Information for Participants

Study title

The Effects of Low Intensity Blood Flow Restricted Exercise in Musculoskeletal Rehabilitation. MODREC Approved Study, Protocol no 442/MoDREC/13

Invitation to take part

We would like to invite you to participate in this research project. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take at least 24 hours to consider if you want to take part or not. If you would like to take part, please let us know if you have been involved in any other study during the last year.

What is the purpose of the research?

The purpose of this research is to investigate if a new training method called "Low-intensity blood flow restriction" training (LI-BFR) can produce similar gains in muscle size, strength and functional ability, as the conventional existing resistance training (weight training) that we are currently using to rehabilitate lower-limb patients at DMRC, Headley Court.

Who is doing this research?

The research is being carried out by the Academic Department of Military Rehabilitation at DMRC, Headley Court. The Chief Investigator is Dr Shreshth Dharm-Datta, Consultant in Rehabilitation Medicine.

Why have I been invited to take part?

You have been invited to take part in this study because you are scheduled to participate in a Early Lower Limb rehabilitation programme at DMRC, Headley Court and you meet the study's inclusion criteria.

Do I have to take part?

You should only participate if you want to; choosing not to take part will not disadvantage you in any way, as you will still receive the current conventional treatment everyone else gets outside of this study.

What will I be asked to do?

Treatment

Should you choose to participate in this study you will be asked to complete the standardised lower-limb rehabilitation programme in terms of physiotherapy, hydrotherapy and group exercises. Only when it comes to the resistance training sessions will you be randomly allocated into 1 of 2 training groups.

1. Existing early-stage resistance training:
This group will perform resistance training 3 times per week, consisting of functional multi-joint exercises using free weights. Training sessions will last approximately 45 minutes. This method of resistance training is currently used for all lower-limb

patients at DMRC, Headley Court.

2. LI-BFR Resistance Training (LI-BFR/RT)
This group will perform daily low-intensity resistance training with partial occlusion of the blood flow to the working muscles. Immediately prior to the exercise session, blood pressure cuffs will be fitted to your legs and inflated to obtain a pre-determined level of partial occlusion. The training session will consist of 2 exercises from a choice of leg press, knee extensions and split squats. Each exercise involves 4 sets of 30, 15, 15 and 15 reps, with 30s rest between each set. We will use a metronome to help set the lifting frequency so that you lift the weight at a tempo of 1s and lower over 1s. By using the metronome, each exercise takes just 4 minutes. The cuffs will be deflated between exercises for 3 minutes. This allows you to move to the next exercise. The cuffs are then re-inflated for the 4 minutes it takes you to perform the next exercise. They are then deflated and removed from your legs.

Each training session will last approximately 15 minutes including warm up time and rest between the two exercises, and will be performed twice daily.

LI-BFR training is a specialist method under evaluation, and we would not intend you to continue LI-BFR training on following discharge from DMRC Headley Court.

Testing

Before commencing the rehabilitation programme you will be asked to undergo a range of tests, which will assess your current muscle size, strength and functional ability. These tests will be repeated just before you are discharged from Headley Court, so we can assess your progress. The tests are:

- Multi-stage Walk Test (MSWT)

The objective of this test is to assess your cardiovascular fitness and requires you to walk/run 20m to the sound of a beep from a CD recording, at continuously increasing speeds.

- Y-Balance

This test will assess your lower-body balance and flexibility.

- Figure of 8 Test

The test will assess you agility and ability to move your body in different directions at speed.

- Muscle Strength

Thigh muscle strength will be assessed using a maximal test performed on a Leg Press and Knee Extension machine. Following a general and specific warm-up you will be asked to lift the maximal weight you can handle for 5 repetitions. Calf strength will be assessed by bent and straight knee calf raises. We will also use a hand-held dynamometer to measure the maximal force your muscles can generate.

- Magnetic Resonance Imaging (MRI)

In addition to these normal tests you will also undergo a procedure known as magnetic resonance imaging (MRI), which will be used to assess your current thigh

muscle size.

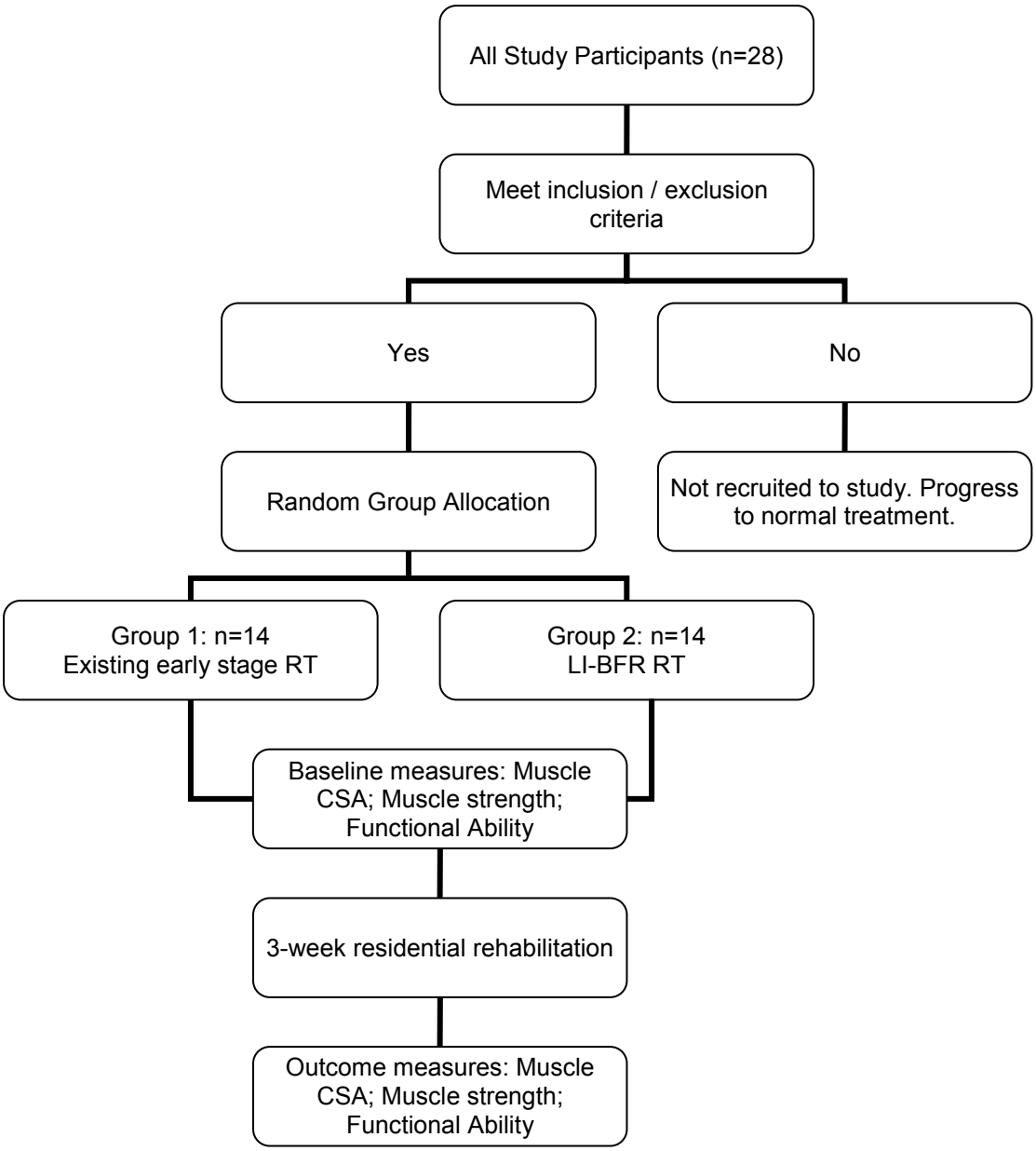
The MRI scanner is a commonly-used research tool, which makes use of magnetic fields to determine your muscle size. The testing itself will be non-invasive and you will be wearing your own choice of loose-fitting clothes, not to contain any metal parts, as this interferes with the scanning results. You will be positioned in a scanner and a scan will be taken of your thigh muscles. The total procedure, including the set-up time will take approximately 30 minutes.

The use of the procedure on participants in this study, along with the safety to participants has been approved by the Ministry of Defence Research Ethics Committee (MoDREC). The results of the MRI scan pre and post intervention will not routinely be reported back to participating patients due to batch analysis at the end of the study period. If you would like to receive the results please contact the Chief Investigator Dr Shreshth Dharm-Datta.

A flow chart depicting the study layout can be found overleaf.

A Pilot-Study Investigating the Effects of Low Intensity Blood Flow Restricted Exercise in Musculoskeletal Rehabilitation (MODREC Protocol No: 442/MoDREC/13).

Trial Design



RT = resistance training; CSA = cross-sectional area

What is the device or procedure that is being tested?

The procedure being tested is known as low-intensity blood flow restricted training (LI-BFR). This method has been researched as a possible alternative to conventional heavy resistance training and results have been very promising so far. In fact, significant gains in muscle size and strength can typically be observed in as little as two weeks when following a LI-BFR training programme.

Existing early-stage resistance training is the default method we currently use at DMRC, Headley Court to increase the muscle size and strength of all lower limb rehabilitation patients. However, with this study we would like to determine if we can obtain the same results with this new training method, which will be less taxing on the joints and less time-consuming.

What are the benefits of taking part?

There are no known benefits to taking part in this study, other than those you will obtain from participating in the general rehabilitation programme. However, on a wider scale, the results we will obtain from you and others participating in this study will potentially enable DMRC, Headley Court to provide more efficient rehabilitation programmes to Lower Limb patients in the future.

What are the possible disadvantages and risks of taking part?

All procedures in this proposed study are considered safe and there are no particular disadvantages or risks of taking part. However, minor bruising at the site of cuff placement is a possibility but is exceedingly rare for most participants.

Can I withdraw from the research and what will happen if I don't want to carry on?

You can withdraw from the study at any time should you wish to do so.

Are there any expenses and payments which I will get?

As you are a residential patient at DMRC, Headley Court no expenses will be given.

Will my taking part or not taking part affect my Service career?

Your decision to take part or not, will in no way affect your service career. It is entirely voluntary.

Whom do I contact if I have any questions or a complaint?

For further question you can contact the Independent Medical Officer:

Name and Title: Dr David Hulse
Post Title: Consultant in Sports & Exercise Medicine

Department: Centre for Lower Limb Rehabilitation
Establishment: Defence Medical Rehabilitation Centre (DMRC)
Address: Headley Court, Epsom, Surrey KT18 6JW
Telephone: 01372 378271 ext 7442
E-mail: DMRC-ConsultantSEM4@mod.uk

What happens if I suffer any harm?

If you suffer harm you will be entitled to compensation under the MoD's "No Fault Compensation Scheme".

What will happen to any samples I give?

N/A

Will my records be kept confidential?

Any information obtained during this trial will remain confidential as to your identity. If it can be specifically identified with you, your permission will be sought in writing before it will be published. Other material, which cannot be identified with you, will be published or presented at meetings with the aim of benefiting others. You may ask the Project Officer for copies of all papers, reports, transcripts, summaries and other published or presented material. All information will be subject to the current conditions of the Data Protection Act 1998.

Who is organising and funding the research?

The research is organised by the Academic Department of Military Rehabilitation at DMRC, Headley Court and is funded by the Defence Medical Services Research Steering Group (DMSRSG).

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee (MoDREC).

Further information and contact details.

For further information:

Name and Title: Dr Shreshth Dharm-Datta
Post Title: Consultant in Rehabilitation Medicine
Department: Academic Department of Military Rehabilitation
Establishment: Defence Medical Rehabilitation Centre (DMRC)
Address: Headley Court, Epsom, Surrey KT18 6JW
Telephone: 01372 378271 ext. 7442
E-mail: Shreshth.Dharm-Datta357@mod.uk

Compliance with the Declaration of Helsinki.

This study complies, and at all times will comply, with the Declaration of Helsinki[1] as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013.

[1] World Medical Association Declaration of Helsinki [revised October 2013]. Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza (Brazil).

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Title of Study: The Effects of Low Intensity Blood Flow Restricted Exercise in Musculoskeletal Rehabilitation.

Ministry of Defence Research Ethics Committee Reference: 442/MoDREC/13

- ☐ The nature, aims and risks of the research have been explained to me. I have read and understood the Information for Participants and understand what is expected of me. All my questions have been answered fully to my satisfaction.
- ☐ I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately without having to give a reason. I also understand that I may be withdrawn from it at any time, and that in neither case will this be held against me in subsequent dealings with the Ministry of Defence.
- ☐ I understand that the screening process to decide if I am suitable to be selected as a participant may include completing a medical screening questionnaire and/or a physical examination by a medical officer and I consent to this.
- ☐ I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.
- ☐ I agree to volunteer as a participant for the study described in the information sheet and give full consent.
- ☐ This consent is specific to the particular study described in the Information for Participants attached and shall not be taken to imply my consent to participate in any subsequent study or deviation from that detailed here.
- ☐ I understand that in the event of my sustaining injury, illness or death as a direct result of participating as a volunteer in Ministry of Defence research, I or my dependants may enter a claim with the Ministry of Defence for compensation under the provisions of the no-fault compensation scheme, details of which are attached.

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information for Participants about the project, and understand what the research study involves.

Signed **Date**

Witness **Name**

Signature

Investigator's Statement:

I _____

confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the Participant.

Signed **Date**

AUTHORISING SIGNATURES

The information supplied above is to the best of my knowledge and belief accurate. I clearly understand my obligations and the rights of research participants, particularly concerning recruitment of participants and obtaining valid consent.

Signature of Chief Investigator

…… **Date**

Name and contact details of Independent Medical Officer (if appropriate):

Dr. David Hulse
Consultant in Sports & Exercise Medicine
Centre for Lower Limb Rehabilitation
Defence Medical Rehabilitation Centre
Headley Court, Epsom, Surrey KT18 6JW
Telephone: 01372 378271 ext. 7052
E-mail: DMRC-ConsultantSEM4@mod.uk

Name and contact details of Chief Investigator:
Dr Shreshth Dharm-Datta
Consultant in Rehabilitation Medicine
Academic Department of Military Rehabilitation
Defence Medical Rehabilitation Centre (DMRC)
Headley Court, Epsom, Surrey KT18 6JW
Telephone: 01372 378271 ext. 7442
E-mail: Shreshth.Dharm-Datta357@mod.uk

ARRANGEMENTS FOR THE PAYMENT OF NO-FAULT COMPENSATION TO HUMAN VOLUNTEERS

1. This section sets out the arrangements for the payment of no-fault compensation to volunteers who suffer illness and/or personal injury as a direct result of participating as a non-patient (healthy) human volunteer in research conducted on behalf of the Ministry of Defence. The no-fault compensation arrangements only apply to volunteers (Military, Civilian, or non-Ministry of Defence) who participate in a Trial that has been approved by the MoD Research Ethics Committee.

2. A volunteer wishing to seek no-fault compensation under these arrangements should contact the the Directorate of Judicial Engagement Policy, Common Law Claims & Policy (DJEP-CLCP) Ministry of Defence, Level 1, Spine 3, Zone J, Whitehall, SW1A 2SB who may need to ask the Claimant to be seen by a MoD medical adviser.

3. CLCP will consider reasonable requests for reimbursement of legal or other expenses incurred by volunteers in relation to pursuing their claim (e.g. private medical advice, clinical tests, legal advice on the level of compensation offered) provided that they have been notified of the Claimant's intention to make such a Claim.

4. If an injury is sufficiently serious to warrant an internal MoD inquiry, any settlement may be delayed at the request of the volunteer until the outcome is known and made available to the volunteer in order to inform his or her decision about whether to accept no-fault compensation or proceed with a common law claim. An interim payment pending any inquiry outcome may be made in cases of special need. It is the Claimant's responsibility to do all that he or she can to mitigate his or her loss.

5. In order to claim compensation under these no-fault arrangements, a volunteer must have sustained an illness and/or personal injury as a direct result of participation in a Trial. A claim must be submitted within three years of when the incident giving rise to the claim occurred, or, if symptoms develop at a later stage, within three years of such symptoms being medically documented.

6. The fact that a volunteer has been formally warned of possible injurious effects of the trial upon which a claim is subsequently based does not remove MoD's responsibility for payment of no-fault compensation. The level of compensation offered shall be determined by taking account of the level of compensation that a court would have awarded for the same injury, illness or death had it resulted from the Department's negligence.

7. In assessing the level of compensation, CLCP, in line with common law principles, will take into account the degree to which the Claimant may have been responsible for his or her injury or illness and a deduction may be made for contributory negligence accordingly.

8. In the event of CLCP and the injured party being unable to reach a mutually acceptable decision about compensation, the claim will be presented for arbitration to a nominated Queen's Counsel. CLCP will undertake to accept the outcome of any such arbitration. This does not affect in any way the rights of the injured party to withdraw from the negotiation and pursue his or her case as a common law claim through the Courts.