PSP PTSI Study

CONSENT FORM

UNIVERSITY OF REGINA

PROJECT FULL TITLE: An Augmented Training Program for Preventing Post-Traumatic Stress Injuries Among Diverse Public Safety Personnel
PROJECT SHORT TITLE: PSP PTSI Study

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Website: www.pspptsi.ca

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PROJECT FUNDING SOURCES: Canadian Institutes of Health Research; Saskatchewan Federation of Police Officers

PROJECT SPONSORS: Regina Fire and Protective Services; Regina Police Service; Saskatchewan Health Authority; Saskatchewan Public Safety Agency.

DISCLOSURES: The current study is being led by Dr. R. Nicholas Carleton, a Professor of Psychology at the University of Regina. The sources of funding and sponsorship of the study are listed above for transparency.

1. OVERVIEW AND BACKGROUND INFORMATION

This consent form contains information about a research study in which you are invited to participate. This consent form includes important information that will help you to make an informed decision about whether you wish to participate, such as 1) why the current study is being done; 2) what you will be asked to do if you agree to participate; 3) the time commitment involved; 4) potential benefits and risks; and 5) how we will protect your privacy. You may take some time to think about whether or not you wish to participate, and you are encouraged to discuss this decision with others, such as your family. Please read the information in this form carefully. If you have any additional questions please feel free to use the contact information above.

Exposure to potentially dangerous, harmful, or stressful situations can be an inherent part of Public Safety Personnel (PSP, specifically for this project: emergency communications, firefighters, paramedics, police) work. Given their reality, PSPs are more likely to experience symptoms of posttraumatic stress disorder or other mental health injuries than the general population. There is very limited research on the long-term relationships between symptoms of posttraumatic stress and individual risk factors (e.g., broadly defined as things that make it harder for us to endure or recover from stressful or traumatic events) and resiliency factors (e.g., broadly defined as things that help us to endure or recover from stressful or upsetting events). The lack of research data makes it very difficult to develop effective training programs to increase resiliency and reduce risk of psychological injury for PSP.

We are inviting you to participate in this study because you are a PSP working in Saskatchewan during the study period. A team of researchers led by professors at the University of Regina are conducting this study. Leaders from five PSP sectors including Fire Services, Paramedics, Police Service, and Public Safety Communications Officials have approved the current study; however, your participation is completely voluntary and **not** a requirement of your employment. **Should you decide to participate, the information you provide cannot be used as part of your supervisors' evaluation of any part of your work.**

2. PURPOSE AND PROCEDURES

2.1 Purpose of the Study

In order to learn more about how to help improve resiliency, researchers need to collect data from people before they are exposed to challenging situations so that the researchers and the participants have a baseline against which to compare their future mental health, with or without symptoms. The current study is designed to test whether factors believed to be helpful in predicting resiliency and risk related to mental health functioning are in fact predictive. There is limited PSP research on the long-term relationships between various factors and mental health; however, there is research on such short-term relationships within the general population. The available research results suggest that some specific factors are particularly

important and may be modifiable such that adapted Unified Protocol training can increase resiliency and reduce risk. The current study will measure such factors using surveys and physiological data, but with PSP instead of the general public, and over a longer period of time 1 year after the adapted Unified Protocol training has been completed.

There is also substantial research evidence that skills-based intervention programs can substantially improve mental health. Such programs are typically administered **after** a mental health injury has occurred. Someone who exercises regularly may be more resilient following a physical injury than someone who only begins to exercise after they have been injured. Similarly, having the tools to manage situations that can cause a mental health injury before such an event takes place may help to improve mental health resiliency. The current study is designed to provide a skills-based intervention program that has been specifically adapted for PSP. The idea is that the skills will increase resiliency and reduce risk. The researchers will then monitor the impact of the adapted training on their mental health over the five years following graduation. The researchers will perform an initial assessment before the intervention then monitor the impact of the adapted training on their mental health over the two years following adapted training to see what, if any, the skills-based intervention program has had on participants.

