uOttawa

Université d'Ottawa
Faculté de médecine
Département de médecine familiale

University of Ottawa
Faculty of Medicine
Department of Family Medicine

INSTITUT DE RECHERCHE Bruyère RESEARCH INSTITUTE

UNIVERSITY OF ALBERTA

Alberta

Project Title: Immersive Virtual Reality for Self-Management of Post-Traumatic Stress Injuries in First Responders and Emergency Healthcare Workers

Principal Investigator: Douglas Archibald, PhD., Department of Family Medicine, University of Ottawa, Ottawa.

Funding: Supporting Psychological Health in First Responders (SPHIFR), Government of Alberta

---

Letter of Information

Participant Informed Consent Form

Invitation to join

You are being invited to participate in the above research study because you are a first responder and/or emergency healthcare worker in Ontario. Participation in this study is voluntary and will not affect your affiliation or activities with your professional associations, colleges and the Faculty of Medicine, University of Ottawa. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like.

Why is this study being done?

The purpose of this study is to implement and test a virtual reality (VR) scuba psychoeducational tool on a sample of first responders and emergency healthcare in two provinces, Ontario and Alberta, to understand the psychological support and benefit of this learning for those living with or at risk of post-traumatic stress injuries (PTSI).

How many participants will be in this study?

This study will recruit 20 participants in each province (20 in Ontario and 20 in Alberta).

Description of Study

The VR scuba psychoeducational experience will take approximately 45-60 minutes to complete. Upon consent, your name will be provided to a member of the research team who will coordinate a screening assessment and schedule the VR experience. This will be done by email or in-person and will

☎ 613-562-5800 ext 2982
201-600 rue Peter Morand Cresc.
Ottawa ON K1G 5Z3
med.uottawa.ca/family

take approximately 10-15 minutes. The screening assessment involves the completion of the posttraumatic stress disorder checklist for DSM-5 (PCL-5) and the generalized anxiety disorder 7-item (GAD-7) questionnaires online via SurveyMonkey to determine your level of PTSI. The study inclusion criteria are listed below, you must be:

1) minimum age of 18 and maximum age of 65; 2) having worked on the front lines during the COVID-19 pandemic (full-time, part-time or casual, working in health care providing in-person publicly-funded services between March 2020 - Present); 3) be within the threshold cut off range on the PCL-5 (11-41 scores) and/or GAD-7 (0-14 scores); 4) absence of a formal diagnosis of PTSD or anxiety disorder; 5) absence of medical disorders (heart disease or high/low blood pressure, neurological disorders, epilepsy); 6) absence of pharmacotherapy that could interfere with the measured data (psychoactive drugs, anti-hypertensive, antidepressants); and 7) no significant visual impairment (normal visual acuity or corrected to normal).

The in-person VR experience will integrate a learning component as well as pre- and post-survey questionnaires administered online via SurveyMonkey. There are three pre-intervention questionnaires (immediately before the intervention, approximately 10 minutes to complete) that serve to evaluate your understanding of the subject matter, the usability of the VR application, and to gather demographic information such as age group. Following the VR experience, there will be a post-intervention questionnaire administered immediately after the intervention (approximately 10-15 minutes) that serve to evaluate the usability of the VR application, the psychological support and/or benefit of this learning, and the learning outcome of participants based on their experience. At 4 weeks post-intervention, an online questionnaire will be administered to measure changes in the psychological support of the tool for those living or at risk of PTSI (PCL-5 and GAD-7 questionnaires) and the learning levels and learning outcomes of participants based on their experience (approximately 10-15 minutes). We will also explore the possibility of collecting heart rate measurements during the VR session (e.g., using a fitbit).

In addition, we will invite you to a follow-up ~30-60-minute interview and/or a ~60-minute focus group at the end of the study period (4-weeks) to better understand how the VR application can be used to teach coping skills for the management of PTSI. This interview will be conducted over the telephone, videoconference (i.e., zoom) or face-to-face and will be audio-taped or transcribed verbatim. In the interview, both you and the researcher will explore your experiences using the VR software application. About a month after your interview, you will be given a transcript and findings of the interview. You will be asked to verify it and add, delete or clarify any information you see fit. Data sent by email will be void of any identifying information. We will also password protect the transcript and share the password in another, follow-up email, for added security or utilize a google doc form with a link that is only accessible by yourself and the research team. The focus group will be conducted over videoconference or face-to-face, following the same procedure as the interview described above.

