

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26495

Bron

NTR

Verkorte titel

Stepped care for severely fatigued breast cancer survivors

Aandoening

Fatigue, breast cancer, stepped care.

Ondersteuning

Primaire sponsor: Radboud University Medical Center

Overige ondersteuning: Pink Ribbon

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fatigue severity, assessed with the subscale fatigue severity of the Checklist Individual Strength.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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- γ 35) 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).

Onderzoeksproduct en/of interventie

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 .

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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 ≥ 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 1) Somatic co-morbidity that can explain the fatigue.
- 2) Current depressive disorder.
- 3) Current psychological treatment for a psychiatric disorder or fatigue.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	128
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	20-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38873
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5041

Register

NTR-old

CCMO

OMON

ID

NTR5179

NL43781.091.13

NL-OMON38873

Resultaten

Samenvatting resultaten

N/A