

**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)**

STUDY PROTOCOL

V4.0 DECEMBER 8th, 2025

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Acknowledgements

This work was supported by a Service Exchange Agreement between the Peter Boris Centre for Addictions Research at McMaster University/St. Joseph's Healthcare Hamilton and Correctional Services of Canada. The authors thank the staff of the Research Branch of Correctional Service of Canada for their support of the project, especially Sara Johnson, Nicholas Chadwick, and Kayla Wanamaker. The authors additionally thank Jane De Jesus at the Peter Boris Centre for Addictions Research and Shawn Billington at the Research Institute at St. Joseph's Healthcare Hamilton.

I. Contractual Agreement

The proposed pilot study is being conducted under the auspices of an ongoing memorandum of agreement between the Correctional Service of Canada (CSC) and the Peter Boris Centre for Addictions Research (Dr. MacKillop is the Principal Investigator of the parent agreement). Both parties have signed a Service Exchange Agreement to govern this collaborative research.

II. Project Summary

A substantial proportion of individuals currently residing in prison have problems with substance use or a substance use disorder (SUD). SUDs can greatly increase an individual's risk for recidivism following release from a correctional institution. Substance use also contributes to re-incarceration as it is associated with other illegal activities, such as driving while intoxicated. Although research demonstrates that treatment can greatly minimize the risk of recidivism, it is rarely accessible for individuals in correctional settings. However, more recent findings by the CSC suggests that digital interventions are both promising and effective and can help individuals re-integrate into the community. Thus, this pilot study will test the feasibility of administering two online-based treatment interventions in individuals recently released from prison, with a history of substance use problems, who are prohibited from using substances as part of their release terms. Furthermore, we will compare the efficacy of these treatments.

III. Background and Rationale

Individuals with SUDs are over represented in the criminal justice system (Butler et al., 2022; Weekes et al., 2004). This is in part because several psychoactive drugs are illegal, so procurement, possession, or distribution are all illegal acts that may lead to incarceration. In addition, intoxication is associated with criminal behaviour, ranging from driving while intoxicated to physical and sexual assault and homicide. Furthermore, the link between criminal behaviour and substance use may be related to environmental factors, such as living in a dangerous neighbourhood, which is associated with both criminal behaviour and substance use (e.g., Cambron et al., 2020), and psychological traits, such as impulsivity, that are associated with a higher likelihood of both criminal behaviour and substance use (e.g., Mathias et al., 2008), a so-called 'third variable'.

Following incarceration, substance use is well known to confer increased risk for recidivism (Zgoba et al., 2020), although there is evidence that interventions may be effective for decreasing recidivism (Clark, 2024; Olson & Lurigio, 2014). Unfortunately, despite the high prevalence of active and historical SUD in incarcerated individuals, a substantial proportion of individuals do not receive treatment (Kurdyak et al., 2022). Additionally, treatments that are implemented in prison or post-release settings typically comprise drug education or low intensity counselling, and are not necessarily evidence-based (Belenko et al., 2013). This is exacerbated by the high cost and resource demands of 'gold standard' treatments, such as cognitive-behavioural therapy or the community reinforcement approach (MacKillop et al., 2018).

In this context, it is important to identify alternative treatment modalities that are based on sound evidence but are also feasible and scalable for correctional settings. One approach is to use digital interventions, which may be implemented in prison settings or post-incarceration. In a previous systematic review supported by the CSC (Punia et al., 2025; in preparation), we

concluded that digital interventions for SUDs are relatively well established, evidence-based, and are comparatively easy to implement in a wide range of settings. Therefore, the goal of the proposed protocol is to conduct a pilot study to evaluate the viability of two candidate digital substance use interventions for offenders with a history of SUD who have recently been released from the custody of the CSC. Such a trial has not been conducted in Canada. Specifically, toward reducing substance use relapse and criminal recidivism following release from a custodial sentence at the CSC, the overall goals of the pilot study are: 1) to determine the feasibility of digital intervention clinical research among CSC post-release offenders; and 2) to determine which of the two digital interventions for SUDs may be best suited for a subsequent larger scale implementation and evaluation.

IV. Trial Design and Purpose

The core trial design is in Table 1 using a Population-Intervention-Comparison-Outcome-Timeframe (PICOT) framework. Overall, the pilot will examine Computer-based Training for Cognitive Behavioral Therapy and Breaking Free Online, the two digital interventions identified as most promising in our systematic review. These two interventions will be evaluated in 10-20 recently released individuals with a history of SUD in terms of feasibility, engagement, perceived utility and effectiveness, in general and in comparison, to each other. As a pilot trial, the evaluation is not intended to be able to definitively test the interventions relative to each other but gather initial descriptive data to establish feasibility and identify one preferred intervention.

Table 1. PICOT framework for the proposed trial

Population	Recently released CSC offenders with a history of substance use disorder (i.e., those prohibited from using substances as part of their parole terms) entering the community on a probationary basis at Community Correctional Centres or Community-based Residential Facilities. The sample size is estimated to be 10-20 individuals per intervention ($N = 20-40$).
Interventions	<ol style="list-style-type: none">1) Breaking Free Online (Telus Health)2) Computer-based Training for Cognitive Behavioral Therapy (CBT4CBT), by sudtech.org/Yale University <p>Participation will be voluntary.</p>
Comparison	The pilot is essentially two parallel pilot open-label evaluations of the interventions, including descriptive comparisons between each.
Outcomes	<ol style="list-style-type: none">1) Feasibility:<ol style="list-style-type: none">a. Number of enrolled pilot trial participants, overall and by intervention2) Engagement:<ol style="list-style-type: none">a. Number and percentage of modules completed3) Perceived Utility:<ol style="list-style-type: none">a. Mean rating/module and overall (e.g., importance, relevance, usefulness)4) Effectiveness:<ol style="list-style-type: none">a. Performance on within-intervention information quizzesb. Substance use relapse (as documented by the CCC staff)c. Institutional readmission (as documented by CSC)
Timeframe	The pilot project will run over a six-month enrollment period.

V. Population

The target population is individuals who (1) have previously served custodial services in the CSC; (2) have a history of a SUD; (3) are residing in Community Correctional Centres (CCCs) or Community-based Residential Facilities (CBRFs); (4) are 18-55 years old. Problems with substance use will be determined on the basis that individuals are prohibited from using substances according to their parole terms. The programs would be considered to be most appropriate to individuals who have been recently released from prison to assist with navigating the transition but are fundamentally applicable to any individual in these settings with a history of SUD and motivation to participate.

VI. Intervention #1: Breaking Free Online

Breaking Free Online (BFO) is a digital intervention for SUD concerns and mild to moderate co-occurring mental health conditions, such as depression and anxiety. It has been implemented in a wide array of settings including, to a limited extent, prisons in the UK. In terms of modality, BFO can be accessed online or via smartphone, and is self-paced, moving at the preferred speed of the individual. In terms of focus, BFO emphasizes relapse prevention and behavioural change techniques to address high-risk situations. This includes cognitive restructuring and mindfulness-based interventions. Anticipating high risk situations and planning to mitigate risk for substance use are also emphasized. Individuals navigate through skills via a dashboard and visually track their progress and substance use.

In terms of criminal justice outcomes, one study included a diverse sample of $N = 2,311$ individuals from specialist community-based substance misuse services, inpatient detoxification settings, community mental health services, and also prisons ($n = 165$). Individuals were first assessed on biopsychosocial functioning, quality of life, depressive/anxiety symptomology, and severity of dependence and were re-assessed eight weeks later. Significant reductions in problems with biopsychosocial functioning, depressive/anxiety symptomology, and alcohol/drug dependence symptoms were observed. Individuals also reported increases in quality of life and recovery progression, albeit to a smaller degree. The degree of change individuals experienced was significantly associated with the number of modules completed. For example, reductions in anxiety were associated with the number of times participants completed strategies in the emotional impact and negative thoughts modules. Changes in quality of life and biopsychosocial functioning were also associated with the number of strategies completed, further underscoring the dose-dependent response that is associated with completing modules in BFO (Elison et al., 2017). On balance, the outcomes reported were favourable but only a minority of participants were from a prison setting and specific outcomes for that subgroup were not reported.

A second study included high-risk incarcerated individuals ($n = 134$) who completed a Pillars of Recovery group (an intervention with similar principles as BFO, but completed in person with a clinician), whereas low-risk offenders completed BFO ($n = 332$) (Garvey et al., 2021). Risk status in this study was based on a score of ± 50 on the Offender Group Recoviction Scale-3. Both groups showed significant increases in quality of life from pre- to post-treatment and both also had significant decreases in dependence severity. Additionally, both groups showed improvements in biopsychosocial functioning (Garvey et al., 2021). Although observational in nature, these results demonstrate that BFO is associated with reduced substance use, increasing quality of life and biopsychosocial functioning. In a qualitative study in incarcerated adults (Elison et al., 2016), prisoners had a positive impression of BFO, highlighting the potential of the program to “build recovery capital” and provide

continued care. In addition, the participants reported they liked the structure of the program and reported they could translate the skills they learned into the community.

During the COVID-19 pandemic, a study used data from 2,187 Ohio prison residents who engaged with BFO (Elison-Davies et al., 2022). Using the progress check within the program as a benchmark, 53% of those who completed a progress check had decreased methamphetamine dependence, depression/anxiety, biopsychosocial impairment and increased quality of life (Elison-Davies et al., 2022). BFO comprises twelve evidence-based behavioural change techniques (BCTs), and those who completed a progress check were found to have completed more BCTs components (Elison-Davies et al., 2022). Interestingly, completion of the Difficult Situations module was associated with better psychosocial functioning, completion of the Unhelpful Behaviours module was associated with decreased substance dependence and an increase in mental health and biopsychosocial functioning, and completion of the Lifestyle module was associated with benefits for mental health, biopsychosocial functioning, and quality of life (Elison-Davies et al., 2022).

Most recently, BFO was evaluated in more than 20,000 offenders in prisons in the United States and the United Kingdom (Elison-Davies et al., 2024). In that study, substantive differences were present between the two settings, with more favourable outcomes in the British sample that had more staff involvement in the implementation. Nonetheless, both samples exhibited positive changes in all outcomes and program engagement was significantly associated with those changes. These findings suggest that BFO is an effective digital intervention for reducing substance use severity, comorbid mental health issues, and further provides evidence for the dose-dependent relationship between using the program more frequently with certain outcomes such as quality of life.

On balance, although most of the research uses observational designs, BFO nonetheless has notable promise for use in Canadian correctional and post-release settings.

VII. Intervention #2: Computer-based Training for Cognitive Behavioral Therapy

Computer-based Training for Cognitive-Behavioral Therapy (CBT4CBT) was developed by Dr. Kathleen Carroll at Yale University, and is a web-based version of Cognitive Behavioural Therapy (CBT) for SUDs (Carroll et al., 2008). CBT4CBT does not require any prior computer experience or reading skills (the text is read by a narrator) and incorporates multimedia style with computer educational games, graphic designs, animation, quizzes, interactive videos and audio voice-overs, modelling and imparting knowledge on skills and strategies (Carroll et al., 2008, 2014; Mallorquí-Bagué et al., 2023). In terms of structure, CBT4CBT has six modules including understanding and changing patterns of substance use, coping with craving, refusing offers of drugs and alcohol, problem solving skills, identifying and changing thoughts about drugs and alcohol, and improving decision-making skills (Carroll et al., 2008). Each module begins with introducing the key concepts, portraying a short video describing an individual being offered drugs or needing to cope with challenges surrounding substance use (Carroll et al., 2008). Following this, core skills to avoid substance use are introduced by the characters highlighting the importance of CBT skills (Carroll et al., 2008). Knowledge and skills gained in the modules are reinforced in additional videos that enable participants to view supplementary videos depicting characters engaging in assertive versus aggressive versus passive communication (Carroll et al., 2008). Additionally, each module contains a short vignette and an interaction video with a narrator providing knowledge on utilizing skills that assisted them to avoid substance use and the application of skills to address other issues (Carroll et al., 2008). Last, each module consists of a narrator reviewing all skills and strategies acquired, demonstration of homework completion and provides an assignment with a reminder sheet (Carroll et al., 2008).

In terms of the efficacy in randomized controlled trials, Carroll et al. (2008) found participants in the CBT4CBT group had significantly reduced positive urine drug screen tests for any drugs (Carroll et al., 2008). Those in the CBT4CBT group also had a longer periods of abstinence while in treatment in comparison to those in treatment as usual (Carroll et al., 2008), although no differences were found between the two groups (CBT4CBT and treatment-as-usual [TAU]) for overall self-reported abstinence for all illicit drugs, alcohol, and cocaine (Carroll et al., 2008, 2014). While investigating treatment outcomes, it was reported that cocaine use outcomes were more favourable among the CBT4CBT group in comparison to treatment as usual alone, with significant abstinence from cocaine observed in the intention to treat sample in the CBT4CBT group (Carroll et al., 2014). As noted, decreased consumption of cocaine was observed among those assigned to the CBT4CBT group in comparison to treatment as usual from baseline until the 6 month follow-up (Carroll et al., 2014).

In terms of correctional settings, one study specifically focused on alcohol use disorder (AUD) and a quarter of the sample was referred for treatment by the criminal justice system (Kiluk et al., 2016). Evaluating treatment retention and completion, 63 of 68 individuals initiated treatment by attending at least 1 session and 52% completed the treatment protocol (Kiluk et al., 2016). Participants in either of the CBT4CBT groups had a higher likelihood to complete the treatment protocol compared to those in treatment as usual (Kiluk et al., 2016) and the large majority of the participants (88.4%) indicated completion of at least 1 of the 6 homework assignments (Kiluk et al., 2016). The primary and secondary indicators of drinking at the 6 month follow-up suggested an increase in the percentage of days abstinent (PDA) and a decrease in percentage of heavy drinking days (PHDD) across all three groups: TAU, TAU + CBT4CBT, and CBT4CBT + brief monitoring (Kiluk et al., 2016). In addition, an overall increase in abstinence was found during the 8-week period in the TAU + CBT4CBT group as compared to TAU (Kiluk et al., 2016). Furthermore, a decline in heavy drinking was significant for participants in the TAU + CBT4CBT group, but not in the CBT4CBT + monitoring group (Kiluk et al., 2016).

al., 2016). Lastly, 91% of the participants completed the final 6-month follow-up and an overall decline in heavy drinking was present (Kiluk et al., 2016). Most recently, investigating the feasibility of CBT4CBT in residential treatment among women with SUDs, Kelpin et al. (2022) found that those in the CBT4CBT group had a decreased likelihood of relapse, increased time to relapse, and lesser number of days of endorsing substance use over the 3-month follow-up in comparison to a TAU group.

Given its electronic structure, program engagement is one candidate mechanism of efficacy. Evaluating this as measured by adherence to the program, Tetrault et al. (2020) found that of $N = 30$ participants in CBT4CBT, 77% completed at least one CBT4CBT session and of those who completed at least one session 78% completed some homework. Further, it was shown that participants preferred to complete CBT4CBT in diverse settings as 44% completed sessions at home, 44% at the clinic, and 12% completed both at home and in the clinic (Tetrault et al., 2020). Reasons reported for accessing CBT4CBT in the clinic was that it provided a quieter environment without distraction as compared to their homes. Notably, diverse electronic platforms were also used, as 61% accessed CBT4CBT on a desktop, 22% on a laptop, 26% on a tablet, and 26% on a smart phone (Tetrault et al., 2020), suggesting accessibility via multiple modalities is a strength of the program.

On balance, although not validated in correctional or post-release settings, its sizable evidence base makes CBT4CBT a promising digital SUD intervention in criminal justice contexts.

VIII. Comparison

This pilot study is a two-parallel open-label (unblinded) feasibility trial of the two interventions. We will use a cross-sectional design, with $N=10-20$ participants randomly assigned to each intervention. We will descriptively compare our feasibility outcomes (i.e., average number of modules completed and overall utility ratings) between the interventions and consider other factors, such as ease of implementation, duration/burden, and cost. For example, one intervention has an additional module compared to the other and if the ratings are descriptively similar, we would interpret the shorter intervention to be more viable. Fundamentally, as a pilot/feasibility study with a small sample size, the goal is to assess patterns of responses toward selecting a particular intervention for future research, without drawing statistically significant conclusions about differences in efficacy, and to confirm the overall feasibility of both treatment interventions in our study population.

IX. Outcomes

The first outcome is feasibility because a fundamental question is whether clinical research on digital interventions can be undertaken in CCCs/CBRFs. That is, any subsequent larger-scale research in these settings is predicated on the feasibility of working with staff and residents there. In terms of operational definitions, feasibility will be defined as the number of enrolled pilot trial participants, overall in the study and by intervention program. Based on evidence that the content module completion is a critical mechanism for benefit from these digital programs (Elison-Davies et al., 2022; Tetrault et al., 2020), the second outcome will be the number of modules completed (i.e., engagement). Third, to evaluate the acceptability and tolerability of the programs for the target population, we will examine the perceived utility by the program participants who will rate each module in terms of its importance for preventing

substance use, relevance to their situation, and usefulness as a post-release resource, via purpose-built questionnaires. Finally, although the project is a pilot study, it will nonetheless collect data on how effective the programs are, defined as a) how well participants perform on the content quizzes within the interventions; b) whether substance use lapses were identified by the CCC/CBRF staff; and whether institutional readmission took place as a result of substance use or substance-implicated recidivism as documented by CSC.

X. Assessments and Study Procedures

Assessments (**Table 2**) for this study will include self-report questionnaires collected via the St Joseph's REDCap on study iPads. Study personnel will travel to CCC's and CBRF's to complete the informed consent process with interested participants. They will be subsequently randomized into the BFO or CBT4CBT treatment intervention, complete a battery of questionnaires, and have their treatment account set up. All assessments and treatment modules will be completed on the study iPads in-person, with study personnel present to provide any necessary assistance. Additionally, iPads will be set up to block the use of all other apps and websites aside from REDCap, BFO, and CBT4CBT. Three months following completion of the treatment intervention, we will submit a request to the CSC to send information about participants' status of relapse and re-incarceration following treatment. CSC staff will only receive a list of names for which this data is requested, but will not have access to data collected by our study team or that collected through the treatment intervention. This query will be submitted via an encrypted email using a password-protected Excel sheet containing the participant names and requested information. The CSC will send back the information containing only the Subject ID numbers, thereby unlinking it from any personal identifiers.

Randomization will be conducted in an Excel sheet. To do so, a column was created with both treatment types split evenly, assuming N=40 participants. A separate column generated random numbers using the RAND() function, and the Treatment column was subsequently sorted by the randomly-generated numbers from smallest to largest. Subject ID's will be inputted into a separate column as participants are enrolled.

Table 2. Self-Report Questionnaire Measures

Construct	Scale/Questionnaire
Demographics	Self-report demographics questionnaire assessing age, gender, race/ethnicity, education, socioeconomic status, etc.
Treatment Utility	A 4-item scale where participants rate how important, relevant, helpful/useful, and likely they are to recommend the treatment program and modules. These will be administered after each individual module, and following completion of the treatment intervention.
Substance Use Behaviour	^a Brief Assessment of Recovery Capital (BARC) <i>Description: 10-item assessment of an individual's personal and interpersonal tools/resources available for recovery from substance use.</i> ^a Commitment to Sobriety Scale (CSS) <i>Description: 5-item self-report assessment of how committed an individual is to maintaining sobriety.</i>

	<p>Substance Use History <i>Description: examining participants' substance use prior to their most recent incarceration (i.e., what substances they used, how often, how often they were under the influence, and whether they have been incarcerated as a result of substance use).</i></p> <p>^a Penn Craving Scale (PCS) <i>Description: 5-item self-report scale assessing recent drug/alcohol cravings.</i></p> <p>^a General Motivation to Change Questionnaire (GMCQ) <i>Description: 3-item assessment of how motivation an individual is to quit or cut down on their substance use.</i></p>
Incarceration History	<p>Self-report questionnaire about the individual's most recent criminal offence and the length of their sentencing.</p>
<p>^a These scales will be administered at baseline (upon enrolment into the study) as well as following treatment completion.</p>	

XI. Timeframe

The project will be executed as part of the 2025-2026 Annual Deliverables Plan for the Memorandum of Understanding between CSC and the Peter Boris Centre for Addictions Research. The first three months will be used for finalizing the protocol, determining the target CCC/CBRFs and establishing working relationships with those settings, and obtaining ethical review board approvals. BFO and CBT4CBT include 6 and 7 modules, respectively; thus, we anticipate each participant to complete treatment in 4-6 weeks at a minimum rate of 1-2 modules per week. Data collection and analyses will be executed over six months and the results will be reported during the final three months.

XII. Participant Recruitment

Participants will be recruited from CCCs and CBRFs. Study flyers will be advertised in the facility and interested participants can contact the team expressing their interest in participating, or otherwise inform staff in the facilities who will generate a list of interested participants to provide to study personnel. This process will be repeated as needed until the target sample of $N=20-40$ participants is reached.

XIII. Analyses

Our feasibility outcomes will be analyzed using basic descriptive measures to assess the number of participants enrolled and the total and average number of modules completed for each intervention. We will use independent sample t-tests to analyze differences in the perceived utility between treatment interventions, as well as differences in our feasibility

outcomes. Secondary outcomes such as recidivism and relapse rates will also be preliminarily compared between treatment groups using independent sample t-tests, and differences in baseline and post-treatment assessments of substance use will be examined using a 2x2 analysis of variance (ANOVA).

XIV. Incentives and Costs

CSC policy prohibits provision of incentives to incarcerated individuals. Participation will be voluntary, with no monetary incentives, and no benefits to the participants beyond the experience of contributing to research and participating in the intervention. This will be clearly explained to participants and is considered to have no risk of coercion. There will also be no costs to participants.

XV. Potential Risks

This study does have several potential risks, and we have implemented several procedures to minimize these risks. Prior to enrolling in the study, all participants will be given a detailed overview of the study and will provide written informed consent. Participants will be reminded that taking part in the study is voluntary and that they can withdraw at any time without penalty.

We anticipate the following potential risks:

1. **Risks associated with discomfort / distress in answering personal questions:** Participants could potentially experience some discomfort resulting from answering some of the personal questions throughout treatment, which ask about previous substance use, triggers for use, and mental health symptoms. Participants will be informed that they can stop treatment at any time point. To further reduce any potential discomfort, participants will be debriefed at the end of treatment, including an opportunity to raise any concerns that they may have about their experience in the study.
2. **Risks associated with breach of confidentiality / loss of privacy:** A potential risk is loss of privacy due to inadvertent disclosure of personal information which could lead to embarrassment or damage to reputation. In addition, we are using two online-based therapeutic interventions which collect participant's data. Both BFO and CBT4CBT are compliant with PIPEDA. Their full privacy statements can also be found online. Any personal data we are viewing will be stored on password-protected servers and paper-based data will only be transported by trusted study personnel directly to our research centre, where it will be stored in a locked office and locked cabinet. Additionally, participants will be assigned a unique Subject ID number that will be kept separate from their name. Finally, results will only be disseminated in aggregate form with no participant names.
3. **Risks for legal disclosure of information:** It is possible that a court may find privilege to the information collected about participants' substance use, if it was subpoenaed. To avoid legal repercussions, we will not collect information about participants' recent substance use patterns. Information collected via treatment and questionnaires will relate to craving, coping, and general recovery, rather than current substance use. Participants will be informed of this possibility in the consent form to ensure they understand all legal risks associated with completing the study. Furthermore, they will be

reminded that their participation, including answering any questions in the study, is completely voluntary.

XVI. Study Budget

A detailed study budget has been uploaded with the REB application.

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