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Virtual-reality based treatment for Canadian armed forces members with combat-related post-traumatic stress disorder (PTSD)

Submission date
29/01/2019

Recruitment status
Recruiting

Registration date
06/02/2019

Overall study status
Ongoing

Last Edited
13/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Trauma-focused psychotherapies are often utilized to facilitate trauma processing and post-traumatic growth. Multi-modal motion-assisted memory desensitization and reconsolidation (3MDR) therapy is an innovative, personalized virtual-reality-supported psychotherapy initially developed in the Netherlands to treat military members and veterans combat-related PTSD (cr-PTSD). 3MDR also holds promise for treating trauma and related conditions among public safety personnel (PSP) and health care providers (HCPs) who face numerous physically and mentally stressful events in the line of duty and civilians. This study will allow researchers to examine the effect of 3MDR therapy on PTSD symptoms of Canadian Armed Forces (CAF) service members (SMs) with chronic cr-PTSD who do not benefit from other therapies, and trauma-affected PSPs, HCPs and civilians.

Who can participate?
CAF SMs with chronic cr-PTSD, PSP, HCPs and civilians who meet specific inclusion/exclusion criteria may participate in this study.

What does the study involve?
Participants will be randomly assigned to a 3MDR group (treatment group) or control group (treatment as usual (TAU) group). For the treatment group, 2 introductory sessions will be followed by 6-10 weekly 3MDR sessions and 2 reconsolidation sessions. The control group will initially receive treatment as usual for 6 weeks, and then 6-10 sessions of 3MDR.

What are the possible benefits and risks of participating?
The nature of the intervention is such that participants will be exposed to a potentially triggering stimulus indicative of a time in their life that triggered their PTSD symptoms. Based on the emerging evidence base around utilizing 3MDR and interventions for PTSD utilizing virtual reality, there is a chance that the participants will see improvements in their PTSD symptoms, overall functioning, and quality of life. Since this is an engaging innovative technology, it is possible that adherence to this intervention could be better than traditional psychotherapeutic interventions.

Where is the study run from?
University of Alberta, 1-94 Corbett Hall, 8205 - 114 Street, Edmonton, AB Canada T6G 2G4

When is the study starting and how long is it expected to run for?
March 2019 to March 2028

Who is funding the study?
Department of National Defence, Royal Canadian Legion, First Response to Fashion, Government of Alberta, Glenrose Rehabilitation Hospital Foundation

Who is the main contact?
Suzette Bremault-Phillips, suzette2@ualberta.ca

Study website
http://3mdr.ca/

Contact information

Type(s)
Scientific

Contact name
Mrs Suzette Bremault-Phillips

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Canada
T6G 2G4

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Pro00084466/RES0042203

Study information

Scientific Title
Multi-modal virtual-reality based (3MDR) treatment for Canadian armed forces members with combat-related post-traumatic stress disorder: a computer-assisted rehabilitation environment (CAREN) waitlist controlled staggered entry study

Acronym
3MDRCAREN

Study objectives
Participants' symptoms of PTSD will decrease during the 3DMR therapy utilizing the CAREN system intervention compared with treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/01/2019, Health Research Ethics Board Biomedical Panel, University of Alberta (308 Campus Tower, University of Alberta, Edmonton, AB, T6G 1K8; +1 780 492 9724; reoffice@ualberta.ca), ref: 00084466

Study design
Wait-list-controlled staggered-entry cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

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 combat PTSD

Interventions
Participants will be randomized to the 3MDR or Treatment as Usual (TAU) groups in a parallel design. Random assignment will be done on a 1:1 basis by a computer program, with a weighted maximum of subscribing three times the same condition in a row. An arms-length research assistant will randomly assign and keep a confidential log of all participants assigned to either 3MDR or TAU treatment.

Prior to beginning 3MDR treatment sessions, participants will undergo a baseline assessment. The baseline assessment will include a series of outcome measures collected online using

REDCap, baseline blood and saliva samples, and a semi-structured interview, all of which aim to gather information about the severity of PTSD symptoms, anxiety and depression symptoms, alcohol use, quality of life, social functioning, avoidance behavior, expectations of the intervention and level of neurofunctioning. Responses to questionnaires will be securely captured and stored online using RedCap, a secure, web-based application for building and managing online research projects. (REDCap is built and supported by a team at Vanderbilt University and is licensed by the Women and Children's Health Research Institute on behalf of the University of Alberta). In addition to baseline and follow up data collection using the aforementioned outcome measures, measures will be routinely administered in the course of the intervention (e.g., the SUD and PDEQ) or as needed for monitoring purposes. Participant responses will be securely collected and stored on REDCap's secure server. Walking and eye scanning patterns, as well as physiological data, will be collected during the training session through the CAREN system, Tobii Mobile Eye -tracking glasses, and Zephyr BioHarness 3. Video-recording of the session will capture qualitative data associated with the exchange between the therapist and participant in the course of the 3MDR session.

