Consent Form

Computer-Assisted Delivery of Cognitive Behavioural Therapy for Mental Health and Addictions in Rural Populations in Canada.

Introduction

You are invited to join a research study. This study will test Computer Based Training for Cognitive Behavioral Therapy (CBT4CBT), an online training program that may be offered alongside your counselling sessions for alcohol/drug abuse. The CBT4CBT program is made up of short videos, interactive forms, and tutorials that teach decision making and coping skills to help overcome addictions. It was developed in the United States by Dr. Kathleen Carroll of the Yale School of Medicine, and it has already been shown to benefit those who have used it. This study will bring CBT4CBT to Canada for the first time to see if adding it to the standard addiction therapy programs at four trial sites will help its users better manage their addictions.

The information collected during the study will be used to test CBT4CBT's usefulness when offered along with addictions counselling at the four trial sites. Should you choose to participate in this research, your feedback will be used to make any changes needed to improve the program. The hope is that the improved CBT4CBT program could be offered to more facilities throughout Canada as a regular treatment option for addictions.

Why Am I Being Asked to Join this Study?

You were identified by your counsellor as someone over the age of 18 who may benefit from CBT4CBT and expressed an interest in participating, or because you contacted us after seeing our advertisement. You may take part in this study if you have been struggling with substance abuse within the past 28 days, but NOT if you are feeling like you may do harm to yourself or to others, have a disorder which may be undiagnosed, or require immediate hospitalization. This will all be discussed with you in more detail by your counsellor.

If you decide to take part in this research, you can stop at any time by telling your counsellor. People who have used the program before you have not had any negative effects and the studies have not shown any risk to participants, but your counsellor is also able to end your participation at any point if they feel your health situation has changed. All data collected up to the date you stop participating in the trial will remain in the study records, to be included in study related analyses.

What Happens in this Study?

Sixty people seeking treatment from each of the four trial sites will be randomly assigned to one of two groups. One group will be given standard treatment and be asked to fill out some questionnaires. The second group will receive standard treatment, access to the CBT4CBT program, and also be asked to fill out some questionnaires. Both groups will meet with a Research Assistant from the Centre for Health and Community Research (CHCR) to fill out the questionnaires on a weekly basis, and results from participant urine tests, when available, will be passed on to the Research Assistant once every two weeks. All participants will be contacted by their counsellor or the Research Assistant to complete a follow-up questionnaire six months after the completion of their trial, even if the participant is unable to complete the 8-week trial.

If you are given access to CBT4CBT you will go to a private room with a computer/tablet and log onto the program for at least 30 minutes each week, for eight weeks. To use CBT4CBT you do not need past experience with computers, and all text on the screen is read aloud. Following the completion of the study, participants may choose to be informed of the results, and their contact information will be kept in a separate file to facilitate this process.

Will it Cost Me Anything?

It will cost you nothing to be in this study. As a thank you for participating, you will be given a $25 gift card for Wal-Mart upon completing the first four weeks of the trial, and another $25 gift card for Wal-Mart after the 8th week of the trial. An additional $50 Wal-Mart gift card will be given to you when you complete the six month follow-up questionnaire.

What about My Right to Privacy?

Your participation means that you will allow the collection, reporting, and transfer of data to The Centre for Health and Community Research (CHCR) at the University of Prince Edward Island (UPEI) for the purposes of this project and future analyses related to it.

We will do everything possible to keep your personal information confidential. The only people in this study who will have access to any of your identifying information will be your counsellor and the Research Assistant that you meet with. Instead, we will use a randomly assigned Participant ID on any information sent outside of your treatment centre. If the results of this study are presented at a meeting or published, nobody will be able to tell that you were involved.

Your records will be kept in a secure area during the study, and afterwards will be kept for a minimum of 5 years in a secure area owned or leased by the UPEI. In the event your study records need to be examined it will be done by people who have a professional responsibility to protect your privacy. These people are the CHCR, and/or Health PEI and their assigned representatives, as well as the Health PEI Research Ethics Board, which is responsible for the protection of participants in research. The information they review will not include any revealing information about your identity.

Who Do I Contact If I Have Any Questions or Problems?

For further information about the study you can contact:

- Dr. Juergen Krause, Principal Investigator, CHBMR Director..... 902-566-0340.
- Dr. Kathryn Bigsby, Chair of the PEI Research Ethics Board…….. 902-569-0576.
- The UPEI Research Ethics Board at reb@upei.ca..... 902-620-5104.

CONSENT FORM SIGNATURE PAGE

After you have signed this consent form, you will be given a Signed Copy.

I have:

- Reviewed all of the information in this consent form.
- Been given the opportunity to discuss this study with my counsellor.
- Had all of my questions answered to my satisfaction.
- Been given a signed copy of this consent form.

My signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time.

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Signature of Participant	Name (Printed)	Year	Month	Day*
Witness to Participant's Signature	Name (Printed)	Year	Month	Day*
Signature of Counselor	Name (Printed)	Year	Month	Day*
Signature of Person Conducting Consent Discussion	Name (Printed)	Year	Month	Day*
Signature of Participant's Legally Accepted Representative	Name (Printed)	Year	Month	Day*

If the consent discussion has been conducted in a language other than English, please indicate _____ (language)

		/ /		
Signature of Translator	Name (Printed)	Year	Month	Day*

**Note: Please fill in the dates personally*

Thank you for your time and patience!

Witness:
Whenever possible the witness to the participant's signature should be a person who is independent of the research team (e.g. – a relative or family member of the potential participant). When this is not possible, the witness to the participant's signature may be a member of the research team that is present when the participant's signature is obtained. The signature of this individual indicates only that they were present to witness the signature of the participant; not the entire consent process.