BMJ Open Peer support and online cognitive behavioural therapy for substance use concerns: protocol for a randomised controlled trial

Lena C Quilty,1,2 Jeffrey D Wardell,1,2,3,4 Gord Garner,5 Sarah Elison-Davies,6 Glyn Davies,6 Elizaveta Klekovkina,1 Michael Corman,7 Jeffrey Alfonsi,8 Allison Crawford,1,2 Claire de Oliveira,4,9 John Weekes10


ABSTRACT

Introduction Hazardous alcohol and drug use is associated with substantial morbidity, mortality and societal cost worldwide. Yet, only a minority of those struggling with substance use concerns receive specialised services. Numerous barriers to care exist, highlighting the need for scalable and engaging treatment alternatives. Online interventions have exhibited promise in the reduction of substance use, although studies to date highlight the key importance of patient engagement to optimise clinical outcomes. Peer support may provide a way to engage patients using online interventions. The goal of this study is to evaluate the efficacy and cost-effectiveness of Breaking Free Online (BFO), an online cognitive-behavioural intervention for substance use, delivered with and without peer support.

Methods and analysis A total of 225 outpatients receiving standard care will be randomised to receive clinical monitoring with group peer support, with BFO alone, or with BFO with individual peer support, in an 8-week trial with a 6-month follow-up. The primary outcome is substance use frequency; secondary outcomes include substance use problems, depression, anxiety, quality of life, treatment engagement and cost-effectiveness. Mixed effects models will be used to test hypotheses, and thematic analysis of qualitative data will be undertaken.

Ethics and dissemination The protocol has received approval by the Centre for Addiction and Mental Health Research Ethics Board. Results will help to optimise the effectiveness of structured online substance use interventions provided as an adjunct to standard care in hospital-based treatment programmes. Findings will be disseminated through presentations and publications to scholarly and knowledge user audiences.

Trial registration number NCT05127733

INTRODUCTION

Harmful alcohol and drug use is reported by a large proportion of adults worldwide1 and is responsible for substantial morbidity and mortality as well as societal costs.2,3 National bodies clearly recognise the public health costs of substance use disorders, as well as the numerous barriers to care that exist. Indeed, only a minority of those experiencing difficulties with substance use receive specialised services.4 Current treatments for substance use concerns exhibit modest efficacy and engagement, highlighting the importance of improving available services for those with substance use concerns.5 Both digital health solutions and peer support involvement have been promoted to meet this critical need.

Computer-based and web-based interventions represent an innovation with substantial promise for substance use concerns, and may promote access and engagement, complement traditional treatment, and improve outcomes. Such digital health solutions overcome numerous barriers to care. In a seminal review, Moore et al.6 concluded that computer-based interventions for substance use concerns are associated with greater motivation and retention as well as improved knowledge and substance use outcomes compared with standard care. Marsch and Dallery7...
further concluded that computer-based treatments are effective at all stages of recovery, and have extraordinary potential to build efficiencies in care. Meta-analyses have generally supported the impact of computer-based interventions for substance use concerns with small-to-medium effect sizes. 8,9

The majority of the digital health solutions comprise interventions made up of cognitive and behavioural change techniques. 10,11 Indeed, despite their efficacy, numerous barriers to the widespread implementation of in-person cognitive behavioural therapy (CBT) for substance use concerns exist, ranging from limited availability of trained professionals, lengthy wait times for care, stigma, and the time and cost to travel to service settings. This evidence-based treatment is rarely implemented with high fidelity in clinical practice, 12 further highlighting the potential for digital technologies to improve access to high-quality care. Online self-guided interventions can consistently deliver the psychoeducation and skills building exercises that are core to numerous evidence-based treatments for substance use concerns, thus ensuring the fidelity of these treatment components, a substantial benefit of this treatment modality.

Breaking Free Online (BFO) is a computer-based treatment initially developed in Manchester, England, but now available across many treatment settings in both the UK and North America, for those aiming to manage their substance use and is based on a CBT model. 13 Seminal investigations have documented user engagement and outcomes, and demonstrated that BFO is associated with benefit in diverse samples using a range of substances 14–16 as well as in those endorsing concurrent depression and anxiety. 17 Despite the strong qualitative and quantitative support for this programme, the added value of BFO to standard care has yet to be empirically tested in a randomised comparison of standard care versus standard care delivered with BFO; its capacity to impact healthcare costs has further yet to be evaluated.

