Fatigue in palliative cancer care: are graded exercise and cognitive behaviour therapy effective treatments and what mediates the treatment response?

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Research questions1. What are the effects of GET and CBT in severely fatigued patients receiving first line of palliative treatment for breast or colon cancer on fatigue severity compared to usual care?2. What are the mediators of the change in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON37781

Source
ToetsingOnline

Brief title
Interventions for fatigued palliative cancer patients

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Koningin Wilhelmina kankerfonds

Intervention

Keyword: cognitive behaviour therapy, exercise, fatigue, palliative cancer

Outcome measures

Primary outcome

Main endpoint is fatigue severity (primary outcome measure).

Secondary outcome

We will also determine if quality of life improves and functional impairments

are reduced following the interventions (secondary outcome measures).

Study description

Background summary

Since oncological treatments have been improved patients who are palliatively treated for breast or colon cancer can live with cancer for years. Prolonging patients* lives and preserving quality of life are the main aims of oncological treatment. Quality of life is also an important parameter to determine whether patients can continue with cancer treatment or start with further lines treatment. Fatigue is an important symptom lowering the quality of life in patients with advanced or metastatic cancer. From our own studies in patients with advanced cancer we know fatigue is the most frequent reported symptom. Patients reported fatigue even more often than pain, nausea and vomiting. Furthermore, we found that nearly half of the palliative patients are severely fatigued and that more severely fatigued patients report more disabilities. Treating fatigue during the palliative trajectory is one of the unused opportunities to improve the quality of life of patients with advanced cancer. There is no evidence based intervention available for the treatment of severe fatigue during the palliative trajectory. Sometimes palliative patients are included in RCTs for fatigue but it remains unclear if this specific subgroup of patients also benefited from the interventions.
Graded exercise therapy (GET) consisting of resistance and aerobic exercises, and cognitive behaviour therapy (CBT) specifically designed for fatigue in the

palliative phase are two promising approaches to reduce fatigue, but the effectiveness for cancer patients in the palliative trajectory has not been demonstrated in controlled studies.
In the proposed project we will test the efficacy of both GET and CBT in a RCT in reducing fatigue severity. Both interventions will be compared with usual care.
GET and CBT assume different mechanisms in reducing fatigue. In GET it is hypothesized that an increased level of physical fitness will reduce fatigue. In CBT for fatigue it is assumed that a reduction in fatigue is mediated by a change in fatigue related cognitions and that an increase in physical activity which is one of the elements of CBT and concurrent improvement in physical fitness, has no mediating role but acts as a catalysator for the change in dysfunctional beliefs about fatigue. However, it could be that the expected positive effect of GET and CBT is brought on by a change in both cognitions and physical/activity fitness. In the proposed project we will test: a) if an increased physical activity and/or fitness mediates the reduction in fatigue in both GET and CBT; and/or b) test simultaneously if a change in fatigue related cognitions, especially an increased self efficacy concerning fatigue and reduced tendency to catastrophise in response to fatigue, mediates the fatigue reduction in the two interventions. Identifying the mediating factors for both interventions will enable us to improve interventions for fatigue in this patient group.

Study objective

Research questions
1. What are the effects of GET and CBT in severely fatigued patients receiving first line of palliative treatment for breast or colon cancer on fatigue severity compared to usual care?
2. What are the mediators of the change in fatigue brought on by GET and CBT? More specifically, are (a) an increased level of physical activity and/or physical fitness; or (b) a change in fatigue related cognitions, mediators for the expected reduction in fatigue brought on by the two interventions?

Study design

Randomized, multi-centre controlled trial, with three conditions, i.e. one control condition and two intervention conditions. Three hospitals will participate in the study: the Radboud University Nijmegen Medical Centre, Ziekenhuis Gelderse Vallei at Ede and Maxima Medisch Centrum at Eindhoven/Veldhoven.

Intervention

Condition 1: Graded exercise therapy: GET consisting of one weekly sessions of two hours of resistance and aerobic training with a physical therapist during

12 weeks. GET will take place in small groups of maximal 5 patients.
Condition 2: Cognitive behaviour therapy (CBT): CBT consisting of eight individual one-hour sessions with a therapist over a period of 12 weeks.

Study burden and risks

- There are risks involved in the physical exertion and exercise patients will do in the GET condition. These will be limited by adapting the program to the physical limitations of patients. Patients will also be screened by their oncologist on their ability to do exercise. The burden is limited: doing exercise and extra travelling for the 24 training sessions in 12 weeks. Benefits: It is expected that severely fatigued palliative cancer patients will benefit from GET. Their physical fitness will increase and their fatigue is expected to decrease. We demonstrated this in a pilot study. This pilot study also demonstrated that this specific form of GET was safe and patients were positive about the intervention.
- There are no or only minimal risks involved in participating in the CBT intervention. The burden is also limited and consists of extra travelling for the sessions, following 8 sessions of CBT and doing home-work assignments. The program is adapted to the physical limitations of the patients. There are substantial potential benefits: CBT for fatigued cancer survivors proved to be a highly effective intervention in reducing fatigue and disabilities and it is likely that palliative cancer patients will also profit and become less fatigued and disabled.
- All participants will do a 6-minute walking test to determine their physical fitness at two assessments. This is not a maximal exercise test and therefore poses only minimal risks for patients.
- Participants have to complete questionnaires, four times in a period of approximately 6 months depending on the duration of the first line of palliative cancer treatment. The questionnaires can be completed online or a paper and pencil version will be send to the participant. It will take patients about a half hour to complete the questionnaires. Completing the questionnaires is without risks and the burden is limited.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age of 18 or above.
• Able to speak, read and write Dutch.
• Being severely fatigued without known and treatable somatic causes

Exclusion criteria

• Contra-indication for exercise (a physical activity potency of walking six minutes successively is a minimum).
• Metastasis in the brain.
• Currently receiving treatment for a psychiatric disorder.
• Karnofsky scale < 70
• WHO (ECOG) performance scale >= 3

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-04-2013
Enrollment:	219
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-12-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL40003.091.12