

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	☒ Prospectively registered ☒ Protocol
Registration date 23/02/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/08/2022	Condition category Mental and Behavioural Disorders	☐ 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

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Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
Talgarn 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
Maesycod
Pontypridd
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CF37 1DZ

Sponsor information

Organisation
Cardiff University

ROR
<https://ror.org/03kk7td41>

Funder(s)

Funder type
Charity

Funder Name
Forces In Mind Trust (FIMT)

Results and Publications

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
HRA research summary	version 6	14/06/2018	28/06/2023	No	No
Protocol file			23/08/2022	No	No