A randomized trial in cancer-related fatigue in palliatively treated patients: protocolized patient-tailored treatment of physical symptoms (PPT) vs care as usual (CAU).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23161

Source
NTR

Brief title
N/A

Health condition

1. Advanced cancer;

2. fatigue;

3. cancer-related fatigue;

4. CRF;

5. palliative care.

(NLD: kanker, vermoeidheid, kankergerelateerde vermoeidheid, palliatieve zorg).

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC zorgonderzoek
Zon MW

Intervention

Outcome measures

Primary outcome

General fatigue at baseline and 1, 2 and 3 months after baseline. Measured with the MFI.

Secondary outcome

1. Quality of life (EORTC QLQ C30);

2. Multidimensional fatigue (MFI);

3. Daily interference of fatigue (BFI);

4. Anxiety and depression (HADS);

5. Survival.

Study description

Background summary

Fatigue is a common and complex symptom in advanced cancer patients and is known to considerably influence daily activity and quality of life. The etiology of fatigue is not yet completely understood, but physical symptoms seem to be part of it. This study focuses on the relationship between physical symptoms and fatigue. Palliatively treated out-patients reporting fatigue are invited to participate in the study for three months. Patients are randomized to the control group or the intervention group. Patients in the control group receive care as usual. Patients in the intervention group are seen by a nurse specialist who monitors their physical symptoms. Depending on the severity of the physical symptom(s), the nurse specialist will give information on how to deal with the symptom(s) or contact the patient's physician for treatment. Participants are requested to complete questionnaires concerning multidimensional fatigue, quality of life, daily interference of fatigue, anxiety and depression at baseline and 1, 2 and 3 months after baseline. Patients in the intervention group are expected to show greater improvement on general fatigue compared to patients

receiving care as usual.

Study objective

Patients receiving systematic monitoring and multidisciplinary protocolized patient-tailored treatment of physical symptoms (PPT) are expected to show greater improvement on general fatigue compared to patients receiving care as usual (CAU).

Study design

T0 = at baseline (before randomization);

T1 = 1 month after baseline;

T2 = 2 months after baseline;

T3 = 3 months after baseline.

Intervention

Patients in both arms of the study participate for 3 months. For patients in the intervention group, physical symptoms will be monitored systematically and treated. Patients in the control group receive care as usual.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically or cytologically proven solid malignancy;

2. Palliatively aimed treatment;

3. Treatment in the outpatient clinic;

4. Fatigue scored as 4 or higher on a scale of 0 to 10;

5. 18 years or older;

6. WHO performance status of 0,1 or 2;

7. Life expectancy at least months;

8. Able to write and speak Dutch;

9. Signed informed consent.

Exclusion criteria

1. Concomitant (or within 4 weeks before randomization) administration of any experimental drug;

2. Untreated depression or anxiety disorders;

3. Severe comorbidity, e.g. heart failure or symptomatic chronic obstructive lung disease;

4. Stay in nursing home;

5. Cognitive limitations.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2007
Enrollment:	152
Type:	Actual

Ethics review

Positive opinion

Date:	19-12-2007
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	NL665
NTR-old	NTR1170
Other	: EMC 07-005
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A