How long will I be involved in the study?

The entire study will last approximately one year. Your participation in the study will last approximately three months, beginning with the screening assessment and online questions and finishing with the review of your interview and/or focus group findings.

Are there any risks?

Participation in this study may evoke stress, anxiety and/or PTSI. This virtual experience is intended for the participant who enjoys overall good mental health and does not meet diagnostic criteria for a major mental health disorder such as Posttraumatic stress disorder, General anxiety disorder, Panic disorder, has psychosis or mania, or has thoughts of self-harm or harm to others.

The virtual experience is a learning experience and not a form of therapy. Should the virtual experience evoke stress and/or PTSI that is out of keeping with the usual, you will be encouraged to seek help from your Family Physician or Nurse Practitioner or seek help at your local Emergency Room.

Are there any benefits?

Participation in this study may help you learn strategies to improve coping through day-to-day stress or PTSI. The VR experience endeavours to teach you how to recognize and ask help of supports and teach skills for the management of PTSI.

On a broader scale, the data collected during this study will help validate and refine the VR experience for its feasibility as a self-learning teaching model and self-management program for those at risk and/or living with PTSI.

Do I have to participate? Can participation end early?

Participation is voluntary. You can withdraw from this study at any time. You may decide not to be in this study, or to be in the study now, and then change your mind later. Your participation or withdrawal from the study will not affect your affiliation or activities with your professional associations, colleges and the Faculty of Medicine, University of Ottawa. If you decide to withdraw from the study, you can call the research associate (see contact information below). The information about you that was collected before you left the study will be destroyed unless you give your consent to use them.

Will I be paid to participate in this study?

You will not be compensated for your participation in this study.

Will there be any costs to me?

No costs are anticipated due to participating in this study.

What will happen to my personal information?

- All information collected during your participation in this study will be identified with a unique study number, and will not contain information that identifies you, such as your names, address, etc.
- All personal identifying information (PII) will be kept confidential.
- The coded data will be securely stored on a separate server at Bruyère Research Institute.
- Any documents leaving the Bruyère Research Institute will contain only your unique study number. This includes publications or presentations resulting from this study.

- Your responses to the surveys will be securely stored in SurveyMonkey's accredited data center that adheres to the best security and privacy practices. Only the research team will have access to the survey results on the online platform. All exported data will be securely stored on a password protected computer.
- The interview and/or focus groups will be recorded using the Zoom platform which has the ability to securely record and store recordings as per their privacy statement. Only the research team will have access to the audio recordings. All exported data will be securely stored on a password protected computer.
- A Master List provides the link between your identifying information and the coded study number. This list will only be available to Dr. Archibald and his staff. It will be stored securely and separate from your study records at the Bruyère Research Institute.
- For audit purposes only, your study records may be reviewed under the supervision of Dr. Douglas Archibald's staff by representatives from:
    1. Bruyère Continuing Care Research Ethics Board
    2. University of Ottawa Health Sciences and Science Research Ethics Board
    3. University of Alberta's Research Ethics Board
- You will not be identified in any publications or presentations resulting from this study.
- Research records with identifying information will be kept for 10 years after study completion, after this time they will be destroyed. All paper records will be shredded and all electronic records will be securely deleted.

Will I be informed about any new information that might affect my decision to continue participating?

You will be informed in a timely fashion of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

Conflicts of Interest

There are no conflicts of interest to declare related to this study.

If I have questions about this study, who should I call?

If you have any questions, concerns or would like to speak to the study team for any reason, please call:

- Maddie Venables, PhD., Senior Research Associate, Department of Family Medicine, University of Ottawa, Maddie.Venables@uottawa.ca, or
- Jeffrey Puncher, Director of Finance and Strategic Initiatives, Department of Family Medicine, University of Ottawa, jpuncher@uottawa.ca.

You can also ask questions to the Principal Investigator of the study:

- Douglas Archibald, PhD., Department of Family Medicine, University of Ottawa, darchibald@bruyere.org.

The Bruyère Continuing Care Research Ethics Board has reviewed the plans for this research study. If you have any questions about your rights as a study participant, or about the way the study is conducted, you may contact the Bruyère Continuing Care REB at 613-562-6262, extension 4003.

uOttawa

Université d'Ottawa
Faculté de médecine
Département de médecine familiale

University of Ottawa
Faculty of Medicine
Department of Family Medicine

INSTITUT DE RECHERCHE Bruyère RESEARCH INSTITUTE

UNIVERSITY OF ALBERTA

Alberta

Project Title: Immersive Virtual Reality for Self-Management of Post-Traumatic Stress Injuries in First Responders and Emergency Healthcare Workers

Principal Investigator: Douglas Archibald, PhD., Department of Family Medicine, University of Ottawa, Ottawa.

Consent to Participate in Research

- I understand that I am being asked to participate in a research study focused on a virtual reality scuba psychoeducational experience to learn about post-traumatic stress injuries (PTSI) and coping skills.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

Would you like to participate in a follow-up ~30-60-minute interview at the end of the study period to help us better understand how the VR application can be used to teach coping skills for the management of PTSI?

❑ YES ❑ NO Participant's email _____

Would you like to participate in a follow-up ~60-minute focus group at the end of the study period to help us better understand how the VR application can be used to teach coping skills for the management of PTSI?

❑ YES ❑ NO Participant's email _____

Would you like to receive a summary of the findings of this research?

❑ YES ❑ NO Participant's Initials_____

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

<u>Investigator or Delegate Statement</u>

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____
Investigator/Delegate's Printed Name

_____ _____
Investigator/Delegate's Signature Date

☎ 613-562-5800 ext 2982
201-600 rue Peter Morand Cresc.
Ottawa ON K1G 5Z3

med.uottawa.ca/family

uOttawa

Université d'Ottawa
Faculté de médecine
Département de médecine familiale

University of Ottawa
Faculty of Medicine
Department of Family Medicine

INSTITUT DE RECHERCHE Bruyère RESEARCH INSTITUTE

UNIVERSITY OF ALBERTA

Alberta

Project Title: Immersive Virtual Reality for Self-Management of Post-Traumatic Stress Injuries in First Responders and Emergency Healthcare Workersy

Principal Investigator: Douglas Archibald, PhD., Department of Family Medicine, University of Ottawa, Ottawa.

Consent to Participate in an Interview

- I understand that I am being asked to participate in a follow-up 30-60 minute interview to help the research team better understand how the VR application can be used to teach coping skills for the management of post-traumatic stress injuries (PTSI).
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this interview.
- I will be given a copy of this signed Participant Informed Consent Form.

I consent to have the interview audio-recorded for the purposes of transcribing and data analysis?

❑ YES ❑ NO Participant's Initials_____

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

<u>Investigator or Delegate Statement</u>

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____
Investigator/Delegate's Printed Name

_____ _____
Investigator/Delegate's Signature Date

☎ 613-562-5800 ext 2982
201-600 rue Peter Morand Cresc.
Ottawa ON K1G 5Z3

med.uottawa.ca/family

uOttawa

Université d'Ottawa
Faculté de médecine
Département de médecine familiale

University of Ottawa
Faculty of Medicine
Department of Family Medicine

INSTITUT DE RECHERCHE
Bruyère
RESEARCH INSTITUTE

UNIVERSITY OF ALBERTA

Alberta

Project Title: Immersive Virtual Reality for Self-Management of Post-Traumatic Stress Injuries in First Responders and Emergency Healthcare Workersy

Principal Investigator: Douglas Archibald, PhD., Department of Family Medicine, University of Ottawa, Ottawa.

Consent to Participate in a Focus Group

- I understand that I am being asked to participate in a follow-up ~60 minute focus group to help the research team better understand how the VR application can be used to teach coping skills for the management of post-traumatic stress injuries (PTSI).
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this interview.
- I will be given a copy of this signed Participant Informed Consent Form.

I consent to have the focus group audio-recorded for the purposes of transcribing and data analysis?

❑ YES ❑ NO Participant's Initials_____

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

<u>Investigator or Delegate Statement</u>

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____
Investigator/Delegate's Printed Name

_____ _____
Investigator/Delegate's Signature Date

☎ 613-562-5800 ext 2982
201-600 rue Peter Morand Cresc.
Ottawa ON K1G 5Z3

med.uottawa.ca/family