

Prince Edward Island
RESEARCH ETHICS BOARD

Research Protocol Guidelines

1. INTRODUCTORY INFORMATION:

Project Title: Computer-assisted delivery of cognitive behavioral therapy for mental health and addictions in Canada

Local Principal Investigator: Juergen Krause
Institution/Department/Divisional: Faculty of Business
Affiliation: UPEI
Address and Telephone : 550 University Ave, Charlottetown PEI, C1A 4P3
Number: 902-566-0340,
Fax Number,
Email Address: jukrause@upei.ca

Co/Sub/Associate Investigators: Michelle Patterson
Institution/Department/Divisional Affiliation: Centre for Health and Community Research
Address: 550 University Ave, Charlottetown PEI, C1A 4P3
Telephone Number: 902-566-0334

Kathleen Carroll
Yale School of Medicine
New Haven, CT
kathleen.carroll@yale.edu

Anticipated Duration of Study: April 01, 2019

Name of Study Sponsor or Funding Agency (if applicable): CIHR

Local Site(s) of Research: Prince Edward Island, New Brunswick, Ontario

Version Number and Date: 1, 7/12/2017

2. SUMMARY:

Computer-based Training for Cognitive Behavioural Therapy (CBT4CBT) is a new on-line addiction treatment developed by Dr Kathleen Carroll at the Yale School of Medicine in New Haven, Connecticut. CBT4CBT consists of seven one-hour long online sessions that teach key concepts, including dealing with cravings, problem solving, and decision making skills, to help users reduce substance abuse. CBT4CBT has been rigorously tested throughout various communities in the United States with great success and is currently being rolled out throughout

the States. The therapeutic approach of CBT4CBT is unique as its efficacy, durability and cost-savings have been proven in several rigorous clinical trials and will be magnified by the fact that the program can be delivered in Canada, allowing for increased and continual improvements in population health. CBT4CBT has been accepted by both patients and addiction treatment personnel alike and has won numerous clinical innovation awards.

A collaboration has now been formed between Dr Carroll and Drs Michelle Patterson and Juergen Krause of the UPEI Centre for Health and Community Research (CHCR) that will bring CBT4CBT to Canada. While CBT4CBT has previously been tested in urban areas, there are many advantages to offering computer-based training to more rural populations (such as PEI). These more remote areas frequently suffer from a lack of services, as well as a lack of continuity with the services currently offered. CBT4CBT may very well provide that needed continuity to Addictions treatment and has also been shown to improve retention.

3. BACKGROUND, RATIONALE AND STATEMENT OF RESEARCH QUESTION(S):

CBT4CBT will be the first computer-based, cognitive behavioural therapy program for Addictions treatment to be offered in Canada. CBT4CBT has been rigorously tested in urban populations in the United States but this collaboration will be the first pilot trial in First Nation and other rural communities in Canada. Prince Edward Island has a self-proclaimed need for innovative new substance abuse treatments and CBT4CBT may provide the continuity and retention to traditional therapy programs that current available treatment options often lack. This study will allow CBT4CBT to be tested in several Prince Edward Island communities to gage its efficacy and effectiveness. The results and feedback received from the pilot study will allow the program to be adapted for Canadian populations in order to optimize its positive outcomes within Canada.

CBT4CBT has been tested in urban populations in the United States in three rigorous randomized clinical trials with great success. The nature of CBT4CBT suggests it would also be beneficial in rural and remote populations which are common across Canada. Computer based treatments are cost-effective and although their nature necessitates human participants they have minimal risk associated with them. As the first computer based training for Addictions in Canada this research project could have broad implications for treatment in Addictions across our country.

Analysis techniques will be based on those used in previous CBT4CBT trials conducted by our collaborator, Dr Carroll.

The primary substance abuse outcomes (self-reported abstinence) will be assessed throughout the study and through a six month follow-up. Additional outcomes will include use of other services (medical, legal), patient and provider satisfaction, as well as the costs of implementing the program. Each week, the counsellors will deliver a questionnaire (provided by the CHCR) which covers this range of topics to their patient participating in the trial. The data will be analyzed with a focus on feasibility (retention in both conditions, levels of substance abuse, health problems, and cost by condition).

4. SUBJECT SELECTION:

Participants will be recruited from Prince Edward Island; Lennox Island Health Centre and Abegweit Health Centre, Mount Herbert Provincial Addictions Treatment Facility Transition Unit and Methadone clinic, Holland College Student Services, University of Prince Edward Island Student Services, Charlottetown Methadone Clinic and Prince County Hospital. At RECAP in New Brunswick and Ontario Shores Mental Health Centre in Ontario.

