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Virtual-reality based treatment for Canadian armed forces members with combat-related post-traumatic stress disorder (PTSD), as well as public safety personnel (PSP), healthcare professionals (HCP), and members of the general public with trauma

Submission date
29/01/2019

Recruitment status
Recruiting

Registration date
06/02/2019

Overall study status
Ongoing

Last Edited
30/09/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 with combat-related PTSD. 3MDR also holds promise for treating trauma and related conditions among public safety personnel (PSP) and healthcare professionals (HCPs) who face numerous physically and mentally stressful events in the line of duty and civilians, as well as members of the general public with trauma experience. This study will allow researchers to examine the effect of 3MDR therapy on PTSD symptoms of Canadian Armed Forces (CAF) service members with chronic combat-related PTSD who do not benefit from other therapies, and trauma-affected PSPs, HCPs, and members of the general public with trauma.

Who can participate?
CAF service members with chronic PTSD, as well as PSP, HCPs, and members of the general public with trauma who meet specific inclusion/exclusion criteria may participate in this study.

What does the study involve?
Participants will be randomly assigned to an immediate 3MDR therapy group or waitlist control group. The immediate 3MDR therapy group will receive a 10-14 week program of 3MDR therapy with one session per week, including 2 3MDR introductory sessions, 6-10 3MDR treadmill intervention sessions, and 2 3MDR reconsolidation sessions. The waitlist control group will wait for a period of 6 weeks (during which they will receive treatment as usual, if any) and then begin the 10-14 week program of 3MDR therapy. If deliberate randomization is not feasible due to

clinical or logistical considerations, natural randomization will be used. With natural randomization, some participants who are screened and accepted into the study will not be available to start 3MDR for 6 or more weeks due to job considerations, scheduling, or other reasons, and these participants will be considered as part of the waitlist control group. Participants able to start 3MDR less than 6 weeks after acceptance into the study will be considered as part of the immediate 3MDR therapy group.

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, Canada.

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

Who is funding the study?
1. Department of National Defence
2. Royal Canadian Legion
3. First Response to Fashion
4. Government of Alberta
5. Glenrose Rehabilitation Hospital Foundation
6. Alberta Innovates

Who is the main contact?
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Type(s)
Scientific

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Protocol serial number
Pro00084466/RES0042203

Study information

Scientific Title
Multi-modal, Motion-assisted, Memory Desensitization and Reconsolidation (3MDR) virtual reality-based treatment for individuals with post-traumatic stress disorder and associated conditions: a randomized waitlist control study

Acronym
3MDRHIMARC

Study objectives
Current study objectives as of 29/09/2026:
Study objectives are to test the following hypotheses:
1. Participants' PTSD symptom severity scores will decrease during 3DMR therapy
2. Reductions in PTSD symptom severity scores will be maintained through follow-up sessions after 3MDR therapy
3. Waitlist control participants' PTSD symptom severity scores will not change substantially during the wait period

Previous 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
Ethics approval required

Ethics approval(s)
Approved 21/09/2019, University of Alberta Health Research Ethics Board (2-01 North Power Plant (NPP), 11312 – 89 Avenue, Edmonton, T6G 2N2, Canada; +1 780 492 9724; ethics@ualberta.ca), ref: Pro00084466

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment-resistant combat-related PTSD, PTSD

Interventions

Current interventions as of 29/09/2026:
Participants will be randomized to the immediate 3MDR therapy or waitlist control 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 immediate 3MDR therapy or waitlist control groups. Participants in the waitlist control group will wait for a wait period of 6 weeks (during which they will receive treatment as usual if any) and then start 3MDR therapy with the same clinical protocol as the immediate 3MDR therapy group. If deliberate randomization is not feasible due to clinical or logistical considerations at a given clinical 3MDR site, natural randomization will be used. With natural randomization, some participants who are screened and accepted into the study will not be available to start 3MDR for 6 or more weeks due to job considerations, scheduling, or other reasons, and these participants will be considered as part of the waitlist control group. Participants able to start 3MDR less than 6 weeks after acceptance into the study will be considered as part of the immediate 3MDR therapy group.

Prior to beginning 3MDR treatment sessions, participants will undergo a baseline assessment. The baseline assessment will include a series of questionnaires collected online using REDCap, a semi-structured interview, and (at certain 3MDR sites only) baseline blood and saliva samples, all of which aim to gather information about the severity of PTSD symptoms, anxiety symptoms, and depression symptoms, as well as 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 SUDS) or as needed for monitoring purposes. Participant responses will be securely collected and stored on a secure University of Alberta REDCap server. At certain sites only, walking and eye scanning patterns, as well as physiological data, will be collected during 3MDR sessions through the 3DMR hardware system, eye-tracking glasses, and physiological monitoring hardware. Video-recordings of the 3MDR sessions will capture qualitative data associated with the exchange between the therapist and participant.

