Introduction

Background and Rationale

Alcohol use disorder (AUD) is a mental health disorder that affects approximately 3.6% of the global population aged 15 to 64 (Rehm et.al. 2009). The disorder is highly prevalent and a major contributor to illness and mortality worldwide (Grant et.al. 2004, Kranzler et.al. 2018). AUD is characterized by impaired control over alcohol use leading to physiological dependence and negative psychological, social, and physical consequences (Kranzler et.al. 2018, Castillo-Carniglia et.al. 2019). The disorder is associated with many physical and psychiatric comorbidities such as major depressive disorder, generalized anxiety disorder, liver cancer, and hypertension (Grant et.al. 2004, Rehm 2011, Samokhvalov et.al. 2010, World Health Organization 2001).

Additionally, the rise in mental health challenges during the COVID-19 pandemic resulted in growing concerns over the health behaviours of individuals with AUD (Drinking alone, 2020). Stay-at-home orders presented complex relationships between financial issues, low social interaction, and anxiety about the future (Da et.al. 2020). Moreover, the disruption to clinical services likely contributed to increased relapse and subsequent negative health outcomes for people with AUD (Clay and Parker 2020). Kim et.al. (2020) demonstrated that out of 182 participants with previous hazardous AUD, 23% increased their consumption during lockdown. Additionally, 17% of the subjects were abstinent for an average of 19.5 months before relapsing during lockdown (Kim et.al. 2020).

AUD treatments typically involve practicing abstinence from alcohol, due to the high failure rates and risks associated with a controlled drinking approach (Barrick and Connors 2002, Glan 1995). However, alcoholism is known as a "relapsing condition", since patients often relapse following abstinence (Chick 1981). Within the AUD framework, a lapse is defined as a single episode of drinking, whereas a relapse involves a return to a pattern of problematic drinking (Da et.al. 2020). Hunt et.al. (1971) found that approximately three months after AUD treatment, there was a 35% to 58% relapse rate. Thus, an effective AUD management program should focus on relapse prevention. This could be achieved through the identification of personal factors increasing the likelihood of a relapse and the development of strategies to decrease the rates and severity of relapses.

Psychosocial interventions are commonly used to treat AUD, with cognitive behavioral therapy (CBT) being one of the most studied psychological approaches (Pearson et.al. 2012, Miller et.al. 2002). CBT for AUD focuses on teaching coping skills to encourage abstinence in the presence of triggers and cravings, by targeting maladaptive thought processes and behaviors. (Carroll et.al. 2017, Monti 2002). This therapeutic approach has demonstrated greater efficacy compared to no treatment and minimal treatment (Magill et.al. 2019). Relapse prevention therapy (RPT) is a form of CBT and is a validated treatment for AUD (Carroll 1996, Irvin et.al. 1999, McCrady 2000), that focuses on relapse prevention by targeting both interpersonal and intrapersonal factors, motivation, and triggers identification. Thus, through this therapy, patients can develop important coping

strategies to apply in situations where alcohol may be available, to prevent a relapse (Heather et.al. 2004).

Nevertheless, despite CBT's effectiveness, financial issues, accessibility, and logistical problems may make it challenging for individuals to receive care face-to-face (Irvin et.al. 1999). Moreover, individuals with AUD frequently experience shame and stigma surrounding their diagnosis which can reduce treatment seeking in this population (Probst et.al. 2015). Previous research has also demonstrated that stress associated with entering AUD treatment can increase alcohol cravings and the risk of relapsing (Sinha 2007). Therefore, online delivery of CBT (e-CBT) in the form of RPT (e-RPT) may address these barriers to care.

