

Evaluating the acceptability and effectiveness of internet cognitive behaviour therapy

Submission date 29/10/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/02/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/11/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Depression and anxiety are common, disabling and under-treated disorders in Canada. Therapist-assisted Internet Cognitive Behavioural Therapy (ICBT) involves patients reviewing therapy materials over the internet while receiving help from a therapist through secure e-mail. Research has consistently shown that ICBT is effective in reducing anxiety and depression. The purpose of this study was to find out the acceptability and effectiveness of ICBT in routine clinical practice.

Who can participate?

Men and women aged 18 years from the Saskatchewan area with symptoms of depression or anxiety and access to a computer.

What does the study involve?

All interested participants participate in a telephone screening to determine if ICBT matches their needs. Screening takes about 60 minutes and asks questions about participants current symptoms and other mental health history. Following the screening, eligible clients receive ICBT immediately. Each online program has 12 treatment modules containing CBT materials that are accessed online, as well as activities that are to be completed offline. Modules include information about the targeted symptoms, how to monitor and challenge unhelpful thoughts, relaxation techniques, behavioural activation, and other coping strategies. Treatment takes a minimum of 12 weeks, although participants can take longer if they wish. All participants are asked to complete questionnaires at the start of the program, mid-way through the program, and immediately following completion of the program.

What are the potential benefits and risks of participating?

The potential benefits include: 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, and 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 ICBT program, 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 started in October 2010 and continued until April 2013.

Who is funding the study?

Canadian Institutes of Health Research and The Saskatchewan Health Research Foundation (Canada).

Who is the main contact?

Dr Heather D. Hadjistavropoulos, Principal Investigator, hadjista@uregina.ca

Ms Marcie Nugent, Unit Coordinator, online.therapy.user@uregina.ca

Study website

<https://www.onlinetherapyuser.ca>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

An evaluation of patient access to, satisfaction with, and outcomes resulting from internet cognitive behaviour therapy

Study objectives

1. It is hypothesized that participants who receive Internet Cognitive Behaviour Therapy (ICBT) 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.
2. It is hypothesized that approximately 80% of patients offered ICBT will complete all modules in the program.
3. It is hypothesized that over 80% of patients who are offered ICBT will report a high degree of satisfaction with the service.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University of Regina; September 21, 2010; File #: 17R1011
2. University of Saskatchewan; November 30, 2010; File #: BEH-10-294
3. The Regina QuAppelle Health Region; October 1, 2010; REB-10-52
4. Sun Country Health Region; December 7, 2010
5. Cypress Health Region; November 15, 2010

Study design

Single-group open trial comparing pre-treatment to post-treatment

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 (GAD), Panic Disorder

Interventions

Examining the effectiveness of therapist-assisted Internet-based CBT. Participants are selected for each program based on symptom levels.

The interventions are titled GAD Online, Depression Online, and Panic Online, which are ICBT programs designed to treat symptoms of generalized anxiety, depression, and panic respectively. The program consists of 12 treatment modules containing CBT materials that are accessed online, as well as activities that are to be completed offline. All programs begin with information on the targeted disorder. Following this, treatment modules contain a mix of cognitive and behavioural strategies for managing the disorder. For example, information on how to identify and challenge unhelpful thoughts, relaxation techniques, behavioural activation, exposure, and other coping strategies are contained within the modules. Clients should engage in ICBT for approximately 12 weeks. Depression Online, GAD Online, and Panic Online are 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 system built into the program website. In the weekly e-mail, the therapist comments on the progress a client has made, addresses homework concerns, and answers any questions the client has for the therapist. The therapists role is also to provide support, encouragement, and motivation for clients to continue with the program.

Intervention Type

Behavioural

Primary outcome measure

1. Depression Anxiety Stress Scale-21 Item (DASS)
2. Patient Health Questionnaire- 9 Item (PHQ-9)
3. Generalized Anxiety Disorder 7 (GAD-7)
4. Panic Disorder Severity Scale (PDSS)

Measured at baseline, during the study treatment (after the 6th module), at the end of treatment (after the final module) and at 3 months after completing the 12 modules.

Secondary outcome measures

1. World Health Organization Quality of Life Assessment BREF (WHOQOL-BREF)
2. Work and Social Adjustment Scale (WSAS)
3. Treatment Satisfaction questions
4. Therapeutic Alliance Questionnaire (TAQ)

Measured at baseline, during the study treatment (after the 6th module), at the end of treatment (after the final module) and at 3 months after completing the 12 modules.

Overall study start date

01/10/2010

Completion date

01/04/2013

Eligibility

Key inclusion criteria

1. Resident of Saskatchewan
2. Aged 18 years or older, either sex
3. Currently experiencing symptoms of depression, generalized anxiety, or panic
4. Has regular access to a computer, Internet, and printer
5. Comfortable using the internet and writing e-mails
6. For panic: PHQ-9 - score of 5 or above
7. Generalized Anxiety Disorder (GAD)-7 score of 5 or above
8. Panic Disorder Severity Scale (PDSS) score of 6 or above

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Total final enrolment

221

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

Date of first enrolment

01/10/2010

Date of final enrolment

01/04/2013

Locations

Countries of recruitment

Canada

Study participating centre
Department of Psychology
Regina
Canada
S4S 0A2

Sponsor information

Organisation
University of Regina (Canada)

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Sponsor type
University/education

Website
<http://www.onlinetherapyuser.ca>

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

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) Partnership for Health Improvement Grant;
Reference #: 101526

Funder Name

Saskatchewan Health Research Foundation (Canada)

Alternative Name(s)

SHRF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Canada

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Training provided to therapists	01/08/2012		Yes	No
Results article		01/12/2014	10/11/2022	Yes	No