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Post-deployment health screening of members of the United Kingdom Armed Forces: the POST study

Submission date
26/10/2011

Recruitment status
No longer recruiting

Registration date
23/12/2011

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
We do not know if asking military personnel about their mental health and offering advice (we call this screening) after a tour of duty is helpful. Some say that screening is a good thing and others think that it is not. So, we want to look at this to find out if it does work. We also want to see if just letting personnel know about where to get help works. Some people who take part will get tailored advice on their current mental health and whatever help they can get. Others will get only general advice. Both groups will be contacted again one year later to ask how they have been getting on.

Who can participate?
6,000 British Army and Royal Marines personnel just back from a tour of duty in Afghanistan are invited to take part in our study. Anyone who is part of this deployed force may be able to participate if selected into the study regardless of age, sex and their current health.

What does the study involve?
Our study will ask participants about their mental health after returning from Afghanistan. Participants will be split into one of two groups and fill in a questionnaire on a computer. The questionnaires are exactly the same, but after completion one group will be given tailored health advice on screen and one group will be given general advice only. We will ask both groups for permission to look at their medical and personnel records. We will look at the medical and personnel records of the two groups to see if there are any differences between them one year after completing the first questionnaire. All participants who agreed will be asked to fill out another questionnaire a year after completing the initial questionnaire. At the end of the study we want to find out if those who were given tailored advice about their mental health got better than those who did not. Participants can leave the study at any time without giving a reason. This will not affect their military career in any way.

What are the possible benefits and risks of participating?
We will find out whether screening personnel after a tour results in fewer people suffering mental health problems and whether people who got advice from our questionnaire did go on to

seek help and get better. This study will help the Armed Forces to decide whether a screening programme should be implemented to all personnel returning from deployment. Participants in the screening arm of the study will obtain health care tailored to their needs or receive reassurance that they are not having any mental health problems. We do not envisage any benefits to those in the control group, except that they will have the opportunity to think actively about their mental health. As with any study, for some people there is a small risk of harm in taking part. For example, a participant may be upset by the advice given in the questionnaire or upset at doing the questionnaire. Although the risk of harm is extremely small we do have an independent medical advisor that participants can contact by telephone or in writing if they have any concerns. The advisor's contact details are on the Information for Participants which is given to the participants to keep.

Where is the study run from?
We will visit military bases in the UK, Germany and Cyprus. The main centre for the POST study is at King's College London.

When is the study starting and how long is it expected to run for?
Recruitment started in November 2011. Data collection will end in July 2013 and the study is funded until September 2014. We are recruiting participants from November 2011 to August 2012.

Who is funding the study?
The study is funded by the United States Department of Defense.

Who is the main contact?
Professor Roberto Rona
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Contact information

Type(s)
Scientific

Contact name
Prof Roberto Rona

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PNM/10/11-112

Study information

Scientific Title
A cluster randomised controlled trial to assess and improve the effectiveness of post-deployment screening for mental illness in 6,000 members of the United Kingdom Armed Forces returning from deployment to Afghanistan

Acronym
POST

Study objectives
This trial will screen personnel for post-traumatic stress disorder (PTSD), depression, anxiety and alcohol misuse.
Survey the prevalence of post-concussion symptoms (PCS) and determine whether screening for PTSD and other mental health problems reduces the prevalence of PCS.

Hypotheses:
1. Assess whether a post-deployment screening programme for Post-Traumatic Stress Disorder (PTSD), depression, anxiety and alcohol misuse is effective in reducing morbidity from these conditions
2. Assess the subsequent health-seeking behaviour of those identified as cases in the intervention group compared to the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UK Ministry of Defence Research Ethics Committee, 30/03/2011, ref: 187/GEN/10
2. US Army Medical Research and Materiel Command Approval Memorandum, 08/04/2011, ref: 10049017, Award Number: W81XWH-10-1-0881
3. King's College Research Ethics Committee, 26/05/2011, ref: PNM/10/11-112

Study design
Cluster two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Post-traumatic stress disorder (PTSD), depression, anxiety, alcohol misuse and post-concussion symptoms (PCS)

Interventions
Participants in the intervention arm of the trial will be offered advice based on their responses to the following questionnaires:
1. PTSD checklist (PCL-C)
2. The Brief Patient Health Questionnaire-9 (PHQ-9)
3. The generalised anxiety disorder questionnaire (GAD)
4. The alcohol misuse test (AUDIT)

Advice to access welfare services:
Those with a PCL-C score of 40 to 49, PHQ-9 indicating other depressive syndrome, an anxiety score of 10 to 14 or an AUDIT score of 20 or over but without indication of alcohol related harm (10 or more) or alcohol dependence (5 or more) will be advised to seek help from a welfare /social worker/chaplaincy professional who is well aware of mental health issues.

Advice to access medical services:
Those with a PCL-C score of 50 or more, PHQ-9 indicating major depressive syndrome, those with a GAD score of 15 or more, or AUDIT indicating alcohol related harm or dependence will be recommended to seek further evaluation and care from the primary care centre (i.e. the Unit Medical Centre).

Advice to those who screened negative:
They will be told that based on the tests their mental health is fine, but if they have any concerns about their mental health they can talk with a welfare officer or a medical officer.

Those in the control group will be given general information only.

Intervention Type
Behavioural

Primary outcome measure
1. Is post-deployment screening for PTSD, depression, anxiety and alcohol misuse effective in reducing the morbidity (level of symptoms and functional impairment) from these conditions?
2. Does the subsequent help seeking behavior of those identified as possible cases in the screening group differ from that in the control group?
3. Are there side effects of the screening program in the intervention group in comparison to the control group?
4. Is a screening programme cost-effective?

Secondary outcome measures
1. We will ascertain the level of impairment and the change in status in the intervention and control groups
2. We will also measure post concussion symptoms (PCS) in the reassessment stage in the two groups to monitor the consequences of screening on the long term manifestations of mTBI

3. We will also measure changes in the score for each of the tests in the efficacy assessment as a complementary analysis, but not as a primary outcome, to assess whether the change has been greater in the intervention than the control group
4. As a complementary aim of the study we will carry out a small survey to assess the attitudes of welfare and health professionals towards a screening program

Overall study start date
01/11/2011

Completion date
30/09/2014

Eligibility

Key inclusion criteria
Healthy volunteers from the Armed Forces who have recently returned from deployment in Afghanistan

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
6,000

Key exclusion criteria
1. Platoons which act as such only during deployment and disperse at reintegration
2. Platoons whose size is below 20
3. Special Forces
4. Those who have deployed for less than 30 days

Date of first enrolment
01/11/2011

Date of final enrolment
01/08/2012

Locations

Countries of recruitment
Cyprus

England

Germany

United Kingdom

Study participating centre
King's Centre for Military Health Research
London
United Kingdom
SE5 9RJ

Sponsor information

Organisation
King's College London (UK)

Sponsor details
The Strand
London
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
United States Army Medical Research and Materiel Command (USA) ref: W81XWH-10-1-0881

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/04/2017		Yes	No