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Standardised stress management mental health training: does it have a beneficial effect?

Submission date	Recruitment status	[ ] Prospectively registered
06/09/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/10/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2017	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Open randomised controlled trial examining whether a standardised stress management mental health training package is an effective tertiary stress intervention in full time military personnel

Study objectives

The aim of this project is to examine whether a standardised stress management mental health training package (delivered over a 6-hour period to a group of up to 10 participants at a time) is an effective tertiary stress intervention in full time military personnel.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ministry of Defence Research Ethics Committee, 30/06/2010, ref: 101/Gen/09

Study design
Single-centre open randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adjustment disorders, mild depression

Interventions
1. Intervention arm:
The standardised Stress Management Mental Health Training package will be delivered over a 6 hour period to up to 10 participants at a time by two Community Mental Health Nurses (CMHNs) based at the Department of Community Mental Health at RAF Brize Norton. The CMHNs will receive standardised training in presenting the Mental Health Training package from a Consultant Psychiatrist. The effectiveness of the standardised training will be verified by documented feedback about the training from the CMHN's and by validation of the standardised intervention by 3 monthly assessment of the standardised intervention by the Consultant Psychiatrist. The content of the standardised Mental Health Training package will consist of a PowerPoint presentation using a standard set of presentation slides, followed by 'break out' sessions allowing smaller group discussion of specific stress related issues. The Mental Health Training package is then concluded with brief relaxation training to help participants manage their stress related symptoms. Concordance to any intervening prescription drugs, psychotropic over the counter (OTC) and psychological treatments will be measured at each study visit by means of a clinical interview with the participant and the results recorded in the Case Report Form (CRF). Those subjects without any changes to their intervening prescriptions or receiving any alternative psychological treatments will be put into the intent-to-treat analysis.

2. Control arm:
Those that do not get the intervention will be allocated to a waiting list to be seen by the clinician who recruited the participant 6 weeks and 3 months post recruitment. No active treatment will be given to waiting list participants during the trial but will be offered after the trial period has ended (visit 5). The usual waiting time for non study patients to be seen for Standardised Stress Management Mental Health Training is currently in excess of 3 months and it is not envisaged that those participants who do participate in the study who do not get the intervention will have their treatment delayed.

Follow up will be at 6 weeks (visit 3) and 3 months (visit 4) with a further psychiatric clinical interview and further outcome measures using the GHQ-28, Beck Depression Inventory (BDI-II), Beck Anxiety Inventory (BAI) and the Clinical Global Impression (CGI). The rater of the CGI will be blinded to the other rating scores as this will be carried out prior to the participant's completion of the other rating scales. Follow up clinical interviews will record the occurrence of stressful events in the interim.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
General Health Questionnaire-28 score recorded as a continuous variable.
All outcomes will be assessed at the start of the trial (visit 2), 6 weeks (visit 3) and 12 weeks (visit 4).

Key secondary outcome(s))
1. Beck Depression Inventory (BDI-II),
2. Beck Anxiety Inventory (BAI)
3. Clinical Global Impression (CGI)
All outcomes will be assessed at the start of the trial (visit 2), 6 weeks (visit 3) and 12 weeks (visit 4).

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Aged ≥18 years, either sex (though mainly male due to military demographics)
2. Suffering from adjustment disorder or mild depression

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Flying phobia
2. Post-traumatic stress disorder (PTSD)
3. More severe depressive disorders
4. Psychosis
5. Alcohol disorders

Date of first enrolment
01/09/2010

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
29 Chavenage Lane
Tetbury
United Kingdom
GL8 8JT

Sponsor information

Organisation
Ministry of Defence (UK)

ROR
https://ror.org/01bvxzn29

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration