Web-based cognitive behaviour therapy for severely fatigued breast cancer survivors.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25235

Source
NTR

Brief title
CHANGE-study

Health condition

Fatigue, Breast cancer, Internet-interventions

Sponsors and support

Primary sponsor: Radboud University Medical Center
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Outcome measures

Primary outcome

Fatigue severity, assessed with the subscale fatigue severity (¡Ý35) of the Checklist Individual Strength.

Secondary outcome

1. Quality of life, assessed with the subscale of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30).

2. Psychological distress, assessed with the total score on the Brief Symptom Inventory 18 (BSI-18)

3. Functional impairments, assessed with the total score on the Sickness Impact Profile-8 (SIP-8).

Study description

Background summary

Approximately 40% of breast cancer survivors suffer from severe fatigue after completion of cancer treatment with curative intent. A randomised controlled trial (RCT) performed by our own research group has shown that face-to-face cognitive behaviour therapy (CBT) specifically designed for postcancer fatigue was effective. Unfortunately, treatment capacity is limited. To meet the need for evidence-based treatment for postcancer fatigue, a web-based version of the CBT with minimal therapist support is developed. The efficacy of the internet therapy will be determined in the CHANGE study. In addition, we will investigate if the time since completion of cancer treatment moderates the effects of the internet therapy on fatigue. At the moment, face-to-face CBT for postcancer fatigue is offered to survivors who finished cancer treatment at least one year previously. If CBT is already effective at 3 months after treatment, patients could receive treatment at an earlier stage.

Study objective

Severe fatigue is a common complaint after completion of breast cancer treatment with curative intent. To extend treatment options for postcancer fatigue, the efficacy of an internet therapy with minimal therapist support is examined in the current study. There are three research questions:
1. What are the effects of internet therapy on fatigue severity compared to care as usual?
2. What are the effects of internet therapy on functional impairments, psychological distress and quality of life compared to care as usual?
3. Does time since end of cancer treatment moderate the effect of internet therapy?

Study design

1. T0: Baseline assessment.

2, T1: After the intervention or control condition (six months post-baseline).

Intervention

1. Internet therapy: patients in this condition will start with two face-to-face sessions with their therapist. Afterwards, they will follow the internet therapy for 6 months. Patients are invited to contact their therapist every three weeks to report on their progress and to receive feedback. The therapy is web-based version of a treatment protocol of cognitive behaviour therapy for postcancer fatigue. There are six treatment modules, aimed at fatigue-perpetuating factors. The intervention is tailor-made and will be completed with a face-to-face evaluation session.

2. Care as usual: Patients assigned to this condition will be on a waiting list for six months. This waiting time is equal to the current waiting time in regular care.

Contacts

Public
Expert Centre for Chronic Fatigue
Radboud University Medical Centre
P.O. box 9101
J.A. Knoop
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3610042
Scientific
Expert Centre for Chronic Fatigue
Radboud University Medical Centre
P.O. box 9101
J.A. Knoop
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3610042

Eligibility criteria

Inclusion criteria

1. Female.

2. Treated for breast cancer with curative intent.

3. Primary cancer treatment (excluding hormone- and targeted therapy) must be completed

since at least three months. There is no upper limit for the time since completion of cancer treatment.

4. Disease-free at start of the study.

5. Being severely fatigued (scoring >=35 on the subscale fatigue severity of the Checklist Individual Strength).

6. Age between 18 and 65.

7. Able to speak, read and write Dutch.

8. Having access to a computer with internet.

Exclusion criteria

1. Somatic co-morbidity that can explain the fatigue.

2. Depressive disorder.

3. Current psychological treatment for a psychiatric disorder or fatigue.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	132
Type:	Actual

Ethics review

Positive opinion

Date:	06-12-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4120
NTR-old	NTR4309
Other	NL43781.091.13 Commissie Mensgebonden Onderzoek (Arnhem-Nijmegen) : 2012.WO26.C139 Pink Ribbon
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A