Although digital interventions such as BFO are increasingly being used in healthcare settings, many people receive little or no support when they engage with these interventions. Peer support, the ability to identify with others through shared understanding of experiences, may be of benefit when patients engage with digital interventions. Indeed, peer support may provide a key mechanism by which to improve treatment engagement and retention across treatment modalities, contexts and settings. Systematic reviews have supported the benefits of peer support in acute treatment, including reduced substance use and relapse, improved treatment and social support, and importantly, increased treatment retention, adherence and satisfaction. 18–20 Notably, meta-analyses have further underscored the methodological limitations in studies to date, and repeatedly called for evaluations of increased rigour including larger sample sizes, blinded outcomes assessment, random assignment, comparison groups, and cost-effectiveness analysis.

The goal of the proposed research is to address these identified gaps within the literature in an investigation of the efficacy and cost-effectiveness of BFO with versus without peer support, in adults seeking treatment for substance use disorder. Outpatients receiving standard care will be randomised to receive clinical monitoring (CM) with group peer support, CM with BFO alone (BFO) or CM with BFO and individual peer support (BFO+PS), for 8 weeks, and will be followed-up monthly for 6 months. Substance use frequency during the past month will be the primary outcome measure; secondary outcomes will include substance use problems, depression, anxiety, quality of life, treatment engagement, and cost-effectiveness.

METHODS AND ANALYSIS

Patient and public involvement

The current proposal represents a novel collaboration between the Centre for Addiction and Mental Health (CAMH) and the Community Addictions Peer Support Association (CAPSA), with project leads from both organisations. Following funding acquisition, a CAPSA Advisory Committee was formed to inform study goals and design, study assessment schedule, and knowledge translation and exchange. Advisors also directly informed the peer support protocol and training to be delivered. Following study launch, advisors remain engaged through quarterly progress reports and other communications and peer supporters meet monthly to provide feedback. Notably, peer supporters and other people with lived and living experience of substance use challenges have historically been involved in the development, implementation, and evaluation of BFO, with updates and improvements made to the programme based on regular feedback. 21–23

Trial design

The study is a three-arm, parallel group, randomised controlled trial with evaluations conducted biweekly for 8 weeks during the intervention and monthly follow-ups conducted for 6 months after the end of the intervention. The trial has been registered with ClinicalTrials.gov. The protocol manuscript is compliant with the Standard Protocol Items: Recommendations for Interventional Trials statement. 24

Recruitment and participants

Participants will be recruited from the CAMH Outpatient Addictions Programme through clinician and self-referral as well as the hospital research registry. All participants will meet the following inclusion criteria: (1) 18 years of age and above; (2) fluency in English; (3) understand and willing to comply with study requirements and provide informed consent; (4) meet diagnostic criteria for a current substance use disorder; (5) have used their primary substance of concern within the past 30 days; and (6) are registered with CAMH Addictions Programme outpatient services. Exclusion criteria
include: (1) meet diagnostic criteria for current psychosis or mania; (2) psychiatric disorder requiring care more urgently than substance use, including acute intoxication or withdrawal requiring medical attention; (3) significant neurological disorder or physical illness likely to interfere with participation; (4) any known practical factors that would preclude participation, such as extended absence; (5) unable to read at a sixth-grade level.

Procedure
Participants will be approached following standard intake procedures in the CAMH outpatient services. All interested and potential participants will complete a brief telephone eligibility assessment, including an initial screening interview to assess basic demographic and clinical characteristics. Individuals who meet the preliminary eligibility requirements will then complete an in-person or videoconference screening interview. Informed consent will be obtained and documented according to hospital standard operating procedures. Eligible participants are enrolled upon their pretreatment assessment, when they complete all baseline measures and are randomised to one of three study conditions. Following randomisation, participants will be approached to complete biweekly study assessments for 8 weeks, a post-treatment assessment and monthly follow-up assessments for 6 months regardless of treatment compliance or attrition status. All outcome assessments will be conducted by research team members blind to condition assignment. See figure 1 for the study flow chart. The study start date was 25 October 2021 and the anticipated study end date is 26 January 2024.

Interventions
All participants will be offered standard care including ancillary services as needed, including psychiatric, pharmacologic, and emergency services. This pragmatic approach prioritises patient safety and has been applied in recent randomised controlled trials of online CBT in substance use.11

Experimental condition A: BFO
BFO is an online intervention designed to provide support to adults struggling with substance use. BFO enables individuals to access tailored clinical content specific to their needs, while maintaining anonymity. It provides psychoeducation and skills building exercises in evidence-based psychosocial intervention strategies, namely CBT and compatible approaches. This programme uses multimedia components through both computerised and mobile application delivery; no coaching or therapist support is provided. Participants actively engage with module content by working through individual exercises in a stepwise manner, which involves reviewing text, audio, and video information, and entering information in a variety of formats (e.g., checkboxes, open text fields) as they reflect on the content and progress towards their goals. The intervention strategies contained within BFO are provided via a six-domain biopsychosocial model, including difficult situations, negative thoughts, emotional impacts, unhelpful behaviours, physical sensations and lifestyle, which are closely aligned with the five factors used in basic CBT models (i.e., environment, thoughts, moods, behaviours, physical reactions.25 26). Each domain of the biopsychosocial model corresponds to a module in the BFO programme which contains a psychoeducation ‘information’ strategy, as well as an ‘action’ strategy to facilitate behaviour change. Data captured during each users’ baseline assessment27 28 is used by the programme to populate the model and to provide feedback to the individual on their levels of functioning across the six domains via a traffic-light colour coding system, with green, amber and red, indicating ‘little’, ‘moderate’ and ‘significant’ impairment, respectively (see figure 2 below). The programme guides the user to concentrate on completing strategies aligned to aspects of their functioning with the greatest impairment.

Experimental condition B: BFO+individual peer support
BFO delivered with peer support will comprise BFO with at least weekly contact with a peer with lived experience. Each participant will be assigned a peer support worker who will meet with them virtually on a weekly basis by appointment. Peer support workers will receive training on how to deliver BFO as a structured, facilitated programme. As part of this training, peer support workers will be given their own access code to use BFO and be encouraged to use the programme to both enhance their knowledge of the programme content and to support their own well-being. Members of BFO will provide both group and individual training, including a review of a
weekly peer support plan. The first session constitutes an initial orientation to the programme and is delivered by peer support workers during the first week. Subsequent lessons review each information and action strategy in the BFO programme, with a series of prompts to guide peer support of this content. Peer support workers follow a manual that includes overall guidance as well as specific topics for discussion in each session. Sessions are generally divided into three components: the session start (including a recap of the previous session, how they have been feeling over the past week, logging into the programme and completing a Progress Check assessment if applicable), session focus (including a collaborative review and discussion of the information or activity module to be completed) and session close (including final discussion, planning for the week, printing PDF summaries of completed strategies and logging out of the programme).

Control condition: CM+group peer support
The control condition will consist of CM with access to group support. That is, participants will complete study assessment visits, as well as receive an orientation to the online peer support group facilitated by trained peers offered through CAPSA multiple times per week. Peer support is part of standard care at CAMH and this facilitation will ensure that all randomised to this condition have access to an active intervention during the acute treatment phase. The group meets weekly and will offer participants a space to share their experiences and receive support.

Data collection
Table 1 provides a summary of assessment measures as well as primary and secondary outcome measures administered during the trial. All self-report measures will be administered online. Interview measures may be administered in-person or via video conference, according to participant preference. To confirm eligibility, all

Table 1 Schedule of assessments

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Screen</th>
<th>Week</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>X</td>
<td>0</td>
<td>2–6</td>
</tr>
<tr>
<td>Clinician-administered assessments</td>
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<td>8</td>
<td>1–5</td>
</tr>
<tr>
<td>Demographics</td>
<td>X</td>
<td>6</td>
<td>1–5</td>
</tr>
<tr>
<td>Medical history</td>
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<td></td>
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<tr>
<td>Treatment history</td>
<td>X</td>
<td>X*</td>
<td>X*</td>
</tr>
<tr>
<td>Structured Clinical Interview for DSM-5</td>
<td>X</td>
<td>X†</td>
<td>X†</td>
</tr>
<tr>
<td>Timeline Follow-Back</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Qualitative interview</td>
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<td>X</td>
<td></td>
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<tr>
<td>Programme and client costs—substance abuse treatment measure</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Questionnaires</td>
<td></td>
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<td></td>
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<tr>
<td>Severity of Dependence Scale</td>
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<td>X</td>
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<tr>
<td>Alcohol Use Disorder Identification Test</td>
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<tr>
<td>Drug Use Disorders Identification Test</td>
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<tr>
<td>Patient Health Questionaire-9</td>
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<tr>
<td>Generalised Anxiety Disorder-7</td>
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<td>WHO Quality of Life Assessment</td>
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<td>Substance Use Calendar</td>
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<tr>
<td>Brief COPE Scale</td>
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<tr>
<td>Adult Hope Scale</td>
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<td></td>
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<tr>
<td>Positive and Negative Affect Schedule—Expanded Form</td>
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<td>X</td>
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<tr>
<td>Contemplation Ladder</td>
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<tr>
<td>Treatment Acceptability/Adherence Scale</td>
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<td>X‡</td>
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<tr>
<td>WHO Disability Assessment Schedule V.2.0</td>
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<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*Current/since last visit treatment section only.
†Structured Clinical Interview for the DSM-5 module E only.
‡Post-treatment version.
participants will be clinically characterised by the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (SCID-5), which will be used to define the psychiatric diagnosis for alcohol and substance use disorders and assess the disorder severity over the past month. The SCID-5 has been demonstrated to have excellent reliability and validity. Participants will also complete the Contemplation Ladder, which is a single-item Visual Analogue Scale ranging from 0 (‘No thought of quitting. I cannot live without the substance(s)’) to 10 (‘I have changed my substance use and will never go back to the way I used before’). It will be used to assess where participants currently are in thinking about and/or changing their substance use for each substance that they use.

**Primary outcome**

The primary outcome measure will be change in frequency (days) of substance use (primary substance of concern) over the past 30 days according to the Timeline Follow-Back (TLFB), a retrospective interview, which assesses substance use over the previous month. The TLFB has accumulated evidence for its validity and reliability.

**Secondary outcomes**

Secondary outcomes measures will include the quantity of substance use (alcohol and cannabis only) over the past 30 days according to the TLFB. Further, the Substance Use Calendar is a self-report questionnaire that will be used to collect self-reports of alcohol and drug use over the previous 14 days, as well as amounts of substance use for the participants’ primary substance of concern, biweekly over the course of acute treatment and monthly over the course of follow-up. This additional measure will promote fulsome assessment of substance use frequency and quantity over both treatment and follow-up.

The Severity of Dependence Scale (SDS) is a 5-item self-report questionnaire that will be used to assess the level of participants’ dependence on their primary substance of concern over the previous 30 days. Items are scored on a Likert scale of 0 (not at all) to 3 (always or nearly always), with a maximum total score of 15, with higher scores indicating more severe dependence. Research has supported SDS score validity and test–retest reliability.

The Alcohol Use Disorder Identification Test (AUDIT) is a 10-item self-report questionnaire that will be used to assess alcohol consumption amounts and frequency, alcohol-related issues, and drinking behaviour adapted to assess the past month to facilitate assessment of change (see for an example). The items are scored on a scale of 0–4 with a maximum total score of 40, with higher scores indicating more severe alcohol use issues. AUDIT scores have demonstrated good internal consistency, sensitivity, and specificity.

The Drug Use Disorders Identification Test (DUDIT) is an 11-item self-report questionnaire that will be used to assess various drug-related issues and identify use patterns also adapted to assess the past month (see for an example). The items are scored on a 3-point scale with total scores ranging from 0 to 44, with higher scores suggesting higher severity of substance use issues. DUDIT scores have demonstrated internal consistency and convergent validity.

The Patient Health Questionnaire-9 (PHQ-9) is a 9-item self-report questionnaire that will be used to assess participants’ symptoms of depression over the previous 14 days. Items are scored on a scale of 0–3, with a total score range between 0 and 27 and higher scores indicating a higher level of depression symptom severity. PHQ-9 scores demonstrate good sensitivity and specificity, as well as internal consistency and reliability.

The Generalised Anxiety Disorder 7-item (GAD-7) is a self-report measure that will be used to assess participants’ symptom severity of GAD over the previous 14 days. The items range on a scale of 0–4, with total scores ranging from 0 to 21 and higher scores indicating more severe GAD symptoms. GAD-7 scores demonstrate good reliability, validity and sensitivity.

The WHO Quality of Life Brief (WHOQoL-BREF) is a 26-item self-report questionnaire that will be used to assess participants’ quality of life over the previous 4 weeks. The items are scored on a 5-point Likert scale, with higher total scores indicating a higher quality of life. The WHOQoL-BREF has been demonstrated to have good internal consistency and validity.

Additional measures will be administered to support the evaluation of healthcare costs and exploratory analyses of moderators and mediators of outcomes suggested by lived experience advisors. The Programme and Client Costs—Substance Abuse Treatment is a clinician-administered interview that will be used to monitor services provided to the participants as part of their standard treatment at CAMH over the past 7 days and associated costs. The Brief COPE Scale is a 28-item self-report questionnaire that will be used to assess frequency of use of different coping strategies in response to stressors. The Adult Hope Scale is a 12-item self-report questionnaire that will be used to assess current level of hope. The Positive and Negative Affect Schedule—Expanded Form is a 60-item self-report questionnaire that assesses positive and negative affect over the past 30 days, as well as additional specific affects. The Treatment Acceptability/Adequacy Scale is a 10-item self-report questionnaire that assesses treatment acceptability and anticipated or actual adherence in response to a given treatment. The WHO Disability Assessment Schedule V.2.0 is a 12-item self-report measure assessing overall level of functioning over the past 30 days.

Finally, participants will complete a semi-structured interview post-treatment following a qualitative description design. Interviews will have a two-pronged focus including (1) barriers and facilitators to the implementation of online CBT and (2) a complementary ethnographic focus on ‘health work’ patients engage in. This dual focus permits a complex understanding of the impact of online CBT and explores ways to optimally
deliver support during the care journey. Thematic analysis of interview data will be undertaken to offer a summative description of how patients give meaning to their experience in light of the intervention received.

Compensation
Participants will receive honoraria in the form of gift cards for study assessments in the following amounts (1) $25 for completing the pretreatment and posttreatment study assessment, and (2) $5 for each monthly follow-up assessment, (3) $25 for completing the 6-month follow-up assessment and (4) a $25 bonus for completing all assessments, for a maximum of $125.

Withdrawal
Patients will be withdrawn prematurely from the study if, at any point during the trial, they ask to exit or they meet any of the study’s exclusion criteria. Patients will be considered for withdrawal from study treatment and assessment procedures if they evidence any urgent medical or mental health issues. Participant attrition and adverse events will be closely monitored and reported to the institutional ethics board as appropriate. Attrition is defined as failure to complete study outcome assessment measures (i.e., a complete loss to follow-up). The research team will track this electronically and also provide a fulsome description of missing data patterns during knowledge dissemination. Adverse events are defined as harmful side effects that a patient experiences when participating in a study, which may or may not be related to the treatment received, and which are classified as mild, moderate or severe. The research team queries adverse events at the beginning of every study visit, which are tracked on a detailed log and reported to the Institutional Review Board on an annual basis (except in the case of severe events, which are reported within 48 hours). A thorough assessment of participants’ baseline health will be completed; determination of any adverse events will be in reference to baseline health for significant changes.

Sample size
A power calculation for a randomised trial indicated that a sample size of n=60 participants per study condition (N=180 in total) will be required to locate a small-to-medium effect size (Cohen’s f=0.13) with a power of 80% (for main effects or interactions), an alpha level of 0.05, and assuming a pre–post correlation of 0.50. This power analysis was conducted using G*Power62 and was based on the power necessary to detect the interactions between pre–post changes in the primary outcome and the planned comparisons among the intervention groups (see proposed analyses below). We anticipate an attrition rate of 20%, and thus will randomise an attrition-adjusted sample size of 225 participants (75 per condition) to compensate for the impact of attrition on statistical power, although we will conduct an intent-to-treat analysis using data from all participants randomised (see below).

