ISRCTN63585315 https://doi.org/10.1186/ISRCTN63585315

The effects of low-intensity blood flow restricted exercise on the clinical outcomes of young active adults following a 3-week in-patient rehabilitation programme

Submission date
24/04/2017

Recruitment status
No longer recruiting

Registration date
25/04/2017

Overall study status
Completed

Last Edited
14/09/2018

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Leg injuries are the most common type of injury seen at the Defence Medical Rehabilitation Centre (DMRC), Headley Court. It is important to ensure that the best possible quality of the care is provided, as well as ensuring that treatment is cost-effective. It is widely accepted that improvements in muscle strength are closely associated with improvements in functional ability during rehabilitation after injury. Therefore, resistance (strength) training is an important component of the rehabilitation programme currently delivered at DMRC. In recent years, low-intensity exercise with blood flow restriction (LI-BFR) has gained popularity as a research topic. It involves the application of pressurised cuffs to the arms or legs, while performing different types of exercise such as cycling, walking, or weight training. The effects of LI-BFR have been promising with increased strength, muscle size, improved endurance capacity and blood flow in both young and old subjects. However, the effects of this new training method in a military rehabilitation setting are yet to be explored. Therefore, this study aims to assess the effects of LI-BFR versus traditional strength training techniques in UK military personnel with leg injuries undergoing in-patient rehabilitation.

Who can participate?
Men aged 18-50 who are serving in the UK Armed Forces and have a leg injury.

What does the study involve?
Participants are asked to join this study while they are undergoing treatment for a leg injury at a military rehabilitation centre. Participants are randomly allocated to one of two groups. Those in the first group will complete a strength training programme that involves restricting the blood flow to the legs for very short time periods of time. The device used in this technique is similar to the cuff used to measure blood pressure. Those in the second group undertake a conventional strength training programme using bars, weights and machines. Both programmes last for three weeks. Participants in both groups undergo tests to measure their muscle strength, functional (walk-run/balance) ability and pain immediately before and after the

treatment period. Participants also undergo a scan to assess any changes in their muscle size before and after treatment.

What are the possible benefits and risks of participating?
Results of the intended study as a whole will be made available to all study participants. Individual results will also be made available to individual study participants if requested. Thus, participants will gain an insight into the effects of either the currently prescribed resistance training programme (HI-RT) or exercise with LI-BFR on their respective muscle size, strength and functional ability. There will also be benefits to future UK military patient's undergoing rehabilitation because the results are likely to influence how strength training is delivered at DMRC Headley Court. The main risk of the LI-BFR is minor bruising at the site of cuff placement, which is a very rare using a 10cm width cuff. Pre-screening and not including patients with a history of cardiovascular (heart and blood vessel) issues will further minimise the very small risk of any side effects. The use of MRI scanning to quantify muscle size is not deemed to be a potential hazard.

Where is the study run from?
Defence Medical Rehabilitation Centre (UK)

When is the study starting and how long is it expected to run for?
February 2014 to February 2018

Ministry of Defence
Ministry of Defence (UK)

Who is the main contact?
Dr Shreshth Dharm-Datta

Contact information

Type(s)
Public

Contact name
Dr Shreshth Dharm-Datta

Contact details
Academic Department of Military Rehabilitation (ADMR)
DMRC Headley Court
Epsom
United Kingdom
KT18 6JW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
442/MoDREC/13

Study information

Scientific Title
The effects of low-intensity blood flow restricted exercise versus conventional resistance training exercise on the physical and functional outcomes in UK Military personnel undergoing a 3-week in-patient rehabilitation programme: a randomised controlled trial

Study objectives
Blood flow restriction combined with resistance training will induce the same increases in muscle size, muscle strength and functional ability as conventional resistance training in military personnel undergoing residential rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ministry of Defence (UK) Research ethics committee, 01/08/2015, ref: 442/MODREC/13

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Lower limb musculoskeletal sports and training injury (various)

Interventions
Participants are randomised to one of two groups using block randomisation.

