Informed Consent Form

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Title of Research: Testing the Efficacy of an Online Self-Help Treatment for Comorbid Alcohol Misuse and Emotional Problems in Young Adult Canadians: A Randomized Controlled Trial

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This consent form, a copy of which can be downloaded and/or printed for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about, who is involved in the research, and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask via the contact information provided. Please take time to read this carefully and to understand any accompanying information.

Before agreeing to participate in this study, it is important that you read and understand the following explanation of the study process. The following information describes the purpose, steps, benefits, risks and precautions associated with this study. It also describes your right to refuse to participate or leave the study at any time. In order to decide whether you want to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the research coordinators to explain any words you don't understand before agreeing to this consent form. Make sure all your questions have been answered to your satisfaction before giving consent.

Purpose of the Study:

The purpose of this study is to examine if an online self-help program created from two different therapies, Cognitive Behavioural Therapy (CBT) and Motivational Interviewing (MI), helps people to reduce their alcohol use and anxiety/depression at the same time. Research has shown that the combined use of these therapies is effective in treating substance use and emotional problems. However, the effectiveness of these treatments specifically for alcohol use and anxiety/depression has not been fully examined in the form of an *online* self-help program.

CBT has been tested in many research studies. The goal of CBT is to help people develop better skills for coping with alcohol and mood/anxiety challenges. These skills become important when you are faced with stressors in everyday life. MI is often described as an approach that helps

people stay motivated when making changes (like reducing drinking). The goal is to help people remove uncertainty about change, and move in a positive direction that is consistent with personal values. Previous research suggests that combining these two treatment methods into one program is helpful for reducing symptoms of both alcohol use and emotional problems. We hope that by offering this program in a user-friendly and accessible way (i.e., online, working at your own pace), we will be able to improve the health and overall well-being of many Canadians.

Study Procedures:

You are receiving this document because you have expressed an interest in participating in this study. If you consent to participate in the research, you will need to register on the study website and verify your account. You can do this via a link you will be sent over e-mail. You will need to verify your account as well as create a username and password in order to access the treatment website. You will use this information for all log ins throughout the study. Once you have provided informed consent and are registered on the treatment website, you will be asked to complete a baseline assessment in order to determine whether you are eligible to participate. Eligible participants will be those that: are between the ages of 18 and 35, have difficulties with alcohol use, anxiety, and depression, are fluent in English, and have weekly internet access. Participants will not be eligible if they are currently engaging in other forms of treatment for alcohol use and/or depression/anxiety, have elevated suicidal thoughts (i.e., score greater than "minimal risk" on the screener), and are currently experiencing psychosis or mania. This eligibility assessment will include a number of questionnaires about alcohol use, anxiety, depression, alcohol related problems, quality of life, substance use, and executive functioning.

If you are eligible to participate, you will be "randomly assigned" to one of two treatment groups. This means that you have a 1 in 2 chance of being put into either group. The two groups are the study CBT/MI group, and the psychoeducation (i.e., control) condition. If you are assigned to the CBT/MI condition, you will be able to start the intervention program as soon as you have completed the baseline measures. At this time, you will immediately be given access to all 12 CBT/MI modules. You will be able to log in to the intervention program with your information from any computer with Internet access. If you are assigned to the psychoeducation (i.e., control) condition will have the opportunity to participate in the full CBT/MI program after the study is complete but will receive informational resources about drinking and emotions right away. Your participation in this study will take place from the time you prove eligible to participate until the final follow up 24 weeks from now. You will have 8-weeks to work through 12 modules at your own pace, which means that some weeks you may need to work through more than one module. Throughout the modules, there will also be exercises that require additional practice. Overall, you should be prepared to commit approximately 3 hours/week.

If you are not eligible to participate, you will still be able to access the program. The only difference is that we will not be tracking your data. Finally, if you have high levels of suicidal thoughts, you will be encouraged to access supports in your area as soon as possible. We will immediately provide a list of resources and phone numbers in this situation.

