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Evaluating an internet-delivered cognitive behavioural therapy program for reducing depression and anxiety after a cardiac event

Submission date
29/06/2016

Recruitment status
No longer recruiting

Registration date
30/06/2016

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Mental and Behavioural Disorders

[X] 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 among people who have experienced an acute coronary event (sudden heart attack or chest pain - angina) but unfortunately they are frequently undertreated due to a lack of access to mental health care. In an attempt to increase timely and accessible psychological treatment for members of the general population, internet-delivered cognitive behavioural therapy (ICBT) has emerged as an alternative to face-to-face psychological services. ICBT is a program which can be worked through online, usually guided by a trained therapist, which teaches strategies to change negative views and behaviours. Although ICBT programs exist to treat depression and anxiety in the general population, there is a growing need to tailor ICBT programs for underserved populations in order to increase the relevance and appeal of ICBT programs among such groups. The aim of this study is to examine the effectiveness of an ICBT program which has been tailored to reduce depression and anxiety symptoms among Canadians who have experienced an acute coronary event (Cardiac Wellbeing Course).

Who can participate?
Adults living in Canada who are currently experiencing some anxiety or depressive symptoms following an acute coronary event which occurred in the past 24 months and are interested in receiving treatment in an online format.

What does the study involve?
All interested participants participate in an online screening questionnaire to determine if ICBT would match their needs. The screening takes about 15 to 30 minutes and includes questions about current symptoms and other mental health history. Suitable participants are then randomly allocated through the online screening software system into either the treatment group, who will receive the Cardiac Wellbeing Course, or an eight-week waiting-list group. Participants assigned to the treatment group are immediately enrolled in the eight-week Cardiac Wellbeing Course, while participants assigned to the waiting-list group are informed that they will have the opportunity to participate in the intervention once the eight-week waiting period has ended. The Cardiac Wellbeing Course includes education, cognitive,

behavioural, and physical strategies, as well as relapse prevention information. Participants complete questionnaires before to the start of the course, before each lesson of the course, once they have completed the course, and four weeks after completing the course, to assess anxiety and depressive symptoms. After completion of the course, participants are also asked to rate the course content, the overall service, and their satisfaction with the course.

What are the potential risks and benefits of participating?
Participants who take part in the Cardiac Wellbeing Course may benefit from a reduction in their depression and anxiety symptoms. There are no notable risks involved with taking part in this study, however it is expected that people in the waiting-list condition will not experience a large improvement in symptoms while waiting to receive the intervention.

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

When is the study starting and how long is it expected to run for?
November 2015 to August 2018

Who is funding the study?
1. Graduate Research Fellowship, Faculty of Graduate Studies at the University of Regina (Canada)
2. Canadian Institutes of Health Research Partnership for Health System Improvement grant (Canada)
3. Saskatchewan Health Research Foundation, Rx & D Health Research Foundation (Canada)

Who is the main contact?
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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
Efficacy of Internet-delivered cognitive behavioural therapy following an acute coronary event: A randomized controlled trial

Study objectives
Participants who receive the Internet-delivered Cognitive Behaviour Therapy (ICBT) Cardiac Wellbeing Course are expected to:
1. Show significant decreases in depression and anxiety symptoms; and
2. Show significant improvements in secondary measures such as functional health and quality-of-life.
It is also expected that participants who receive the Internet-delivered Cognitive Behaviour Therapy (ICBT) Cardiac Wellbeing Course will report a high level of course acceptance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Regina Research Ethics Board, 27/01/2016, ref: REB#2015-200

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Depression, Anxiety, Acute myocardial infarction, Unstable angina

Interventions
Participants will be randomized through the online screening software system into either the treatment group, who will receive the Cardiac Wellbeing Course, or an eight-week waiting-list group. Following the online screening, eligible clients will be contacted by telephone to complete a telephone screening in which applicants will be further assessed for study eligibility. During the telephone call, suitable applicants will be provided with information regarding their random assignment.

Cardiac Wellbeing Course: The intervention has been adapted from a prior transdiagnostic ICBT program (i.e., Wellbeing Course; Dear. et al., 2011) designed to treat symptoms of anxiety and depression among adults. In order to increase the relevance of the intervention to people who have experienced an acute coronary event (i.e., acute myocardial infarction or unstable angina), several modifications were made to the Wellbeing Course in order to develop the Cardiac Wellbeing Course. First, lesson content was altered to reflect prevalence rates of anxiety and depression in the cardiac population rather than the general population. Slight wording changes were also made to increase lesson material relevance to people who have experienced an acute coronary event. Secondly, two new patient vignettes were created which illustrate people with depression and anxiety following an acute coronary event. Third, an additional resource was developed in order to address an issue relevant to people in Cardiac Wellbeing (i.e., managing the fear of future cardiac events). Permission to use and modify the Wellbeing Course has been obtained through a research agreement between the Online Therapy Unit at the University of Regina and the eCentre Clinic, at Macquarie University in Australia.
The Cardiac Wellbeing Course consists of five self-directed 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, 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 vignettes which illustrate past participants who successfully used the skills in each lesson to overcome depression and anxiety. Participants can access several additional resources outlining topics such as assertiveness, communication skills, sleep, and problem solving. The Cardiac Wellbeing Course is guided, which means that each client is assigned a guide (i.e., primary researcher or research-assistant) to provide support, encouragement, and to answer questions regarding application of the concepts and skills learned. Participants receive weekly contact from their guide by email or phone. Participants also receive automated emails to remind them about the course and direct attention to the content.

Both the intervention and control group will complete baseline measures (either when starting the intervention or starting the 8-week waiting period, depending on the group) and well as measures after 8 weeks (again, either when finishing the intervention or finishing the 8-week waiting period, depending on the group). Only participants who have taken the intervention will complete the four week follow up measures. Please let me know if further clarification is needed.

Intervention Type
Behavioural

Primary outcome measure

1. Depressive symptoms will be measured using the Patient Health Questionnaire- 9 Item scale (PHQ-9) at pre-treatment, before each lesson, immediately following completion of the course, and four weeks following completion of the course (intervention group only)
2. Symptoms of generalized anxiety will be measured using the Generalized Anxiety Disorder -7 Item scale (GAD-7) at pre-treatment, before each lesson, immediately following completion of the course, and four weeks following completion of the course (intervention group only)
3. Physical activity will be measured using the Godin Leisure-Time exercise Questionnaire (GLTEQ) at pre-treatment, before each lesson, immediately following completion of the course, and four weeks following completion of the course (intervention group only)

Secondary outcome measures
1. Cardiac anxiety symptoms will be measured using the Cardiac Anxiety Questionnaire (CAQ) at pre-treatment, before each lesson, immediately following completion of the course, and four weeks following completion of the course (intervention group only)
2. Depression symptoms will be measured by the Depression and Anxiety Stress 21-item scale (DASS-21) at pre-treatment, immediately following completion of the course, and four weeks following completion of the course (intervention group only)
3. Health-related quality of life will be measured using the Short Form 12-item Health Survey (SF-12) at pre-treatment and post-treatment
4. Computer anxiety and self-efficacy levels will be measured using computer self-efficacy and computer anxiety questions at pre-treatment and post-treatment
5. Participant satisfaction with treatment is measured using treatment satisfaction questions at post-treatment and four weeks following completion of the course (intervention group only)
6. Participants will be invited to participate in a brief telephone interview to further explore aspects of course satisfaction, which will be evaluated using open-ended satisfaction questions at post-treatment
7. Negative effects associated with completing the course will be examined using negative effect questions at post-treatment and four weeks following completion of the course (intervention group only)
8. Number of log-ins will be measured at post-treatment
9. Days accessing service will be measured at post-treatment
10. Number of emails sent to guide will be measured at post-treatment
11. Number of emails received from guide will be measured at post-treatment
12. Number of phone calls will be measured at post-treatment
13. Number of lessons completed will be measured at post-treatment

Overall study start date
27/11/2015

Completion date
01/08/2018

Eligibility

Key inclusion criteria
1. Citizen of Canada who will be in Canada during the 8 week course period
2. Aged 18 years or older
3. Must have experienced an acute coronary event (i.e., myocardial infarction or unstable angina) within the last 24 months
4. Experiencing symptoms of depression and/or anxiety

5. Has access to a computer and the Internet
6. Willing to provide a medical contact (e.g., family physician) for an emergency contact
7. Has an interest in the Cardiac Wellbeing Course

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140

Total final enrolment
62

Key exclusion criteria
1. Not a citizen of Canada
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. Has an acute health threatening disease (e.g., cancer)
6. Has an unstable heart condition
7. High current risk of suicide or attempt in past year
8. Is experiencing unmanaged symptoms psychosis or mania
9. Alcohol or drug problem that requires primary treatment
10. Hospitalization for mental health problem in past year

Date of first enrolment
15/07/2016

Date of final enrolment
01/05/2018

Locations

Countries of recruitment
Canada

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

Regina
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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
University/education

Funder Name
University of Regina

Alternative Name(s)
The University of Regina, U of R

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Saskatchewan Health Research Foundation

Alternative Name(s)
SHRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Funder Name
Rx&D Health Research Foundation

Results and Publications

Publication and dissemination plan
Following data analysis, the results of this study are anticipated to be disseminated at research conferences and by way of a research manuscript which will be submitted to a high-impact peer-reviewed journal for publication.

Intention to publish date

01/04/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/05/2020	07/05/2021	Yes	No