

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

<b>Submission date</b> 16/02/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/08/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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)**  
Scientific

**Contact name**  
Prof Jonathan Bisson

**ORCID ID**  
<http://orcid.org/0000-0001-5170-1243>

**Contact details**  
Cardiff University  
Hadyn Ellis Building  
Maindy Road  
Cathays  
Cardiff  
United Kingdom  
CF24 4HQ  
+44 (0)292 068 8321  
bissonji@cf.ac.uk

**Type(s)**  
Public

**Contact name**  
Miss Kali Barawi

**Contact details**  
Cardiff University  
Hadyn Ellis Building  
Maindy Road  
Cathays  
Cardiff  
United Kingdom

CF24 4HQ  
+44 (0)292 068 8321  
barawik1@cf.ac.uk

## **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**  
Talgarn County Hospital  
Coed-Y-Gric Road  
Pontypool, Gwent  
United Kingdom  
NP4 5YA

**Study participating centre**  
**Cwm Taf University Health Board**  
Maritime Resource Centre  
Woodland Terrace  
Maesycod  
Pontypridd  
United Kingdom  
CF37 1DZ

## **Sponsor information**

**Organisation**  
Cardiff University

**Sponsor details**  
Research and Innovation Services  
7th Floor

McKenzie House  
30-36 Newport Road  
Cardiff  
Wales  
United Kingdom  
CF24 0DE  
+44 (0)29 2087 9277  
falconerhe@cardiff.ac.uk

**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?
<a href="#">Results article</a>	results	01/08/2020	16/09/2020	Yes	No
<a href="#">Protocol file</a>	version 6	14/06/2018	23/08/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No