

# Evaluating an online cognitive behaviour therapy program with different levels of support for recent cancer survivors

<b>Submission date</b> 23/06/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims:

Many cancer survivors face difficulties adjusting to life after cancer, with approximately 14-24% of individuals experiencing problems with anxiety, depression, and/or worry about the future. Depression and anxiety have significant consequences for survivors in terms of distress, quality of life, and physical health. In an attempt to increase timely and accessible psychological treatment, Transdiagnostic Internet-delivered cognitive behavioural therapy (T-ICBT) has emerged. This is a type of therapy using strategies from cognitive behavioral therapy (a type of talking therapy aiming to change the way a person behaves) in order to manage depression and anxiety via structured online modules. These programs also typically include some form of therapist guidance. Recently, some evidence has emerged suggesting that T-ICBT may be as effective when participants do not receive additional support from a therapist. This treatment has only recently been used within a cancer population, with several small scale trials demonstrating promising results. The aim of this study is to examine the efficacy of two forms of a T-ICBT program for treating anxiety and depression among recent cancer survivors, one with therapist guidance and another without (self-guided).

### Who can participate?

Adult cancer survivors (who were diagnosed in the past five years and who have completed active treatment) living in Canada who are currently experiencing anxiety or depressive symptoms and are interested in receiving treatment in an online format.

### What does the study involve?

All interested participants participate in an online screening to determine if T-ICBT matches their needs. Screening takes about 15 to 30 minutes and includes questions about their current symptoms and other mental health history. Following the screening, eligible participants are randomly allocated into one of two treatment groups (either self-directed T-ICBT or technician-assisted T-ICBT). Both groups receive T-ICBT immediately. Participants in both groups receive the same eight week T-ICBT program for cancer survivors with depression and anxiety, however those the technician assisted group are contacted weekly by telephone or email to have any questions answered and be given encouragement. The program includes education, cognitive,

behavioural, and physical strategies, as well as relapse prevention information. Participants complete questionnaires prior to the start of the program, before each lesson of the program, once they have completed the program, and 1 month after completing the program, in order to assess anxiety and depressive symptoms. After the treatment, participants are also asked to rate the program content, the overall service, and their satisfaction with the program.

What are the potential risks and benefits of participating?

Participants benefit from the program being delivered online and so avoid having to visit an office which may be inconvenient. Participants are able to access the online material at a time and location that is convenient and are able to save and print off program materials free of charge. There is a risk that assessment may be more difficult when the participant is not seeing a therapist in person and that online messages sent by technicians can be misunderstood. Additionally, the online format increases risk for breaches of confidentiality, and there is potential for technology failures that may result in messages not being received by either participants or technicians. As with any form of psychological treatment, there is a small risk of temporary discomfort and/or slight increases in negative emotions due to increased focus on and awareness of these emotions. However, with the continuation of Wellbeing After Cancer, these emotions typically lessen and improve as a result of treatment.

Where is the study run from?

The study is run from the Online Therapy Unit for Service, Education, and Research, University of Regina, and takes place online (Canada).

When is the study starting and how long is it expected to run for?

February 2016 to January 2018

Who is funding the study?

1. Canadian Institutes of Health Research (Canada)
2. Saskatchewan Health Research Foundation (Canada)
3. Rx&D Health Research Foundation (Canada)

Who is the main contact?

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## **Study information**

**Scientific Title**  
A randomized non-inferiority trial of technician-assisted and self-guided transdiagnostic Internet-delivered cognitive behaviour therapy for cancer survivors: making treatment scalable

**Study objectives**  
Hypotheses:  
1. Participants receiving both forms of Internet-delivered cognitive behaviour therapy (ICBT), namely technician-assisted ICBT and self-guided ICBT, will demonstrate significant improvement in anxiety and depressive symptoms from pre-treatment to post-treatment  
2. Improvements between groups will not be significantly different with both groups evidencing medium to large effect sizes

3. Participants in both groups will report high satisfaction ratings of the program and the majority will not express a need for more intensive support

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

University of Regina Research Ethics Board, 16/05/2016, ref: REB#2016-066

### **Study design**

Two-group non-inferiority randomized parallel trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Internet/virtual

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Depression and anxiety in cancer survivors

### **Interventions**

Participants are randomised to one of two groups, who each receive the same internet-based cognitive behavioural therapy (ICBT). The intervention is titled Wellbeing After Cancer. It is based on the Wellbeing Course (Dear. et al., 2011), which is a transdiagnostic-ICBT program designed to treat symptoms of anxiety and depression among adults. The program consists of five lessons containing CBT materials that are accessed online. The lessons include information about the symptoms of anxiety and depression, strategies for identifying and changing unhelpful thoughts, strategies for increasing activity, relaxation techniques, and strategies for overcoming avoidance. Each lesson also includes a Do-It-Yourself Guide which breaks down central concepts and offers additional practice activities. Furthermore, each lesson contains stories about individuals who have completed the lessons in the past. Participants can access several additional resources outlining topics such as assertiveness, communication skills, sleep, and problem solving. Participants also receive automated emails to remind them about the Course and direct attention to the content. Unique to Wellbeing After Cancer is that two of the four patient stories are adapted to be cancer specific, presenting cases of cancer survivors working through the lessons. There is also an additional supplementary resource that addresses fear of cancer recurrence. The self-guided group will not have the support of a technician.

In the technician-assisted condition, participants will be contacted weekly (via email or phone) by a technician (research-assistant) who will summarize content, answer questions, reinforce progress and encourage practice of skills, and normalize challenges of treatment. The self-guided group will not have the support of a technician.

Participants in both conditions will be contacted if there is a sudden elevation in symptoms or suicidal thoughts are endorsed.

Participants who complete Wellbeing After Cancer complete symptom measures at pre-treatment, before each lesson, post-treatment and then one month after completing the program.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Depressive symptoms are measured using the Patient Health Questionnaire- 9 Item (PHQ-9) pre-treatment, before each lesson, immediately following completion of the program, and 1 month following completion of the program
2. Symptoms of generalized anxiety are measured using the Generalized Anxiety Disorder -7 Item (GAD-7) pre-treatment, before each lesson, immediately following completion of the program, and 1 month following completion of the program

## **Secondary outcome measures**

1. Fear of cancer recurrence is measured using the Fear of Cancer Recurrence Inventory (FCRI-SF) pre-treatment, immediately following completion of the program, and 1 month following completion of the program
2. A secondary measure of anxiety and depressive symptoms will be measured using the Depression and Anxiety Stress Scales (DASS-21) pre-treatment, immediately following completion of the program, and 1 month following completion of the program
3. Quality of life will be measured using the 12-Item Short Form Health Survey (SF-12) pre-treatment, immediately following completion of the program, and 1 month following completion of the program
4. Participant satisfaction with treatment will be measured using satisfaction questions immediately following completion of the program
5. Participants satisfaction with level of support will be assessed using satisfaction questions immediately following completion of the program
6. Number of log-ins are measured immediately following completion of the program
7. Days accessing service are measured immediately following completion of the program
8. Number of emails sent to technician (if applicable) are measured immediately following completion of the program
9. Number of emails received from technician (if applicable) are measured immediately following completion of the program
10. Number of phone calls are measured immediately following completion of the program
11. Number of lessons completed are measured immediately following completion of the program

## **Overall study start date**

05/02/2016

## **Completion date**

31/01/2018

## **Eligibility**

**Key inclusion criteria**

1. Resident of Canada and will be in Canada during the 8 week course period
2. 18 years of age or older
3. Experiencing symptoms of depression and/or anxiety ( $\geq 8$  on the PHQ-9 or GAD-7)
4. Diagnosed with cancer in the past 5 years and have completed active treatment (radiation, chemotherapy, or surgery)
5. Has access to a computer and the Internet
6. Willing to provide a medical contact (e.g., family physician) for an emergency contact

**Participant type(s)**

All

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

94

**Key exclusion criteria**

1. Currently receiving regular psychotherapy for depression or anxiety elsewhere or in some other form
2. Started a new psychotropic medication for anxiety or depression or had a change in dosage within the past month
3. Using illicit drugs or three or more standard drinks/day
4. Current self-reported psychotic disorder or bipolar disorder or severe symptoms of depression (total score  $> 22$  or a score  $> 2$  on question 9 of the PHQ-9, or specific plan/intent of suicide)

**Date of first enrolment**

15/07/2016

**Date of final enrolment**

30/06/2017

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Online Therapy Unit for Service, Education, and Research, University of Regina

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### Sponsor type

University/education

### ROR

<https://ror.org/03dzc0485>

## Funder(s)

### Funder type

Government

### Funder Name

Canadian Institutes of Health Research

### Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR),  
CIHR\_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

**Location**

Canada

**Funder Name**

Health Research Foundation

**Alternative Name(s)**

Fondation pour la Recherche en Santé, HRF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Canada

**Funder Name**

Rx&D Health Research Foundation

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

15/07/2019

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available