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Comparing remote and face-to-face delivery of eye movement desensitisation and reprocessing (EMDR) therapy for post-traumatic stress disorder in military veterans

Submission date
17/08/2022

Recruitment status
Stopped

Registration date
30/09/2022

Overall study status
Stopped

Last Edited
07/12/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Eye movement desensitization and reprocessing (EMDR) is a type of therapy used for post-traumatic stress disorder (PTSD). By encouraging patients to focus on a traumatic memory while simultaneously receiving stimuli in a rhythmic left-right pattern, such as eye movements, the therapy has been associated with a reduction in traumatic stress symptoms. The main aim of the proposed research is to determine whether remotely delivered EMDR has the potential to reduce traumatic stress symptoms in British military veterans with combat-related PTSD.

Who can participate?
Adult patients who meet specific criteria for combat-related PTSD

What does the study involve?
This is an exploratory study to assess fidelity, adherence and factors that influence the outcome. All treatment will be delivered through Veterans' NHS Wales. Face-to-face treatment will occur in usual clinics; remote treatment will take place via Attend Anywhere. All recruitment and research interviews will be undertaken remotely.

The main aim of the proposed research is to determine whether remotely delivered EMDR has the potential to reduce traumatic stress symptoms in British military veterans with combat-related PTSD.

The main objective is to answer the following research questions:
1. For British military veterans with combat-related PTSD, does remotely delivered EMDR reduce symptoms of PTSD to a significantly greater degree than a waiting list?
2. For British military veterans with combat-related PTSD, does remotely delivered EMDR reduce symptoms of PTSD to a similar degree as face-to-face delivered EMDR?
3. For British military veterans with combat-related PTSD, what is the impact of remotely delivered EMDR on quality of life, functioning, symptoms of depression, symptoms of anxiety,

insomnia, alcohol and illicit substance use, and perceived social support?
4. Is remotely delivered EMDR acceptable to British military veterans with combat-related PTSD and those delivering the intervention?
5. What is the likely effect size of remotely delivered EMDR?
6. What factors may impact the effect and successful roll-out of remotely delivered EMDR for combat-related PTSD, if it is shown to be effective?
7. Can the results from this study be used in the planning of a phase III definitive trial?
8. Is a phase III study advisable and feasible?

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
Cardiff University (United Kingdom)

When is the study starting and how long is it expected to run for?
July 2021 to August 2024

Who is funding the study?
1. Health and Care Research Wales (United Kingdom)
2. TEC Cymru (United Kingdom)

Who is the main contact?
Prof Jonathan Bisson (United Kingdom)
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
301730

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPON1872-21, IRAS 301730, CPMS 54173

Study information

Scientific Title
Feasibility randomised controlled trial of remotely delivered eye-movement desensitisation and reprocessing (EMDR) versus face-to-face EMDR for post-traumatic stress disorder (PTSD) in military veterans

Study objectives
The study proposes that remotely delivered eye-movement desensitisation and reprocessing (EMDR) has the potential to reduce traumatic stress symptoms in British military veterans with combat-related PTSD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2022, Wales Research Ethics Committee 5 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)1686 252101, +44 (0)2920 230457, +44 (0)7920 565664; Wales.REC5@wales.nhs.uk), ref: 22/WA/0062

Study design
Exploratory single-blind randomized parallel-group-assigned controlled trial

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
Combat-related post-traumatic stress disorder (PTSD)

Interventions

Study design:
The study will be an exploratory single-blind randomised parallel group controlled trial with nested process evaluation to assess fidelity, adherence and factors that influence the outcome.

Setting:
All treatment will be delivered through Veterans' NHS Wales. Face-to-face treatment will occur in usual clinics; remote treatment will take place via Attend Anywhere. All recruitment and research interviews will be undertaken remotely.

Sample size:
A standard power calculation is not appropriate for a Phase II exploratory trial but, based on previous research, we believe that a sample size of 20 per group will be sufficient to allow us to achieve our objectives.
For the qualitative arm of the study, the sample size will be guided by preliminary analysis and constant comparison (comparing and contrasting themes from other interviews) during each data collection phase, until the research team is satisfied that there is data saturation and no new themes which are important to the research question arise.
However, it is helpful to have a guide to sample size for study planning. Based on previous research, we propose that interviews will be conducted with around 10 participants who receive treatment remotely, purposively sampled, and all therapists.

Groups:
1. Eye-movement desensitisation and reprocessing (EMDR) delivered remotely
2. Eye-movement desensitisation and reprocessing (EMDR) delivered face-to-face
3. Waiting list

Intervention Type

Behavioural

Primary outcome measure

Diagnosis and severity of PTSD measured using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at baseline, 20 and 40 weeks after randomisation

Secondary outcome measures

1. Presence and severity of PTSD symptoms measured using the PTSD Checklist (PCL) at baseline, 20 and 40 weeks after randomisation
2. Core symptoms of PTSD and complex PTSD measured using the International Trauma Questionnaire (ITQ) at baseline, 20 and 40 weeks after randomisation
3. Impairment in functioning measured using the Work and Social Adjustment Scale (WSAS) at baseline, 20 and 40 weeks after randomisation
4. Severity of depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 20 and 40 weeks after randomisation
5. Severity of generalised anxiety disorder (GAD) measured using the GAD-7 assessment at baseline, 20 and 40 weeks after randomisation
6. Alcohol harm measured using the Alcohol Use Disorders Test (AUDIT-O) at baseline, 20 and 40 weeks after randomisation
7. Nature, severity, and impact of insomnia measured using the Insomnia Severity Index (ISI) at baseline, 20 and 40 weeks after randomisation

8. Health-related, quality of life measured using the EQ5D-5L at baseline, 20 and 40 weeks after randomisation
9. Digital skills measured using a Digital Ability questionnaire at baseline

Overall study start date
01/07/2021

Completion date
29/08/2024

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Informed consent
3. Meet DSM5 criteria for combat-related PTSD
4. Access to stable internet access in a private location

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Psychosis
2. DSM5 severe major depressive episode
3. Substance dependence
4. Change in psychotropic medication within one month
5. Suicidal intent

Date of first enrolment
10/10/2022

Date of final enrolment
19/08/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff & Vale University Health Board
University Hospital of Wales,
Heath Park,
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Swansea Bay University Local Health Board
One Talbot Gateway, Seaway Drive
Seaway Parade Industrial Estate
Baglan
Port Talbot
United Kingdom
SA12 7BR

Study participating centre
Cwm Taf Morgannwg University Local Health Board
Dewi Sant Hospital
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre

Aneurin Bevan University Lhb
Headquarters - St Cadoc's Hospital
Lodge Road
Caerleon
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United Kingdom
NP18 3XQ

Sponsor information

Organisation
Cardiff University

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Sponsor type
University/education

Website
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ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Llywodraeth Cymru TEC Cymru

Alternative Name(s)
Welsh Government, The Welsh Government

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Dissemination will start at the beginning of the project; early activities will include finalising a strategic dissemination plan, promotion and awareness raising. Findings will be disseminated widely using a variety of tailored methods targeting specific audiences. A summary report of trial results written in lay-language will be sent to study participants and other key stakeholders. We will hold a participant-centred meeting at the end of the study to present the results orally and allow time for questions and clarification. We will send reports of trial results to NHS commissioners and disseminate the findings publicly through news items on the Veterans' NHS Wales and National Centre for Mental Health (NCMH) websites.

We will publicise the trial through social and local media not for recruitment but to inform the public that the trial is running. We have experience of successfully engaging local and national media and will work with the 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. We 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. We 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). We aim to publish the results in high impact open-

access, peer reviewed journals. We expect at least two high impact peer reviewed publications and three conference presentations.

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the National Centre for Mental Health (NCMH)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No