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Evaluating the feasibility and effectiveness of internet cognitive behaviour therapy for anxiety and depression among cancer survivors

Submission date
31/01/2014

Recruitment status
No longer recruiting

Registration date
27/02/2014

Overall study status
Completed

Last Edited
27/02/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Although most cancer survivors tend to adjust well over time, a small number of people experience anxiety and depression following the completion of cancer treatment. Therapist-assisted Internet Cognitive Behavioural Therapy (ICBT) involves patients reviewing therapy materials over the Internet while receiving support and assistance from a therapist through secure e-mail. Research has consistently shown that therapist-assisted ICBT is effective in reducing anxiety and depression. The use of ICBT has recently expanded to populations, including cancer patients and survivors. However, an ICBT program designed to specifically target depression and anxiety among cancer survivors has yet to be developed and tested. The current study will therefore find out whether such an ICBT program is effective in reducing anxiety and depression and improving quality of life, fatigue and pain among cancer survivors. As this service is newly available, this study will also find out the feasibility and acceptability of the program.

Who can participate?
Adults living in the province of Saskatchewan who have completed primary cancer treatment within the past 18 months and are experiencing at least mild symptoms of anxiety and/or depression can take part in this study.

What does the study involve?
Interested people will participate in a telephone screening to find out if ICBT matches their needs. The screening is a two-part process that takes about 60 minutes in total. Participants will be asked about their symptoms of anxiety, depression, other mental health history as well as cancer diagnosis and treatment. Following the screening, eligible individuals will receive ICBT immediately. Wellbeing After Cancer consists of five self-led lessons containing CBT materials and additional therapeutic resources that are accessed online. The lessons include information about the symptoms of anxiety and depression, how to identify and challenge unhelpful thoughts, relaxation techniques, behavioural activation strategies, and other coping strategies. Patients should engage in Wellbeing After Cancer for about 8 weeks. All participants are asked to complete questionnaires at the start of the program, immediately following completion of

the program and 3 months following completion of the program. Participants will also be asked to participate in a short telephone interview after completion of the program. This interview is designed to receive participants direct feedback on the program and their experiences with it.

What are the potential benefits and risks of participating?
There are several potential benefits associated with participating in this study. They include: you do not need to schedule an appointment to engage in internet-based CBT, you avoid having to visit an office if things like transportation, travel, stigma, medical conditions/symptoms or your own availability are a concern, you can access the online material at a time and location that is convenient to you, you can save and print off program materials for your own review, you can e-mail your therapist at any time through our secure website, and the service is affordable as it is provided free of charge. In addition, participating in this study may help participants manage symptoms of anxiety and depression more effectively. Symptoms of anxiety and depression may also
decrease as a result of learning more helpful coping strategies. Additional difficulties such as pain and fatigue may also improve as a result of learning coping strategies. The potential risks or challenges include: assessment and diagnosis may be more difficult without meeting in person, potential misinterpretation of e-mail messages between you and your therapist, risk for breaches of confidentiality, potential for technology failures that may result in messages not being received by either you or your therapist. As with any form of psychological treatment, there is also 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, Regina, Saskatchewan, Canada.

When is the study starting and how long is it expected to run for?
Recruitment for the study began in February 2013 and is expected to run until July 2014.

Who is funding the study?
The Canadian Institutes of Health Research, Canada.

Who is the main contact?
Ms Nicole Alberts, Nicole.alberts@uregina.ca
Dr Heather D. Hadjistavropoulos, hadjista@uregina.ca

Study website
https://www.onlinetherapyuser.ca/wac/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A feasibility open trial of a transdiagnostic Internet cognitive behaviour therapy (ICBT) for cancer survivors

Study objectives
1. It is predicted that patients who receive ICBT will demonstrate significant improvement from pre- to post-treatment on (a) primary outcome measures of anxiety and depression and, (b) secondary outcome measures of fatigue, pain, and quality of life.
2. It is predicted that patients will report a high level of satisfaction with the program.
3. It is expected that improvements will be maintained at 3-month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Regina; 6/11/2012; Renewal: 6/11/2013; ref. 22S1213
2. University of Saskatchewan; 22/01/2013; ref. BEH 13-23

Study design
Non-randomised controlled study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Major Depressive Disorder, Generalized Anxiety Disorder, Panic Disorder, Social Phobia

Interventions
Therapist-assisted Transdiagnostic Internet-based CBT.

