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Using online-cognitive behaviour therapy (Online-CBT) to treat general anxiety and worry among older adults: Is it effective and does client engagement matter?

Submission date
18/06/2013

Recruitment status
No longer recruiting

Registration date
27/09/2013

Overall study status
Completed

Last Edited
05/08/2021

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
Anxiety is common among adults aged 60 years and older. Research shows that Cognitive Behaviour Therapy (CBT), a structured psychological therapy, is effective for treating anxiety; however, anxiety in older adults often goes untreated due to a lack of access to treatment providers, mobility difficulties in attending appointments, and the stigma of seeking help for mental health problems. To address this issue, researchers have developed therapist-assisted Online-CBT for the treatment of anxiety, depression and other mental health concerns. To date, there has been very little research studying the use of Online-CBT by adults aged 60 years and over. Therefore, this study will determine whether an Online-CBT program, made to meet the needs of an older population, is effective at reducing anxiety, worry and depression, and for improving quality of life. Because this service is newly available, this study will also look at older adults engagement with the treatment program and their therapists, and will collect feedback about their experiences to help improve the service for future seniors.

Who can participate?
This study aims to recruit adults aged 60 years or over living in the province of Saskatchewan who experience at least moderate general anxiety symptoms or meet criteria for generalized anxiety disorder.

What does the study involve?
All interested individuals will participate in a telephone screening to determine if Online-CBT matches their needs. The screening is a two-part process that takes 15 to 60 minutes and will ask questions about their anxiety and other mental health history. Following the screening, they will be randomly allocated to either receive Online-CBT immediately or after waiting 10 weeks. The Online-CBT program, titled GAD Online for Older Adults, is designed for treating older adults with generalized anxiety symptoms. The program consists of seven treatment modules containing CBT materials that are accessed online, as well as activities that are to be completed offline. The modules include information about generalized anxiety, how to monitor anxiety and

worry, relaxation techniques, how to monitor thoughts and challenge them, how to reduce and control worry, and other coping strategies. Clients should engage in Online-CBT for about 7 to 10 weeks. All participants are asked to complete questionnaires at the start of the study and again 10 weeks later. Those who receive Online-CBT are also asked to complete a brief set of questionnaires one month after finishing treatment.

What are the possible benefits and risks of participating?
For participants assigned to receive Online-CBT and for those waiting list participants who opt to receive Online-CBT after the waiting period, there are potential benefits and challenges associated with the therapy delivered online. The potential benefits include: you do not need to schedule an appointment with Online-CBT, you avoid having to visit an office if things like transportation, stigma or your own availability are a concern, you can have more control over the pace of therapy, you can access the online material from the location of your choice at your convenience for up to four weeks after the end of therapy, 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. For participants assigned to the waiting list, there are no anticipated risks associated with the online questionnaires. The only cost to you will be the time required to complete the questionnaires. This research may help participants to deal with their general anxiety more effectively in a variety of ways. Furthermore, if the treatment program is found to be effective, it may help other older adults who experience anxiety. The potential risks or challenges include: assessment and diagnosis may be more difficult when visual cues are not present; Online-CBT may require more self-motivation than other forms of therapy; without non-verbal cues, there is a greater potential for 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; Online-CBT is a newer form of treatment, so there has been less research conducted when compared to other, more-established forms of treatment; Online-CBT is not meant to be a long-term form of therapy; Online-CBT is not meant for use in the event of an emergency.

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 study starting and how long is it expected to run for?
Recruitment for this study began in the winter of 2012 and is expected to be completed in the fall of 2013.

Who is funding the study?
Funding has been provided by the Canadian Institutes of Health Research, Canada.

Who is the main contact?
Ms Shannon Jones, jones23s@uregina.ca
Dr Heather D. Hadjistavropoulos, hadjista@uregina.ca

Study website
http://www.onlinetherapyuser.ca/gadoa/

Contact information

Type(s)

Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Nil known

Study information

Scientific Title
An efficacy trial of therapist-assisted internet cognitive behaviour therapy for older adults with generalized anxiety

Study objectives
1. It is hypothesized that participants who receive Online-CBT will demonstrate significantly more improvement from pre- to post-treatment than waitlist participants on (a) primary outcome measures of generalized anxiety, anxiety symptom severity and worry; and, (b) secondary outcome measures of depressive symptoms and quality of life. Based on the percentage reported in a previous Online-CBT for GAD study (Titov et al., 2009), it is expected that around 80% of Online-CBT participants will report symptoms below the cut-off score on a measure of generalized anxiety (Generalized Anxiety Disorder-7) at post-treatment.
2. It is hypothesized that higher client engagement with Online-CBT will be associated with better treatment outcomes. More specifically, it is hypothesized that (a) clients who rated Online-CBT as credible and likely to be successful and had stronger belief in ones ability to change at baseline, (b) clients who rate therapeutic alliance and treatment satisfaction high at post-treatment, and; (c) clients who access and use the website more frequently and complete lengthier emails and/or check-ins to their online therapist, will be associated with lower symptoms of anxiety, worry and depression at post-treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. University of Regina; January 10, 2012; File #30S1112
2. University of Saskatchewan; March 7, 2012; BEH# 12-13
3. The Regina Qu'Appelle Health Region; March 1, 2012; REB-12-02

Study design
Single-centre randomized controlled trial (waitlist control) using a between-subjects design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

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
Generalized anxiety disorder

Interventions
Comparing active treatment (therapist-assisted Online-CBT) to a non-active control group (waitlist)

The intervention is titled GAD Online for Older Adults, which is an Online-CBT program designed for treating older adults with generalized anxiety symptoms. The program consists of seven treatment modules containing CBT materials that are accessed online, as well as activities that are to be completed offline. The modules include information about generalized anxiety, how to monitor anxiety and worry, relaxation techniques, how to monitor thoughts and challenge them, how to reduce and control worry, and other coping strategies. Clients should engage in Online-CBT for approximately 7 to 10 weeks. GAD Online for Older Adults 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 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.

Participants who receive Online-CBT will be contacted one month after completing the program to be asked to complete follow-up measures.

Participants randomized to the waitlist control group will be offered the intervention upon completing the second set of questionnaires. They will then be followed for the duration of completing the intervention and the follow-up measures.

Intervention Type

Behavioural

Primary outcome measure
1. Generalized Anxiety Disorder-7 (GAD-7)
2. Patient Health Questionnaire-9 (PHQ-9)
3. Geriatric Anxiety Inventory (GAI)
4. Penn State Worry Questionnaire-Abbreviated (PSWQ-A)

These will be administered at baseline and post-treatment, as well as one-month follow-up for those randomized to receive the intervention.

Secondary outcome measures
1. Geriatric Depression Scale (GDS)
2. WHO-Quality of Life-BREF (WHO-QOL-BREF)
3. Credibility/Expectancy Questionnaire (CEQ)
4. Anxiety Change Expectancy Scale (ACES)
5. Therapeutic Alliance Questionnaire (TAQ)
6. Treatment Satisfaction Questionnaire-Modified

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

Baseline: Generalized Anxiety Disorder-7 item (GAD-7), Patient Health Questionnaire (PHQ-9), Geriatric Anxiety Inventory (GAI), Penn State Worry Questionnaire-Abbreviated (PSWQ-A), Geriatric Depression Scale (GDS), WHO-Quality of Life-BREF (WHOQOL-BREF), Credibility /Expectancy Questionnaires (CEQ), Anxiety Change Expectancy Scale (ACES)

Post-Treatment: Generalized Anxiety Disorder-7 item (GAD-7), Patient Health Questionnaire (PHQ-9), Geriatric Anxiety Inventory (GAI), Penn State Worry Questionnaire-Abbreviated (PSWQ-A), Geriatric Depression Scale (GDS), WHO-Quality of Life-BREF (WHOQOL-BREF), Anxiety Change Expectancy Scale (ACES), Treatment Satisfaction Questionnaire-Modified (TSQ-M), Therapeutic Alliance Questionnaire (TAQ), Client Feedback Open-Ended Questions

One-Month Follow-Up: Generalized Anxiety Disorder-7 item (GAD-7), Patient Health Questionnaire (PHQ-9), Geriatric Anxiety Inventory (GAI), Penn State Worry Questionnaire-Abbreviated (PSWQ-A), Geriatric Depression Scale (GDS)

Overall study start date
01/03/2012

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Resident of Saskatchewan
2. Aged 60 years of age or older, either sex
3. Meets DSM-IV-TR criteria for Generalized Anxiety Disorder or sub-clinical criteria
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
Senior

Sex
Both

Target number of participants
The goal is randomize at least 46 participants.

Total final enrolment
46

Key exclusion criteria
1. Not a resident of Saskatchewan
2. Less than 60 years of age
3. Has no regular access to a computer and/or the internet
4. Currently receiving psychotherapeutic treatment elsewhere or in some other form
5. Meets criteria for current substance abuse (drugs or alcohol)
6. Meets current criteria for a psychotic disorder or bipolar disorder, or severe symptoms of depression, including suicidal ideation
7. Reports having a serious medical condition that may account for anxiety symptoms or may interfere with treatment (i.e., untreated thyroid disorder or other endocrine disorder, Parkinson s disease, recent stroke, acute cardiac disease)
8. Currently cognitively impaired

Date of first enrolment
01/03/2012

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Canada

Study participating centre
Department of Psychology
University of Regina
3737 Wascana Parkway
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Sponsor information

Organisation
University of Regina (Canada)

Sponsor details
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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) - Frederick Banting and Charles Best Canada Graduate Scholarship Doctoral Award ref:200910GSD-226274-190834

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		02/11/2015	05/08/2021	Yes	No