Stepped care for severe fatigue in breast cancer survivors: a randomized noninferiority trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26495

Source
NTR

Brief title
Stepped care for severely fatigued breast cancer survivors

Health condition

Fatigue, breast cancer, stepped care.

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 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

Severe fatigue is a common complaint after completion of curative breast cancer treatment. In the current noninferiority trial, stepped care will be compared to care as usual for severe fatigue in breast cancer survivors. Patients in the stepped care condition will directly receive internet therapy. If they are not recovered after the internet therapy, additional F2F sessions will be offered. Patients in the care as usual condition will receive regular F2F therapy. We will evaluate whether the efficacy of stepped care on fatigue severity is noninferior to care as usual with respect to its effect on fatigue severity.

Study objective

One out of three breast cancer survivors suffer from severe fatigue after curative cancer treatment. Cognitive behavioural therapy (CBT) for severely fatigued cancer survivors is an effective intervention. However, the intervention is intensive and requires considerable therapist capacity, which is limited. CBT also requires patients to travel to the treatment centre and to fit the sessions into their schedules. To extend treatment options, stepped care for severely fatigued breast cancer survivors will be evaluated in this noninferiority trial. This trial will consist of two conditions:

1) Stepped care: Patients in this condition will first receive web-based CBT , based on the CBT protocol for severe fatigue in cancer survivors. This web-based intervention is less intensive than regular face-to-face (F2F) CBT and forms the first step of the stepped care. If patients are not recovered from severe fatigue (>=35 subscale fatigue severity, Checklist Individual Strength) after completion of web-based CBT, more intensive F2F CBT sessions will be offered as a next step.

2) Care as usual: Patients in this condition will follow regular F2F therapy (after a waiting period of six months).

We will examine whether the efficacy of stepped care with respect to the reduction of fatigue severity is noninferior to care as usual. This noninferiority trial is a follow-up study of a randomized controlled trial testing the efficacy of internet therapy compared to a waiting list condition for severe fatigue in breast cancer survivors (CHANGE-study, NTR4309).

Study design

All patients will have a baseline assessment prior to randomization (T0). Six months after randomization, all patients will be assessed again (T1). For patients who are recovered from severe fatigue after internet therapy, T1 will be the outcome measure. If patients are still severely fatigued (CIS¡Ý35) at T1, they will be offered regular F2F CBT. Patients who are not recovered from severe fatigue after internet therapy will be assessed at six months after start of additional F2F CBT (T2). Patients in the waiting list condition will be assessed at six months after start of the F2F CBT (T2).

Intervention

1) Stepped care: Patients in this condition will directly receive internet therapy. This is a web-based minimal version of an evidence-based CBT for fatigue in cancer survivors. Patients start with two F2F sessions with their therapist. Afterwards, they follow the internet therapy for six months. There are six treatment modules that coincide with six factors assumed to perpetuate severe fatigue. The intervention is tailor-made. After the internet therapy, there is an evaluation session. If patients are not recovered from severe fatigue, additional F2F CBT sessions will be offered.

2) Care as usual: Patients in this condition have been on a waiting list for six months. After the waiting period, regular F2F therapy will be offered, consisting of twelve to fourteen sessions of CBT in a period of six months .

Contacts

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Eligibility criteria

Inclusion criteria

1) Female.

2) At least 18 years old.

3) Treated for breast cancer with curative intent.

4) 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.

5) Disease-free at start of the study.

6) Being severely fatigued (scoring ¡Ý 35 on the subscale fatigue severity of the Checklist Individual Strength).

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) Current 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:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-04-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38873
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5041

Register	ID
NTR-old	NTR5179
CCMO	NL43781.091.13
OMON	NL-OMON38873

Study results

Summary results
N/A