A total of 240 Participants will be recruited during years 1-2 and an additional 440 participants will be recruited during years 3-4 ending in April 2019.

Counsellors already employed by the Centres will recruit participants who are willing to consent to a randomized trial of CBT4CBT. In order to create as representative a sample as possible, the inclusion criteria will be fairly broad, including any consenting individual who reports substance abuse in the past thirty days. Individuals who are currently suicidal, homicidal, or require immediate hospitalization will be excluded.

The participants will be patients who have reported substance abuse in the past thirty days. For the initial trial, all participating individuals will be over eighteen years of age and be approved to participate by their addictions counsellors.

Counsellors will ask individuals seeking treatment for substance abuse if they would be interested in learning about and participating in a substance abuse treatment project. If yes, participants will be introduced to the study Research Assistant who will go through the consent form(attached) with them. The Research Assistant will orally read the forms if necessary and individuals will be informed of their right to withdraw from the program should the need arise.

5. RESEARCH PLAN:

The individuals recruited for this study will each fall into one or more subgroup of the trial (transitioning patients [inpatient to outpatient], youth [18-24 years], maintained on methadone, and indigenous individuals) and will be analyzed individually as well as collectively by compiling results from all sites. A subgroup analysis based on gender is also planned to investigate any differences in outcomes between male and female participants, these two groups, historically, can show significant differences in response to mental health and addictions treatment.

Participants will be randomized to either test or control groups. Participants in the control group will receive treatment as usual (the conventional treatment offered at that site) and will also meet with the Research Assistant during week 4 and week 8 to complete questionnaires (attached) either in hard copy or online on a tablet provided. These participants will also be contacted six months after their eight-week participation in the trial ended to complete a follow-up questionnaire.

Participants randomized to the test group will receive treatment as usual but will also be asked to spend at least thirty minutes per week using the program. CBT4CBT use by each participant will be monitored throughout the trial to ensure that this requirement is being met. They may choose to do this on location at the site or from their personal computer/tablet. The individuals in this arm of the trial will also meet with a Research Assistant once a week for eight weeks to complete questionnaires and will be contacted six months after their eight-week participation in the trial ended to complete a follow-up questionnaire. These questionnaires can be completed online. Each participant will be asked to participate in the eight-week long treatment period regardless of group (test or control). In addition to participants' treatment as usual, this will involve a

commitment of approximately 10 minutes as a weekly average from participants in the control group, and approximately 45 minutes as a weekly average from participants in the test group. Please see the consent form table outlining the time commitments in more detail.

This trial design will mirror the designs in the trials already successfully conducted in the United States. Once an individual consents to participate, the counsellor will contact the Research Assistant who will meet with the individual and assign them a participant number generated using Randomizer.org (Geoffrey C. Urbaniak, 2015). This number will have been previously assigned to either test or control. The participant will be notified about the trial arm that they are placed into so that their participation may commence.

A Research Assistant will deliver the questionnaires to the trial participants. Questionnaires may be answered in hard copy or online in private. This removes the pressure from the participants to 'improve' in the eyes of their counsellor. Other than the addition of sections specifically relating to the CBT4CBT program, the questionnaires between groups will be identical.

As mentioned above, three previous/pilot studies in urban areas of the U.S. have been performed (Carroll et al., 2008, 2009, 2014). The trial described herein will follow a very similar design.

Questionnaires, data analysis and protocols are based on those previously used by our collaborator in the US and have all been tailored to better suit Canadian populations. Based on the significant success that Dr Carroll had using these outcomes, tools and protocols we are confident in their reliability and validity.

Individuals who consent to this trial will be notified at the beginning of the trial that they have the right to remove themselves from the trial at any time. They also have the right to contact their counsellor or either co-investigator (phone numbers and emails provided on the consent form) at any time should they have questions or concerns. The counsellors also hold the ability to remove any of their patients from the trial at any time if they see fit.

6. ANALYSIS OF DATA:

Statistical analysis techniques previously used by the Co-Investigator Dr Carroll and her team will be performed on the generated data from this trial (Carroll et al., 2008, 2009, 2014). These include one and two-way analysis of variance (ANOVA's) where appropriate. This will ensure a relevant analysis approach is used for the field of addictions treatment research as well as ensuring that the generated results may be compared with those previously established at other sites.

