Palliation through physical training

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34284

Source
ToetsingOnline

Brief title
PALFIT

Condition

- Other condition

Synonym
cancer, oncology

Health condition

oncologische aandoeningen in palliatief behandelstadium

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cancer, palliative, quality of life, training

Outcome measures

Primary outcome

Main study parameter is:

- Feasibility of the study

Secondary outcome

Secondary study parameters are:

- Quality of life (EORTC QLQ C30).

- Physical fitness (six minute walk and muscle strength)

- Fatigue (MFI-20).

Study description

Background summary

A lot of evidence is generated for training interventions before, during, and after cancer treatment (Galvao, 2005; Knols, 2005; De Backer, 2008; Van Weert, 2006; Adamsen, 2006; Young, 2003) but maintenance and recovery of physical functioning has received relatively little attention in palliative care research and in clinical practice. Only a few centers offer physical training for advanced cancer patients and studies concerning physical training for advanced cancer patients are poor and lacking quality (Lowe, 2009). This is in contrast to patients* priorities. Physical functioning, physical condition and fatigue are among the most important determinants of palliative patients* quality of life (Cohen, 2002). The majority of cancer patients express a wish to remain physically independent as long as possible and want to maintain strength and endurance throughout the course of their disease (Oldervoll, 2006; Clark, 2007).

Study objective

This pilot study focuses mainly on the feasibility and safety of the study (inclusion, randomization, testing procedure, evaluation of the training).

The main objective of the intended study is to investigate whether a 12-week, group wise supervised, personalized physical training program for advanced cancer patients improves physical fitness and physical performance, reduces complaints of fatigue and improves health related quality of life.

Study design

It concerns a randomized, single blinded, controlled pilot study of one year. The intervention will be carried out in the University Medical Center Utrecht at the department of Rehabilitation, Nursing Science & Sports.

Intervention

The intervention group receives a training program, twice a week, during 12 weeks. This program will be personalized to the patient*s abilities and preferences. Total length will be 60 minutes and includes a warming-up (10 minutes), a personalized training program with both aerobic and muscle strength training (40 minutes, emphasis on muscle strength training) and a cooling down (10 minutes). The control group receives usual care.

Study burden and risks

Patients included in the study will be asked to visit the University Medical Center Utrecht three times to complete questionnaires and to perform several physical tests.

Testing and training will take place under supervision of experienced staff and a medical specialist will be available in case of emergencies. Patients allocated to the intervention group are supposed to participate in a 12-week group wise supervised physical training program, twice a week. The estimated extra risk for the patient while participating in this study is low. However, exercise related injuries can occur. We expect the physical training program to be effective on the patients* health status (decrease fatigue, improve physical fitness and therefore improve quality of life).

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

- Functional Status: WHO-score 0 up to 2
- Incurable form of cancer (patients are allowed to receive palliative treatment)
- Treated within the Department of Medical Oncology, UMC Utrecht or receiving daycare from hospice Demeter
- Prognosis of more than six months
- Able to read and understand the Dutch language
- Not reporting contra indications for physical activity

Exclusion criteria

- Participatie in a phase 1 study
- No informed consent
- Patients with an increased risk of pathological fractures
- Patients with central neurological problems
- Not able to perform the physical tests, or visit the training twice a week

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	01-12-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32042.041.10