# PARTICIPANT INFORMATION SHEET

**Title of Study: Pilot Trial of Digital Substance Use Disorder Interventions to Prevent Post-release Substance Use Disorder Relapse in Offenders in Correctional Service of Canada Custody (PROCESS)**

**Principal Investigators:**

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**Funding Source:** Funding will be provided by Correctional Service of Canada (CSC).

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You are being invited to participate in a research study because you have reported problems with substance use, which may have contributed to a previous incarceration or increase your risk for re-incarceration. This pilot/feasibility study is investigating the efficacy of two digital health apps meant to minimize substance use and associated mental health problems.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand this study, you will be asked to sign this form if you agree to participate. Please take your time to make your decision.

The principal investigator, Dr. James MacKillop (McMaster University/SJHH), is conducting this study with support from Correctional Service of Canada (CSC).

## WHY IS THIS RESEARCH BEING DONE?

There is a high prevalence of substance use disorders (SUDs) in incarcerated individuals. Substance use has been found to be a strong risk factor for re-incarceration. However, there are several potential interventions which may help reduce the risk of relapse and re-incarceration. Many individuals following release from a federal correctional facility do not have access to therapy. Online-based interventions may help increase the accessibility of treatment in these settings. Thus, this pilot study aims to test the feasibility of administering online-based therapy and inform future clinical studies on how it can reduce the risk for re-incarceration and relapse. As a pilot study, we hope to gather general information about the efficacy of each treatment intervention and draw comparisons between the two.

## WHO ARE THE PARTICIPANTS IN THIS STUDY?

Participants in this study will include individuals recently released from a CSC facility, currently residing in a Community Correctional Centre (CCC) or Community-Based Residential Facility (CBRF), with a history of substance use problems. We will enroll individuals between 18-55 years old, with a total of 20-40 participants.

**WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?**

If you participate in the study, you will be randomly assigned (with a 50% chance) to one of two online digital treatments meant to help with substance use: (1) Breaking Free Online (BFO); (2) Computer-based Training for Cognitive Behavioral Therapy (CBT4CBT). Treatment will be completed over 4-6 weeks in-person at your facility with study personnel present.

*Breaking Free Online*

BFO is a digital intervention used to treat substance use disorders and other mental health conditions, such as depression and anxiety. It is self-paced and can be used online or by smartphone. It helps you develop cognitive restructuring skills (i.e., coping with and reframing negative thoughts) and increase mindfulness. You can identify situations which may increase your risk for substance use and create a plan to minimize your use. The dashboard allows you to navigate through skills and track your progress over time.

*Computer-Based Training for Cognitive Behavioral Therapy*

CBT4CBT is a digital version of Cognitive Behavioural Therapy (CBT), used for substance use disorders. CBT focusses on reframing unhelpful thoughts/behaviours and helps you develop effective coping mechanisms. This intervention provides six different modules that focus on changing substance use patterns, coping with craving, problem solving and decision-making, and changing thoughts on drug and alcohol use. Modules include educational computer games, animations, quizzes, and more.

You will also complete a short series of questionnaires regarding your demographic information (e.g., age, race, etc.), incarceration history, substance use history and cravings, motivations to minimize substance use, and commitment to your sobriety. Questionnaires will be completed at baseline (upon your enrolment in the study), as well as following the completion of the treatment program (directly following completion of your final treatment module). You will also rate each individual module on how much you liked it and how useful it was to you. Treatment modules and questionnaires will be completed on iPads provided by our study team at your facility.

We will also be requesting records from the CSC regarding your substance use and incarceration status 3 months following your completion of the treatment program, using your Fingerprint Section (FPS) number. Therefore, the CSC will be aware of your participation in the study, but will not have access to any data that we will be collecting from you, or any information provided throughout the treatment program.

Please also note that while enrolled in this study, you are not to participate in other ongoing research studies. This is to avoid any external influences on treatment outcomes while completing this study. You are also consenting to us keeping record of your study data for up to 10 years, after which it will be destroyed. All identifiable data will be destroyed after we receive information from the CSC about your incarceration and substance use status, which will be requested 3 months following your completion of the treatment program.

## WHAT INFORMATION WILL BE COLLECTED FROM ME?

Aside from the treatment intervention, we will administer several questionnaires at your enrollment and completion of the study. Questionnaires will collect your demographic information (i.e., month/year of birth, age, gender, etc.), your incarceration history, and assess several aspects of your substance use recovery (e.g., motivation to change, craving, and commitment to sobriety). We will also ask for your Fingerprint Section (FPS) number during data collection. This will allow us to request information regarding your incarceration status and substance use status 3-months following the completion of the treatment program from the CSC. Consenting to this form means you agree to us requesting your FPS number as well as linking it to your status with the CSC 3-months following your participation in the study.

## WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

It is possible you may experience some emotional discomfort while completing treatment, as you are discussing your substance use and mental health. However, your participation is completely voluntary and you can choose to not answer any question that makes you uncomfortable, or withdraw your consent at any point during the study. There may also be circumstances where researchers are collecting information that requires mandatory disclosure of your information if required by law, or if you are at serious risk of harming yourself or others.

Another risk is the potential for loss of privacy. To minimize this, all participants are assigned a Subject ID number which is kept separate from any personal identifiers. Additionally, all study data is stored on a password-protected computer or in a locked office and cabinet in our research centre at the Peter Boris Centre for Addictions Research, St Joseph's Healthcare Hamilton. Questionnaire data collected by our study team is done through a secure encrypted electronic program called REDCap (Research Electronic Data Capture), which is kept on a secure server at St Joseph's Healthcare Hamilton. Please note that we are using CBT4CBT and BFO treatment interventions, which are externally hosted services. You can review their privacy statements online at https://breakingfreeonline.ca/privacy-policy and https://cbt4cbt.com/wp-content/uploads/2019/12/Privacy-Policy_12182019.pdf. Your data will be stored in Canada, hosted in Toronto-based server facilities (BFO) or otherwise on an AWS cloud-based Data Centre, which uses AES standard encryption (CBT4CBT). BFO requires you to accept their Terms of Use and End-User License Agreement when creating your account. If you do not agree with these, you should let our study team know, as you may not be able to take part in this study.

It is also possible that a Court could find the information collected about your pre-incarceration substance use to be legally privileged (but there is a chance it may not be legally privileged and could therefore be used against you). Please note, we will not be collecting information about any current substance use. Information collected via the digital platform will only inquire about cravings, coping mechanisms, or other recovery related outcomes, not substance use. You may also refuse to answer any questions or stop participating at any point throughout the study.

## HOW MANY PEOPLE WILL BE IN THIS STUDY?

There will be approximately 20-40 individuals enrolled in this study.

## WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?

We cannot promise any personal or medical benefits to you by taking part in this study. However, the results will be used for larger studies to examine the feasibility and efficacy of online-based treatment for substance use disorders in individuals recently released from a federal correctional facility.

**IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

It is important for you to know that you can choose not to take part in this study. An alternative to the procedures described above is not to participate. Choosing not to participate in this study will have no negative repercussions. To withdraw your participation, please inform our team verbally or otherwise contact us by phone (289-442-2170) or email (process@stjosham.on.ca), and we will destroy your data.

**WHAT INFORMATION WILL BE KEPT PRIVATE?**

Your data will not be shared with anyone except with your consent or as required by law. All personal information such as your name or date of birth will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure place, separate from your file. The data, with identifying information removed, will be securely stored in a locked office in our research centre at St Joseph's Healthcare Hamilton. While information regarding your substance use and incarceration status will be requested from the CSC, their staff will not have access to any information collected from you throughout the duration of the study. After we have collected information about your substance use and incarceration status from the CSC, all identifiable data will be permanently destroyed. A summary report will be written and provided to the CSC, but any results for this report or other publications will not include your name or any information that discloses your identity.

For both treatment interventions, your data cannot be sold for commercial purposes and they cannot disclose your personal information to third parties. Personal data collected by BFO will include your email for the purposes of account verification. CBT4CBT does not require you to provide any personal information or protected health information. Disclosure of your personal information can only occur if required by law. CBT4CBT can collect your IP address, browser type, domain names, access times, and referring website addresses, while BFO does not store any such information and only tracks locations you have marked in the modules as potential risks for your sobriety. However, you will complete treatment on study iPads provided by our team rather than using your own device.

To ensure the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board (HiREB) or St. Joseph's Healthcare Hamilton may consult your research data for quality control purposes. However, no records which identify you by name or initials will leave the research centre. By signing this consent form, you authorize the release of your research data to the HiREB for such monitoring purposes.

**CAN PARTICIPATION IN THE STUDY END EARLY?**

If you volunteer to be in this study, you may withdraw at any time and this will in no way affect your experience in this institution. If you decide to withdraw from the study, please contact the study team [P: 289-442-2170, E: process@stjosham.on.ca] or let us know verbally. You do not need to provide a reason. You also have the right to withdraw your data up until the time of data analysis. Information relevant to your decision to continue or withdraw from this study will be

given to you in a timely manner throughout the course of the study session, and will also initiate the withdrawal of your data from BFO or CBT4CBT. The Principal Investigators may withdraw you from this research without your consent if: a) the Principal Investigators decide that continuing in this study would be harmful to you; b) you are unable or unwilling to follow the study procedures.

If you would like your data to be deleted from the BFO system, you can submit a “Purge Request” via the “Purge my Data” link found on the “My Data” section of the main menu, or by request through their Contact Form. You can request your data to be deleted from the CBT4CBT website by contacting their team directly (E: cbt4cbt.llc@gmail.com). Alternatively, you can let our study team know that you would like us to put in a request to CBT4CBT/BFO to delete your data.

**WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**

You will not be paid to participate in this study.

**WILL THERE BE ANY COSTS?**

Your participation in this research project will not involve any additional costs to you.

**WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?**

Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

**IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?**

If you have any questions about the research now or later, or if you think you have a research-related injury, please contact the Principal Investigator Dr. James MacKillop at 905-522-1155, ext. 39492.

## CONSENT STATEMENT

**I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.**

**Participant:**

**I agree to participate in this study. I understand that I will receive a signed copy of this form.**

| Name | Signature | Date |
|---|---|---|

**This study has been reviewed by the Hamilton Integrated Research Ethics Board (HiREB). The HiREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905.521.2100 x 42013.**

**Person obtaining consent:**

**I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.**

| Name, Role in the Study | Signature | Date |
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