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Military motion-assisted memory desensitization and reconsolidation for treatment resistant post traumatic stress disorder in military veterans

Submission date
16/02/2017

Recruitment status
No longer recruiting

Registration date
23/02/2017

Overall study status
Completed

Last Edited
23/08/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Around 4% of British military veterans suffer from post-traumatic stress disorder (PTSD). PTSD is an anxiety disorder caused by very stressful, frightening or distressing events. Psychological therapy with a focus on the traumatic event is the treatment of choice for PTSD and can be very helpful but, unfortunately, treatment resistance (inadequate response to treatment) is high. There is an urgent need to find effective treatments for military veterans who do not respond to, or are unable to engage with, current first-line treatments. Modular motion-assisted memory desensitisation and reconsolidation (3MDR) is a new treatment that is based on the principles of existing trauma-focused treatments in a new context in which the patient walks on a treadmill whilst interacting with a series of self-selected images that are displayed on a large screen. It aims to help patients learn how to move through their avoidance by, literally, approaching their traumatic memories. The aim of this study is to find out whether 3MDR can help British military veterans with PTSD who have not responded to the current first-choice treatment for PTSD.

Who can participate?
Veterans with PTSD, aged 18 or over, who have not benefitted from trauma-focused psychological treatment

What does the study involve?
Participants' symptoms of PTSD, depression, anxiety and functioning are assessed and they are randomly allocated to receive either 3MDR immediately or after a delay of 12 weeks. The assessments are repeated at the end of treatment and four weeks later. The 3MDR is delivered weekly over six weeks by experienced psychological therapists. An evaluation of the process of 3MDR treatment is also undertaken by collecting information during the 3MDR sessions and by interviewing therapists and participants regarding their experiences.

What are the possible benefits and risks of participating?
Participants may benefit from a treatment that helps reduce their symptoms of PTSD. As with

any trauma-focused therapy, there is a risk of increased distress when considering the traumatic experiences.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
January 2017 to August 2019

Who is funding the study?
Forces In Mind Trust (FIMT) (UK)

Who is the main contact?
1. Prof. Jonathan Bisson (scientific) (bissonji@cf.ac.uk)
2. Miss Kali Barawi (public) (barawik1@cf.ac.uk)

Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SPON 1546-16

Study information

Scientific Title
Phase II randomised controlled trial of military motion-assisted memory desensitization and reconsolidation for treatment resistant post traumatic stress disorder in military veterans

Acronym
3MDR for TRPTSD

Study objectives
3MDR (Military Motion-Assisted Memory Desensitization and Reconsolidation) will reduce symptoms of PTSD (Post Traumatic Stress Disorder) in British military veterans with treatment-resistant, combat-related PTSD to a significantly greater degree than a waiting list.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 3, 14/02/2017, ref: 17/WA/0005

Study design
Exploratory single-blind randomised parallel group controlled trial with nested mechanistic and process evaluation to assess fidelity, adherence and factors that influence outcome

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Treatment-resistant post traumatic stress disorder

Interventions
An experienced researcher blind to randomisation will conduct all assessments. The initial assessment will ensure that the inclusion criteria are satisfied. Demographic and other background data will be collected along with completion of all the outcome measures. Participants will then be asked to monitor their symptoms for two weeks. The baseline assessment of all the outcome measures will occur after this; those who continue to fulfil the inclusion criteria will be randomised (computer generated via a trials unit) to one of the two groups:
1. The 3MDR therapy delivered weekly over nine weeks (two weeks preparation, six weeks 3MDR and one concluding session) by experienced psychological therapists, trained in 3MDR and supervised by its originators, who work with Veterans' NHS Wales and Cardiff University.
2. The waiting list group receive no intervention for 12 weeks post-randomisation and then receive 3MDR over nine weeks.

Follow up will occur 12 and 26 weeks after randomisation. This will involve re-administration of all the outcome measures. At 26 weeks participants will be asked to participate in semi-structured interviews to elicit their experience and views of the programme. Progress will be monitored with the IES-R, PHQ-9 and GAD-7 at each treatment session.

Intervention Type
Other

Primary outcome measure
Symptoms of PTSD, measured using the Clinician Administered PTSD Scale for DSM5 (CAPS5) at baseline, 12 and 26 weeks

Secondary outcome measures
1. Traumatic stress, measured using the Impact of Event Scale – revised
2. Quality of life/functional impairment, measured using the Work and Social Adjustment Scale
3. Depression, measured using the Patient Health Questionnaire-9 (PHQ-9)
4. Anxiety, measured using General Anxiety Disorder-7 (GAD-7)
5. Alcohol use, measured using AUDIT-O36
6. Changes in sleep, measured using the insomnia severity index (ISI)
7. Perceived social support, measured using the Multidimensional Scale for Perceived Social Support
8. Health-related quality of life, measured using the EQ5D-5L
All measured at baseline, 12 and 26 weeks

Overall study start date
02/01/2017

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Informed consent
3. Meet DSM529 criteria for combat-related PTSD
4. Treatment resistance, defined as prior receipt of a trauma focused psychological treatment without loss of PTSD diagnosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Total final enrolment
42

Key exclusion criteria
1. Psychosis
2. DSM5 severe major depressive episode
3. Substance dependence
4. Change in psychotropic medication within 1 month
5. Suicidal intent
6. Inability to walk at a normal pace for 30-45 minutes on a treadmill

Date of first enrolment
01/04/2017

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff and Vale Health Board
Monmouth House
University Hospital of Wales
Heath Park Campus
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Abertawe Bro Morgannwg University Health Board
71 Quarella Road
Bridgend
United Kingdom
CF31 1YE

Study participating centre
Aneurin Bevan University Health Board
Talygarn County Hospital
Coed-Y-Gric Road
Pontypool, Gwent
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NP4 5YA

Study participating centre
Cwm Taf University Health Board
Maritime Resource Centre
Woodland Terrace
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Forces In Mind Trust (FIMT)

Results and Publications

Publication and dissemination plan
The trial results will be publicised through social media. The trialists have experience of successfully engaging local and national media and will work with the National Centre for Mental Health (NCMH) communications team to formulate strategies for press releases and the dissemination of findings through newspaper articles, television and radio features. Study outcomes will be presented to the academic community at national and international conferences by means of oral presentation, poster presentation, and interactive workshops. The trialists will target conferences likely to be attended by large numbers of therapists and managers working in IAPT and other primary and secondary care NHS psychological treatment services across the UK. They will also disseminate to the third sector and other services likely to deal with individuals with PTSD who could potentially benefit from treatment (e.g. the UK veteran mental health charity Combat Stress). The aim is to publish the results in high impact open-access, peer reviewed journals such as the British Journal of Psychiatry. The trialists expect at least two high impact peer reviewed publications and three conference presentations.

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Jon Bisson (bissonji@cf.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2020	16/09/2020	Yes	No
Protocol file	version 6	14/06/2018	23/08/2022	No	No
HRA research summary			28/06/2023	No	No