Date of final enrolment
24/06/2022

Locations

Countries of recruitment
China

Study participating centre

Qingdao Haici Hospital
No. 4, Renmin Road, Qingdao
Qingdao
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066033

Sponsor information

Organisation
Qingdao Haici Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/10/2022	09/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			13/05/2022	No	No