Online psychotherapy, such as eCBT has flourished in recent years, due to its accessibility and affordability for the patient and clinician (e.g. not requiring office space, lower demands on therapists' time, accessible at any time and from anywhere with internet connection, etc.). Furthermore, some studies have demonstrated that e-CBT is just as effective as in-person CBT for the management of AUD (Johansson et.al. 2020). e-CBT commonly follows the same structure as in-person CBT sessions. and consists of predesigned online modules and homework with asynchronous personalized therapist's feedback. However, despite these benefits, research studying that examines the effectiveness of e-CBT and e-RPT is limited. Hence, more research is needed to supplement this gap and the development of accessible, and cost-effective online psychotherapy programs for this population (Andersson and Titov 2014).

Therefore, offering asynchronous online therapy modules teaching e-RPT, can be a viable solution to address the potential accessibility, stigma, and financial issues presented by traditional in-person therapies (Andersson and Titov 2014). This study aims to examine the effectiveness of e-RPT at reducing alcohol consumption and preventing relapse. Also, additional impacts of this therapy will be studied by assessing quality of life, resilience, depressive symptomatology, and self-efficacy. The results of this study should supplement the available literature and aid in the establishment of a novel e-RPT program for the management of AUD. Also, it will inform clinical practice about the use of e-RPT to increase accessibility to this type of care.

Objectives

The primary objective of this study is to determine the effectiveness of a secure online e-RPT treatment for AUD at decreasing relapse rates, in comparison to face-to-face RPT. Based on the evidence comparing face-to-face and online psychotherapies, we hypothesize that both face-to-face RPT and e-RPT will have similar effectiveness in the management of symptoms of AUD – decreasing alcohol consumption and lowering relapse rates. The secondary objective involves determining whether using e-RPT results in beneficial effects to quality of life, self-efficacy, resilience, and depressive symptomatology. The tertiary objective involves determining whether the use of e-RPT results in better therapists' time efficiency, by tracking the amount of time that a therapist spends with each patient in e-RPT compared to face-to-face RPT

Methods

Participants

Participants (n = 60) diagnosed with AUD will be recruited through physician referrals from Kingston Health Sciences Centre, family physicians, and other healthcare providers, and through self-referrals in Kingston, Ontario. After providing consent to participate in the study, a Mini International Neuropsychiatric Interview 7.0.2 (MINI) will be conducted to confirm the diagnosis of mild to moderate AUD and other eligibility parameters (Sheehan et.al. 1981). The MINI is a diagnostic interview that assesses 17 common mental disorders by following the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) diagnostic criteria (Sheehan et.al. 1981). After the MINI, the Readiness To Change Questionnaire (RCQ) will be administered in an interview format to understand the individual's desire to change their alcohol consumption (Rollnick et.al. 1992). In addition to the RCQ, participants will be asked the following questions to get a better understanding of their history of AUD: Have you been diagnosed with AUD?; If Applicable: When were you diagnosed with AUD?; Are you currently enrolled in another relapse prevention program?; In the past month how many times have you had an alcoholic beverage?; If applicable: in those times, on average how many drinks did you have?; If applicable: in the past month on average, how many drinks did you have per week?. The intake MINI and questions will be reviewed with the head psychiatrist, to ensure that the participant meets eligibility criteria and to confirm the diagnosis of AUD.

Participant inclusion criteria include being 18 to 64 years of age at the start of the study and having a diagnosis of mild to moderate AUD according to the DSM-5 (AUDIT score > or = to 8 for males and 7 for females and below 19 for both) (Carroll et.al. 2017). Competence to consent and participate, ability to speak and read English, and consistent and reliable access to the internet. Additionally, contemplation about stopping or having stopped consuming alcohol in the past 30 days is required. This will be assessed by the RCQ (participants should be in the contemplation or action stage according to the questionnaire) and by asking them about when they stopped drinking or began considering alcohol cessation (Cougle et.al. 2017, Witkiewitz et.al. 2019). Exclusion criteria are acute hypomanic/manic episodes, acute psychosis, active substance use disorder classified as moderate or severe, active suicidal or homicidal ideation, untreated clinically significant somatic symptoms or mental disorders (PHQ $\geq$ 15, GAD-7 $\geq$ 15), and/or current enrollment in another relapse prevention program. Additionally, men who drink more than four drinks per day or 14 drinks per week and women who drink three drinks per day or seven drinks per week in the past month will be excluded (Dawson et.al. 2005). This exclusion criteria is intended to minimize the risk that a participant will experience withdrawal symptoms while going through the program.

Interventions

Upon completion of the eligibility assessments, participants will be randomly assigned through a computerized system to one of two groups; e-RPT or face-to-face RPT. Participants will be equally stratified (e-RPT n = 30; face-to-face RPT n = 30). These treatments will be delivered as an augmentation to treatment as usual (TAU) (e.g., medications, regular physician or clinician visits,

referrals or consultations that are conducted outside of the current research study). The e-RPT program will be delivered through the Online Psychotherapy Tool (OPTT; OPTT Inc.), a secure and interactive platform developed by the Queen's Online Psychotherapy lab (QUOPL). The face-to-face RPT program will be delivered through video conference sessions using Microsoft teams. Though, it is important to note that participants in the face-to-face group will also have access to OPTT. Participants in both groups will need access to OPTT to complete module 0 before starting with their respective programs, and to access their drinking diary to report their daily drinking. Module 0 will only serve to quickly introduce participants to OPTT, the programs and to access their drinking diary.

E-RPT

Participants in the e-RPT group will receive 10 weekly predesigned online modules. The content of this program will involve interactive therapy modules and homework, for which participants will receive asynchronous individualized feedback from a therapist each week.

Participants in the e-RPT condition will receive one module per week and have continuous access to them on the OPTT platform. On average each module consists of 30 slides and should take approximately 45 minutes to complete. At the end of each module, participants will be assigned homework to be completed and submitted to their respective therapists up to 48 hours before their next weekly session. The therapists will develop personalized feedback by using session-specific therapy feedback templates. These templates ensure that feedback is also more standardized and structured between different patients and therapists. In previous studies, therapists have been able to effectively use these templates to prepare feedback in approximately 15-20 minutes. Therefore, compared to one-hour long face-to-face therapy sessions, online sessions require around 15-20 minutes of therapist time, which can enhance the scalability of the online intervention and increases the number of individuals assigned to a therapist.

Following the principles of CBT and RPT, this e-RPT program will focus on teaching essential cognitive and behavioural skills such as identifying maladaptive thought processes, increasing engagement in day-to-day activities, and developing strategies to reduce alcohol consumption. The content of the sessions is outlined below:

Session 1: Understanding Addiction – Introduces relapse prevention and what to expect from the course. The session explains what addiction is, including symptoms, signs, consequences, and the different types of addiction. Participants will create a SMART goal that they will try to achieve throughout the weeks. They will also share their personal experience with addiction

Session 2: Exploring and Strengthening Your Motivation – Focuses on the five stages of motivation and the role of motivation in relapse prevention. Helpful techniques are discussed to reflect on and boost motivation throughout their recovery journey. Participants will create a pros and cons list about stopping alcohol use and will reflect on different aspects of their ability to stop using alcohol.

Session 3: Triggers – Describes what triggers are and how to recognize them, including both internal and external triggers. This session also provides strategies for how to handle triggers

through avoidance and careful planning. Participants will be asked to identify their triggers and how to prepare for them if encountered.

Session 4: Handling Cravings and Signs of Relapse – Presents skills to use when confronting cravings, and how to identify and prevent a potential relapse. For instance, by applying distraction methods when they experience stressful situations to decrease their urge to consume alcohol. Also, it asks participants to identify their warning signs by reflecting on previous relapse experiences.

Session 5: The 5 Part Model – Provides further introduction about CBT and its components. Also, it explains the 5 Part Model, which highlights the importance of differentiating between our thoughts, feelings, physical reactions, and behaviours in stressful situations. Participants are asked to complete the 5 Part Model with an example from their life.

Session 6: The Thought Record - Part 1 – Introduces the thought record and its relation to CBT to help in the understanding of the connection between feelings, behaviours, and thoughts. This session focuses on the first three columns of the Thought Record (out of 7 columns). The first three columns include the situation, followed by the feelings and automatic thoughts associated with the situation. Participants are asked to complete the first three columns of a thought record for at stressful situation they experienced within the past week.

Session 7: The Thought Record - Part 2 – This session continues with the remaining 4 columns of the Thought Record including, gathering evidence in support and against the identified automatic thoughts, and finding alternative and balanced thoughts after examining the evidence. Thus, this session highlights how to challenge irrational thoughts by developing more balanced and helpful thoughts. Participants have to complete a full thought record from a stressful situation related to their AUD within the past week.

Session 8: Thinking Errors and The Activity Record – Explores irrational thinking and common thinking errors. This session also presents and highlights the importance of the Activity Record; a tool designed to record and plan weekly activities. Participants are asked to complete an activity record for an entire week.

Session 9. Mindfulness and Breathing Techniques – Presents mindfulness, breathing techniques, and other helpful skills to reduce urges and craving associated with alcohol and to promote increased awareness. Participants are asked to incorporate one or more of these practices into their daily routines for a week and to reflect on how these practices made them feel. Also, to reflect on which practice, if any, they found to be the most effective.

Session 10. Review - This session is a review of the program. It summarizes all the useful tools and techniques for relapse prevention learned throughout the program. Participants are asked to reflect on the activities that they found to be the most effective throughout the sessions.

Face-to-Face RPT

Participants in the face-to-face intervention will meet with their therapist weekly through Microsoft Teams (video conference). During these 1-hour sessions, therapists will follow the same 10-week structure and content as e-RPT. Though compared to e-RPT, in face-to-face sessions, the

homework will be reviewed with the participant, during the session, providing the appropriate feedback. Then the therapists will prepare a weekly patient report of each session for the principal investigator. At the end of each session, participants will receive the same homework as the e-RPT condition which they will receive feedback on during the following face-to-face session. Following the 10-week face-to-face intervention, participants will have the opportunity to join the e-RPT program.

Training

Therapists for both e-RPT and face-to-face RPT will consist of research assistants who are trained in RPT and writing feedback. All therapists are trained by the principal investigator, who is an expert in the electronic delivery of psychotherapy (Alavi and Hirji 2020, Alavi et.al. 2016, Alavi and Omrani 2018). During training, the principal investigator will closely guide the therapists through their first patient (assigning modules, reviewing homework, writing feedback, and conducting face-to-face sessions). Then through the study the therapists will be supervised by the principal investigator to ensure the quality and reliability of the treatment programs. To ensure the quality of the feedback, therapists will practice by writing feedback on practice homework templates. All feedback will be examined and revised by the principal investigator before being sent to the participants.

Outcome measures

The primary objective of this study will be to determine if e-RPT has similar effectiveness as face-to-face RPT at reducing alcohol consumption and preventing relapses. The current study defines relapse as either the consumption of at least 60g of pure ethanol (approximately four and a half standard drinks (Baltieri et.al. 2008)) per occasion or hospitalization because of alcohol drinking (Baltieri et.al. 2008). Therefore, to determine the effectiveness of this program, daily alcohol consumption will be recorded in a drinking diary accessible through OPTT. This diary will ask the participants to report how many drinks they had on each day of the week, where they had those drinks and with whom. Also, this diary will ask if the participant was hospitalized as a result of alcohol consumption.

As a secondary objective this study will determine whether e-RPT and face-to-face RPT had a beneficial effect on self-efficacy, quality of life, resiliency, coping behaviors and depression symptomatology. These metrics will be assessed by using the following scales SCQ (Miller et.al. 1989), Q-LES-Q-SF (Endicott et.al. 1993), RS-14 (Aiena et.al. 2015), CBI (Litman et.al. 1983), and PHQ-9 (Löwe et.al. 2004) respectively. These assessment scales will be completed at study entry (baseline), mid-program (week 5), and post-treatment (week 10). Other behavioural data regarding patients' interaction and engagement with their therapy such as module and homework completion in e-RPT, and session attendance in face-to-face RPT will be collected to provide qualitative information about these programs. Finally, the tertiary objective involves determining whether using e-RPT is more time efficient than face-to-face RPT. Thus, this study will track the amount of time that e-RPT therapists spend writing feedback compared to the one-hour face-to-face session as a measure of therapists' time efficiency.

Ethics and privacy:

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All components of this study were approved by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (TRAQ: 6033212). Participants were only identifiable by an ID number and hard copies of consent forms were stored securely on-site and will be destroyed 5 years after study completion. Participant data was only accessible by the care providers and anonymized data was provided to the analysis team. Participants could withdraw from the study at any point and request for their data to be removed from the analysis. The research team will safeguard the privacy of the participants to the extent permitted by the applicable laws and duty to report.

OPTT is Health Insurance Portability and Accountability Act, Personal Information Protection and Electronic Documents Act, and Service Organization Control - 2 compliant. All servers and databases are hosted in Amazon Web Service Canada cloud infrastructure to assure provincial and federal privacy and security regulations are met. OPTT does not collect identifiable personal information or IP addresses. OPTT collects anonymized metadata to improve service quality and provide advanced analytics to the clinician team.

Data Analysis

At first, data will be assessed for outliers, missing, and/or nonsensical variables. These variables will not be imputed since they will be handled as missing. Similar studies that involved CBT and e-CBT demonstrated a drop-out rate of up to 40% for both conditions once the study concluded (Bados et.al. 2007). Thus, this study will intentionally over-sample the experimental and control groups to account for this drop-out rate. Given that several outcomes will be used, it is difficult to calculate a single sample size or provide a specific power calculation. However, applying the IMMPACT recommendations for treatment outcomes associated with pain and function, the minimal clinically important difference (MCID) for mood related outcomes is a change higher than 2 to 12 points in mood related scores from baseline (Dworkin et.al. 2008, Gatchel et.al. 2013). Thus, with a sample of 60 participants (30 per arm) and applying the sample size calculation presented by Rosner (2011) with p = 0.05 and a power of 0.95, our study would be able to significantly detect changes in mood scores of 3 to 12 points or higher (depending on the scale). Baseline mood scores related to AUD applied to the sample size calculation were obtained from the literature (O'Reilly et.al. 2019, Jordans et.al. 2019).

Using Mann-Whitney-U tests, demographic information from individuals who completed the program and those who dropped out will be compared to identify possible differences. Additionally, an intention-to-treat analysis will be conducted to assess the clinical effects of the program on participants who dropped out prematurely. Linear regression (continuous outcomes) and binomial regression analysis (categorical outcomes) were used to identify variables associated with outcome measures. Comparative analysis between groups was analyzed using group and paired t-tests. OPTT collected usage statistics (i.e., number of logins per day, amount of time spent logged in) will be compared to face-to-face metrics to determine cost and time savings between the two programs.

Current progress

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According to the literature on the efficacy of CBT in AUD we hypothesize that both e-RPT and face-to-face RPT will reduce alcohol consumption, relapse(s) risk, and improve other outcome measures of interest (depressive symptom, self-efficacy, quality of life, and resilience) (Connor et.al. 2016). This randomized controlled trial was approved by the Queen's University Health Science and Affiliated Teaching Hospitals Research Ethics Board in April 2022 and began recruitment in October 2022. We expect to finalize recruitment and data gathering in October 2023 and analyze the findings by December 2023 at which point we will begin our process of knowledge dissemination (including but not limited to peer-reviewed publications, scientific presentations, grant proposals, and reports).

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