# Cognitive behaviour therapy to reduce severe fatigue and impairment in daily life after curative treatment for cancer

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
12/09/2005		Protocol		
Registration date 12/09/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
23/10/2012	Cancer			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number KUN 2001-2378

# Study information

Scientific Title

## **Study objectives**

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 one to six 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.

## Hypotheses:

- 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 six months after treatment and at one-year follow-up?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee

## Study design

Randomised, active controlled, parallel group, single blinded trial

## Primary study design

Interventional

## Study type(s)

Quality of life

# Health condition(s) or problem(s) studied

Tumour, fatigued cancer survivors

#### **Interventions**

All patients who are suitable for this study, based on the inclusion 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 six 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).

## Intervention Type

Other

#### Phase

**Not Specified** 

## Primary outcome(s)

The major outcome variables in this study are:

- 1. Fatigue severity
- 2. Impairment in daily life
- 3. Psychological well-being

## Fatigue severity:

This will be measured using the Checklist Individual Strength. A Self-Observation List (SOL) has been constructed in order to obtain information about severity and frequency of fatigue and other complaints during a two-week period.

## Impairment in daily life:

This will be assessed with eight subscales of the Sickness Impact Profile.

## Psychological well-being:

This will be measured with the Symptom CheckList. A total score of psychological well-being can be obtained as well.

## Key secondary outcome(s))

Besides the questionnaires used to measure the major outcome variables, additional questionnaires will be used to measure:

- 1. Depression, anxiety and sleep: the SOL will be used to measure these variables, patients register their quality of sleep every day during a two-week period
- 2. Social support: this will be measured with the Social Support Questionnaire
- 3. Physical activity: this will be measured with the actometer, an apparatus developed by our department of Medical Psychology. It records the number of movements in every five minute period. It is worn around the ankle day and night for a consecutive two-weeks
- 4. Quality of life: 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
- 5. Self efficacy: this will be measured using a 5-item Self Efficacy Questionnaire
- 6. Difficulties in getting over the cancer experience: this will be measured with the Dutch version of the Impact of Events Scale

## Completion date

31/12/2005

# **Eligibility**

Key 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 oneyear and maximal ten years ago
- 3. Disease-free, as defined by the absence of somatic disease activity parameters
- 4. Aged between 18 and 65
- 5. No physical comorbidity
- 6. No current psychological or psychiatric treatment
- 7. Checklist Individual Strength (CIS) fatigue score of 35 or higher

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

All

## Key exclusion criteria

Does not comply with above inclusion criteria.

### Date of first enrolment

01/09/2001

## Date of final enrolment

31/12/2005

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre

P.O. Box 9101

Nijmegen Netherlands 6500 HB

# Sponsor information

# Organisation

Radboud University Nijmegen Medical Centre (The Netherlands)

## ROR

https://ror.org/05wg1m734

# Funder(s)

# Funder type

Charity

## Funder Name

Dutch Cancer Society (The Netherlands)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/09/2007		Yes	No
Results article	results	01/07/2012		Yes	No