The purpose of the program is to help you build skills and set goals for yourself, with the hopes that you will be able to reduce your alcohol use, as well as improve your overall mood. While we recommend that you work through these modules in order, you can complete the modules in any

order. Similarly, you are welcome to work through the modules at your own pace. You will have 8 weeks in total to complete the intervention (i.e., all 12 modules). As a recommendation, you may wish to complete one to two modules per week. After 8 weeks, you will be asked to complete similar questionnaires to the ones you completed before treatment. Again, this assessment will include a number of measures regarding alcohol use, anxiety, depression, alcohol related problems, quality of life, substance use, and executive functioning. Finally, we will ask you to complete a third round of questions 16-weeks after you complete the treatment (i.e., 24 weeks since the beginning) in order to follow-up. Once you have completed the final measures, you will be finished the program. The purpose of the final assessment is to determine whether the combined use of the two therapy styles (i.e., CBT and MI) helped to reduce alcohol use and improve overall mood. We hope that this self-help program will help you build skills, develop coping mechanisms, and set/achieve your goals. By completing these final measures, we will be able to use this information to help individuals who may be struggling with alcohol use and emotional problems. Finally, we hope that you will provide feedback about your experience in the program once you are finished. This will help us learn about what we did well, and what we can do to improve in future programs like this.

It is important to know that this program is meant to be mainly self-guided – meaning that you work through the program at your own pace. However, you will be interacting occasionally with an Intervention Support Person by email, who is an individual with training in clinical psychology. They will send you tips and feedback every so often, and will answer your questions as you go through the program. The function of the Intervention Support Person is to help you stay on course during the self-help program, and therefore, the Intervention Support Person is not meant to be therapists per se. Research shows that people with your level of difficulties with alcohol and emotions are able to change while doing the work largely on their own, with minimal support (like that of an Intervention Support Person). If at any point you notice a sudden change in your wellbeing and feel you need more intensive support (e.g., in person counselling) please see the "Help Me" tab on the intervention website for resources in your area.

If you are interested in receiving the results of this study, please check the box at the end of this form. You will receive an email summary of the study once it has been completed. Please provide your email in the space provided at the end of this form if you are interested.

Potential Risks and Benefits of the Research:

Although there are no known risks of participating in a combined CBT and MI self-help intervention, it is possible that you may find some of the content during the program difficult or emotional. Furthermore, some individuals who have difficulty with emotions sometimes get thoughts of wanting to harm themselves. If you report significant thoughts of harming yourself and/or plans at the beginning, you will be given a recommendation to visit your local doctor or hospital for support as soon as possible. You will also be provided with ongoing supports 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. You will have access to these resources and may use them at any time. If you feel uncomfortable at any time during the program, you are free to stop participating at any time. While completing the questionnaires, you may be answering questions of a sensitive nature about your mental health and substance use behaviour and attitudes. If you experience significant distress after completing the survey, please use any of the resources we previously provided you

for assistance. Again, if you have thoughts of harming yourself and/or plans, it is recommended that you refer to the resources provided to you, as well as visit your local doctor or hospital for support as soon as possible.

There are also a number of benefits we expect by participating in the current study. First, you will be given skills to cope with both drinking and emotional challenges. As a result, you may experience an improvement in your overall mental and physical health. We also hope that by offering the program online, we will be able to reach as many people as possible who otherwise may not have had access to treatment. We hope that the information in this study can be used to benefit other individuals struggling with alcohol use and emotional challenges in the future. The results of this study may also be used by future researchers and professionals in order to continue improving the health and well-being of individuals struggling with mental health issues. Finally, the program is being offered free of charge. While this is a self-help program, standard rates of therapy are as high as $180/hour.

Compensation:
As a token of appreciation for your participation in the study, you will be given a $10 Amazon gift card for each study survey that you complete (i.e., baseline, end of treatment, and follow-up), with a total potential of earning $30.

Voluntary Participation:
Participation in this study is completely voluntary and you may decline consent or withdraw from participating at any time without punishment by simply discontinuing your participation on the treatment website. You may also refuse to answer any questions that you do not wish to answer. However, if you do not answer, we will not be able to determine whether you are eligible to participate in the study.

Freedom to Withdraw:
It is your choice whether or not to participate in this study. Participation is voluntary and you may withdraw at any time with no penalty. If you decide to withdraw from participation in this research, your anonymous data will still be kept according to the study procedure (i.e., on the treatment website). Although there are **no** consequences of a sudden withdrawal from the study, it is helpful for us to understand why you are withdrawing or in what ways we could have made your visit more comfortable, as this may inform future studies. If this is the case, we would strongly appreciate your feedback. Although there are no consequences of a sudden withdrawal from the study, it is helpful for us to understand why you are withdrawing or in what ways we could have made your visit more comfortable, as this may inform future studies. If this is the case, we would strongly appreciate your feedback.

Confidentiality:
All personal information, including potentially identifiable information, you provide over the course of the study will remain confidential, and there are many safeguards in place in order to make sure your information stays private. The collection of personal information will be limited to your e-mail address and the username you create for the study website, however, potentially identifiable information may also be collected. Risks to confidentiality associated with the use of the study website are minimal and are similar to those associated with many e-mail and secure

websites. To decrease risk of becoming identifiable, we recommend that you create a username that maintains your anonymity (i.e., not your full name), and refrain from providing personal, identifiable information in your answers. The only individuals who will have access to your responses are Dr. Keough, his colleague Dr. Edward Johnson, and his primary research assistants, Jona Frohlich and Karli Rapinda. All data will be stored on the secure study website, www.takecareofme.ca. Data collected during the study (i.e., responses to measures, scores) will be generated from the study website and contained on a separate file, which will be held in the strictest of confidence.

The information obtained during this study may be published or presented to the public in the form of papers or research conferences. However, any personal information or potentially identifiable information will be stripped from the results and then aggregated prior to the publication of the findings. Once the study is complete, the anonymized data, will be stored confidentially on password-protected computers in the Duff Roblin building at the University of Manitoba. Only the principal investigator and associated researchers will have access to the data. However, the anonymized data may also be made available upon request to authorized researchers outside the University of Manitoba. There are no plans to destroy the anonymized data.

To further safeguard your responses to the clinical trial, we recommend that you log out of the computer entirely once you have ended your session. In the event that you are using a computer within a public space, the treatment website will automatically log you out after you have been inactive for 20 minutes.

Notice Regarding Collection, Use, and Disclosure of Personal Information by the University:
Your personal information is being collected under the authority of The University of Manitoba Act. The information you provide will be used by the University for the purpose of this research project. Your personal information will not be used or disclosed for other purposes, unless permitted by The Freedom of Information and Protection of Privacy Act (FIPPA). If you have any questions about the collection of your personal information, contact the Access & Privacy Office (tel. 204-474-9462), 233 Elizabeth Dafoe Library, University of Manitoba, Winnipeg, MB, R3T 2N2.

Questions or Concerns:
If you have any questions about this study, please do not hesitate to contact Dr. Matthew Keough at (204) 474-7400 or Matthew.Keough@umanitoba.ca

For questions about your rights as a research participant, you may contact The University of Manitoba Psychology/Sociology Research Ethics Board Office at (204) 474-7122.

Do not provide consent unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Dr. Matthew Keough and/or his study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I can download a copy of this consent form for my records I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

By clicking "Agree" below, you will indicate that you have understood to your satisfaction the information regarding participation in the research project and agree to participate. I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I understand that The University of Manitoba may look at my research records to see that the research is being done in a safe and proper way. If any of your medical/research records need to be copied and provided to any such organization, your name and all identifying information will be removed. No information revealing any personal information will leave the institution. You have a right to review your medical records and to request corrections to your personal information.

Clicking "Agree" on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the researchers, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time, and /or refrain from answering any questions you prefer to omit, without prejudice or consequence. However, if you refrain from answering questions, we will not be able to determine your eligibility for the study. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

This research has been approved by the Psychology/Sociology Research Ethics Board at the University of Manitoba, P2017:128 HS21125. If you have any concerns or complaints about this project you may contact any of the above-named persons or the Human Ethics Coordinator at 204-474-7122. A copy of this consent form has been given to you to keep for your records and reference.

- ○ **Agree**

The results of this study should be available by August 2020. If you would like to receive a summary of the results, please check the "YES" box below.

- ☐ YES, I would like to receive the results of this study via e-mail.