Intervention Group. All participants in the Intervention Group will undergo seven main assessments* and 5 smaller in session assessments**:
*baseline assessment to determine if inclusion criteria are met (T0, week 1)
*one assessment at first 3MDR session (T1.1, week 4)
**five in-session assessments (T1.2-1.6, week 5 to 9)
*one post-intervention assessment (T2, week 10)
*one assessment sixteen weeks (T3)
*one assessment at 3 months (T4)
*one assessment at 6 months (T5)
*one assessment at 12 months (T6)

Control Group. The Control Group will receive the same baseline assessment at T0 as the intervention group, followed by 10 weeks of TAU while the intervention group is receiving the 3MDR intervention. Both the control and interventions groups will undergo a post-intervention assessment at week 10 (T2). Following the T2 assessment, participants in the control group will be provided with an opportunity to receive the 3MDR intervention, crossing over into the Intervention Group at that point. Assessments for the control group crossing over into the intervention group will be as follows (Figure 2):
*baseline assessment (T0, week 1)
*one assessment after 10 weeks TAU (T0-1, week 10)
*one assessment at first 3MDR session (T1.1, week 4)
**five in-session assessments (T1.2-1.6, week 5 to 9)
*one post-intervention assessment (T2, week 10)
*one assessment sixteen weeks (T3)
*one assessment at 3 months (T4)
*one assessment at 6 months (T5)
*one assessment at 12 months (T6)

Participants in the Control Group who do not wish to participate in the 3MDR intervention, will undergo the following assessments:
*baseline assessment (T0, week 1)
*one assessment after 10 weeks TAU (T0-1, week 10)
*one assessment sixteen weeks (T3)
*one assessment at 3 months (T4)
*one assessment at 6 months (T5)
*one assessment at 12 months (T6)

Prior to initiating the 3MDR, the participant will have 2 introductory sessions for the purpose of transfer of trust from their attending mental health therapist to the research therapist as well as an introduction to the CAREN. In preparation of 3MDR treatment sessions, participants will come to the Glenrose Hospital to become accustomed to the CAREN system by practising simple standing and walking tasks. Participants will wear a safety harness at all times when in the CAREN system. The harness is secured to the CAREN safety support attachment so that participants do not fall to the ground during a potential stumble. The CAREN system operator will explain all safety procedures during this session. Also, the participant will be asked to bring an array of pictures from their deployment. This can include all material that induced strong memories of the deployment, including letters or decorations. With their therapist, the participant will select the pictures and rank the pictures from lowest to highest affect. The participant will also be asked to bring two digital music tracks: 1 song that reminds the participant of their deployment and 1 song that provides positive feelings.

One week after the initial assessment and introductory sessions, the 3MDR therapy will be initiated.
After arriving for the first of six 3MDR sessions, a physiological monitor will be secured to the participant via a chest strap (Zephyr Bioharness 3). Participants will also be fitted with the CAREN safety harness. At the beginning of each treatment session, the study participant will walk on a level treadmill at a comfortable, fast pace for five minutes while music that reminds the participant of their deployment will be played. Afterwards, a repetitive cycle will start. This cycle has three phases (described below) evolving around one of the deployment-related photographs with high emotionality that are projected on the screen. The emotionality of the stimulus will increase with each cycle. Blood and saliva samples will be procured at the beginning of each 3 MDR sessions.This will be completed by a certified Alberta Health Services Phlebotomist or research nurse. This will take place before and after the 3MDR CAREN intervention. Walking and eye scanning patterns, as well as physiological data will be collected during the training session through the CAREN system, Tobii Mobile Eye -tracking glasses, and Zephyr BioHarness 3. Video-recording of the session will capture qualitative data associated with the exchange between the therapist and participant in the course of the 3MDR session. After each session, the therapist and patient will discuss the experience. If the discussion goes beyond the allotted time, the adjacent conference room will be reserved in advance for the participant and therapist to continue the discussion. Also, during subsequent sessions, treatment starts with an evaluation of the previous week, including the thoughts that the patient had between sessions about the events and the intervention. Audio recordings of these semi-structured interviews may happen at this time.
After completing all 3MDR sessions, participants will be asked to complete the same questionnaires from T1 again and answer additional questions about their treatment experience. Each assessment will take approximately 2.5 hours. This would be repeated 6 times over the course of 1 year. Those in the intervention group will also take part in 6 3MDR sessions (2 hours) and 3 introductory/follow up sessions (1 hour). It is estimated that over a 12 month period, each participant would have donated 30 hours to the study.

Data gathering will involve the following methods:
Interviews and/or Focus Groups
Participant Observation
Surveys and Questionnaires (including internet surveys)
Biobanking (collection of samples to put in a Biobank/Sample Repository)
Collection of Human Biological Materials (ie. blood, tissue etc.)
Chart Review/Review of Health Data

As part of the therapeutic intervention, there will be semi-structured interviewing within the intervention and pre/post assessment with the CAPS assessment by trainer therapists. There will also be semi-structured interviewing around the U-TAUT model. All interviews will be on a one to one basis and will be recorded for later transcription and analysis.

Intervention Type
Behavioural

Primary outcome measure
PTSD symptomology measured using the clinically administered PTSD Scale (CAPS), PTSD symptoms (PCL-5), posttraumatic avoidance behaviour questionnaire (PABQ), neurofunctioning (Brain FX), and dissociative experiences (PDEQ) measured pre/post-intervention, as well as follow up at 3 and 6 months.

Secondary outcome measures
1. Measured at baseline, week 11, 3 months, 6 months, and 12 months:
1.1. Moral Injury (Moral Injury Symptom Scale)
1.2. Alcohol Consumption (AUDIT)
1.3. Depression (PHQ-9)
1.4. Anxiety (GAD-7)
1.5. Social Function (OQ-45)
1.6. Quality of Life (EQ5D-5L)
2. Sessions 3 to 8 on the CAREN System (weeks 5 to 11):
2.1. Gait Analysis (CAREN)
2.2. Heart Rate (Zepher Bio Harness 3)
2.3. Breathing Rate (Zepher Bio Harness 3)
2.4. Force Plate Analysis (CAREN)
2.5. Eye tracking (Tobii Pro)
2.6. EEG (Tobii Pro 2)
2.7. Client Satisfaction (CSQ-8)
3. Final CAREN Session Only (week 11)
3.1. Usability of CAREN (UTAUT)
3.2. 3MDR Satisfaction (3MDR-Q)

Overall study start date
23/08/2018

Completion date
31/03/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/03/2025:
Individuals being considered for participation in the 3MDR study must:
1. Be aged 18 or more years
2. Be English speaking
3. Be from one or more of the following groups:
3.1. Regular and reserve Canadian Armed Forces service members, and Veterans
3.2. Public safety personnel (PSP - e.g., paramedics, police, firefighters, and correction officers)
3.3. Healthcare professionals (HCP) and Essential service providers (ESP)

3.4. Adult family members of the aforementioned groups
3.5. General public
4. Have one or more of the following concerns present for at least 3 months:
4.1. Official diagnosis of PTSD from a mental health professional
4.2. A post-traumatic or operational stress injury or other related mental health condition
4.3. Score below 30 on the Clinician-Administered PTSD Scale (CAPS-5)
4.4. Trauma associated with service provision during the COVID-19 pandemic
4.5. Military sexual trauma
4.6. Moral injury; and/or
4.7. Stress-related condition
5. Agree to be screened by a research team member for study eligibility
6. Be able to participate in 3MDR at one of the study sites for 2 hours, once a week for 10 to 14 consecutive weeks and engage in follow-up sessions
7. Be under the care of a healthcare provider or team (primary service provider) for mental health needs during the course of 3MDR and following receipt of the intervention. If the individual's 3MDR therapist is not their regular mental healthcare provider, the primary service provider would need to provide authorization for the individual's potential participation in the 3MDR study, as well as consent for the release of information to the research team. Note that the research team will not provide ongoing physical or mental health support
8. Be able to walk on a treadmill for 1 hour (or, if the individual uses a wheelchair, be able to maintain a regular wheelchair pace for 60 minutes on a wheelchair trainer unit, which is equivalent to a treadmill for a wheelchair user)
9. Would benefit from psychotherapy and be able to process trauma, learn new things, and reconsolidate memories
10. If engaging in psychotherapeutic intervention, be stable on a consistent treatment regime and agree not to enter into new interventions during receipt of the 3MDR intervention
11. If undergoing pharmacotherapy, be stable on their current psychotropic medication for a period of 4 weeks before entering the trial and agree to not increase dosages or add any new medications during the course of the trial
12. If using substances (e.g., alcohol or cannabis), its use must be stable and not interfere with effectively engaging in trauma therapy
13. If individuals have co-morbid conditions, other inclusion/exclusion criteria must be satisfied