Randomisation
Randomisation will be stratified according to sex (male, female) and by diagnosis (Alcohol Use Disorder (AUD) only, AUD and/or other Substance Use Disorders [SUDs]) in randomly generated block sizes. Randomisation will be overseen by the CAMH Biostatistical Consultant. Randomisation is stratified to ensure comparable distribution of these participant variables across treatment groups, and to facilitate our capacity to conduct exploratory analyses across these important participant features. Allocation will be concealed from the study coordinator, with the use of sequentially numbered, opaque, sealed envelopes.

Statistical analyses
To evaluate efficacy, we will use a mixed effect model, wherein time will be entered as a within-subject factor with two levels (pretreatment, post-treatment), and study condition (between-subject factor) will be represented by two orthogonal contrasts comparing each intervention condition to the control condition (i.e., BFO vs CM and BFO+PS vs CM). The primary hypothesis will be tested via the interaction between time and each contrast. Random intercepts will be specified to capture variability across individual participants. We will follow the intention-to-treat principle and analyse all randomised participants. Mixed effect models handle missing values by maximum likelihood estimation, which is able to use all available information from randomised participants, and has been associated with the least bias in a comparison of methods for dealing with missing data.63 We plan to examine several predictors (e.g., demographies, treatment compliance, baseline severity of SUD, comorbid symptomatology) of both the missing data on the outcome and the outcome itself and will include any significant predictors as auxiliary variables in the analysis. When auxiliary variables are included in Full Information Maximum Likelihood analyses, bias due to missing data can be substantially reduced.64 We will examine patterns of missing data in the entire data set to determine if the Missing at Random assumption is tenable,65 although we will include auxiliary variables if necessary, based on their correlation with missingness or the outcome itself. We will also examine whether the assumption of normality is met and use a robust estimator or model the outcome as a count variable with a Poisson or negative binomial distribution using a log link function where appropriate.

To evaluate change in secondary outcomes, we will follow the same procedure, and will also conduct post hoc models that include a contrast for BFO+PS versus BFO to directly compare the two intervention conditions. To evaluate durability of effects over the extended follow-up period, we will examine the interactions between treatment group contrasts and the trajectory of outcomes from post-treatment through the monthly follow-ups.

To evaluate the cost-effectiveness of the intervention for the primary outcome (change in frequency of substance use over the past 30 days), we will undertake an economic evaluation in line with the Canadian Agency
for Drugs and Technologies in Health’s Guidelines for the Economic Evaluation of Health Technologies. We will take the perspective of public third-party payer (i.e., the healthcare system). We will collect all relevant costs associated with delivering each arm of the intervention. All costs will be reported in 2024 Canadian dollars, using the Consumer Price Index for Health and Personal Care. The time frame of the cost-effectiveness analysis will be up to the last follow-up and the primary outcome of the cost-effectiveness analysis will be the incremental cost-effectiveness ratio. To determine whether the intervention is considered cost-effective or not, we will assume a willingness to pay a threshold of $C50,000 per life year gained, as typically done within the Canadian context. Relevant sensitivity analyses will be performed to evaluate the robustness of the results. Exploratory analyses will include a cost-utility analysis, where we will determine quality-adjusted life-years in conjunction with treatment costs associated with each treatment condition.

To evaluate the mediational role of engagement, we will use path analysis within MPlus, applying maximum likelihood estimation and specifying condition as the independent variable (using the same two orthogonal contrasts), engagement at post-treatment as the mediator, and substance use frequency at follow-up as the outcome (controlling for pretreatment substance use frequency). We will assess engagement using a multifaceted measure in line with recommendations. We will use 10,000 bootstrap resamples to provide stable estimates of direct, indirect, and total effects. To compare pretreatment participant characteristics across conditions, analyses of variance will be conducted for continuous variables and $\chi^2$ tests for categorical variables. To compare intensity and type of standard care across conditions, similar analyses will be conducted.

Data statement
The project will use the standard CAMH Neuroinformatics Platform processes to make data available, which adhere to the highest standards of privacy and security, including anonymisation frameworks and data sharing processes.

DISCUSSION
Strengths and limitations
This study is the first to examine BFO in Canada, after the adaptation of BFO in 2020 to include both Canadian English and Canadian French voice overs as well as written and video content. Peer support has been recommended as a supplement to online interventions; this study is further the first to investigate BFO in conjunction with peer support and may provide evidence about possible ways to enhance online treatment for substance use disorder. The combination of quantitative and qualitative measures will allow for a broader understanding of the factors contributing to the effectiveness of BFO with and without peer support.

One potential limitation of the study could be generalisability of its findings when applied to populations who do not have access to the same standard care that is provided at CAMH, as psychiatric consultation and psychotherapy have limited availability particularly in publicly funded healthcare settings. These results may inform further investigations regarding whether the BFO programme is able to enhance standard care or to otherwise improve efficiency of care. Another potential limitation of the study could be high attrition and low engagement rates, as has been demonstrated in past research on online interventions. However, the study design includes various modes of contact with participants, which may decrease attrition rates. A further limitation of the study is that it does not include a formal cross-cultural component. This would be a valuable future direction for this area of research. Notably, there is no existing consensus on the minimum level of adherence to either peer support or BFO that would support evaluations such as per-protocol analyses; the development of such guidance would be a valuable future area of research as well.

Ethical considerations
The proposed study is anticipated to have limited risks to participant safety. Participation is voluntary and can be discontinued at any time. There are no known risks associated with BFO, which has been endorsed by the UK’s National Institute for Health and Care Excellence (part of the UK Government’s Department of Health and Social Care) and is listed as a Vendor of Record by the Ontario Telemedicine Network (now known as Ontario Health). All participants will continue to receive the standard of care at CAMH.

Data confidentiality
Participant information will be anonymised and stored on a secure CAMH network or in a locked filing cabinet. Only members of the research team will have access to the data, unless required by law or by an audit of the research ethics board/quality assurance. All data will be electronically captured using the secure, customisable Research Electronic Data Capture tools. Publications using this data will fully protect participants’ anonymity.

Dissemination of findings
Knowledge dissemination will include several steps. First, we will target the scientific community and opinion leaders by publishing in scholarly journals and presenting at academic conferences. Second, we will release reports to clinicians and patient groups, in the form of clinician-friendly and patient-friendly reports and summaries, co-developed with these knowledge users. Third, we will communicate results in conference presentations to academic and clinician audiences. Additional knowledge translation activities will be co-developed with those with lived experience.
CONCLUSION

In conclusion, both digital technologies and peer support have been recommended to overcome barriers to care for those with substance use concerns. BFO has demonstrated therapeutic benefits across numerous investigations; yet, the incremental value of BFO, delivered with and without peer support, has yet to be quantified in a randomised trial. The current randomised controlled trial will address this gap and inform improved care for this population for whom accessible, engaging, and cost-effective intervention approaches could have significant public health impact.

Author affiliations
1 Campbell Family Mental Health Research Institute, Centre for Addiction and Mental Health, Toronto, Ontario, Canada
2 Department of Psychiatry, University of Toronto, Toronto, Ontario, Canada
3 Department of Psychology, York University, Toronto, Ontario, Canada
4 Institute for Mental Health Policy Research, Centre for Addiction and Mental Health, Toronto, Ontario, Canada
5 Community Addictions Peer Support Association, Ottawa, Ontario, Canada
6 Institute for Mental Health Policy Research, Centre for Addiction and Mental Health, British Columbia, Canada
7 School of Culture, Media, and Society, University of the Fraser Valley, Abbotsford, British Columbia, Canada
8 Schulich School of Medicine & Dentistry, University of Western Ontario, City of London, Ontario, Canada
9 Institute for Clinical Evaluative Sciences (ICES), Toronto, Canada
10 Department of Psychology, Carleton University, Ottawa, Ontario, Canada

Twitter Claire de Oliveira @clairede0

Contributors LQ, JE, SE, GS, MC, CD, and GG were involved in the design of the study. LH, JWA, SED, MC, CdO and EK contributed to the first draft of the manuscript. All authors, including LQ, JWA, SED, GD, JA, MC, AC, CdO, JWe, GG and EK, contributed to and have approved the final manuscript.

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Competing interests Co-investigators SE, GG, and SE are part of LifeWorks, which makes Breaking Free Online available to qualified providers and organisations on a commercial basis. SED and GG have been involved in designing the study and will also be involved in the process of interpreting results of data analyses and disseminating findings. None of the investigators conducting this study will receive direct commercial benefit.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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ORCID iD Elizaveta Klekovkina http://orcid.org/0000-0002-6199-0867

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