

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

<b>Submission date</b> 29/01/2019	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/02/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/03/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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](mailto:suzette2@ualberta.ca)

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Suzette Bremault-Phillips

### ORCID ID

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### Contact details

2-64 Corbett Hall

8205 - 114 Street NW

Edmonton

Canada

T6G 2G4

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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 3MDR 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

## **Study type(s)**

Treatment

## **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(s)**

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.

## **Key secondary outcome(s)**

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)

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

75 years

### **Sex**

All

### **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

**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****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?
<a href="#">Protocol article</a>	protocol	29/10/2020	30/10/2020	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes