

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

Gepubliceerd: 20-09-2007 Laatste bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON27409

Bron

NTR

Verkorte titel

N/A

Aandoening

1. tumour;
2. fatigued cancer survivors.

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre, Expert Centre Chronic Fatigue, the Netherlands. Expert Centre Chronic Fatigue.

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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 questionnaires, 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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patient does not meet the herefore mentioned inclusion criteria.

Onderzoeksopzet

Opzet

| | |
|------------------|-----------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Blinding: | Enkelblind |
| Controle: | N.v.t. / onbekend |

Deelname

| | |
|-----------|-----------------|
| Nederland | |
| Status: | Werving gestart |

(Verwachte) startdatum: 20-09-2007
Aantal proefpersonen: 100
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 20-09-2007
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

| Register | ID |
|----------------|------------------------------------|
| NTR-new | NL1030 |
| NTR-old | NTR1063 |
| Ander register | : VNK 2007/175 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

Resultaten