The 3MDR therapeutic protocol consists of 10-14 weekly sessions including 2 3MDR preparatory sessions, 6-10 3MDR treadmill intervention sessions, and 2 3MDR reconsolidation sessions.

The two 3MDR preparatory sessions include introduction to 3MDR procedures, the 3MDR hardware system, as well as selection of personalized images and two music pieces. Participants are accustomed to the 3MDR hardware system through simple standing and walking tasks. If appropriate, participants wear a safety harness when using the 3MDR hardware system. The participant is also asked to bring a set of pictures related to their trauma. With their therapist, the participant selects pictures and ranks them from lowest to highest affect. The participant is also asked to bring two digital music tracks: one song that reminds the participant of their trauma and one song that provides positive feelings.

Participants complete six 3MDR treadmill intervention sessions, with up to four additional 3MDR treadmill sessions if determined to be clinically indicated by the research team, 3MDR therapist, and the participant, on a case-by-case basis. Each of the 6-10 3MDR treadmill intervention sessions proceeds as follows:
- At the start of the 3MDR treadmill intervention session, the therapist and participant select

seven images and the order that they will appear during the session. If applicable, the participant is fitted with physiological monitoring equipment. If applicable, the participant is fitted with the safety harness and the safety harness clipped to the 3MDR system's safety support. The 3MDR therapist assumes a position next to the participant throughout the session.
- Each 3MDR treadmill intervention session has three phases: warm-up, intervention, and cool-down.
- Warm-up Phase: The 3MDR intervention session begins with the warm up phase, during which the participant walks on a level treadmill at a comfortable to fast pace for five minutes. The participant walks virtually along a pathway while their chosen song is played to bring them back to a time of their trauma.
- Intervention Phase: The intervention phase includes a repetitive cycle with 7 repetitions, each focused on a different trauma-related image. The emotionality of the images varies with each cycle. In each cycle, the participants walks on the treadmill while viewing a virtual environment centred around one of the images. The 3MDR therapist asks the participant a series of questions to guide them through processing the image and related trauma experiences and trauma themes. The participant then completes a 30-60 sec dual attention task, in which a ball moves across the screen from left to right with the participant calling out numbers appearing on the ball. This process is repeated 7 times during the course of the intervention phase.
- Cool-down Phase: During the cool-down phase, the participant walks on the treadmill while viewing a virtual outdoor pathway and listening to a piece of music, previously chosen by the participant, to assist with returning back to the present moment.
- After the treadmill portion of the session, the therapist and patient discuss the experience. Also, during subsequent 3MDR treadmill intervention 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.
- If applicable (at certain sites only), participants will provide the 3MDR therapist with a salivary sample before and after the 3MDR treadmill session.
- If applicable (at certain sites only), walking and eye scanning patterns, as well as physiological data will be collected during the treadmill portion of the session through
the 3MDR hardware system, eye-tracking glasses, and physiological monitoring hardware.

3MDR clinical reconsolidation sessions are psychotherapeutic sessions during which the participant integrates the changes and insights gained in the preceding 3MDR treadmill intervention sessions.

Immediate 3MDR Therapy Group. All participants in the immediate 3MDR therapy group will undergo six main assessments* and 6-10 smaller assessments**:
*baseline assessment to determine if inclusion criteria are met (T0)
**6-10 assessments during 3MDR treadmill intervention sessions (T1.1-1.10)
*one assessment during 3MDR Reconsolidation Session #1 (T2.1)
*one assessment during 3MDR Reconsolidation Session #2 (T2.2)
*one assessment at 3 months follow-up (T3)
*one assessment at 6 months follow-up (T4)
*one assessment at 12 months follow-up (T5)

Waitlist Control Group. The waitlist control group will receive the same baseline assessment at T0 as the intervention group, followed by a 6+ weeks wait period (including treatment as usual if any), followed by 3MDR therapy. Participants in the waitlist control group will undergo seven main assessments* and 6-10 smaller assessments**:
*baseline assessment (T0)
*crossover baseline assessment after wait period (T0.2)
**6-10 assessments during 3MDR treadmill intervention sessions (T1.1-1.10)

*one assessment during 3MDR Reconsolidation Session #1 (T2.1)
*one assessment during 3MDR Reconsolidation Session #2 (T2.2)
*one assessment at 3 months follow-up (T3)
*one assessment at 6 months follow-up (T4)
*one assessment at 12 months follow-up (T5)

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

As part of the 3MDR therapeutic intervention, there will be semi-structured interviewing within the intervention and pre/post assessment with the CAPS-5 interview by 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.

Previous 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)
1. PTSD symptoms measured using the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) and the PTSD Checklist for DSM-5 (PCL-5) at pre-3MDR baseline, crossover baseline (after wait period, for waitlist control participants only), 3MDR reconsolidation session 1 (PCL-5 only), 3MDR reconsolidation session 2, and follow-up at 3 months, 6 months, and 12 months

Previous primary outcomes as of 29/09/2026:
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. Depression measured using the Patient Health Questionnaire-9 (PHQ-9) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), 3MDR treadmill intervention

sessions 1 to 10, 3MDR reconsolidation sessions 1 and 2, and follow-up at 3 months, 6 months, and 12 months

2. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), 3MDR treadmill intervention sessions 1 to 10, 3MDR reconsolidation sessions 1 and 2, and follow-up at 3 months, 6 months, and 12 months

3. Social function measured using the Outcome Questionnaire-45 (OQ-45) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), 3MDR reconsolidation sessions 1 and 2, and follow-up at 3 months, 6 months, and 12 months

4. Alcohol consumption measured using the Alcohol Use Disorders Identification Test (AUDIT) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), and 3MDR reconsolidation session 1

5. Resilience measured using the Connor-Davidson Resilience Scale (CD-RISC-25) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), and 3MDR reconsolidation session 1

6. Moral injury measured using the Moral Injury Outcome Scale (MIOS) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), 3MDR reconsolidation sessions 1 and 2, and follow-up at 3 months, 6 months, and 12 months

7. Emotion regulation measured using the Difficulties in Emotion Regulation Scale (DERS-18) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), and 3MDR reconsolidation session 1

8. Avoidance measured using the Post-traumatic Avoidance Behaviour Questionnaire (PABQ) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), and 3MDR reconsolidation session 1

9. Quality of life measured using the EuroQol 5D (EQ-5D) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), and 3MDR reconsolidation session 1

10. Dissociative experiences measured using the Peritraumatic Dissociative Experiences Questionnaire (PDEQ) at pre-3MDR baseline, crossover baseline (for waitlist control participants only), and 3MDR reconsolidation session 1

11. Client satisfaction measured using the Client Satisfaction Questionnaire (CSQ-8) at 3MDR reconsolidation session 1

12. Satisfaction with 3MDR measured using the 3MDR Questionnaire (3MDR-Q) at 3MDR reconsolidation session 1

13. Usability of the 3MDR system measured using the Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire at 3MDR reconsolidation session 1

14. Neurofunctioning measured using BrainFX at pre-3MDR baseline and 3MDR reconsolidation session 2 (at certain sites only)

15. Gait (collected at certain sites only) measured using gait analysis at 3MDR treadmill intervention sessions 1 to 10

16. Balance and force generation (collected at certain sites only) measured using force plate analysis at 3MDR treadmill intervention sessions 1 to 10

17. Heart rate (collected at certain sites only) measured using heart rate monitoring at 3MDR treadmill intervention sessions 1 to 10

18. Breathing rate (collected at certain sites only) measured using breathing rate monitoring at 3MDR treadmill intervention sessions 1 to 10

19. Eye movements (collected at certain sites only) measured using eye tracking at 3MDR treadmill intervention sessions 1 to 10

Previous key secondary outcomes as of 29/09/2026:
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 key inclusion criteria as of 30/09/2026:

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 of 30 or higher 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

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Previous 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

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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
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

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

Alternative Name(s)
The Glenrose Rehabilitation Hospital Foundation, Glenrose Foundation, Glenrose Rehabilitation Hospital, GRHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Funder Name
Ministère de la Défense Nationale

Alternative Name(s)
Ministry of National Defence, Department of National Defence, Department of National Defence of Canada, Department of National Defence (Canada), Canada's Department of National Defence, Canadian Department of National Defence, DND

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Funder Name
Royal Canadian Legion

Funder Name
First Response to Fashion

Funder Name
Government of Alberta

Alternative Name(s)
Alberta's Government, Alberta Government, YourAlberta (Government of Alberta), gouvernement de l'Alberta

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Funder Name
Alberta Innovates

Alternative Name(s)
ABInnovates, albertainnovates, AI

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2026	18/05/2026	Yes	No
Protocol article	protocol	29/10/2020	30/10/2020	Yes	No
Protocol article		30/07/2025	28/07/2026	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes