Testing the Efficacy of an Online Integrated Treatment for Comorbid Alcohol Misuse and Emotional Problems

Ethics Amendment Approved February 28th, 2018

Study Protocol

Summary of Project

Background: It is currently estimated that between 50-60% of individuals with an alcohol use disorder also suffer from comorbid anxiety and/or depression (Swendsen & Marikangas, 2000). This statistic makes alcohol dependence and emotional disorders the highest co-occurring disorders among general populations (Conway, Compton, Stinson, & Grant, 2006). Individuals who suffer from both disorders often experience poor overall health, physical injury, marital dysfunction, increased suicidality, early mortality (Beidel, Frueh, & Hersen, 2014). Given the increased consequences for adults suffering from both disorders, there is a critical need for research aimed at designing effective treatments for alcohol misuse and co-occurring emotional problems.

Individuals with alcohol problems who also suffer from an emotional disorder (compared to those who do not) experience high rates of relapse, have greater functional impairment, and have poorer responses to treatment among individuals with significant alcohol problems. Existing treatments for alcohol misuse and co-occurring anxiety/depression typically include parallel or sequential interventions, meaning that individuals are treated for one disorder followed by the other, or separate treatments are conducting at similar times by two different professionals (DeVido & Weiss, 2012; Mueser, Noordsy, Drake, & Fox, 2003). However, neither approach takes into consideration the interconnectedness of these highly comorbid disorders, and often times there is little communication between professionals when the disorders are treated separately. For example, a person who suffers from depression would find it difficult to quit drinking if their depressive symptoms (i.e., triggers for drinking) were not addressed in treatment. In turn, this same person's depressive symptoms would likely be made worse by repeated unsuccessful attempts to control their drinking. In this case, it would be challenging for the individual to make progress for either disorder/in either treatment. Therefore, treatments that do not target the symptoms of both alcohol use and anxiety/depression *simultaneously* may not be sufficient. There are limited integrated treatments designed to target alcohol use and emotional problems simultaneously.

Goal: Considering the limitations of current interventions for comorbid alcohol misuse and anxiety and/or depression, and the staggering rates of these co-occurring disorders, there is a need for integrated treatments designed to target both disorders simultaneously. Furthermore, it is important that said integrated treatment options are both cost-effective and feasible, thus reducing the burden on the health care system. Therefore, an *online* integrated treatment stands to provide both an effective and economical option. There is a growing body of literature suggesting the potential effectiveness of combining Cognitive Behavioural Therapy (CBT) and Motivational Interviewing (MI) to treat alcohol misuse and comorbid emotional problems (Riper et al., 2014). These treatments teach people coping skills for both disorders (e.g., challenging negative thoughts), while simultaneously improving their motivations to change problem behaviours (Hofman, 2012; Lundahl & Burke, 2009). To date, the only intervention of this nature has been developed at the Swiss Research Institute for Public Health and Addiction in German (Schaub et al., 2016). This study will adapt this intervention for use in English speaking young adults in Canada. By developing an online integrated treatment for alcohol use and emotional problems, we will be able to reach rural and Northern communities where the prevalence rates of these disorders are particularly high. Furthermore, online treatments are

associated with less stigma and shame, which may provide additional opportunities for early intervention through participation in the intervention. Overall, this accessible and cost-effective treatment stands to reduce the symptoms of both alcohol misuse and anxiety/depression, thus potentially improving the overall health and well-being of hundreds of Canadians.

Method

The study design will be a two-arm randomized controlled trial (RCT). This method is considered the "gold standard" in conducting clinical research in order to determine the effectiveness of an intervention. Prior to initiating the full study, a pilot-testing phase will be used to ensure that the intervention components are translated, created, and presented in ways that are most helpful and engaging for young adults. This will also be done in order to receive feedback on the modules prior to opening them up to the public. In order to obtain this pilot feedback, the full intervention will be provided to both knowledge users and professionals. Once we have received feedback, we will meet as a team (i.e., primary investigators, graduate students, research assistants), to discuss changes and apply feedback as necessary.

After completion of the pilot phase, we will begin the active study phase. First, interested participants will be encouraged to contact the lab via e-mail. Once they have expressed an interest in the study, they will be given access to information about the study and the consent form. After reading the informed consent form, they will be able to provide informed consent on the study website and then register for an account. Once they have consented to participate and registered, they will visit their e-mail inbox to verify their e-mail address and create a password. Once they have confirmed their login information, they will immediately be directed to the baseline assessment measures. These measures will also be used to determine whether participants are eligible to participate. If at any point a participant is deemed ineligible on a measure, they will automatically be redirected to a "Thank You" page so as not to make them fill out questionnaires unnecessarily. In order to determine eligibility, participants will first be assessed for suicidality. Individuals who are deemed "Minimal" or "Lower" risk on the screener will be able to proceed to the remainder of the questionnaires in order to determine eligibility. Those that are identified as "Higher" risk will immediately be deemed ineligible. At this time, they will be directed to a screen with urgent information on how to proceed next. This page will provide them a list of resources in their area that we will urge them to contact as soon as possible. We will make it clear that their safety and well-being is our utmost concern by stating that we are concerned about their safety and strongly encourage them to access supports as soon as they can.

If individuals meet the eligibility criteria in terms of suicidality (i.e., minimal or low risk), they will then be provided with the remainder of the baseline measures. If participants do not meet our eligibility criteria, we will still provide them with access to the intervention, but will not track their data, and their responses to the baseline measures will not be retained. After eligible participants complete the baseline measures, they will be randomly assigned to one of the two treatment conditions using a 1:1 ratio. The first condition will be the integrated treatment (i.e., active experimental condition) where participants will have access to the 12 treatment modules, developed using combined elements of CBT and MI. Throughout the modules, participants will identify goals related to alcohol use and mood, learn strategies to cope with alcohol cravings, triggers, and social pressures, and learn how to prevent relapse. Modules will also include

content designed to target anxiety and depression, focusing on strategies designed to help reduce negative thinking and worry, increase behavioural activation, and increase self-care (e.g., relaxation techniques, sleep hygiene).

Participants will have 8-weeks to complete the modules and will immediately be given access to all modules. While it is technically possible to work through the modules in any order, they will be encouraged to work through the modules sequentially. In order to bring a small social presence to the treatment, each module will begin with a brief introduction video. Previous research suggests that adding this social factor will personalize the online program and may influence accountability (Mohr, Cuijpers, & Lehman, 2011), especially considering that it is self-guided. The purpose of these videos will be to summarize the content of the upcoming module, as well as provide motivation to continue with the program. Participants will also be supported by an e-coach during active treatment. This coaching content will all be automated, with the exception of specific questions participants may have for their e-coach. They will be able to ask these questions over e-mail. The purpose of the e-coach will be to answer any questions the participant may have as they work their way through the modules. Coaches will provide ongoing feedback about module progress and provide reminders about completing each section of the intervention. They will also provide support to participants should have they additional questions or concerns throughout the program. Therefore, the use of e-coaches will help to reduce the risk of attrition. Research shows that both automatic and personal feedback are central to improving adherence during self-guided behaviour change interventions (Mohr et al., 2011). At the outset of treatment, participants will also be asked to select an animated personal companion whom they identify with in terms of sex, age, occupation, and family background. The purpose of this companion is to provide advice and examples pertaining to the content throughout the intervention. The personal companion will appear in each module at least once.

The second condition will be psychoeducational (i.e., the control condition). Participants randomly assigned to the control condition will receive links to websites that provide general psychoeducation about alcohol (e.g., https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets), and mental illness (e.g., https://www.jack.org/resources). Therefore, the control group will have access to available online psychoeducational material. A psychoeducation control group is common in clinical research in order to determine the efficacy and effectiveness of online interventions (Schaub et al., 2016). It is also important as we do not want to harm patients in any way or prevent them from getting something that is already established are effective. For ethical reasons, participants in the psychoeducation control group will be given access to the active integrated treatment at the end of the study, regardless of whether they have completed all of the assessments.

Research Instruments: Participants will be assessed at three time points throughout the study: at baseline (i.e., prior to treatment; T0), immediately following the 8-week treatment (T1), and at follow-up (i.e., 24 weeks, T2). The primary outcome of interest will be the number of standard drinks consumed during the seven days prior to the assessment. This will be assessed using the Timeline Follow-Back (TLFB; Sobell & Sobell, 1992) procedure at all assessment points (T0-T2). The TLFB has been widely used in studies, including treatment studies (Keough, O'Connor, & Colder, 2016; Schaub et al., 2016). As a secondary outcome, depressive symptoms will also be assessed at all time points using the CES-D, a 20-item self-report questionnaire used to indicate

depression severity (Radloff, 1977). Anxiety symptoms will also be assessed at all three assessment points using the GAD-7, a 7-item self-report questionnaire used to measure the severity of anxiety symptoms (Spitzer, Kroenke, Williams, & Löwe, 2006). In order to determine clinically significant and combined reduction in alcohol use and comorbid emotional problems, we will use a combined outcome of alcohol use on the AUDIT, and cut-offs from the GAD-7 and CES-D. We will also measure participants' quality of life using the World Health Organization Quality of Life assessment (WHOQOL-BREF). This is a 26-item self-report measure that assesses functionality in various life domains (The WHOQOL Group, 1998). A sum score will be used to assess overall quality of life at all assessments points (i.e., T0-T2). We will also collect information on participants' use of other substances using the National Institute on Drug Use (NIDA ASSIST; National Institute on Drug Abuse, 2009), and their executive functioning using the WebEx (Buchanan et al., 2010). This information will be collected to examine transfer effects to other substances, as well as to examine the potentially moderating effects of executive functioning. Finally, we will obtain a measure of participants' level of motivation in terms of importance, confidence, and readiness. Participants will complete all measures at each of the three time points, with the exception of the Demographics questionnaire and the AUDIT, which will only be completed at baseline.

Participants

A target sample of 400 participants will be recruited for the study. Participants will include Canadian young adults struggling with moderate alcohol misuse and emotional problems. Inclusion criteria will include: 1) individuals between 18 and 35 years old, 2) reporting difficulties with alcohol indicated by a score >3 for women and >4 for men on a brief version of the Alcohol Use Disorders Identification Test [AUDIT; Saunders et al., 1993] known as the AUDIT-C, 3) reporting depression and/or anxiety symptoms indicated by a score >16 on the Center for Epidemiological Studies Depression Scale [CES-D] and/or a score of >5 on the Generalized Anxiety Disorder Scale-7 [GAD-7], 4) fluency in English, and 5) have weekly Internet access. Exclusion criteria will include the following: 1) self-reported engagement in other psychological or pharmacological treatments for alcohol misuse and/or depression/anxiety; 2) elevated suicidality (defined as scoring greater than "minimal risk" on a screener); and 3) current psychosis or mania. Interested participants will be invited to contact the primary investigators for a link to the study website. Participants will be sent a link with information about the study and be able to provide informed consent electronically directly on the treatment website. They will also be provided with detailed instructions on how to create a user account for the self-help program, and be encouraged to contact the researchers should they have any trouble at this stage. After they have provided informed consent, they will be able to register on the study website. They will need to create a username as well as verify their account via e-mail before they can access the website. After informed consent has been obtained and their account has been verified, they will immediately be asked to complete the baseline assessment measures. If they are eligible, they will be able to access the 12 treatment modules and continue with the study procedure. Interested adults with clinically-elevated symptoms (i.e., those who score above the cut-offs on our screening tools) will be still given access to the integrated intervention, and will be given the contact information for a mental health professional in their area. However, they will be excluded from the study and their data will not be tracked.

Participants will be recruited both in-person (e.g., presentations, posters) and online through university clinics, community agencies, online advertisements (e.g., Google Ads, Kijiji), social media, and word of mouth. All participants who request it will receive a summary of the study results once the study is complete. These summaries will debrief participants about the main goal of the study. Furthermore, all participants will be offered the option of receiving an electronic summary of the study results after it is complete. This summary will be sent to participants by email.

Informed Consent

Participants will first read about the study rationale and procedure, and then will be told the following during informed consent: 1) the potential risks and benefits of the interventions, 2) safety arrangements that have been put in place for them during and after the study, 3) the circumstances under which they should contact a professional from an emergency list that will be accessible at all times via the menu item "Help Me" on the intervention website, and 4) that participation is voluntary and they are free to withdraw from the study at any time without penalty. As previously mentioned, participants endorsing significant suicide ideation and/or plans will be told to visit a hospital or other resources for support immediately. Following informed consent, participants will be able to register on the intervention website where they will have access to the treatment modules.

Participants will not able to participate until they have provided informed consent. Participants will provide electronically recorded informed consent through the treatment website. They will be taken to this page by receiving a link from the researchers. The website will first show a brief version of the consent form with the main components highlighted. However, participants will be provided with a downloadable version of the consent form on this same page as well. They will be told to download and read the entire version in full before signing it. They will also be encouraged to save this copy of the form. The goal of this procedure is to reduce space on the website page as well as increase the likelihood of the participant retaining a copy for their records. This procedure is being utilized by our colleagues in Switzerland, as well as in similar online self-help programs around the world.

After they have provided informed consent, they will be invited to create login information on the treatment website, and from there will complete the baseline assessment measures to determine eligibility. Therefore, we will not obtain information from individuals who do not consent to participate. After the completion of baseline measures, participants that are deemed eligible will be given access to the intervention. In other words, consent will be obtained from the participant prior to the baseline assessment. Should participants have any questions about the study before and/or after completing it, the name and contact information of the Principal Investigator, Dr. Matthew Keough, will be included on the consent form. Participants are encouraged to delay their participation until their research related questions have been asked and answered.

Risks and Benefits

Possible Risks: There are increased risks associated with recruiting young adults with alcohol misuse and emotional symptoms. We would expect higher base rates of suicidal ideation and self-harming behaviours in these individuals relative to those without these mental health

concerns. Therefore, we will have safeguards in place in order to minimize the risk of harm. Young adults who report significant suicide ideation and/or plans during screening will be given a recommendation to visit their local medical professional (GP or hospital) for support as soon as possible. We will also be monitoring changes in suicidality at three time points, and will direct participants to emergency services if needed. Supports will also be accessible to participants at all times via the menu item "Help Me" on the intervention website. This will include a list of mental health services, including community resources, public and private psychologists, hospitals, and helplines. Participants in the control condition (psychoeducational) will be given access to the active treatment after the final assessment (6-months). They will receive all elements of the integrated intervention. While there is a risk that the content may be potentially distressing to some participants, resources will be provided as safeguards in order to mitigate these feelings of distress.

Possible Benefits: There are also potential benefits to participating in the current research. By working through the 12 modules, participants will be provided with the skills to cope with emotional challenges that are often triggers for alcohol use. The development of protocols is empirically informed, and there is a strong evidence base suggesting their success. Thus, completing each module throughout treatment stands to elicit a reduction in symptoms of both alcohol misuse and emotional problems. Furthermore, the proposed intervention stands to benefit Canadians as a whole by offering a potentially successful and cost-effective treatment option by which to improve their mental health. By offering the program online, we will be able to reach Northern and rural communities who otherwise may not have had access to treatment. By offering this widespread treatment in a user-friendly manner (i.e., online), participants also stand to benefit from access to treatment without any stigma, which is a known barrier to accessing treatment among substance users (Livingston, Milne, Fang, & Amari, 2012). Additionally, the program is being offered free of charge, when standard rates of therapy are as high as $180/hour. Finally, the proposed treatment may provide an opportunity for early intervention to a population that is already struggling.

Anonymity and Confidentiality

In order to determine who is eligible to participate in the study, potential participants will need to create a unique username to access the program. Outside of this username, no identifying information will be collected on the study website. Therefore, the only potentially identifying information collected would be if participants create a username using their first and last name. Eligible participants will also be given a unique participant ID. Participant ID numbers will be automatically generated by the study website immediately after registration using an incremental number system. The data collection file will contain these participants ID's and scores on each measure, but will not contain identifiable information (i.e., usernames). The data file used for statistical purposes will remain completely anonymous at all times. The de-identified raw data will be retained indefinitely for dissemination purposes/meta-analyses in order to inform future research. While we will be using e-mail addresses to contact interested participants this information will never be recorded nor linked to their data. All study data will be automatically collected on the website without identifying information.

Since we will not be collecting identifying information, no formal records of client data will be retained. The only data retained will be the scores to questionnaires obtained through the study

website itself. Furthermore, while the program was designed using in-person treatment methods, it is ultimately a self-help program. Therefore, it is not necessary nor feasible to make a client record for each participant given the nature of the self-guided program as well as the lack of identifying information being obtained.

Only primary researchers and coaches will have access to the e-mails received by participants who decide to contact their e-coach. These e-mails will come to the e-mail address affiliated with the treatment website, and for which only coaches and primary researchers will have access. Although limited identifying information will be collected from participants, Dr. Keough, his graduate students, and all other research assistants involved in the project will complete PHIA training and sign a pledge prior to becoming involved in the research. Dr. Keough and the two primary graduate students involved in the project (i.e., the Research Assistants who will also be acting as e-coaches) have already signed this pledge. The only potential breach of confidentiality will be if clients accidentally leave their computer screen open in a public space with the clinical trial open on the desktop. In order to mitigate this, the treatment website will automatically log the participant out after they have been inactive for 20 minutes. Limits to confidentiality will be: if the participant poses an imminent risk to themselves or another individual, if issues surrounding child welfare are disclosed, or if the researchers are legally subpoenaed. All participants will be made aware of issues surrounding confidentiality in the consent form.

Results of the study will only be presented at the aggregate level - individual data will not be reported or presented. Data will be collected on the treatment website. Further, data will be kept and analyzed on a password-protected computer in Dr. Keough's locked laboratory. Only Dr. Keough and members of his laboratory will have access to the data for projects and theses.

Compensation

Participants will be compensated with a $30 Amazon gift card for completing all three assessments ($10 per assessment).

Dissemination

The results of this study will be presented at academic conferences and published in peer-reviewed journals on addictive behaviours. Results will only be presented at the aggregate level, and individual data will not be presented. This will inform both research and practice by making the findings accessible to academics, practitioners, and the general public. Results of this study may have implications for the clinical treatment of alcohol misuse and emotional problems among adults. Specifically, if effective, this study will demonstrate the effectiveness of a novel integrated treatment for individuals suffering from alcohol misuse and comorbid emotional disorders, and thus offer a feasible treatment options for said individuals.

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