Letter of Information and Consent Form

Developing and Implementing an Online Relapse Prevention Psychotherapy Program for Patients with Alcohol Use Disorder

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Background Information and Study Overview

You are being invited to participate in a research study directed by Dr. Nazanin Alavi and Dr. Megan Yang, to evaluate the usefulness of a treatment procedure in online Cognitive Behavioural Therapy (CBT) for the treatment of Alcohol Use Disorder. This program will be delivered through a web-based platform called the Online PsychoTherapy Tool (OPTT). We are planning to have approximately 60 participants enrolled in this study. This study has been reviewed for ethical compliance by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

Conflicts of Interest Disclosure

Dr. Alavi is the PI on this study who has co-founded the care delivery platform in use (i.e., OPTT) and has ownership stakes in OPTT Inc. To mitigate this potential conflict, Dr. Yang will oversee the study. Dr. Omrani is the CEO of OPTT and the co-investigator on this study who has ownership stakes in OPTT Inc.

Study Details

The purpose of this study is to evaluate the feasibility and effectiveness of an electronically delivered therapy program (e-CBT) to treat alcohol use disorder. Each week, participants will complete online modules, questionnaires, and receive feedback from a trained therapist. The 2 questions we hope to answer from this study are:

1. What is the effect of the therapy program on alcohol consumption and relapses?
2. What is the effect of the therapy program on self-efficacy, quality of life, resilience, and depressive symptoms?

Description of the Study

If you consent to take part in our study, you will first take part in an assessment by a psychiatrist on our research team to confirm a diagnosis of alcohol use disorder (AUD). This will occur through a secure video call (via Microsoft Teams). Following this, you will be randomly assigned to 1 of 2 arms. The first arm is the control group in which you will receive face-to-face relapse prevention therapy content through secure videoconference sessions (via Microsoft Teams). The second arm is the e-relapse prevention group, and you will receive a 10-week online program. The content of the program will involve interactive and engaging therapy modules, for which you will receive individualized feedback from a therapist each week. The program will occur through a secure online platform, OPTT, and the therapy modules will be accessible to you anytime throughout the week. Each week's module will consist of about 30 slides. The slides will involve specific topics, and provide information, overview of skills, and homework on the topics. You will be submitting homework assignments every week to a therapist through OPTT, and they will provide you personalized feedback. Homework assignments may include things such as activity scheduling, thought records, journaling, etc. Regardless of your group, you will be completing questionnaires that will measure alcohol consumption, relapses, self-efficacy, quality of life, resilience, and depressive symptoms/prevalence at the beginning of the study, halfway through, and at the end. The primary outcome being measured is a change in symptoms. Your answers to the questionnaires will be used to measure the effectiveness of using OPTT to deliver CBT for people with alcohol use disorder. Additionally, other

behavioural data regarding your interaction and engagement with the therapy (e.g., number of logins per day, amount of time spent on each session, etc.) will be collected directly through OPTT to provide further insight.

Time Commitment

Task	e-Relapse Prevention Group	Control Group
Initial Assessment	30-45 Minutes	30-45 Minutes
Therapy Modules	45 Minutes/Week	45 Minutes/Week
Homework/Feedback Review	15 Minutes/Week	15 Minutes/Week
Questionnaires	45 Minutes (Weeks 1, 5, 10)	45 Minutes (Weeks 1, 5, 10)

Attention

With this CBT web-based program, the facilitator only receives and reads the participants' messages on OPTT on a specific day each week. Therefore, if you are in crisis during the week, do not send an email to the facilitator regarding your crisis. This program is designed to help people with mental health problems and/or excessive alcohol consumption learn basic skills that can benefit their day-to-day life and has not been designed for emergencies. As a result, if you are in a crisis you should call 911, a mental health crisis line (Kingston and Frontenac 24/7 Mental Health Crisis Line: 613-544-4229), go to the nearest emergency room, or call your family doctor. The facilitator is not able to assist you if you are in crisis.

