HEROES IN MIND ADVOCACY & RESEARCH CONSORTIUM
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PARTICIPANT INFORMATION LETTER AND CONSENT FORM

Clinician/Regulated Healthcare Professional 3MDR Training

Study Title: Multi-Modal Virtual-Reality Based Treatment for Canadian Armed Forces Members with Combat Related Posttraumatic Stress Disorder: A Computer Assisted Rehabilitation Environment (CAREN) Randomized Wait List Control Study (3MDR Study)

Principal Investigator: Dr. Suzette Brémault-Phillips, Associate Professor, Faculty of Rehabilitation Medicine, University of Alberta, 2-64 Corbett Hall, 8205 - 114 Street, Edmonton, AB, T6G 2G4, suzette2@ualberta.ca, 780-492-0404

Why am I being asked to take part in this research study?

You are being asked to participate because you are a licensed clinician/regulated healthcare professional (social workers, nurses, psychologists, psychiatrists, occupational therapists, mental health chaplains, etc.) who is completing or has completed training for Motion-Assisted, Multi-Modal Memory Desensitization Reconsolidation (3MDR) therapy, offered as part of Dr. Suzette Brémault-Phillips' 3MDR research project, with the support of international collaborators.

What is the reason for doing the study?

The research study that is the subject of this information and consent form will help in evaluating and improving clinical training for 3MDR therapy, which is described next.

Canadian Armed Forces members, public safety personnel, and other service providers face numerous stressors and potentially traumatic events in the line of duty or course of service. As a result, they are at greater risk of developing operational stress injuries including post-traumatic stress disorder (PTSD). The standard treatments for PTSD include psychotherapeutic interventions such as prolonged exposure therapy, eye-movement desensitization and reprocessing (EMDR), and cognitive processing therapy (CPT), as well as medication. For most people with PTSD, these interventions are helpful. For some, they are not as effective at treating PTSD as we would like. We often refer to those individuals who do not respond well to these traditional interventions as "treatment resistant." There is a need for interventions that can target those who are treatment-resistant to the typical interventions used for PTSD. 3MDR is a promising new option for treating treatment resistant PTSD. It is currently being tested at the University of Alberta and multiple clinical sites internationally.

What is the 3MDR Intervention?

3MDR, or 'Multi-modular Motion-assisted Memory Desensitization and Reconsolidation,' is a

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treatment for individuals who have been diagnosed with posttraumatic stress disorder (PTSD). 3MDR uses self-selected photographs and music, treadmill walking and Virtual Reality Exposure therapy, and Eye Movement Desensitization and Reprocessing (EMDR) therapy to help treat PTSD. The 3MDR intervention takes place in a 3MDR hardware setup, including large format visual displays (large monitors or projectors) and a treadmill, along with 3MDR software to present the appropriate visual display. The 3MDR intervention involves minutes sessions. In each session, the individual, with a clinician standing next to him/her, walks on an embedded treadmill while briefly viewing one of several self-selected photos of traumatic events, and then engaging in Eye Movement Desensitization and Reprocessing (EMDR) therapy. The goal is to break the pattern of avoidance, enabling emotional release and creating space for memories to be integrated and re-stored in a new, modified form.

What will happen in the study?

Either toward the end of the 3MDR training programme or once the programme is completed (depending on logistics), you will fill in an anonymous online survey (15-20 minutes), which will ask about demographics, your clinical qualifications and experience, and your assessment of the 3MDR training programme (quality, what worked well, what could be improved, etc.). There will also be an online brainstorming session (30-60 minutes) where you will be asked to provide anonymous free-form feedback on the training programme.

What are the risks and discomforts?

There should no risk of discomfort from participating in the study.

What are the benefits to me?

While you may not get any benefit from being in this research study, the study will enable improvement in the 3MDR training programme.

You will contribute to an international, multi-site collaboration involving participants from the United Kingdom, Netherlands, and the United States.

Do I have to take part in the study? Are there other choices to being in this research study?

Your participation in this study is voluntary, and there is no cost to participate.

You may decide to participate in the study, not to be in this study, or to be in the study now, and then change your mind later without any repercussions.

If you decide to participate, and then later withdraw your consent, the study team will securely store the data that we have already collected but will no longer collect any further information. It will not be possible to remove your previously-collected data because data will be collected anonymously and there will be no way to identify your data to remove it.

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Will I be paid to be in the research?

You will not be paid for your participation.

Will my information be kept private?

Data collection will be anonymous; your name and identifying information will not be associated with any data you provide. Your name will be collected on the consent form only. Your name will not be shared except with members of the research team, University of Alberta research study auditors, or members of the University of Alberta Research Ethics Board.

By signing this consent form you are giving permission for the study staff to collect, use and disclose personal information about you as described above.

When the study is finished, anonymous data that was collected in the study will be securely stored in a confidential long-term data repository that can be used for further research and analysis. If we use the data we obtain from this study in future research, approval from a Research Ethics Board will be sought and data will be handled confidentially.

What if I have questions?

If you have any questions about the research now or later, please contact the **Heroes in Mind, Advocacy and Research Consortium (HiMARC)** by e-mail at **himarc@ualberta.ca** .

If you have any questions regarding your rights as a research participant, you may contact the University of Alberta's Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

The study is being conducted/sponsored by the Heroes in Mind, Advocacy and Research Consortium (HiMARC) at the University of Alberta.

HiMARC
Heroes in Mind Advocacy & Research Consortium

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NOTE: Please do not fill this form in. You will be provided an online version of this form to sign.

CONSENT FOR PARTICIPATION IN RESEARCH STUDY
Study Title: 3MDR
Principle Investigator: Dr. Suzette Brémault-Phillips, suzette2@ualberta.ca, 780-492-9503

By signing, you are agreeing to all of the below statements:

I understand that I have been asked to be in a research study.

I have read and received a copy of the attached Information Sheet.

I understand the benefits and risks involved in taking part in this research study.

I have had an opportunity to ask questions and discuss this study.

I understand that I am free to leave the study at any time, without having to give a reason.

The issue of confidentiality has been explained to me.

I understand who will have access to my anonymous data.

I agree to my de-identified data being stored long-term in a secure data repository for use in future analysis and research.

I agree to take part in this study.

Who explained this study to you?_____

Signature of Research Participant _____

(Printed Name)_____Date:_____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM.