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Examining the efficacy of online cognitive behaviour therapy with different levels of therapist support

Submission date
19/04/2016

Recruitment status
No longer recruiting

Registration date
21/04/2016

Overall study status
Completed

Last Edited
25/03/2019

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 conditions that are unfortunately often undertreated. A particularly effective treatment for both anxiety and depression is cognitive behavioural therapy (a type of talking therapy which helps patients to cope better by changing the way they think and behave). Unfortunately, many patients are unable to access this type of treatment when they need it. In an attempt to combat this, transdiagnostic internet-delivered cognitive behavioural therapy (T- ICBT) has emerged. T-ICBT is a type of cognitive behavioural therapy program which involves elivering therapy to manage depression and anxiety via structured online modules, usually under therapist guidance. Over the past two years, the research team has been delivering T-ICBT in Saskatchewan. In terms of therapist-guidance, therapists are required to email or phone participants on a weekly basis for 8 weeks while participants work on the modules. This approach has been found to be acceptable to participants and clinically effective, resulting in significant reductions in depression and anxiety symptoms. Recently, there is some evidence emerging that T-ICBT may be just as effective when participants do not receive weekly therapist support. With this approach, participants rather than therapists initiate contact as needed. This approach appears to require less clinician time but is as effective and takes into account participant preferences. The aim of this study is to compare the efficacy of T-ICBT with varying levels of support in treating the symptoms of anxiety and depression.

Who can participate?
Adults living in Saskatchewan (Canada) experiencing symptoms of depression and/or anxiety.

What does the study involve?
All interested participants take part in an online screening to find out if T-ICBT would match their needs. Screening takes about 15 to 30 minutes and includes questions about their current symptoms and mental health history. Following the screening, eligible participants are randomly allocated to one of two groups. Both groups receive the same 8 week T-ICBT program for depression and anxiety. The program includes education, cognitive, behavioural, and physical strategies, as well as relapse prevention information. Those in the first group receive weekly contact from a therapist by email and phone. Those in the second group receive a variable level

of contact from the therapist as and when they feel they need it. Participants complete questionnaires prior to the start of the program, before each lesson of the program, once they have completed the program, and 3 months after completing the program, to assess anxiety and depressive symptoms. As part of the battery of questionnaires administered after the completion of the program, clients are also asked to rate the program content, the overall service, and their satisfaction with the program.

What are the possible benefits and risks of participating?
Participants benefit from receiving cognitive behavioural therapy without having to deal with the difficulties associated with getting to an appointment (such as travel, availability and worries about what people may think). The therapy could then help participants to better manage their anxiety/depression symptoms better. There are no notable risks involved with taking part in the study.

Where is the study run from?
The study is run from the Online Therapy Unit for Service, Education, and Research at University of Regina and takes place on the internet (Canada)

When is the study starting and how long is it expected to run for?
January 2016 to December 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?
Dr Heather Hadjistavropoulos
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Study website
https://www.onlinetherapyuser.ca/wellbeing_s/welcome/

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 randomized trial examining the efficacy of online cognitive behaviour therapy with different levels of therapist support

Study objectives
Participants who receive the transdiagnostic-internet-delivered cognitive behaviour therapy (T-ICBT) Wellbeing Course will demonstrate significant improvement from pre- to post-treatment on symptom outcome measures, with moderate to large, significant, and clinically significant reductions in relevant symptoms regardless of whether participants are contacted by their therapist weekly or if participants receive different levels of support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Regina Research Ethics Board, ref: REB#2016-001

Study design
Phase 1: Two-group non-inferiority open randomised parallel trial.
Phase 2: Two-group non-inferiority open trial with preference assignment.

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

1. Depression
2. Generalized Anxiety Disorder
3. Panic Disorder
4. Social Phobia

Interventions

Current interventions as of 28/11/2017:
Transdiagnostic Internet-based CBT:
The intervention is titled the Wellbeing Course (Dear. et al., 2011), 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 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. The Wellbeing Course is therapist-assisted. Each client is assigned an online therapist to provide support, encouragement, and to answer questions regarding application of the concepts and skills learned.
In both Phases of this study participants will be assigned to one of two groups.

Group 1: Participants undergo the T-ICBT program and receive weekly contact from the therapist by email or phone.
Group 2: Participants undergo the T-ICBT program. The therapist's contact schedule will be modified to explore if outcomes can be maintained with differing levels of therapist contact with participants.

All clients in both conditions will be contacted if there is a sudden elevation in symptoms or suicidal thoughts are endorsed.
In phase one of the trial participant's group assignment will be randomly assigned and in phase two clients will be invited to select their group based on personal preference.

Participants who complete the Wellbeing Course complete symptom measures at pre-treatment, before each lesson, post-treatment and then three months after completing the program.

Previous interventions:
Participants are randomly allocated to one of two groups.

Group 1: Participants undergo the T-ICBT program and receive weekly contact from the therapist by email or phone.
Group 2: Participants undergo the T-ICBT program. The therapist's contact schedule will be modified to explore if outcomes can be maintained with differing levels of therapist contact with participants.

Transdiagnostic Internet-based CBT:
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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 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. The Wellbeing Course is therapist-assisted. Each client is assigned an online therapist to provide support, encouragement, and to answer questions regarding application of the concepts and skills learned.

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

Participants who complete the Wellbeing Course complete symptom measures at pre-treatment, before each lesson, post-treatment and then three months after completing the program.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measures are administered at baseline (pre-treatment), before each lesson, immediately following completion of the program, and 3 months following completion of the program.

1. Depressive symptoms are measured using the Patient Health Questionnaire- 9 Item (PHQ-9).
2. Symptoms of generalized anxiety are measured using the Generalized Anxiety Disorder -7 Item (GAD-7)

Secondary outcome measures
Measured at baseline (pre-treatment), immediately following completion of the program, and 3 months following completion of the program.

1. Social phobia symptoms are measured using the Social Interaction Anxiety Scale 6-Item and Social Phobia Scale 6-Item Composite (SIAS6/SPS6)
2. Panic symptoms are measured by use of the Panic Disorder Severity Scale Self Rating (PDSS-SR)
3. Distress due to anxiety and depression symptoms is examined using the Kessler-10 (K-10)
4. The level of self perceived disability that is experienced by participants is measured using the Sheehan Disability Scales (SDS)
5. Health Service Utilization is determined using open-ended questions which ask participants to list the total number of visits to a variety of health professionals because of symptoms of anxiety or depression.

Measured post-treatment and at 3-month follow-up

1. Working Alliance will be measured using the Working Alliance Inventory Short Revised (WAI-SR)
2. Participants satisfaction with treatment will be measured using the Treatment Satisfaction questions

Overall study start date
01/01/2016

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Resident of Saskatchewan and will be in Saskatchewan during the 8 week course period.
2. Aged 18 years or older, either sex
3. Experiencing symptoms of depression and/or anxiety
4. Has access to a computer and the Internet
5. Has a score of >4 on the Phq-9 or GAD-7
6. Has an interest in the Wellbeing Course

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

Total final enrolment
180

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 regular psychotherapy for depression or anxiety elsewhere or in some other form
5. Is unwilling to have their physician, a medical clinic, or an emergency hospital be notified of their participation in the program
6. High current risk of suicide or attempt in past year
7. Is experiencing unmanaged symptoms psychosis or mania

8. Alcohol or drug problem that requires primary treatment
9. Hospitalization for mental health problem in past year
10. Does not complete online or telephone screening
11. Does not consent to treatment or complete pre-treatment questionnaires

Date of first enrolment
03/01/2016

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
Canada

Study participating centre
University of Regina
Online Therapy Unit for Service, Education, and Research
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Sponsor information

Organisation
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

Funder Name
Saskatchewan Health Research Foundation

Funder Name
Rx & D Health Research Foundation

Results and Publications

Publication and dissemination plan
Study information may be used to prepare symposia to be presented at future research conferences. The primary results of this study will be used to prepare a manuscript, which will be submitted for publication in a peer-reviewed journal.

Intention to publish date
31/05/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2017	25/03/2019	Yes	No