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

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Ethical review	-
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON30469

Source
ToetsingOnline

Brief title
Cancer-related fatigue: systematic treatment of physical symptoms

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer-related fatigue

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: fatigue, palliative care, randomized clinical trial, symptom management

Outcome measures

Primary outcome

Mean decrease over time in general fatigue measured by Multiple Fatigue

Inventory (MFI).

Secondary outcome

Physical fatigue, reduced activity, reduced motivation and mental fatigue

measured by MFI; quality of life; daily interference; severity of symptoms;

anxiety and depressed mood.

Study description

Background summary

Fatigue is one of the most prevalent symptoms among advanced cancer patients in the palliative phase and is most frequently reported to considerably influence quality of life and daily functioning. The specfic mechanisms underlying fatigue are not fully known, but several physical factors play a role.
Depending on the study populations and designs different independent predictors of fatigue have been reported in the literature. These include physical symptoms, anxiety, depression, cancer treatment, stage of disease and primary cancer site. In a previously study performed at the Palliative Care Unit of the Erasmus MC, physical symptoms were found to be associated with the different dimensions of fatigue.
Since the underlying pathogenesis of fatigue remains relatively unknown to this date, cancer-related fatigue is difficult to treat. The existing (non-) pharmacological interventions are only succesful or even possible under limited circumstances. Although several physical symptoms are found to be significantly associated with fatigue, to this date no studies have been conducted on the

effect of treatment of symptoms on fatigue.

Study objective

The objective of this study is to determine the effectiveness of receiving a multidisciplinary protocolized patient-tailored treatment of physical symptoms (PPT) in combination with structurally monitoring of reported symptoms (the intervention) on multidimensional fatigue, quality of life and daily interference.

Study design

This is a single-centre, randomized intervention-phase III study in palliative cancer patients with solid tumours. Patients will be randomly allocated in a 1:1 ratio between two study arms (intervention or treatment as usual). The planned study duration per patient is three months. The planned duration of the entire period is approximately three years.

Intervention

Patients randomized in the intervention-arm of the study will participate for 3 months in a complex intervention. The intervention will be conducted by a trained nurse specialist. This nurse specialist is responsible for the monitoring and exploration of the experienced physical symptoms, patient-tailored education and she is responsible for the communication with the physician.
During the intervention the patient will have at least three face-to-face contacts with the nurse specialist (baseline, 2 and 6 weeks). Also one telephone contact will take place, 9 weeks after baseline. The intervention consist of two parts: receiving multidisciplinary protocolized treatment for one or more symptoms and structurally monitoring these symptoms in a diary. Treatment protocols are available for the following seven symptoms: pain, dyspnoea, constipation, nausea/vomiting, dry mouth, cough and lack of appetite.

Study burden and risks

There are no risks associated with participation of this study.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301
3075 EA Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301
3075 EA Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

a. Histologically or cytologically proven solid malignancy;
b. Curative treatment is not possible anymore;
c. Treated in the outpatient clinic;
d. Presence of fatigue scored as >=4 on a scale of 0 to 10;
e. Age >=18 years;
f. WHO performance status <= 2;
g. Life expectancy >= 3 months;
h. Able to write and speak Dutch;
i. Signed informed consent.

Exclusion criteria

a. Concomitant (or within 4 weeks before randomization) administration of any experimental drug;
b. Stay in a nursing home;

c. Untreated depression or anxiety disorders;
d. Severe comorbidity, e.g. heart failure or symptomatic chronic obstructive lung disease
e. Cognitive limitations

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

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

Ethics review

Approved WMO Date:	03-04-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL14164.078.06