2.2 Procedures

A total of 200 frontline PSP from Saskatchewan (primarily Regina and area) with 5 to 11 years of experience working in their sector will be recruited with the assistance of Knowledge Users from each of the four PSP sectors in the proposed study: communications, fire, paramedics, , , and police (n=50 per sector). Additionally, approximately five PSP leaders (staff sergeant or equivalent and higher) per sector (n=20) will participate in the PSLT, all of whom will be invited to attend a focus group prior to T1. To address one of the secondary research questions, biometric data will be collected from a sample (n=30) of participants from the police sector; the rationale for selecting this particular sector was based on logistics, as this sector is providing the additional funding required to purchase the necessary hardware for that portion of the study. A sub-sample of frontline PSP (~8 per sector; n=32) will be invited to participate in sector-specific focus groups after T2. The women's focus group (T2) will include PSP from all four sectors to examine pan-PSP gender issues. Please refer to Table 1 for an overview of which parts and tasks will be involved for each study team. Please note that some aspects of the study procedures will be available immediately and some aspects may not be available until a few months after you begin. In all cases participants will be encouraged to engage regularly with the study as described below.

Table 1. Procedures

Procedures

Initial Testing (Once in Spring 2020)
• Full Assessment Including
  ○ Baseline Full Self-Report Survey (~90 minutes)
  ○ Interview with a Clinician (~60 minutes)

Ongoing Self-Report Assessments • Daily Survey (~1 minute) • Monthly Survey (~30 minutes)
Training Augmented with the PSP-Specific Adapted Skills-Based Training (16 sessions + follow-ups)

Post-training Testing
• Full Assessment Including
  ○ Full Self-Report Survey (~90 minutes)
  ○ Interview with a Clinician (~60 minutes)

Ongoing Assessments for 1 Year After Initial Training
• Daily Survey (~1 minute)
• Monthly Survey (~30 minutes)
• Full Assessment at 1-year After the Initial Training Including
  ○ Full Self-Report Survey (~90 minutes)
  ○ Interview with a Clinician (~60 minutes)

Wearable Biometric Technology and Support Technology for ongoing physiological measurements that you may also use personally (Baseline through to the end of the final Full Assessment 1 year after adapted training)

Full Assessments – Before and After Adapted Training
Should you agree to participate, you will be invited to complete a first "Full Assessment" early in your adapted training. The Full Assessment will start with a self-report survey administered by computer (which we expect will take less than 90 minutes), followed by a standardized structured clinical interview (which we expect will take less than 60 minutes) designed to assess mental health.

The surveys will be administered through a Moodle smartphone application which is also accessible through a web-based browser. The more components you complete, the more beneficial your data will be for yourself, the research study, and ultimately, for all PSP members.

Interviews may be conducted in person or remotely (i.e., using a telecommunication technology, such as a toll-free conference call line). You will be invited to complete a second Full Assessment after the adapted training, and then again one year after that.

The first interviews will be administered after the adapted training session by one or two qualified psychologists or supervised clinical trainees. All interviewers will have been granted the necessary security clearance to work with participants. All interviewers will also be bound by the Code of Ethics of the Canadian Psychological Association. The trained clinicians or supervised clinical trainees will protect your confidentiality during the interview. The data collected will be confidential to all users.

Your individual results from the Full Assessment self-report surveys and clinical interviews will not be transmitted or otherwise available to anyone outside the PSP study team; therefore, your data cannot be used to evaluate your fitness to be a PSP Member at any time. The summary information only will be used to help the researchers understand the overall psychological profile of participants and to accomplish the goals outlined for the study.

If the research team finds evidence that you might benefit from mental health support during an interview you will be informed and provided with information on how to access such support if you choose to access support. **PSP employers will not be informed regarding the individual results of our contact with you.**

Monthly and Daily Surveys

You will be invited to complete short "Monthly Surveys" consisting of a series of self-report questionnaires, which we expect will take less than 30 minutes. You will also be invited to complete a brief "Daily Survey", which we expect will typically take about 1 minute. You will then be able to track your own mental health over time, which we suspect will be beneficial to you personally for several reasons, including allowing you to actively support your own mental health. The surveys will be administered through the Moodle smartphone application and will also be accessible through a web-based browser. As with the annual surveys, the more components you complete, the more beneficial your data will be for yourself, the research project, and ultimately, for all PSP members.

