The safety, feasibility and effect of an exercise training program in palliative care on quality of life for patients with cancer: a randomized controlled trial.

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The aim of this randomised controlled trial is to evaluate the safety, feasibility and effect on quality of life of an exercise training program for 12 weeks in palliative care for patients with advanced cancer. This will be achieved by measuring...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON46195

Source
ToetsingOnline

Brief title
Exercise training in palliative care

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, Neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Nog te bepalen na terugtrekking beoogde sponsor

Intervention

Keyword: Neoplasm, physical activity, quality of life

Outcome measures

Primary outcome

The main study outcome is the self-reported health-related quality of life

(HRQOL) at baseline and after 12 weeks of exercise training.

Secondary outcome

Secondary outcomes are aerobic capacity, level of fatigue, muscle strength and

mobility.

Study description

Background summary

In cancer patients receiving curative treatment, research showed an improvement in quality of life and level of fatigue after finishing an exercise program during and after cancer treatment. Despite these positive findings in curative cancer patients, only a few small-scale studies have investigated the role of an exercise program in palliative care.

Study objective

The aim of this randomised controlled trial is to evaluate the safety, feasibility and effect on quality of life of an exercise training program for 12 weeks in palliative care for patients with advanced cancer. This will be achieved by measuring the self-reported health-related quality of life (using the QLQ-C30 core questionnaire version 3.0), aerobic capacity (using the steep ramp protocol on a stationary bicycle), muscle strength (using a hand-held dynamometer), level of fatigue (using the FACIT-F questionnaire) and mobility

(using the timed up and go test and a pedometer).

Study design

Open randomised controlled trial with interim analysis.

Intervention

12 week exercise training program consisting of a combination of strength and endurance training. Training will be twice a week for one hour.

Study burden and risks

Previous research in curative cancer care patient showed an improvement in quality of life and level of fatigue after finishing an exercise training program during and after cancer treatment. In this relative well-functioning group of palliative patients, we expect outcomes to be positive as well. This is also seen in most small scale studies of exercise training in palliative care. Furthermore, previous research in curative cancer patients showed that an exercise training program is safe. However expected to be small, there may be some minor risks by participating in this study. With every kind of exercise there may be a risk of muscle soreness or getting injured. Overtraining and injuries caused by a poor technique will be prevented by supervision of a physiotherapist during training sessions. Besides, some patients will be confront with their physical limitations by filling in the quality of life questionnaire. However, it can be useful to confront your limitations to seek help for it. Furthermore, we have kept the questionnaires to a minimum to avoid participants overly reflect on their own health.

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

1) Patients aged * 18 with all types of cancer without options for curative treatment and a life-expectancy of one to five years.
2) Karnofsky performance score * 80

Exclusion criteria

1) Concurrent medical conditions
2) Inability to walk without walking aids in the home situation
3) Inability to understand the Dutch language.
4) Participation in other exercise training programs.

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:	Will not start
Enrollment:	255
Type:	Anticipated

Ethics review

Approved WMO Date:	05-09-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-09-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL56748.098.16