Intervention 1 - LI-BFR Group: will perform low-intensity RT combined with blood flow restriction using two exercises from a choice of three exercises which the ERI will cycle through: (1) bilateral leg press using a leg press machine (Pulse Fitness, Congleton, UK); (2) bilateral knee extensions using a knee extension machine (Pulse Fitness, Congleton, UK); (3) split squat using dumbbells to increase weight. The choice of three exercises mirrors the choice in the conventional high

resistance training group of squat, deadlift and dumbbell lunge to avoid boredom and enhance adherence in the two groups. Specifically, prior to exercise contoured 66x10cm width blood pressure cuffs (Schuco Tourni-Cuff, Schuco International, Watford, UK) will be placed around the most proximal part of each thigh and slowly inflated using a PTSii portable tourniquet system (Delfi Medical Innovations, Vancouver, Canada) to -60% occlusion pressure, technique detailed below18,19 Subsequently, subjects will be asked to perform 4 sets of 30, 15, 15 and 15 repetitions at 30% of 1RM, with an inter-set interval of 30 sec, in accordance with previously published protocols.8,15,17. A metronome is set at 60 bpm, with 1s for the concentric phase; no pause; and 1s for the eccentric phase of the lift (1:0:1 tempo) to ensure consistency of lifting between patients. This means the total cuff inflation duration is (30reps x2 + 30s + 15reps x2 + 30s +15reps x2 +30s +15reps x2 =) 240s or 4 minutes. The inflation pressure will be maintained for the duration of the exercise (4 min) and then deflated for 3 min to allow the patient to move to the next exercise/equipment station. It will then be re-inflated to the target 60% occlusion pressure. Thus the total time under the inflated cuff will be 8 min per training session. Training will be performed twice daily from Monday-Thursday and once daily on Friday, for a total of 9 training sessions per week. Daily LI-BFR sessions will be separated by at least 5 hours. As patients strengthen over the 3 week residential programme, the 1RM would be expected to increase and therefore even when exercising at 30% 1RM, we would expect to increase the weight lifted by small increments (e.g. 1.25-5kg increase per week).

Intervention 2 - Conventional Resistance Training: x4 sets of x3 exercises (dead-lift, back-squat and dumbell lunges) performed x3 times per week. Repetitions per set is 4-6 repetitions tailored to the individual needs of the patient. Loading is established as 75% of a 1-repetition maximum test. Rest intervals between each set is 3-mins.

At baseline and after each three week programme, participants undergo assessments of muscle size, strength and functional ability.

Intervention Type
Other

Primary outcome measure
1. Muscle Cross Sectional Area (CSA) will be assessed using magnetic resonance imaging (MRI), using a GE Sigma scanner at baseline and day 15
2. Muscle strength will be assessed using a dynamic 5-repetition maximum (5RM) test performed on a bilateral knee extension machine at baseline and day 15

Secondary outcome measures
1. Functional ability will be assessed using the following standardised tests already in use at the Defence Military Rehabilitation Centre (DMRC), Headley Court at baseline (day 1) and completion (day 15) of the in-patient rehabilitation programme. The specific tests are:
1.1. Multi-stage Fitness Test (MSFT)
1.2. Y-Balance Test
1.3. Figure of 8 Test
2. Pain and Discomfort is assessed using a Visual Analogue Scale (VAS) immediately prior to starting each scheduled training period during the training period and 5-mins post-exercise

Overall study start date
01/02/2014

Completion date

01/02/2018

Eligibility

Key inclusion criteria
1. Male
2. Lower limb injury (ex. Achilles/patellar tendinopathy, anterior knee pain, ACL reconstruction, ankle injuries, projectile/blast-related injury)
3. Age range 18-50 years
4. Serving regular UK Armed Forces personnel

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Male

Target number of participants
28

Key exclusion criteria
1. Female
2. Prior history of cardiovascular disease (ex. hypertension, peripheral vascular disease, thrombosis/embolism, ischaemic heart disease, myocardial infarction)
3. Amputation
4. Peripheral neuropathy
5. History of formally diagnosed mental illness
6. History of formally diagnosed learning disability
7. Brain Injury
8. ACL surgery within the last 4 weeks
9. Surgical insertion of metal components in lower limbs (may affect MRI results)

Date of first enrolment
02/07/2016

Date of final enrolment
02/07/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Defence Medical Rehabilitation Centre (DMRC)
Headley Court
Epsom
United Kingdom
KT18 6JW

Sponsor information

Organisation
Academic Department of Military Rehabilitation (ADMR)

Sponsor details
DMRC Headley Court
Epsom
England
United Kingdom
KT18 6JW

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
All results will be published in a relevant journal regardless of the study outcomes.

Intention to publish date
03/09/2018

Individual participant data (IPD) sharing plan
Because this study is undertaken in a military organisation using data collected from serving members of the UK Armed Forces the data has crown copyright security protection. Therefore, it is not possible at the time of registration to provide confirmation that the dataset will be made available. However, it is possible that some data will be available on completion of the study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		24/04/2017	25/04/2017	No	Yes
Protocol article	protocol	08/12/2017		Yes	No
Results article	results	10/09/2018		Yes	No