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

Gepubliceerd: 19-12-2007 Laatst bijgewerkt: 18-08-2022

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).

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23161

Bron
NTR

Verkorte titel
N/A

Aandoening

1. Advanced cancer;

2. fatigue;

3. cancer-related fatigue;

4. CRF;

5. palliative care.

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

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC zorgonderzoek
Zon MW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

T0 = at baseline (before randomization);

T1 = 1 month after baseline;

T2 = 2 months after baseline;

T3 = 3 months after baseline.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-10-2007
Aantal proefpersonen:	152
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-12-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL665
NTR-old	NTR1170
Ander register	: EMC 07-005
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A