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Internet-delivered cognitive behavioural therapy (iCBT) with main carer access for depression and anxiety among breast cancer survivors

Submission date
21/10/2020

Recruitment status
No longer recruiting

Registration date
19/01/2021

Overall study status
Completed

Last Edited
16/06/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Current plain English summary as of 19/01/2021:

Background and study aims
Depression and anxiety are common problems among breast cancer survivors. Carer support is one of the most important determinants of women's psychological well-being. Survivors' distress can be alleviated by giving carers access to survivors' evidence-based treatment, which will help them understand what they have been going through and may improve their communication and relationship quality. Considering the limited access to evidence-based treatments an adapted internet-delivered cognitive behavioural therapy (iCBT) intervention for depression and anxiety symptoms for breast cancer survivors, but also open for carers' access, may overcome these challenges.
This study aims to (1) compare the effectiveness of an adapted guided iCBT intervention with and without main carer access in the treatment of breast cancer survivors' depression and/or anxiety symptoms and treatment-as-usual control, and (2) evaluate the acceptability and satisfaction with iCBT programme among breast cancer survivors and their main carers.

Who can participate?
The intervention is open to all female breast cancer survivors in Ireland and the UK who completed their breast cancer treatment and are cancer-free (can still be on hormone therapy). For the survivors who have a main carer (a partner, family member, or friend who provides emotional support), their carers will also be invited to take part based on survivors' preference.

What does the study involve?
Breast cancer survivors are randomly assigned to either a 7-week iCBT treatment or a control group. Then survivors in the treatment group who have carers will be asked if they would like to give their main carers (e.g. partners, family members, or friends) access to the same programme content but using a separate account to maintain the privacy of breast cancer survivors. This will allow survivors and carers to discuss what they learned in the programme. Survivors who do not

have carers and do not prefer to give access to their carers will be in the iCBT alone group, and survivors who prefer to give their carers access to their treatment will be in the iCBT with the main carer access group.
Both groups will receive the treatment through an online platform with asynchronous support from a master's level psychologist over 7 weeks. Depression and anxiety symptoms, quality of life, coping styles, breast cancer-related worry, perceived social support, communication, and relationship quality of the survivors will be measured at the start of the intervention, end of the intervention, and 2 months after the completion of the programme. The acceptability of the programme and satisfaction with the programme for survivors and carers will be measured at the end of the study. Voluntary participants will also be interviewed about their experiences of using the programme at the end of the study.

What are the possible benefits and risks of participating?
The main benefit for breast cancer survivors is that they will receive a cognitive behavioural therapy treatment for depression and anxiety symptoms over the internet (if they are allocated to the treatment group). This will allow them to easily access an evidence-based treatment at a time and place that is convenient for them. They will also have an option to give their main carers access to the same programme which makes it possible for them to discuss the information and practice the skills they learned with their carers.
The main benefit for the carers is that it will help them to better understand what survivors have been going through, widen their knowledge about cancer-related issues from the survivors' perspective, and understand how to help them. Access to the same programme content will also give survivors and carers an opportunity to discuss and practice the skills that they learned together to deal with cancer-related psychological distress, which can help survivors to alleviate depression and anxiety symptoms.
Possible risks are that breast cancer survivors allocated to the treatment-as-usual control group will not get the treatment so will not get the same treatment effect.

Where is the study run from?
Trinity College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
April 2018 to August 2021 (updated 20/01/2021, previously: October 2020 to August 2021)

Who is funding the study?
Trinity College Dublin (Ireland)

Who is the main contact?
Selin Akkol Solakoglu
akkolsos@tcd.ie

Previous plain English summary:

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October 2020 to August 2021

Who is funding the study?
Trinity College Dublin (Ireland)

Who is the main contact?
Selin Akkol Solakoglu
akkolsos@tcd.ie

Contact information

Type(s)
Scientific

Contact name
Dr David Hevey

ORCID ID
https://orcid.org/0000-0003-2844-0449

Contact details
School of Psychology
Aras an Phiarsaigh
Trinity College Dublin
College Green
Dublin 2
Dublin
Ireland
D02 PN40
+353 (0)1 896 3914
heveydt@tcd.ie

Type(s)
Scientific

Contact name
Ms Selin Akkol Solakoglu

ORCID ID
https://orcid.org/0000-0002-9720-5517

Contact details
School of Psychology
Aras an Phiarsaigh
Trinity College Dublin
College Green
Dublin 2
Dublin
Ireland
D02 PN40
+353 (0)1 896 3913
akkolsos@tcd.ie

