Cognitive Behaviour Therapy to reduce severe fatigue and impairment in daily life after curative treatment for cancer.

No registrations found.

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

Summary

ID

NL-OMON25553

Source
NTR

Brief title
N/A

Health condition

Fatigued cancer survivors.

Sponsors and support

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Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

Assessment instruments:

The major outcome variables in this study are fatigue severity, impairment in daily life and psychological well-being. Fatigue severity, will be measured using the Checklist Individual Strength (Vercoulen et al., 1994; Vercoulen et al., 1999). SOL has been constructed in order to obtain information about severity and frequency of fatigue and other complaints during a two-week period. The second outcome variable, impairment in daily life, will be assessed with eight subscales of the Sickness Impact Profile (Bergner et al., 1981; Jacobs et al., 1990).

Finally, the third outcome variable, psychological well-being, will be measured with the Symptom CheckList (Arindell et al., 1986). A total score of psychological well-being can be obtained as well.

Secondary outcome

Besides the questionnaires used to measure the major outcome variables, additional questionnaires will be used to measure depression, anxiety, sleep, social support, physical activity, quality of life, self efficacy and difficulties in getting over the cancer experience. Furthermore, in the Self-Observation List, patients register their quality of sleep every day during a two-week period.Social Support will be measured with the Social Support Questionnaire (van Sonderen, 1993). Physical activity will be measured with the actometer, an apparatus developed by our department of Medical Psychology (Vercoulen et al, 1997). It records the number of movements every five minute period. Worn around the ankle day and night for a consecutive two-weeks. The EORTC consists of five functional scales (physical-, role-, cognitive-, emotional-, and social functioning), nine symptom scales and one scale for global health status.Locus of control will be measured with the Multidimensional Health Locus of Control questionnaire.
Self efficacy will be measured using a 5 –item Self Efficacy Questionnaire (Vercoulen et al.,

1996). Finally, difficulties in getting over the cancer experience will be measured with the Dutch version of the Impact of Events Scale (Horowiz et al., 1979; Brom and Kleber, 1985).

Study description

Background summary

Introduction:

Quality of life is an integrated part within treatment for cancer. An important but neglected part of quality of life is fatigue, during but also after treatment for cancer. Three recent studies in our institute have shown that 20- 40% of disease-free cancer patients mention invalidating fatigue as a frequent complaint 1- 6 years after curative treatment for cancer has ended. No relations were found between fatigue long after treatment for cancer and initial disease- and treatment variables. Somatic treatment for these complaints of fatigue is lacking. Cognitive Behaviour Therapy is a promising treatment to reduce fatigue and related functional impairment in patients with Chronic Fatigue Syndrome.

The purpose is to evaluate whether Cognitive Behaviour Therapy is effective in reducing chronic fatigue complaints in disease-free cancer patients, in a randomised-controlled study.

Treatment:

Cognitive Behaviour Therapy for fatigue in disease-free cancer patients is directed at change of cognitions and behaviour related to fatigue and impairment. In the treatment program one can discern five phases. The importance of each phase depends on the relevance for the individual patient, which is determined by multidimensional individual assessment. During all phases, use of diaries (self observation of cognitions and behaviour) with various instructions will help patients to increase self management and self control.

Relevance of this study:

Fatigue long after cancer is a rather frequent and invalidating problem, which until recently has been neglected by researchers and clinicians. The complaints of chronic fatigue have important consequences for quality of life in these patients. Cognitive Behaviour Therapy is

directed at fatigue and impairment related cognitions and behaviour. When Cognitive Behaviour Therapy for fatigue long after treatment for cancer appears to be effective, it has important positive consequences for the quality of life of these patients.

Study objective

1. What is the effect of Cognitive Behaviour Therapy in severely fatigued disease-free cancer patients on fatigue, functional impairment and psychological well-being, compared to patients waiting for this treatment?

2. Is the effect of Cognitive Behaviour Therapy lasting at 6 months after treatment and at 1 year follow-up?

Study design

N/A

Intervention

All patients who are suitable for this study, based on the in- and exclusion criteria, will be approached for this study. Patients will be asked to give informed consent and will be randomly allocated to the intervention- or waiting list condition. Next, base-line assessment (T1) will take place. The patients in the intervention condition start immediately with Cognitive Behaviour Therapy. At the end of the therapy, after 6 months, second assessment will take place in both conditions (T2). At this point changes in both conditions will be compared to analyse the effect of treatment. Subsequently, treatment will be offered to the patients in the waiting list condition. Six months later, follow-up assessment for the patients in the intervention condition will take place (T3). At the same time, post-treatment assessment for the patient in the waiting list condition will take place. Finally, again six months later, second follow-up assessment for the patients in the intervention condition will take place and (first) follow-up assessment for the patients in the waiting list condition will take place (T4).

Contacts

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Eligibility criteria

Inclusion criteria

1. Treated for breast cancer, colorectal cancer, testis cancer, ovarian cancer, uterus cancer, Hodgkin and non-Hodgkin disease of bone and soft tissue tumours;

2. Completion of treatment for cancer minimal 1 year and maximal 10 years ago;

3. Disease-free, as defined by the absence of somatic disease activity parameters;

4. Age between 18 and 65;

5. No physical comorbidity;

6. No current psychological or psychiatric treatment;

7. CIS fatigue score of 35 or higher.

Exclusion criteria

N/A

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):	01-09-2001
Enrollment:	112
Type:	Actual

Ethics review

Positive opinion

Date:	02-08-2005
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	NL76
NTR-old	NTR107
Other	: KUN 2001-2378
ISRCTN	ISRCTN44562532

Study results

Summary results

1. Bleijenberg G, Gielissen M, Bazelmans E, Berends T, Verhagen C. Cognitieve gedragstherapie voor vermoeidheid na kanker: een behandelprotocol. TSG 2004; 82: 364-370.
2. J Clin Oncol. 2006 Oct 20;24(30):4882-7.