If you are discovered to be actively suicidal or at risk of harm to yourself or someone else during the initial assessment, we will call the emergency department and police and will send you to the emergency department to get the care you need in this crisis situation. If we discover you are actively suicidal or at risk of harm to yourself or someone else during the online therapy process, we will direct you to the proper resources (listed previously). There are no anticipated expenses associated with your participation in this study. If the research team becomes aware of any new information or incidental findings that may be relevant to your decision to continue or withdraw from the study, you will be informed.

Risks and Benefits

There is a minimal risk that privacy could be breached if your consent form or registration is viewed by someone not on the research team. However, all participant information that is online is password protected and you will only be identifiable through a randomized participant ID. Additionally, consent forms will be password protected and in a locked file cabinet.

Through partaking in CBT, you will be asked personal questions and may possibly confront unwanted thoughts. The CBT modules are designed to mirror in-person CBT. The emotional and psychological risk is low as they are structured to be inclusive and to benefit your emotions.

Additionally, the topic of suicide can come up during this project. This is, of course, a sensitive and personal issue. We will be providing a safe space with a validating therapist, present clear expectations delineated at the outset, and provide resources for any potential crisis. The topic of suicide will be brought up in a sensitive manner and if you express current suicidal thoughts, you will be directed to the proper resources (emergency department, helplines, etc.).

Other potentially uncomfortable topics may be covered in the modules. However, they are from a therapeutic perspective and involve education about what is involved in relapse, and provide methods to cope with difficulties in this area.

While you may not benefit directly from participating, results from this study may improve the understanding of the effectiveness and feasibility of delivering CBT through OPTT for patients with mental

health problems in the context of alcohol use disorder and may benefit patients in the future. There are no incentives provided for participation in this research study. There are no anticipated injuries that could occur during this participation. However, if this does happen, you may contact the principal investigator (Dr. Megan Yang) at megan.yang@kingstonhsc.ca.

Confidentiality
All information obtained during the course of this study is strictly confidential and your identity will be protected at all times unless required by law. Each participant will have a file through the web-based platform OPTT. This program is secure, and password protected. Messages and homework that you submit via OPTT can only be accessed by Drs. Yang and Alavi and the facilitators directly involved in your care. The data from this research will be saved without any identifying information. You will be identified by an identification number in the data from this study. Data will be stored in password-protected encrypted files and will be available only to Drs. Yang and Alavi and the facilitators involved in your treatment. You will not be identified in any publication or reports. An encrypted, password protected, participant master list will have your name and contact information for the purposes of reaching out to participants during the study. Any study data that is collected will only be identifiable with a participant ID number that will be randomly assigned to you, protecting your identity.

The only individuals who will have access to the study data during collection, use, analysis, dissemination, retention, and/or disposal are the members of the study team. The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) may require access to study-related records to monitor the ethical conduct of the research.

All encrypted files will be stored on a secure Queen's University server. Once printed, these forms will be stored in a locked filing cabinet in the principal investigator's office for 5 years after the study completion date, being destroyed after this. Participant identity will be protected in future plans for knowledge dissemination and publication of results.

All information obtained during the course of this study is strictly confidential and your identity will be protected at all times unless required by law (child abuse/neglect, elder abuse, etc.).

Voluntary Nature of Study/Freedom to Withdraw or Participate
Your participation in this study is voluntary. You may withdraw from this study at any time without providing a reason and your withdrawal will not affect your current or future medical care. If you do not wish to participate in this study, you may continue receiving standard of care procedures. If you do wish to withdraw and withdraw your study data, you may email opt4.ecbt@queensu.ca at any time expressing this and your information and your data will be deleted from the system by the researcher.

The physician may decide to withdraw you from this study if you are in a crisis that might need urgent help.

Participant Statement Section
I have read and understand the consent form for this study. I have had the purposes, procedures and technical language of this study explained to me. I have been given sufficient time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily consenting to take part in this study. I understand that my consent will be obtained verbally.
If at any time I have further questions, problems, or adverse events, I can contact Dr. Yang at 613-544-3400 ext. 2551. If I have questions regarding my rights as a research participant, I can contact Dr. Albert Clark,

Chair, Queen's University HSREB at 1-844-535-2988 or HSREB@queensu.ca. By consenting to take part in this study, you are not waiving any legal rights in the event of research-related harm.