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SPREC022020-09

Study information

Scientific Title
Acceptability and effectiveness of an adapted internet-delivered cognitive behavioural therapy (iCBT) with main carer access for depression and anxiety among breast cancer survivors

Study objectives
Current hypothesis as of 19/01/2021:

Hypothesis about the primary outcomes:
H1. Survivors in both treatment groups (Group 1 and Group 2) are expected to show a greater reduction in depression and anxiety symptoms than survivors in the TAU (Group 3) at post-treatment and 2-month follow-up.
Hypotheses about the secondary outcomes:
H2. Survivors in both treatment groups (Group 1 and Group 2) are expected to have greater improvements in cancer-related quality of life, coping, and fear of recurrence compared to survivors in the TAU (Group 3) at post-treatment and 2-month follow-up.
H3. Survivors in both treatment groups (Group 1 and Group 2) are expected to use more active coping strategies than survivors in the TAU (Group 3) at post-treatment and 2-month follow-up.
H4: A reduction in depression and anxiety symptoms of survivors in both treatment groups (Group 1 and Group 2) is expected to be mediated by the change in coping strategies after controlling for depression and anxiety levels at baseline.
H5: An improvement in cancer-related quality of life in both treatment groups (Group 1 and Group 2) will be mediated by the change in coping strategies after controlling for cancer-related quality of life at baseline.
The effects of carer access will be explored using the following research questions:
RQ1. Is there a difference in depression and anxiety scores between iCBT alone (Group 1) and iCBT with the carer access (Group 2) at post-treatment after controlling for baseline depression and anxiety scores?
RQ2. Is there a difference in perceived social support between iCBT alone (Group 1) and iCBT with the carer access (Group 2) at post-treatment after controlling for baseline perceived social support?
RQ3. Is there a difference in survivor-carer relationship outcomes (cancer-related communication quality and relationship quality) of survivors in iCBT with carer access between baseline and post-treatment?
RQ4. Is there a difference in survivor-carer relationship outcomes (cancer-related communication quality and survivor-carer relationship quality) of carers between baseline and post-treatment?

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Previous hypothesis:

Hypotheses regarding the effect of iCBT treatment:
H1. Survivors in both treatment groups (iCBT alone (Group 1) and iCBT with carer access (Group 2)) will show greater reduction on depression and anxiety symptoms than survivors in the TAU (Group 3) at post-treatment and 2-month follow-up.
H2. Survivors in both treatment groups (Group 1 and Group 2) will have greater improvements in their cancer-related quality of life, coping, and fear of recurrence compared to survivors in the TAU (Group 3) at post-treatment and 2-month follow-up.
H3: A reduction in depression and anxiety symptoms of survivors in both treatment groups (Group 1 and Group 2) will be mediated by the change in coping strategies.
H4: An improvement in cancer-related quality of life in both treatment groups (Group 1 and Group 2) will be mediated by the change in coping strategies.

Hypotheses regarding the effect of carer access to iCBT treatment:
H5. Survivors in the iCBT with carer access (Group 2) will have greater reduction in depression and anxiety scores than iCBT alone (Group 1) and TAU (Group 3) at post-treatment and 2-month follow-up.
H6. Survivors in the iCBT with carer access (Group 2) will have greater increase in perceived social support compared to the iCBT alone (Group 1) and TAU (group 3) at post-treatment and 2-month follow-up than pre-treatment.
H7. Survivors in the iCBT with carer access (Group 2) have greater cancer-related communication quality and survivor-carer relationship quality at post-treatment and 2-month follow-up than their pre-treatment scores.
H8: A reduction in depression and anxiety symptoms of survivors in the iCBT with carer access will be mediated by improved perceived social support, cancer-related communication and survivor-carer relationship quality.
H9. Carers will have significantly greater cancer-related communication quality and survivor-carer relationship quality at post-treatment and 2-month follow-up than their pre-treatment scores.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/07/2020, Trinity College Dublin School of Psychology Research Ethics Committee (School of Psychology, Aras an Phiarsaigh, Trinity College Dublin, Dublin 2, Ireland; +353 (0)1 896 1886; psych.ethics@tcd.ie), ref: SPREC022020-09

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Depression and anxiety symptoms in female breast cancer survivors

Interventions

Informed consent, screening questionnaire assessing inclusion and exclusion criteria, demographic information, and pre-treatment measures will be collected through a Qualtrics link which will be shared in the study advertisement. Both survivors and their carers will be responsible for self-screening as their eligibility will be determined based on their responses to the questions set-up in Qualtrics. The survey is designed to automatically exclude respondents who select “yes” to the questions asking current suicidal ideation or intent, current alcohol or drug misuse, enduring mental health condition (such as schizophrenia, psychosis, and bipolar disorder), and currently being in treatment for depression or anxiety. Participants also required to be at least mildly confident in reading and writing in English and using computers and the internet. Potential participants who responded yes to the questions regarding current suicidal ideation and intent are provided contact details for recommended support services in Qualtrics. Eligible survivors will be able to continue with baseline questionnaires (Time 1) for the assessment of depression and anxiety symptoms, quality of life, coping style, breast cancer-related worry, perceived social support, relationship, and communication quality with their carer (if they have one).

Survivors who have a carer will also be asked whether they would prefer giving their access to the treatment programme content using a separate log in. If they prefer carer access, they are asked to provide their carers’ email address. Eligible breast cancer survivors will be automatically randomized to either iCBT or treatment-as-usual control using a 2:1 ratio in Qualtrics. At the end of the baseline assessments, participants will immediately know their group assignment. Those in the iCBT condition will be provided a link in Qualtrics to log in to the programme once they submit their responses to the measures. Survivors in the iCBT group will be assigned to either in the iCBT alone or iCBT with the main carer access based on their preference. Both iCBT groups will complete the 7-week, online guided Space in Breast Cancer from Depression and Anxiety programme. The treatment-as-usual group will continue their usual care and will not receive any treatment. Carers will be contacted through email provided by breast cancer survivors and will be asked to complete the informed consent, screening questionnaire, and two scales measuring relationship and communication quality between survivors and carers through a separate Qualtrics link prepared for carers. At the end of the questionnaire, they will be provided a link to sign in to the programme.

All survivors and carers will be reassessed online at the end of the intervention (7 weeks after they started, Time 2), and at 2-month follow-up (Time 3). At the end of the intervention, voluntary survivors and their main carers in both treatment groups will be asked about their perspectives on the helpful aspects of the programme and their satisfaction with the programme.

Intervention Type

Behavioural

Primary outcome(s)

Depression and anxiety symptoms measured using the Hospital Anxiety and Depression Scale (HADS) at pre-test, post-test, and 2-month follow-up

Key secondary outcome(s))

1. Survivors' quality of life measured using a single item from the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) at pre-

treatment, post-treatment, and 2-month follow-up
2. Survivors' use of coping styles for breast cancer-related stress measured by Brief COPE at pre-treatment, post-treatment, and 2-month follow-up
3. Survivors' cancer-related worries measured using Cancer Worry Scale at pre-treatment, post-treatment, and 2-month follow-up
4. Survivors' perceptions of social support measured using the Emotional/Informational subscale of the Modified Medical Outcomes Study Social Support Survey (MOS-SS) at pre-treatment, post-treatment, and 2-month follow-up
5. Survivors' and carers' communication quality measured using Survivor-Carer Cancer Communication at pre-treatment, post-treatment, and 2-month follow-up
6. Survivors' and carers' relationship quality measured using a single-item Relationship Quality scale at pre-treatment, post-treatment, and 2-month follow-up
7. Helpful aspects of the programme for survivors and carers measured using Helpful Aspects of Therapy Form (HAT) at post-treatment
8. Survivors' and carers' satisfaction with the programme measured using Satisfaction with Online Treatment (SAT) at post-treatment

Completion date
30/08/2021

Eligibility

Key inclusion criteria
Breast cancer survivors and their carers (people who support them such as a partner, family member, or friend) will be recruited online and screened for eligibility using Qualtrics.

Survivors:
1. Female
2. Completed breast cancer treatment
3. At least mildly confident with using the internet
4. At least mildly confident in reading and writing in English

Main carers:
1. Currently caring or have cared for a woman living with breast cancer (such as partner, spouse, friend, or relative of the patient)
2. At least mildly confident with using the internet
3. At least mildly confident in reading and writing in English

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment

Key exclusion criteria
1. Current suicidal ideation or intent
2. Current alcohol or drug misuse
3. Enduring mental health disorders such as schizophrenia, psychosis, and bipolar disorder
4. Currently being in treatment for depression or anxiety

As it is a pilot study, no limit has been set for the time since the treatment completion or cancer stage as an exclusion criterion for survivors.

Date of first enrolment
26/10/2020

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Ireland

Study participating centre
Trinity College Dublin
College Green
Dublin 2
Dublin
Ireland
D02 PN40

Sponsor information

Organisation
Trinity College Dublin

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
University/education

Funder Name
Trinity College Dublin

Alternative Name(s)
Coláiste na Tríonóide, Baile Átha Cliath, TCD

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/01/2023	16/06/2023	Yes	No
Protocol article		21/01/2021	17/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes