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Evaluating an internet cognitive behaviour therapy wellbeing course for anxiety and depression

Submission date
05/11/2013

Recruitment status
No longer recruiting

Registration date
31/01/2014

Overall study status
Completed

Last Edited
13/08/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depression and anxiety are common, disabling and undertreated disorders in Canada. 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. ICBT has now been offered in Saskatchewan, Canada for generalized anxiety disorder, depression, and panic disorder in a 12-module format. Although previous programs were effective in reducing symptoms, feedback suggested that clients wanted a shorter program that could help improve anxiety and depression at the same time. The Wellbeing Course is a Transdiagnostic ICBT (T-ICBT) program that was originally developed and tested by researchers as the eCentreClinic in Australia. It is referred to as a T-ICBT program because it is designed to treat both depression and anxiety. Research conducted in Australia has shown that depression and anxiety can be effectively treated with the Wellbeing Course. This study will provide and evaluate the eCentreClinics Wellbeing treatment program with residents of Saskatchewan, Canada.

Who can participate?
Adults aged 18 and older living in the province of Saskatchewan with symptoms of anxiety, depression, social phobia, or panic.

What does the study involve?
All interested participants will participate in an online screening to determine if T-ICBT matches their needs. Screening takes about 15 to 30 minutes and will ask questions about their current symptoms and other mental health history. Following the screening, eligible clients receive T-ICBT immediately. The T-ICBT program, entitled the Wellbeing Course, is designed to treat symptoms of anxiety and depression among adults. The program 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. Clients should engage in the Wellbeing Course 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.

What are the potential benefits and risks of participating?
There are several potential benefits associated with participating in the Wellbeing Course. You do not need to schedule an appointment with Internet-based CBT, you avoid having to visit an office if things like transportation, travel, stigma 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, you may feel more comfortable disclosing personal information online than in person, and this service is provided free of charge. In addition, this research 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. If the program is found to be effective, it may help other adults who experience anxiety and low mood.
The potential risks or challenges include: assessment and diagnosis may be more difficult when visual cues are not present, potential misinterpretation of e-mail messages between you and your therapist, there is a risk for breaches of confidentiality, there is 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 a small risk of temporary discomfort and/or slight increases in your negative emotions due to increased focus on and awareness of these emotions. However, with the continuation of the Wellbeing Course, 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, Canada.

When is the study starting and how long is it expected to run for?
Recruitment for the study began in November 2013 and is expected to continue until June 2015.

Who is funding the study?
Funding has been provided by the Canadian Institutes of Health Research and the Partnership for Health Improvement, Saskatchewan Health Research Foundation, Rx & D Health Research Foundation, Canada.

Who is the main contact?
Dr Heather D. Hadjistavropoulos, Principal Investigator, hadjista@uregina.ca
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Study website
https://www.onlinetherapyuser.ca/wellbeing/

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
Transdiagnostic Internet Cognitive-Behaviour Therapy (T-ICBT) for anxiety and depression

Study objectives
1. It is predicted that patients who receive T-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 social anxiety, stress, and disability.
2. It is expected that over 80% of patients will complete all T-ICBT modules.
3. It is predicted that patients will report a high degree of satisfaction with T-ICBT.
4. 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, 18/01/2013, ref.: 60R1213
2. University of Saskatchewan; 18/01/2013; ref.: BEH 12-348
3. The Regina QuAppelle Health Region, 18/01/2013, ref.: REB 12-112
4. Saskatoon Health Region, 26/022013, ref.: BEH- 12-348
5. Five Hills Health Region, 24/05/2013
6. Sun Country Health Region, 06/11/2013
7. Cypress Health Region, 07/10/2013

Study design
Single-group open trial comparing pre-treatment to post-treatment and post-treatment to 3-month follow-up

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
Depression, Generalized Anxiety Disorder, Panic Disorder, Social Phobia

Interventions
Therapist-assisted Transdiagnostic Internet-based CBT.

The intervention is titled the Wellbeing Course, which is a T-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 strategy. 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, and problem solving. The Wellbeing Course is therapist-assisted. Each client is assigned an online therapist who communicates with the client 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 the progress the client has made, addresses any concerns they client might have, and answers questions regarding application of the concepts and skills learned. The therapists role is also to provide support and encouragement as clients progress through the program.

Participants who complete the Wellbeing Course will be contacted three months after completing the program to be asked to complete follow-up measures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient Health Questionnaire- 9 Item (PHQ-9)
2. Generalized Anxiety Disorder 7 (GAD-7)

Measured at baseline, immediately following completion of the program, and 3 months following completion of the program.

Secondary outcome measures
1. Social Interaction Anxiety Scale 6-Item and Social Phobia Scale 6-Item Composite (SIAS6/SPS6)
2. Panic Disorder Severity Scale Self Rating (PDSS-SR)
3. Kessler-10 (K-10)
4. Sheehan Disability Scales (SDS)
5. Working Alliance Inventory Short Form (WAI-SF)
6. Treatment Satisfaction questions

Measured at baseline, immediately following completion of the program, and 3 months following completion of the program.

Overall study start date
04/11/2013

Completion date
01/06/2015

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment
458

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 psychotherapy elsewhere or in some other form
5. Started a new psychotropic medication within the past month or had a change in dosage
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
8. Has a primary diagnosis of obsessive compulsive disorder or post-traumatic stress disorder, unless T-ICBT can be offered as an adjunct to in person care for these conditions.

Date of first enrolment
04/11/2013

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
Canada

Study participating centre
Department of Psychology
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Sponsor information

Organisation
University of Regina (Canada)

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Sponsor type
University/education

ROR
https://ror.org/03dzc0485

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (Canada) Partnership for Health Improvement Grant Reference #: 293379

Funder Name
Health Research Foundation, Saskatchewan Health Research Foundation (Canada), Reference #: N/A

Funder Name
Rx & D Health Research Foundation (Canada)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016	13/08/2020	Yes	No