An explorative study on physiological and neurophysiological determinants of fatigue in cancer survivors.

No registrations found.

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

Summary

ID

NL-OMON20578

Source
NTR

Brief title
FICS (Fatigue In Cancer Survivors)

Health condition

Vermoeidheid na kanker

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Center; Department of Medical Oncology
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

The baseline and second assessment both include:

1. Magnetic resonance imaging (MRI) and magnetic resonance spectroscopy to assess brain morphology and brain metabolites, respectively;

2. A two-minute endurance test will be administered at maximal voluntary (isometric) contraction to assess peripheral and central fatigue. During the test changes in EMG and force indicate peripheral fatigue, while central fatigue is studied by the twitch interpolation technique;

3. A maximal exercise test will be performed to assess physical fitness and deconditioning;

4. Fatigue severity will be measured using the Checklist Individual Strength. The Checklist Individual Strength is designed to measure fatigue severity, concentration, motivation, and physical activity;

5. Additional questionnaires will be used to measure general health, the impact of the disease on daily life, difficulties in getting over the cancer experience, depression, anxiety, sleep, social support, physical activity, quality of life, and self efficacy;

6. Patients will perform neurological tests to assess information processing and motor speed;

7. Blood and urine samples of the patients will be analyzed to find possible explanations for cancer related fatigue;

8. Daily observed fatigue will be measured during a two-week period with the Self-Observation List. The latter instrument gives the actual level of daily fatigue and will be used during two weeks;

9. Daily activity will be measured during two weeks using an actometer. The actometer used is a motion-sensing device that can register and quantify human physical activity. To assess the effect of the maximal exercise test on the daily activity of patients, they will wear the actometer for an additional five days after the maximal exercise test.

Secondary outcome

N/A

Study description

Background summary

Fatigue long after treatment for cancer is a frequently occurring problem, which has important consequences for quality of life in these patients. Identification of characteristic (neuro)physiological factors of fatigue in disease-free cancer patients may not only serve a theoretical understanding of this invalidating condition, but may also provide an objective

biological marker that could support the diagnosis and follow-up treatment. The identification of (neuro)physiological factors which play a role in fatigue after cancer may aid in the early recognition of patients who are at risk for developing fatigue and may lead to early intervention and/or different treatment strategies.

Study objective

1. What are characteristic (neuro)physiological factors of fatigue in disease-free cancer patients?

2. To which degree can these factors be influenced by Cognitive Behavior Therapy?

Study design

N/A

Intervention

In this explorative study, disease-free cancer patients who finished treatment for cancer at least one year ago, will be approached for this study. Patients who are suitable for this study, based on the in- and exclusion criteria, will be asked to give written informed consent. Next, baseline assessment will take place in these patients. Based on the Checklist of Individual Strength Fatigue score, patients will be divided into a non-fatigued and a severely fatigued group. Differences in (neuro)physiological factors will be assessed between the non-fatigued and fatigued group. After the baseline assessment the fatigued patients will be randomized to start immediately with Cognitive Behavior Therapy, especially designed for fatigued cancer patients, or to be placed on a waiting list. At the end of the therapy, after 6 months, a second assessment will take place in the group of fatigued patients. This assessment will include the same measurements as at baseline. The fatigued patients on the waiting list will then start with Cognitive Behavior Therapy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Treated for a malignant, solid tumor;

2. Completion of treatment for cancer minimal 1 year ago;

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

4. Age between 19 and 65;

5. Age at disease onset minimal 18.

Exclusion criteria

1. Current psychological or psychiatric treatment;

2. Physical comorbidity which could explain the fatigue;

3. Contra-indication for MR-examinations;

4. Treatment with anti-depressive drugs, anti-epileptic drugs, or benzodiazepines;

5. Insufficient command of the Dutch language to fill out questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	78
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-02-2009
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	NL1604
NTR-old	NTR1685
Other	CMO UMC St. Radboud : no 2008-200
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A