Previous inclusion criteria:
1. CAF service members (CAF-SMs) aged 18-60 years
2. Meet DSM-5 Criteria for PTSD diagnosis (with chronic cr-PTSD (symptoms >3 months)
3. Treatment-resistant to treatment as usual (TAU) psychotherapeutic PTSD treatment, i.e. have not responded to at least two types of evidence-based treatments, at least one of which must be a psychotherapeutic intervention
4. Have a score of 50 or higher on the Clinician-Administered PTSD Scale for DSM-5 (CAPS).
5. Stable on their current psychotropic medication for a period of 4 weeks before entering the trial and agree to not increase dosages or add any new medications during the course of the trial
6. Individuals with co-morbidity will be included if they satisfy the other inclusion/exclusion criteria and PTSD is considered the primary diagnosis
7. Must provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
Current exclusion criteria as of 13/03/2025:
1. Acute suicidality
2. Inability to walk at a normal pace for 30-45 minutes on a treadmill
3. Acute psychosis
4. Participant is not socially appropriate
5. Reduced cognitive processing that would exclude the participant from following directions
6. Significant history of non-attendance in previous therapies
7. The physical size or abilities of the participant are not compatible with the CAREN system
8. Significant history of non-attendance in previous therapies

Previous exclusion criteria:
1. Acute suicidality
2. Inability to walk at a normal pace for 30-45 minutes on a treadmill
3. Acute psychosis
4. Participant is not socially appropriate
5. Reduced cognitive processing that would exclude the participant from following directions
6. Significant history of non-attendance in previous therapies
7. The physical size or abilities of the participant are not compatible with the CAREN system

Date of first enrolment
01/03/2019

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
Canada

Study participating centre
Glenrose Rehabilitation Hospital
10230 111 Avenue Northwest
Edmonton
Canada
T5G 0B7

Study participating centre
Alberta Hospital Edmonton
17480 Fort Road NW
Edmonton
Canada
T5Y 6A8

Study participating centre
University of Alberta - Calgary Centre Downtown Faculty of Rehabilitative Medicine
906-8 Avenue SW
Calgary
Canada
T2P 3B6

Study participating centre
Edmonton Operational Stress Injury Clinic (Veterans Affairs Canada)
Northgate Centre, 9499 137 Ave NW
Edmonton
Canada
T5E 5R8

Study participating centre
Calgary Carewest Operational Stress Injury Clinic (Veterans Affairs Canada)
3625 Shaganappi Trail NW
Calgary
Canada
T3A 0E2

Study participating centre
University of Alberta, Faculty of Rehabilitation Medicine
8205 114 St NW
Edmonton
Canada
T6G 2G4

Study participating centre
Northern Lights Regional Health Centre
7 Hospital Street, Room # 3081

Fort McMurray
Canada
T9H 1P2

Study participating centre
Lethbridge Chinook Regional Hospital
960 19th Street South
Lethbridge
Canada
T1J 1W5

Study participating centre
Addictions and Mental Health
4733 49 Street, Room #140
Red Deer
Canada
T4N 1T6

Study participating centre
Misericordia Hospital
16940 87 Ave NW
Edmonton
Canada
T5R 4H5

Study participating centre
Sheldon M. Chumir Health Centre
1213 4 Street SW
Calgary
Canada
T2R 0X7

Study participating centre
Canmore General Hospital
1100 Hospital Place
Canmore
Canada
T1W 1N2

Study participating centre
Deer Lodge Operational Injury Clinic
2109 Portage Avenue
Winnipeg
Canada
R3J 0L3

Study participating centre
Peace River Mental Health & Addictions
10015 98 St
Peace River
Canada
T8S 1R7

Sponsor information

Organisation
Glenrose Rehabilitation Hospital Foundation

Sponsor details
10230 111 Avenue Northwest
Edmonton
Canada
T5G 0B7

Sponsor type
Charity

Website
https://glenrosefoundation.com/pg1.asp?siteID=1&PIT=home

ROR
https://ror.org/02n2n9a06

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Glenrose Rehabilitation Hospital Foundation

Funder Name
Department of National Defence

Funder Name
Royal Canadian Legion

Funder Name
First Response to Fashion

Funder Name
Government of Alberta

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 13/03/2025:
If 3MDR is shown to be efficacious, the proposed research will benefit (1) CAF-SMs with treatment-resistant PTSD, and trauma-affected PSPs, HCPs, and civilians by providing a new treatment option; (2) clinical services by providing a means of treating PTSD and related conditions that have not responded to standard psychological treatment; and (3) the families and friends of CAF-SMs, PSPs, HCPs, and civilians more generally by minimising the burden of PTSD and related conditions.

The project will involve ongoing partner engagement. We will also publicise the trial through social and local media with the aim of informing the public that the trial is running. Knowledge dissemination will continue thereafter using a variety of tailored methods targeting specific audiences (e.g. infographics, newsletter, website, and social media). A summary report of trial results written in lay language will be sent to study participants and other key stakeholders. The report will also be displayed and available at venues used for recruitment.

Study outcomes will be presented at an end-of-project KT event, First Response to Fashion Galas, and Spotlight on Innovation. Findings will also be disseminated to the academic community at national and international conferences by means of oral/poster presentations, and interactive workshops. We will target conferences likely to be attended by large numbers such as the Military and Veteran Health Research Forum by the Canadian Institute for Military and Veteran Research (CIMVHR), and the International Trauma and Stress Studies and Treatment (ITSST) Conference. We aim to publish the results in high-impact, open-access, peer-reviewed journals.

All the dissemination activities will be supported by web pages such as HiMARC.ca and 3mdr.ca. The web pages will include descriptions of the project, its progress and achievements in plain and scientific language, press releases, publications and conferences.

The proposed research will increase our understanding of the potential benefits and advantages of 3MDR as a potential treatment option for treatment-resistant PTSD and related conditions.

Previous publication and dissemination plan:
If 3MDR is shown to be efficacious, the proposed research will benefit (1) CAF-SMs with treatment-resistant PTSD by providing a new treatment option; (2) clinical services by providing a means of treating PTSD that has not responded to standard psychological treatment; and (3) the families and friends of CAF-SMs more generally by minimising the burden of PTSD.

The project will involve a key stakeholder engagement at the launch of the project. We will also publicise the trial through social and local media with the aim of informing the public that the trial is running. Knowledge dissemination will continue thereafter using a variety of tailored methods targeting specific audiences (e.g. infographics, newsletter, website, and social media). A summary report of trial results written in lay language will be sent to study participants and other key stakeholders. The report will also be displayed and available at venues used for recruitment.

Study outcomes will be presented to key stakeholders at an end-of-project KT event and Glenrose Rehabilitation Hospital Foundation's First Response to Fashion Gala and Spotlight on Innovation. Findings will also be disseminated to the academic community at national and international conferences by means of oral/poster presentations, and interactive workshops. We will target conferences likely to be attended by large numbers such as the Military and Veteran Health Research Forum by the Canadian Institute for Military and Veteran Research (CIMVHR), and the International Trauma and Stress Studies and Treatment (ITSST) Conference. We aim to publish the results in high-impact, open-access, peer-reviewed journals.

All the dissemination activities will be supported by web pages such as HiMARC.ca. The web pages will include descriptions of the project, its progress and achievements in plain and scientific language, press releases and announcements of and registration for conferences.

The proposed research will increase our understanding of the potential benefits and advantages of 3MDR as a potential treatment option for treatment-resistant PTSD in CAF-SMs.

Planned publications in multiple high-impact peer-reviewed journals such as the Journal of Medical Internet Research (JMIR) Protocols as well as the Journal of Military and Veteran Family Health Research

(Updated 04/06/2020, previously: Planned publications in multiple high-impact peer-reviewed journals, however the target is the Journal of Military Veterans and Family Health Research)

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available due to their containing information that is sensitive in nature and could compromise the privacy of the research participant.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/10/2020	30/10/2020	Yes	No