The intervention is titled Wellbeing After Cancer, which is a transdiagnostic ICBT program designed to treat symptoms of anxiety and depression among adults. The program consists of five self-led 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 additional coping strategies. Each lesson also includes a Do It Yourself Guide which breaks down central concepts and offers additional practice activities. Participants can access several additional resources outlining topics such as assertiveness, communication skills, sleep, problem solving, and the fear of cancer reoccurring. Participants also receive access to educational stories outlining the experiences of two cancer survivors experiencing anxiety and depression. Wellbeing After Cancer is also therapist-assisted. Each patient is assigned an online therapist who communicates with the patient on a weekly basis via e-mail using the secure e-mail built into the program website. In the weekly e-mail, the therapist comments on progress made, addresses any concerns the patient might have, and answers questions regarding application of the concepts and skills learned. The therapists role is to also provide support and encouragement as patients progress through the program.

Participants who complete Wellbeing After Cancer will be contacted following treatment completion and asked to participate in a brief telephone interview. The purpose of this interview is to gain further feedback regarding participants perceptions of the program (e.g., strengths, weaknesses). Participants will also be contacted three months after completing the program to be asked to complete follow-up symptom measures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient Health Questionnaire 9 Item
2. Generalized Anxiety Disorder 7 Item
3. Hospital Anxiety and Depression Scale

These will be administered at baseline, post-treatment, and 3-month follow-up.

Secondary outcome measures
1. Medical Outcomes Study Short Form
2. Brief Pain Inventory
3. Fatigue Symptom Inventory
4. Short Health Anxiety Inventory
5. Treatment Satisfaction Questionnaire
6. Post-Treatment Program Check-List
7. Working Alliance Inventory
8. Client Feedback Open-Ended Questions (administered via telephone interview)

Most measures are administered at baseline, post-treatment, and 3-month follow-up. Some are administered exclusively at post-treatment. Some measures are administered weekly.

Baseline: Patient Health Questionnaire 9 Item, Generalized Anxiety Disorder 7 Item, Hospital Anxiety and Depression Scale, Medical Outcomes Study Short Form, Brief Pain Inventory, Fatigue Symptom Inventory, Short Health Anxiety Inventory

Weekly: Patient Health Questionnaire 9 Item, Generalized Anxiety Disorder 7 Item, Working Alliance Inventory (administered only at Week 5)

Post-Treatment: Patient Health Questionnaire 9 Item, Generalized Anxiety Disorder 7 Item, Hospital Anxiety and Depression Scale, Medical Outcomes Study Short Form, Brief Pain Inventory, Fatigue Symptom Inventory, Short Health Anxiety Inventory, Treatment Satisfaction Questionnaire, Post-Treatment Program Check-List, Working Alliance Inventory, Client Feedback Open-Ended Questions

3-Month Follow-Up: Patient Health Questionnaire 9 Item, Generalized Anxiety Disorder 7 Item, Hospital Anxiety and Depression Scale, Medical Outcomes Study Short Form, Brief Pain Inventory, Fatigue Symptom Inventory, Short Health Anxiety Inventory

Overall study start date
01/02/2013

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Resident of Saskatchewan
2. Aged 18 years or older, either sex
3. Currently experiencing clinically significant symptoms of depression, anxiety, social phobia, and/or panic
4. Has regular access to a computer, Internet, and printer
5. Comfortable using the Internet and writing e-mails
6. In remission from any stage and any type of cancer as long as at least 1 month has passed since the completion of active treatment (radiation, chemotherapy, or surgery) but no longer than 18 months
7. Willing to have their physician, a medical clinical, or an emergency hospital be notified of participation in the program

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Not a resident of Saskatchewan
2. Less than 18 years of age
3. Has no regular access to a computer, Internet, and use of printer
4. Currently receiving psychotherapeutic treatment for anxiety or depression elsewhere or in some other form
5. Started a new psychotropic medication within the past month or had a change in dosage within the past month
6. Meets criteria for current substance abuse or dependence (drugs or alcohol)
7. Meets current criteria for a psychotic disorder or bipolar disorder, or severe symptoms of depression, including frequent suicidal ideation

Date of first enrolment
01/02/2013

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
Canada

Study participating centre
University of Regina
Regina
Canada
S4S 0A2

Sponsor information

Organisation
University of Regina (Canada)

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Sponsor type
Not defined

Website
http://www.onlinetherapyuser.ca/

ROR
https://ror.org/03dzc0485

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) Frederick Banting and Charles Best Canada Graduate Scholarship Doctoral Award, ref. GSD - 113481

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration