ISRCTN44562532 https://doi.org/10.1186/ISRCTN44562532

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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2005	Completed	[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

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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

Primary study design
Interventional

Study design
Randomised, active controlled, parallel group, single blinded trial

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
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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