The power calculations performed to calculate the sample size are based on three similar published trials of CBT4CBT in urban populations in the US. Primary outcome measurements of this trial will be a subset of measurements collected in these previous trials. We believe retention and follow up rates will be similar if not higher than the previous trials as PEI has a less transient community than most urban centers like Connecticut. Based on the three previous trials (Carroll et al., 2008, 2009, 2014), the average drug use measurement (measured by the percent days abstinence from all drugs) in the test groups was 75% and control group 66% with a common standard deviation of 24% at the end of the eight week trial. Retention during the eight week trial was on average 77% and follow-up success was approximately 87% six months post trial. These values were used to calculate the sample size of 30 (for each group) to achieve statistical significance with an alpha of 0.5 and a power of 0.8 for subgroup analysis of the initial trials on PEI, and an alpha 0.05 and a power of 0.8 for combined analysis (i.e. combining results from

all 240 participants across the four trial settings). Power calculations to achieve statistical significance with an alpha of 0.05 and a power of 0.9 were calculated for the large-scale effectiveness trials and a sample size of 110 was found.

Primary outcomes measured include retention, changes in drug use, changes in health (e.g. medical visits, family and social satisfaction, etc.) and program implementation costs. The outcomes to be determined are identical in the four parallel trials to foster comparability across populations.

Secondary outcomes measured include feedback from patients and counsellors. This information will be used to refine CBT4CBT as an ideal treatment approach for each relevant population. Analysis of this data will be on a qualitative level. Drs Krause, Patterson and Carroll place a high priority on patient feedback and advisement and are in agreement that the patients who participate in these trials can contribute to quality improvement at both the individual and collective level. The populations in which CBT4CBT will be implemented throughout this program may have differing needs and desires for substance abuse treatment. Dr. Carroll and her team to date have created three versions of the CBT4CBT program (drug abuse, alcohol only abuse, and a culturally specific version for Spanish speaking individuals in the U.S.). With the feedback from this initial trial, we aim to create potentially revised versions of the CBT4CBT program, which are tailored to better suit Canadian, specifically First Nation, youth, and rural/remote environments.

7. RISKS AND BENEFITS:

CBT4CBT has been shown to hold no more than minimal risk for all participants. In all previous trials, no adverse effects were demonstrated. For this implementation, all participants will be referred to the trial at the sole discretion of their counsellor and anyone who is deemed suicidal, homicidal, has an undiagnosed psychiatric disorder, or is requiring immediate hospitalization will be excluded. If at any point throughout the trial a participant wishes to withdraw, or if the counsellor feels they should be withdrawn from the trial, exposure to CBT4CBT will be immediately withdrawn.

CBT4CBT has demonstrated excellent results in improving retention and in allowing participants to significantly reduce their substance abuse. The goal of these initial trials is to have CBT4CBT become a standard treatment option in Mental Health and Addictions treatment programs throughout Canada by providing refined, or potentially new, versions of the program to populations across the country. This may significantly increase the success of addictions treatment across Canada and in turn largely benefit our society as a whole.

Participants in the 'test' group who respond well to CBT4CBT will have the opportunity to continue accessing the program at their leisure (using their provided login information) beyond the time frame of the study. Participants in the 'control' group may have the opportunity to access CBT4CBT once the trial is complete and assuming that positive effects of CBT4CBT are verified on PEI.

8. CONFIDENTIALITY:

The CHCR team currently work with Health PEI and the PEI Department of Health and Wellness on a CIHR-funded initiative which built the UPEI Secure Island Data Repository on the UPEI campus which holds de-identified PEI health records as well as any research-generated data from clinical trials such as this one. Therefore, the non-identifiable data generated

throughout this study will be stored, after collected and analysed, on secure servers in the UPEI Secure Data Facility. Only CHCR researchers (via password protection and key codes to the room) will have access to the data. All Data will be retained for a minimum of five years.

9. LIABILITY:

N/A

10. DISCLOSURE OF ANY FINANCIAL COMPENSATION:

N/A

11. REFERENCES:

Attached

12. APPENDICES:

Questionnaires or measuring instruments and appropriate copyright release (if applicable) should be included as appendices to the proposal when appropriate.

Any advertisements intended for use to recruit participants should be submitted for review.

Please see the General Guidelines (Section 3.11) concerning Advertisements.

Administrative Requirements for Research Protocols:

- Please use a font-size large enough to be legible (12pt Times New Roman font is preferred).
Protocols may be returned if this criterion is not met.
- Please include page numbers, as well as a version number and date on your proposal (which must be revised whenever the proposal is amended) and any appended data collection tools or measures.

Additional Considerations:

- Submissions based on a grant proposal (e.g. CIHR, PEI Research Fund), the level of data might not in all instances provide enough information about the methodology to meet the REB's requirements for ethical and scientific review. In these cases the grant proposal should be supplemented by further information based on the guidelines of the this REB.
- All documentation that will be provided to family doctors, participants, participant relatives and caregivers (including study introductory letters) must be reviewed and approved by the REB prior to use.