Your individual results from the Monthly and Daily self-report surveys will not be transmitted or otherwise made available to your PSP section; therefore, your data cannot be used to evaluate your employment fitness. The summary information only will be used to help the researchers understand the overall psychological profile of participants and to accomplish the goals outlined for the study.

2.3 Technological Considerations

Physiological Measurements:
Some participants will be invited to provide physical data about themselves, including heart rate, breathing, and movement (please see Table #2 for details). Tracking of these characteristics is broadly defined as "physiological data". The necessary equipment will be provided. You will be able to use this technology for the study and for your own personal activities until the research study ends, until the equipment is updated or recalled by the study team, or until you leave or are withdrawn from the study.

Participants will be provided biometric devices and software for submitting physiological data. We expect that participants will take reasonable care of all provided equipment. There will be no cost to participants for upkeep or replacement of damaged or defective equipment. Information regarding what to do in the event there is a problem with any part of the equipment is available in the research portal. Other participants will use their own devices for study purposes.

Data is collected from the biometric device continuously while the devices are turned on and being worn. The biometric device will monitor and record respiration (breathing rate) and a built-in electrocardiogram (ECG) will be used to measure heart activity and physical activity levels (e.g., steps). The ECG records signals produced naturally by the body and there is no evidence that regular use of an ECG monitor can cause any harm. Please see Table # 2 for details on all the types of data recorded by each device.

We ask that participants wear the biometric device as directed. Step-by-step instructions for using the technology and inputting data will be provided during training as well as on the website.

All of the physiological data gathered via the biometric device during your adapted training will establish your individual physiological baselines. The physiological data recording will continue after adapted training, allowing for comparisons with your baselines and associations with your self-reporting. We expect that the physiological data, associated analyses, and automated feedback will help to support your mental health. The physiological data will also help the research team to understand the relationships between physical responses and mental health functioning.

2.4 Augmented Training

Participants will receive mental health training augmented with a skills-based intervention program, specifically adapted for the PSP (i.e., Augmented Training), which we expect will further strengthen and maintain their future mental health. The skills-based interventions have received substantial research support for improving mental health among persons in the

general population who have experienced high levels of stress. Each training session will last approximately 1 hour and will occur as part of the Study training. There will be approximately 16 sessions in total and participants will be asked to practice and use the associated skills throughout their time during the training, while at work, and while at home. Participants will have ongoing access to the training materials for review to help them practice their skills. Participants will also be asked questions to assess their new skill levels and to assess how often they use their new skills.

Table 2. Data Collections

SELF-REPORT SURVEYS	
All of the self-report survey data is collected through a secure web-based survey tool.	
• Baseline Survey • Annual (pre-deployment, deployment anniversary) • Monthly Surveys • Daily Surveys • Significant Event • Significant Emotion • Significant Emotion Management Practice	
ASSESSMENTS WITH CLINICAL TEAM MEMBER	
All of the assessments with a Clinical Team Member are conducted verbally with responses recorded securely through a web-based application called NView.	
• Upon commencement of study/project • After training • 12-months after training	
PHYSIOLOGICAL DATA – Biometric Device	
• Heart Rate	Number of times per minute the heart beats
• Heart Rate Recovery (HR2)	Length of time it takes your heart rate return to resting heart rate after exercise.
• Heart Rate Variability (HRV)	Variation in the time between heart beats.
• QRS	The name of the curve in an electrocardiogram (ECG). An ECG is a graph of the electrical activity of the heart.
• RR interval	Elapsed time between two R-waves of the QRS in the ECG. Measurement of time between heart beats.
• Breathing Rate	Number of breaths a person takes per minute.
• Tidal Wave Volume (L)	Volume of air inhaled or exhaled in each breath
• Minute Ventilation (L/min)	Volume of air inhaled or exhaled in a minute
• Breathing Expiration Event	
• Breathing Inspiration Event	
• Actigraphy	Monitoring rest and activity
• Activity Classification	
• Step Counting	
• Cadence	Strides per minute

3. CONFIDENTIALITY AND PRIVACY

3.1 Ensuring Confidentiality

The study involves three interviews that may be conducted in person, via telephone, or via video conferencing, as well as the completion of numerous self-report measures. Please note that a portion of participants may be invited to participate in additional interviews. We recognize that you will be asked to share sensitive information if you agree to participate in the current study. **Your privacy is very important to you and to us**; therefore, we have incorporated multiple safeguards to protect your privacy. The research has been designed such that study team members will keep the identity of participants confidential. The interviews will be conducted by one or two trained and supervised clinicians or clinical trainees, all of whom will also be bound by professional ethical guidelines and policies, including the Code of Ethics of the Canadian Psychological Association. **All data collected as part of the study will be kept strictly confidential within the legal boundaries of consent as described below in the Limits to Confidentiality section.** The study team members will not confirm or deny your participation without your written consent.

The PSP employers will **not** have access to individual participant data from the research study. The research results from the study will be analyzed and presented in summary fashion that do not allow individuals to be identified.

As a participant, your data will be stored securely on Canadian servers in password protected, multi-factor authentication (MFA) enabled files within a secure facility at the University of Regina in Saskatchewan, Canada or a secure cloud environment within Canada. The data is only accessible according to the Limits to Confidentiality section below.

Some demographic information will be requested by the research team to characterize the participants (e.g., age or employment status). If you believe providing a piece of information will allow you to be identified, you may choose not to provide that information; however, you may be asked to confirm that you do not wish to provide the information to avoid accidental omissions.

3.2 Other Privacy Precautions

Several additional steps have been taken to ensure the confidentiality of your participation and your information. Specifically:

1) A privacy impact assessment was completed on all information gathering technology and the Saskatchewan Office of the Information and Privacy Commissioner was consulted in the areas of privacy, security, confidentiality, and access.
2) The study team members, including those conducting the interviews, do not include PSP.

3) During the study, the data collected will be accessible only to the study team or a qualified independent researcher for the purpose of auditing statistical assessments, but not available to PSP employers.
4) The clinicians completing the interviews will only have access to individual participant data for limited periods of time just prior to, and shortly after, scheduled interview.
5) No members of the study team will attempt to compromise your confidentiality or except as required by law, and the legal limits to confidentiality.

3.3 Limits to Confidentiality

If significant evidence of a mental health disorder is identified during the scheduled assessment interviews with the study team's clinicians or clinical trainees, you will be notified that you have screened positive and you will be encouraged to access health resources through your PSP employer, your health care system, or through a third-party provider. In the event that we become concerned that there is an imminent risk to your own safety or the safety of someone else, we may be legally required to contact you in order to ensure your own safety or that of others. Nevertheless, before any such attempt is made we will attempt to discuss alternatives with you that ensure your safety or others' safety without compromising your confidentiality (e.g., by encouraging you to reach out for help on your own). In the event that we are still concerned about your safety or another person's safety, we will report this concern to the relevant authority (e.g., emergency services for self-harm, Ministry of Social Services for child harm).

4. SUPPORT SERVICES

Please note that the self-report surveys are not monitored in real time. In some cases the software will provide you with a notification that your self-reported responses indicate you may benefit from accessing additional mental health support and various options may be suggested; however, in the current design of the study, there is no real time monitoring by a human being and we have prioritized your confidentiality above other considerations. In cases where you believe you need additional support you will be responsible for deciding to reach out to available resources to access care.

Please note that the physiological data is not monitored by the research team in real time. In some cases the software may provide you with heart rate notifications and indicate you may benefit from accessing additional health support and various options may be suggested; however, in the current design of the study, there is no real time monitoring by a human being and we have prioritized your confidentiality above other considerations. In cases where you believe you need additional support you will be responsible for deciding to reach out to available resources to access care.

Please note that the help desk is not available 24 hours a day, 7 days a week, and is not intended to provide mental healthcare. Please also note that the staff monitoring the helpdesk are technicians who do not have clinical training and are intended to support technical or process questions. We are required to refer any participants seeking clinical help from the study team to one of the listed available resources. As such, we strongly advise you to choose one or more of the listed available resources as your first point of contact for accessing mental health care, or a similar professional, accredited, and licensed mental health care professional.

Please note that the electronic communications through the Research Portal are not monitored in real time and are not intended to provide mental health care and that the staff monitoring the website are technicians who do not have clinical training and are intended to support technical or process questions. We are required to refer any participants seeking clinical help from the study team to one of the listed available resources. Accordingly, we strongly advise you to choose one or more of the listed available resources as your first point of contact for accessing mental health care, or a similar professional, accredited, and licensed mental health care professional.

Available Mental Health Support Resources

Find a therapist in Canada: http://www.cpa.ca/public/findingapsychologist/
Find Suicide Crisis Resources in Canada: http://www.crisisservicescanada.ca/
Call for help 24/7 with suicide right now 1-833-456-4566
For Residents of Quebec, call for help 24/7 with suicide right now 1-866-277-3553
Text 45645 for help with suicide 4PM to 12AM EST

5. DATA STORAGE

5.1 Storage of Data during the Study

Data being transferred from one device (e.g., your phone) to another (e.g., the secured servers) is protected using Transport Layer Security (TLS), which provides cryptographically secure communications between a client (such as a web browser) and the server. The TLS protocol provides both privacy and data integrity, as traffic between a website and the web browser is secured using the protocol. We employ a PKI Class 3 SSL Certificate the highest level of online trust and assurance, with a 2048 bit digital signature and 256 bit encryption.

The study data in the secured servers will reside in Canada on Canadian servers. All stored data on the servers are automatically encrypted using server-side AES-256 (Advanced Encryption Standard) encryption before being saved to disk and decrypted before data is downloaded.

5.2 Storage of Data After the Study is Over

All data for the study, including the consent form, will be presented and stored electronically. Data will be stored securely for a period of no less than seven (7) years after data collection stops and the study has been completed. Once the data is no longer needed, electronic copies will be deleted using methods that ensure that the data is non-recoverable.

Approximately one month after all the data has been collected and analyzed (e.g., in approximately 2 years), all participants will be notified that within five months their software access will be discontinued. This will be done as part of our effort to ensure that your confidentiality is protected and to even further reduce the risk of any possible privacy breach. The warning will also provide participants with another opportunity to export their clinical information for their own records.

Other researchers may obtain copies of the anonymized data (i.e., data that does not have any identifying information) by request, but for verification and/or research purposes only. Due to the unique nature of data and its large scope and size, it is likely that researchers may decide to conduct numerous secondary analyses of the data, but under no circumstances will the data be used or shared for commercial purposes. The PSP employers and individual PSP members will **not** have access to individual participants' responses (other than their own data, where applicable) to the individual surveys, interview responses, or physiological data (except for the Limits to Confidentiality outlined above). Results from the study will be published in peer-reviewed journals and other academic forums, but those results will only be presented in aggregate form so that no individuals can be identified.

6. POTENTIAL RISKS AND BENEFITS

6.1 Potential Risks

Any potential risks associated with this study are expected to be minimal. The physiological measurement equipment is not expected to carry any physical risks.

Some of the survey questions are sensitive in nature and could produce some uncomfortable feelings (e.g., sadness, worry, stress). If this happens, we expect those feelings to be temporary and manageable. In the event that troublesome emotions surface and persist while answering the questions, and you would like to talk to someone about the emotions, you have access to health resources from the external professional resources listed in Section 4 above.

6.2 Potential Benefits

The results of this study will substantially increase our understanding of risk and resiliency factors related to symptoms of posttraumatic stress and mental health. Improved understanding of these factors will contribute to the development of future training and will inform future treatment.

You will not be paid to participate in the study. **You will be allowed to participate in the study as part of your paid time at work.**

You will be able to answer your survey questions and review your own scores through the secured website or through the Moodle Study app. The more components you complete, the more beneficial your data will be for yourself. Based on all of the available research, regular monitoring of mental health and associated activities typically improves mental health; as such, a key potential benefit for all participants should be improved mental health. The data from your interviews, your surveys, and in some cases your physiological monitoring, should also provide important information allowing you to identify trends, tailor your activities, and help you to access care based on your own needs and choices. We also fully expect that your regular participation should help you to choose to access care earlier, if needed, which should mean faster recovery times for those who experience a mental health injury; however, obtaining evidence to support such anticipated benefits is a key reason for conducting the current study.

Based on all of the available research, the skills-based intervention program also typically improves mental health; accordingly, a key potential additional benefit should be improved mental health as a result of the additional skills-based training. Obtaining evidence to support such anticipated benefits is another key reason for conducting the current study.

We believe the physiological monitoring may also, ultimately, allow for physical evidence that a mental health injury has occurred, which would allow for even earlier identification of symptoms, faster access to help for future PSP members, and may help with the development of new treatment options. Obtaining evidence to support such possibilities is another key reason for conducting the current study.

7. LEAVING THE STUDY

7.1 Right to Withdraw

As with any research study, participants have the right to refuse to answer any or all of the questions. Participants may also change their mind about participating at any time and leave the study. Participants who wish to leave the study are directed to complete the Exit Form available in the web portal. Please note that failure to complete the surveys does not constitute formal withdrawal from the study and your data will remain in the study.

You may also request that the data you have provided up until that point in time be removed and not used for future analyses or reporting. If you request your data be removed, the researchers will do so as quickly as possible, typically within 30 calendar days of receiving your request. You also have the right to download your survey results and/or physiological data summaries before they are erased. Once you have downloaded your data, you have sole

responsibility for the security of your data. Please note that if your data has been made part of a summary set of data that has already been reported, we have no way to remove your data after the summarizing and reporting has occurred.

7.2 Removal of Participants

There are certain conditions under which the researchers may need to remove a participant from the study. If you choose to participate in this study, you understand and accept that you will be removed from the study if any of the following occur:

1) You choose not to participate in any one of the Full Assessments, recognizing that, as noted above, you may participate and still choose not to answer any or all of the questions.
2) You move away from a PSP employer in the study area
3) You leave your PSP employer and are no longer a PSP

7.3 Returning Wearable Technology and Support Technology

If you choose to leave the study or are removed from the study, you will be required to return all study-related wearable technology and support technology that was provided to you. It is expected that the returned technology will be in good working condition (i.e., not damaged beyond what would be reasonable wear and tear from typical use).

7.4 Feedback

Please note that at any point in time you are encouraged to provide feedback to the study team that you think may help us to better serve you and other public safety participants in the future.

7.5 Access to Research Results

Results produced from the current data will be made available through several avenues, including but not limited to summaries presented on the project website, at academic research conferences, in peer-reviewed articles and, where practical, in publicly accessible conference formats. When new aggregated research results are made available PSP leadership will be made aware and will be provided directions on how to access those results.

7.6 Questions and Concerns

If you have any questions, please feel free to ask at any time. You may contact the research team by email PSP.PTSI.Study@uregina.ca, or messaging through the Research Portal.

8. ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Research Ethics board approval

The Research Ethics Boards at the University of Regina (File #2020-TBD) have approved this study. If a participant has any questions or concerns about their rights or treatment as a research participant, they may contact the Chair of the University of Regina Research Ethics

Board at 1-306-585-4775 (out of town participants may call collect) or by e-mail: research.ethics@uregina.ca.

CONSENT:

Checking the yes box below indicates that you:

1) **have read and understand the description of the study provided;**
2) **have had an opportunity to ask questions and those questions have been answered;**
3) **understand you can receive a copy of this Consent Form for your own records;**
4) **consent to participate in the current study.**

By continuing to submit the self-report surveys, participate in the interviews, and/or use the provided technology, your ongoing free and informed consent is implied and indicates that you understand the above conditions of participation in this study. Please note that a copy of this consent form will be available in the web portal.

☐ Yes, I understand, wish to participate, and am ready to proceed

☐ No, I do not wish to participate

Thank you for your interest and participation.