Cognitive behaviour therapy for postcancer fatigue: analyses of the different components.

No registrations found.

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

Summary

ID

NL-OMON27409

Source
NTR

Brief title
N/A

Health condition

1. tumour;

2. fatigued cancer survivors.

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre, Expert Centre Chronic Fatigue, the Netherlands. Expert Centre Chronic Fatigue.
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Fatigue: Checklist Individual Strength- subscale fatigue severity.

Functional impairment: Sickness Impact Profile.

T1: Assessment before start of therapy

T2: Assessment in the middle of therapy
Condition A: After the module “dysregulation of activity” is fully treated
Condition B: When all modules are fully treated, except “dysregulation of activity”

T3: Assessment after therapy

The difference in CIS-fatigue severity and SIP-total between T1 and T2 for condition A is compared with the difference scores of condition B.

Secondary outcome

The six perpetuating factors of postcancer fatigue:

1. coping with the experience of cancer;

2. fear of disease recurrence;

3. cognitions concerning fatigue;

4. sleep;

5. activity;

6. social support and negative social interactions.

Study description

Background summary

The existing evidence suggest that until now CBT especially designed for postcancer fatigue [1,2] (1 randomised controlled trial (RCT)) and exercise programmes [3,4] (2 RCT’s) are effective in treating postcancer fatigue. A common element in those interventions is within the area of physical activity. Two different kinds of activity enhancement were investigated, graded exercise and graded activity. Graded exercise is a program of usually 12 weeks aimed at increasing cardiorespiratory fitness. Patient engage in strenuous exercise and the intensity is often monitored with a hart-rate recorder. Graded activity is a program with gradual increase in physical activity, without striving for increase of cardiorespiratory fitness. In the three trials different goals of physical activity were used. Courneya at al. [4] investigated a

graded exercise program, with the aim of increasing cardiorespiratory functioning. Pinto et al. [3] investigated a home-based graded exercise program and recommendations were done for moderate-intensity physical activities. Graded activity is one of the treatment modules of the CBT for postcancer fatigue [2]. Ninety-four percent of the therapy time was spent on issues around graded activity. These studies seem to suggest that some increase in physical activity is necessary to relieve fatigue, although the exact mechanism by which activity enhancement decreases fatigue remains to be determined. On the contrary, there is some evidence that an increase in cardiorespiratory fitness does not lead necessarily to a decrease of fatigue [5,6]. The CBT is focused on six perpetuating factors of postcancer fatigue. They involve (1) insufficient coping with the experience of cancer, (2) fear of disease recurrence (3) dysfunctional cognitions concerning fatigue (4) dysregulation of sleep (5) dysregulation of activity (6) low social support and negative social interactions. So, CBT for postcancer fatigue addresses also other factors besides physical activity. Therefore we think that other factors are also important in relieving fatigue, supported by the larger effect size of the CBT-study compared to the graded exercise studies. The goal of the current study is to determine the contribution of the module “dysregulation of activity” in the reduction of postcancer fatigue, compared to the other modules.

1. Gielissen MFM, Verhagen S, Bleijenberg G. Cognitive behaviour therapy for fatigued cancer survivors: a long term follow-up. Brit J Cancer, 2007; 97: 612-618.
2. Gielissen MFM, Witjes JA, Verhagen S, Bleijenberg G. The effects of cognitive behaviour therapy in severely fatigued disease-free cancer patients compared to patients waiting for cognitive behaviour therapy. A randomised control trial. J Clin Oncol 2006; 24(30): 4882-4887.
3. Pinto BM, Frierson GM, Rabin C et al. Home-based physical activity intervention for breast cancer patients. J Clin Oncol 2005; 23(15): 3577-3587.
4. Courneya KS, Mackey JR, Bell GJ et al. Randomized controlled trial of exercise training in postmenopausal breast cancer survivors: cardiopulmonary and quality of life outcomes. J Clin Oncol 2003; 21(9): 1660-1668.
5. Thorsen L, Skovlund E, Strømme SB, Hornslien K, Dahl AA, Fosså SD. Effectiveness of physical activity on cardiorespiratory fitness and health-related quality of life in young and middle-aged cancer patients shortly after chemotherapy. J Clin Oncol 2005; 23(10): 2378-2388
6. Moss-Morris R, Sharon C, Tobin R, Baldi JC. A randomized controlled graded exercise trial for chronic fatigue syndrome: outcomes and mechanisms of change. J Health Psych 2005; 10(2): 245-259

Study objective

Increase in physical activity alone is not enough in relieving post cancer fatigue.

Intervention

Cognitive behaviour therapy (CBT) especially designed for fatigued cancer survivors is effective in reducing fatigue. The CBT is focused on six perpetuating factors of postcancer fatigue.

They involve:

1. insufficient coping with the experience of cancer;

2. fear of disease recurrence;

3. dysfunctional cognitions concerning fatigue;

4. dysregulation of sleep;

5. dysregulation of activity;

6. low social support and negative social interactions.

Each perpetuating factor is a module in the therapy protocol. Because of the existence of large differences within the group of fatigued cancer survivors, the therapy was adapted to each individual. To determine which modules were necessary, each perpetuating factor was measured with specific questionnaires. If a patient scored problematic on one of these questionnaire, the accessory module became part of the treatment, resulting in an individualized treatment protocol per patient. The module 'dysregulation of activity' was part of the treatment protocol for each patient. The goal of the current study is to determine the contribution of the module "dysregulation of activity" in the reduction of postcancer fatigue, compared to the other modules.

The study exists of two conditions. Both conditions will be offered the individualized CBT for postcancer fatigue. However, the treatment protocol of the two conditions will be different. The order in which the modules of the therapy will be offered are different in the two conditions.

Condition A : The therapist starts with the module "dysregulation of activity" and none of the other necessary modules are treated. After the module "dysregulation of activity" is fully treated, an assessment will take place. After the assessment the other necessary modules are treated.

Condition B: The therapist treats all the modules, except "dysregulation of activity". If all modules are fully treated, an assessment will take place. After the assessment the module "dysregulation of activity" will be treated.

Contacts

Public

University Medical Center St. Radboud, Expert Center Chronic Fatigue,
P.O. Box 9011
G. Bleijenberg
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3610030
Scientific
University Medical Center St. Radboud, Expert Center Chronic Fatigue,
P.O. Box 9011
G. Bleijenberg
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3610030

Eligibility criteria

Inclusion criteria

Fatigued cancer survivors are treated with cognitive behaviour therapy as normal clinical practice in our Expert Centre Chronic Fatigue of the Radboud University Nijmegen Medical Centre:

Completion of treatment for cancer is minimal 1 year.

1. Patients are disease-free, as defined by the absence of somatic disease activity parameters;

2. Patients have no physical comorbidity that could explain the fatigue complaints.

3. Patients have no current psychological or psychiatric treatment.

4. All patients have a CIS fatigue score of 35 or higher.

Exclusion criteria

Patient does not meet the herefore mentioned inclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-09-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-09-2007
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	NL1030
NTR-old	NTR1063

Register	ID
Other	: VNK 2007/175
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results