PARTICIPANT INFORMATION SHEET

ARMED
SERVICES
TRAUMA
REHABILITATION
OUTCOME
STUDY

The ADVANCE Study
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The ADVANCE Study
ArmeD SerVices TrAuma RehabilitatioN OutComE Study
MoDREC Reference No: 357/PPE/12

We would like to invite you to participate in this research project being undertaken by a collaboration of the Defence Medical Rehabilitation Centre at Stanford Hall, King's College London, Imperial College London and Bournemouth University. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. 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.

Commonly Asked Questions:

What is the purpose of the study?

The purpose of the study is to investigate the long term outcomes of battlefield trauma casualties and to compare these outcomes to those of a similar group of non-battlefield trauma individuals. The outcomes we are investigating include medical (in particular cardiovascular disease and osteoarthritis) and psychosocial outcomes. There is some evidence to suggest that battlefield trauma casualties may have some unfavourable outcomes but this evidence is limited and often only covers shorter periods of time. Also the types of injuries sustained in previous conflicts are different from those sustained in recent conflicts and therefore it is still unclear whether or how the type of injuries we are seeing from Afghanistan and Iraq will affect the long-term outcome of injured servicemen.

We think it is incredibly important to investigate these different medical and psychosocial outcomes so we can, where possible, support the injured individuals but also to learn from these outcomes and try and prevent any adverse outcomes in future injured servicemen.

Why have I been chosen?

You have been chosen to participate as you have either sustained significant battlefield trauma while on deployment with the British Armed Forces or you have been deployed but not injured and would therefore be suitable for the comparison group.

Do I have to take part?

You do not have to take part. If you do decide to take part, you can keep this sheet and you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason. Your participation will not interfere with the standard of care you receive.

What will happen to me if I take part?

Your participation will involve the following:

1. A baseline visit to DMRC Stanford Hall. In some cases this may be very soon after injury, in others it may be as many as a few years after injury.
2. Subsequent follow up visits to DMRC Stanford Hall will occur 3yrs, 5yrs, 10yrs, 15yrs and 20yrs after the baseline visit.
3. Each visit wil linclude the assessments below. Each visit will last approximately 4-5 hours.

   a) History

   Basic details of:

   - Age
   - Regiment/unit/work
   - Current social circumstances
   - Details of traumatic injuries
   - Past medical history
   - Medication/Drug history
   - Smoking history
   - Method of discharge from the armed services (if appropriate)

   b) Examination:
   - Blood pressure
   - Resting heart rate
   - Body Mass Index
   - Abdominal circumference

   c) Participant filled questionnaires covering outcomes such as:
   - Mobility
   - Pain
   - Prosthetic use/satisfaction/comfort (if applicable)
   - Knee, hip and shoulder pain and function
   - Quality of life
   - Symptoms of post traumatic stress
   - Alcohol intake
   - Sexual function
   - Mood

   d) Blood tests (which will be after a 8 hour fast):
   - Cholesterol
   - Kidney and liver function
   - Blood count measuring for anaemia
   - Blood sugar measuring for diabetes
   - Markers of inflammation
   - Male sex hormones
   - Genetic test for predisposition to inflammatory back pain (which characteristically occurs in young men)
   - Storage of serum and blood long term to test for new markers of disease that may be developed in the future

   e) Urine test:
   - Storage of urine to test for new markers of disease that may develop in the future

   f) Imaging:
   - X-rays of hips and knees assessing for evidence of osteoarthritis
   - DEXA scan (non-invasive painless scan) assessing for total body fat and bone mineral density (bone strength)
   - Ultrasound assessment of pulse wave velocity. This is a non-invasive, pain-free assessment of the stiffness of your arteries and is used to establish cardiovascular risk

g) Other assessments:

- Distance you are able to walk in 6 minutes
- Basic lung function test (a short maximum blowing test as would be used to assess for asthma)
- Audiometry–discharged personnel only
- Amp Q–amputees only

What do I have to do?

A research nurse will explain the study to you. If you agree to take part in the study the research nurse will ask you to sign a consent form and take some contact details from you. The research nurse will arrange for a convenient date and time for you to come for your first review.

How do I get to DMRC Headley Court or DMRC Stanford Hall, is accommodation provided if necessary and is there any payment for taking part?

If you are still in the military then MT will be provided to get you to and from your research appointments. If you have left the military travel expenses will be covered if receipts are provided. If accommodation is required then this will be provided by the DMRC free of charge.

There is no payment for participating in the study however, as appreciation for your significant time and effort in participating in the study you will be given £100 for the first (baseline) visit and £200 for each follow-up visit as compensation for your time.

There is also a cash prize draw for each follow up point, which with your consent you will be entered into, to encourage participants to return for follow up appointments in this incredibly important study. The total cash prize available is £25,000 and this will be divided up at each of the 5 follow up points with cash prizes ranging from £100 to £3000.

What are the possible benefits of taking part?

The results of the study are primarily designed for benefitting battlefield trauma casualties of the future. However the extra medical assessments that you would receive during the study are in some cases above and beyond what you would receive as standard clinical care in the military or NHS, whether you be a battlefield trauma casualty or a control for the comparison group. Any clinically significant medical issues/abnormalities detected will be reported back to your regular doctors, whether they be GPs or hospital specialists.

The study may hopefully also give you an opportunity to catch up with old friends and colleagues and we would do our best to co-ordinate visits if requested.

Will the research influence the treatment I receive?

The study is not designed to provide you with specific treatments, however, as mentioned above if any medical issues are uncovered the study team will be able to advise you and, with your permission, pass on the information to your treating doctors.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential.

Who is organising and co-ordinating the study?

The study is being co-ordinated by Gp Capt Alex Bennett, DMRC Stanford Hall.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time, and free to withdraw any of your data that has previously been collected from the study without having to give a specific reason, and this will not affect your future treatment in any way. We would just ask that if you do decide to withdraw from the study that you inform the research team. If you withdraw from the study then previous data collected from you will still be used in the research unless you specifically ask for it to be withdrawn.

Who will have access to my medical data?

By participating in this study you will be consenting, to members of the research team only, to be able to access your NHS medical records (via your NHS number), and military medical records.

What will happen to the samples and data you collect on me?

- Approximately 50mls of fasted blood will be taken via a venous puncture to measure full blood count, kidney and liver function, cholesterol and sugar levels. 20mls of blood will be stored for batch testing for levels of inflammation and for testing any future markers of cardiovascular or musculoskeletal disease that are not currently available but may be discovered in the next 20 years during the course of the study. 10mls of whole blood/plasma will also be stored for genetic analysis at later date.
- 50mls of urine will also be stored for testing of future markers of cardiovascular or musculoskeletal disease.
- The X-ray and DEXA images and all other data will be kept confidentially in secure filling systems. Experimental records, including paper records and computer files, will be held for a minimum of 15 years after the end of the study in conditions appropriate for the storage of personal information. You have right of access to your records at any time.
- If participants unexpectedly die during the 20 year study period their previously collected data will still be used in the study.
- The data collected in this study will strictly be used in this study and other related military medical studies only.

Who will get to see the information I give in the questionnaire and how will my information be stored?

Your information will be stored securely, and the answers you give in the questionnaires and other data we record will be stored separately to your personal details. Only the research team will have access to your data and questionnaire responses. We may share anonymised datasets with other research institutions, however, we will never share your questionnaire answers or other data linked with information that would identify you (i.e.your name or date of birth).

We may need to obtain additional details from your records to help our research. In order to do so, we may need to use your name, date of birth and NHS number to request your health and death records from central/national information centres (for example, your medical records if you have consented for us to do so). We will NOT pass any of your contact details (address, email address or phone number) to third parties.

Will I be exposed to large amounts of radiation from the x-rays or DEXA scans?

No you will not. The total dose of radiation that you will receive over the 6 visits over a 20 year period is very small (2.5mSv) and is equivalent to a maximum of 13 months background radiation based on the UK average.

The lifetime risk of fatal cancer for an effective dose of 2.5 mSv is approximately 1 in 8000 based upon the nominal risk coefficient for an adult published in the 2007 recommendations of the International Commission on Radiological Protection. This can be compared against the natural lifetime risk of fatal cancer of 1 in 3 to 1 in 4.

What will happen to the results of the research study?

Results of these studies will be published in scientific journals and presented at national and international medical meetings in an aim to improve international medical understanding and knowledge of the outcomes and potential treatment of battlefield trauma casualties. You may ask the Principal Investigator 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 2018. In no circumstances will any identifiable data be published.

What if I am unhappy with the conduct of the study or study staff?

An independent medical officer will be available throughout the study. Their sole function is to act independently of the study team to ensure your safety and wellbeing. They may terminate your participation in the trial on medical grounds at any time, and you may consult with him/her at any time.

What happens if I suffer any side effects as a result of the study?

Given the type and design of this trial, this is extremely unlikely; however, in the event of you suffering any adverse effects as a consequence of your participation in this study, you will be eligible to apply for compensation under the MoD's 'No-Fault Compensation Scheme' (see details attached).

What's new for the 3 year follow up?

Additional questionnaires have been added to the 3 year follow up (and future follow up visits) including questionnaires about foot and ankle injuries, generalised pain and specific types of pain and educational and social outcomes. In addition to the blood tests that were taken and stored at baseline, male hormone levels will also be measured at the 3 year follow up and at future follow up visits.

What is the National Health Service Central Register (NHSCR)?

This is a register for all patients in the UK. We will let the NHSCR know if you participate in the study. This is because in the highly unlikely circumstances of you dying during the study period over the next 20 years the NHSCR will inform us. This will prevent us trying to contact you for the next study follow up appointment.

Does this study have full ethical approval?

A full scientific protocol for this research has been approved by the Ministry of Defence Research Ethics Committee. This study complies, and at all times will comply, with the Declaration of Helsinki[1] as adopted at the 52nd WMA General Assembly, Edinburgh, October 2000 and with the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, (Strasbourg 25.1.2005). Please ask the Project Officer if you would like further details of the approval or to see a copy of the full protocol.

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For more information please call the study team on: 01509 251 500 ext 3408

Email: dmrc-advancestudyteam@mod.gov.uk

Thank you for taking time to read the information sheet, which you should keep for future reference.

[1] ***World Medical Association (2000) Declaration of Helsinki. Ethical principles for medical research involving human subjects. 52nd World Medical Association General Assembly, Edinburgh, Scotland October 2000.***

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 Directorate of Safety & Claims (DS&C) St. George's Court, 2-12 Bloomsbury Way, London, WC1A 2SH who may need to ask the Claimant to be seen by a MoD medical adviser.
3. DS&C 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, DS&C, 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 DS&C 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. DS&C 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.

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