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A novel internet-based self-help intervention for anger in armed forces veterans and civilians

Submission date
11/10/2017

Recruitment status
No longer recruiting

Registration date
12/10/2017

Overall study status
Completed

Last Edited
26/03/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anger is a common and normal emotion. However, it can become problematic if it becomes more frequent, more intense, or harder to control. Anger can cause distress and have negative effects on family, friends and jobs. However, there are few widely available treatments for anger available. This study aims to test a self-help internet-based treatment for anger, specifically prepared for armed forces veterans.

Who can participate?
Armed forces veterans from the UK or members of the general population who report elevated levels of anger

What does the study involve?
Participants are randomly allocated to one of two groups: the intervention group and the wait-list group. Participants in the intervention group are given access to the self-help internet-based treatment immediately and can work through the intervention at their own pace, although it is recommended that they complete one module per week. Follow-up questionnaires are completed at 12 weeks and 3 months. Participants in the control group are informed that they will be able to access the trial after a 12-week wait period, with questionnaires again completed at 12 weeks and 3 months. Participants have 12 weeks to complete the intervention with final follow-up at 3 months.

What are the possible benefits and risks of participating?
It is hoped that the internet-delivered CBT self-help will help participants by reducing their symptoms of anger and providing access to the latest techniques to treat anger. A small study using the techniques used in this study found positive results. However, it cannot be guaranteed that this self-help will help. The information from this study may help to improve the treatment of future patients with anger by making self-help more effective and more widely available. If anyone in the study shows signs of worsening symptoms then they are signposted to appropriate help, with their GP contacted in the event that risk is reported. Being part of this study will involve participants giving their time to complete the questionnaires and the exercises included in the program on multiple occasions. Some of the questions are personal and sometimes people can find it upsetting to report on these issues, but they do not have to

provide answers if they do not want to. Most people find that any upset or distress is short-lived and on a par with events that typically happen in daily life. It is possible that the internet self-help will not work. If this is the case, then participants can still talk to their GP about other options that may be offered in their area. There are no other known side effects, disadvantages, or risks of taking part in this study or receiving internet-delivered CBT.

Where is the study run from?
University of Exeter (UK)

When is the study starting and how long is it expected to run for?
September 2017 to May 2018

Who is funding the study?
1. University of Exeter (UK)
2. Help for Heroes (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Anger RCT 1.1

Study information

Scientific Title
Developing and evaluating an internet-based self-help intervention for anger in armed forces veterans: a randomised controlled feasibility trial

Study objectives
The primary aim of this randomised controlled trial will be to test the feasibility of an internet-based unguided self-help intervention for anger in armed forces veterans (and as necessary community individuals) reporting elevated anger issues compared to a wait list control (WLC). The areas to be addressed will include the acceptability of an internet intervention for anger in this population, the recruitment and retention rate, and estimates of incident rate and effect size. The goal is to work towards a definitive randomised controlled trial to provide strong causal inference of the effect size of the intervention: as such, the feasibility study will use the same design and will provide a proof-of-principle test of the value of this approach. The wait list control will be given access to the intervention after twelve weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. CLES Psychology Ethics Committee, 06/10/2017, ref: eCLESPsy000034 v4.1
2. CLES Psychology Ethics Committee, 15/02/2018, ref: eCLESPsy000034 v8.1

Study design
Single-centre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

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
Anger

Interventions
Participants will be randomised via stratified block randomisation. Following screening participants identified as eligible to take part in the study will be randomised to one of two groups: the intervention group and wait-list group. Participants in the intervention group will be given access to the intervention immediately and can work through the intervention at their own pace, although it is recommended that they complete one module per week. Follow-up

measures will be administered at 12 weeks and 3 months. Participants in the control group will be informed that they will be able to access the trial after a 12 week wait period, with measures again completed at 12 weeks and 3 months. Participants will have 12 weeks to complete the intervention with final follow-up at 3 months.

The internet intervention is based on a novel anger-as-a-habit intervention that is being trialled by the Hidden Wounds service at Help for Heroes. The intervention posits that anger is a result of habitual behaviour and that changing habits might be beneficial for individuals experiencing anger (Gentry, Chesney, Kennedy, Hall, Gary Jn & Harburg, 1983). It builds on the principle that a habit is formed through 3 key factors; the behaviour is repeated, it is an automatic response and that it is cued by stable contexts, and that through this repetition a habit is formed and reinforced (Orbell & Verplanken, 2010). The intervention encourages participants to break into the habit cycle through the use of implementation interventions to replace the existing angry response to a situation with an alternate response that stops the reinforcement of their anger.

Intervention Type
Behavioural

Primary outcome measure
The feasibility and acceptability of data collection procedures, levels of attrition, effect size and the acceptability of the unguided anger intervention will be measured to aid planning for a fully powered, definitive, phase III trial:
1. The feasibility of data collection procedures is assessed by measuring the missing items on the clinical outcome measures, the number and timing of drop-outs and whether these vary across arms
2. The acceptability of the intervention is assessed using a behavioural index measuring the number of modules completed, the time spent logged into the site and which modules are completed more easily or frequently than others

Secondary outcome measures
1. Depression, measured using PHQ-9 at baseline, final module, 12 weeks and 3 months follow-up
2. Anger, measured using NAS-PI at baseline, final module, 12 weeks and 3 months follow-up
3. PTSD symptomatology, measured using PCL at baseline, 12 weeks and 3 months follow-up
4. Anger, measured using DAR in each intervention module and final module

Updated 26/03/2018: The DAR will now be used to measure levels of anger throughout the study.

Overall study start date
01/09/2017

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Armed forces veterans from the UK or members of the general population who report elevated levels of anger represented by a score of ≥75 on the NAS-PI provocation subscale (Novaco, 2003). This measure has been selected as it identifies individuals experiencing levels of anger that are higher than those experienced in a general population which is indicative of

problematic anger
2. Aged 18+
3. Individuals who have accessed the Help for Heroes Hidden Wounds service or community based advertising and who screen as eligible for inclusion in the study
4. Participants will primarily be armed forces veterans as described under the British definition of a veteran 'Those who have served for at least one day in HM Armed Forces, whether as a regular or reservist' (Ministry of Defence, 2013). With members of the general public recruited as necessary to meet recruitment targets as long as they meet the other eligibility criteria
5. In addition to this the participants must be able to understand written English and have access to a private internet connection to ensure they are able to give informed consent, engage with the intervention and ensure their confidentiality when engaging with the intervention

Updated 26/03/2018: A DAR score of ≥23 will be used rather than the NAS-PI.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Participants will be excluded from the study if:
1. They are actively serving members of the armed forces
2. Under the age of 18
3. They report elevated symptoms of post-traumatic stress disorder on the Posttraumatic Stress Disorder checklist (PCL; Weathers, Litz, Keane, Palmieri, Marx, Schnurr, 2013) indicated by a score of ≥50 (the recommended cut off score)
4. They report suicidal ideation measured using the PHQ-9 (Kroenke, Spitzer & Williams, 2001) question 9 and risk protocol follow up questions
5. They report moderately severe levels of depression on the PHQ-9 (Kroenke, Spitzer & Williams, 2001)

Date of first enrolment
01/10/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Exeter
Sir Henry Wellcome Building for Mood Disorders Research
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Sponsor information

Organisation
University of Exeter

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Sponsor type
University/education

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
University/education

Funder Name
University of Exeter

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Help for Heroes

Results and Publications

Publication and dissemination plan
1. A trial protocol paper is being compiled with the intention to publish this in an academic journal making it widely available. The data analysis intentions will be included in this.
2. The RCT will form part of Luke O'Shea's PhD thesis with the intention to also publish it in a peer reviewed academic journal.

Intention to publish date
31/05/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date