Tired of being fatigued? Extending evidence-based treatment options for fatigued breast cancer survivors using the internet

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Increase the evidence-based treatment options by testing the efficacy of self-guided web-based CBT for fatigued breast cancer survivors with minimal therapist support in a randomised controlled trial.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON38873

Source
ToetsingOnline

Brief title
CHANGE study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: stichting Pink Ribbon

Intervention

Keyword: breast cancer, cognitive behavior therapy, Fatigue, web-based

Outcome measures

Primary outcome

Main endpoint is fatigue severity (primary outcome measure) at T1.

Secondary outcome

Secondary outcome measures are quality of life, psychological distress, and

functional impairments at T1.

Study description

Background summary

Up to 40% of breast cancer survivors suffer from severe fatigue that impairs daily functioning and reduces quality of life. A randomised controlled trial (RCT) performed by our own research group showed that face-to-face cognitive behaviour therapy (CBT) specifically designed for postcancer fatigue significantly reduced fatigue and functional impairments in fatigued cancer survivors [1]. The substantial positive effects were maintained at a two years follow up [2]. Unfortunately, treatment capacity for face-to-face CBT for postcancer fatigue in the Netherlands is limited. To meet the need for evidence-based treatment for postcancer fatigue we will develop a web-based intervention with minimal support from therapists and test its efficacy. If its efficacy can be demonstrated, internet therapy will have several advantages compared to face-to-face CBT. First, treatment capacity can be increased because less therapist capacity is needed to deliver the intervention. Secondly, the accessibility of the intervention can be increased. Finally, the burden for patients is reduced, because they no longer need to travel and can choose the moments that they want to use the intervention.
At this moment, face-to-face CBT for postcancer fatigue is offered to survivors who finished cancer treatment at least one year previously. However, there are indications that fatigued survivors could be offered this CBT at an earlier stage, i.e. 3 months post-treatment [3], but this has not been tested. If CBT is already effective at 3 months post-treatment, patients could receive treatment earlier and do not necessarily need to suffer from postcancer fatigue

for at least one year. In the current study we will investigate if time passed since the end of cancer treatment moderates the effects of internet therapy on fatigue.

Study objective

Increase the evidence-based treatment options by testing the efficacy of self-guided web-based CBT for fatigued breast cancer survivors with minimal therapist support in a randomised controlled trial.

Study design

A multicenter randomized controlled trial with two conditions, i.e. one control condition (care as usual) and one intervention condition (internet therapy). Two hospitals will participate in the study: Radboud University Nijmegen Medical Centre and Ziekenhuis Gelderse Vallei at Ede. Participants will be assessed twice, i.e. at baseline (T0), and after 6 months (T1).

Intervention

Internet therapy: Fatigued breast cancer survivors will receive internet therapy; a web-based version of the face-to-face CBT protocol for postcancer fatigue, with self-guidance instructions. Patients will be guided through the treatment modules with the help of assignments and instructions in a period of 6 months. They will e-mail with a therapist about their progress and difficulties. In addition to e-mail contact, we will offer distance video contact through FaceTalk. This e-Health application mimics a *real* face-to-face CBT session by using a high-quality video link on a secure connection. In the first two sessions and during the last session patients will have face-to-face contact with their therapist. If a patient remains fatigued after internet therapy, regular face-to-face CBT for postcancer fatigue will be offered.
Care as usual: Participants assigned to this control condition will receive care as usual. After the second assessment, these participants will be offered regular face-to-face CBT for postcancer fatigue. In routine care a waiting period exists for regular face-to-face CBT of at least six month. Therefore participation in the study will not lead to longer waiting periods.

Study burden and risks

There are no risks involved in participating in the internet intervention. Previous studies indicated that both face-to-face CBT and Internet CBT is a safe treatment for patients suffering from chronic fatigue syndrome [4-6]. In addition, the burden is limited and less than face to face CBT. It consists of visiting the treatment centre for two assessments, 3 face-to-face sessions with a therapist, following the CBT via the Internet and doing home-work

assignments. There are substantial potential benefits: face-to-face CBT for cancer survivors proved to be a highly effective intervention in reducing fatigue and disabilities and it is likely that participants of the present study will also profit and become less fatigued and disabled.
Participants have to complete questionnaires, two times in a period of approximately 6 months. The questionnaires can be completed at home, online, or (upon request) a paper and pencil version will be send to the participant. It will take patients about 45 minutes to complete the questionnaires. Completing the questionnaires is without risk and the burden is limited.
Face-to-face CBT for postcancer fatigue is part of clinical routine at the Expert Centre for Chronic Fatigue (ECCF). Due to limited treatment capacity patients have to wait at least six month for this treatment. Therefore, participation in the current study will not lead to a longer waiting period. Allocated to the internet therapy condition patients have the opportunity to start earlier with treatment and allocation to the usual care condition will lead to the standard waiting period of the current clinical routine.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Female.
- Treated for breast cancer with curative intent, and finished primary cancer treatment at least three months previously. Survivors who currently receive hormone therapy are also eligible.
- Disease-free at entry of the study, as defined by the absence of somatic disease activity parameters.
- Age between 18 and 65.
- Able to speak, read, and write Dutch.
- Being severely fatigued (scoring 35 or higher on the subscale fatigue severity of the CIS).
- Having access to a computer with Internet.

Exclusion criteria

A potential subject will be excluded from participation in this study if:
- A somatic co-morbidity is present that can explain the fatigue.
- A subject suffers from a depressive disorder.
- A subject receives current psychological treatment for a psychiatric disorder.
- A subject currently follows a CBT program for fatigue.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	24-01-2014
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-05-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26495
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL43781.091.13
OMON	NL-OMON26495

Study results

Date completed:	26-10-2016
Actual enrolment:	132