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

Submission date
23/06/2016

Recruitment status
No longer recruiting

Registration date
24/06/2016

Overall study status
Completed

Last Edited
16/01/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 stategies 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?
1. Miss Dale Dirkse (public)
dirkse2d@uregina.ca
2. Dr Heather Hadjistavropoulos (scientific)
hadjistavropoulos@uregina.ca.

Contact information

Type(s)
Public

Contact name
Miss Dale Dirkse

ORCID ID
https://orcid.org/0000-0003-4007-7996

Contact details
Department of Psychology
University of Regina

3737 Wascana Parkway
Regina
Canada
S4S 0A2
+1 306 337 2598
dirkse2d@uregina.ca

Type(s)
Scientific

Contact name
Dr Heather Hadjistavropoulos

ORCID ID
https://orcid.org/0000-0002-7092-9056

Contact details
Department of Psychology
University of Regina
3737 Wascana Parkway
Regina
Canada
S4S 0A2
+1 306 585 5133
hadjistavropoulos@uregina.ca

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 (ICPT). 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(s)
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

Key secondary outcome(s))
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 pimmediately 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

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 (≥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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Online Therapy Unit for Service, Education, and Research
Department of Psychology
3737 Wascana Parkway
Regina
Canada
S4S 0A2

Sponsor information

Organisation
University of Regina

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 - Welcome to the Canadian Institutes of Health Research, 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, FRS

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available