Optimising physical fitness in patients receiving chemoradiotherapy for head and neck cancer: a feasibility study

Published: 16-11-2017
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON47819

Source
ToetsingOnline

Brief title
the Move-FIT study

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
head and neck cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Wereld Kanker Onderzoek Fonds en Nationaal Fonds tegen Kanker

Intervention

Keyword: exercise, feasibility, head and neck cancer, intervention

Outcome measures

Primary outcome

Primary outcome is feasibility of the exercise intervention. Adherence and compliance will be monitored throughout the programme in a CRF (physiotherapist) and an exercise log/fitness tracker (patient). Recruitment rate will be registered in study file. Retention rate and number of supervised sessions will be registered in study file. Patient satisfaction will be explored by semi-structured interviews focusing on the beliefs, thoughts, perceptions and engagement with the exercise intervention before (week 0) and after (week 12).

Secondary outcome

Secundary study parameters include; health related Quality of life (questionnaires), physical fitness (6-minute walking test,hand grip strenght, 30 sec chair stand test), muscle strength (Microfet and hand grip strength), body composition (bio electric impedance analysis), energy expenditure (indirect calorimetry) and nutritional status (PG-SGA).

Study description

Background summary

Treatment of advanced Head and Neck Cancer (HNC) with Chemoradiotherapy (CRT) has a negative impact on physical functioning, body composition, fatigue and health related quality of life (HRQoL). Unintentional weight loss, of which a large percentage is lean body mass, often occurs despite intensive nutritional

support. Besides dietary interventions, physical exercise is a prerequisite for maintaining and rebuilding muscle mass. Current evidence, mainly from research with breast cancer patients, shows that exercise interventions offered during chemotherapy treatment have positive effect on physical functioning, fatigue and HRQoL. HNC patients may also benefit from exercise during CRT, although studies in this population are scarce. Based on our clinical experience and (limited) available evidence, we developed an exercise program tailored to preferences and abilities of HNC patients during CRT.

Study objective

This study will evaluate feasibility in terms of adherence and compliance to, patient satisfaction with, and recruitment and retention of, an exercise intervention during CRT in advanced HNC patients. Secondary objectives are to obtain preliminary outcome data for (change in) HRQoL, physical performance, muscle strength,body composition, nutritional status and energy expenditure for future power calculations.

Study design

Two-centre feasibility study using a mixed methods design, including quantitative measures to obtain data on feasibility, physical performance, muscle strength and mass, HRQoL outcomes, and qualitative methods (semi-structured interviews) to gain insight into the participants* perspectives on feasibility and satisfaction.

Intervention

The 10-week exercise intervention combines endurance and resistance training, and starts between one week prior to and two week after the start of 7 weeks of CRT and continues for 2-4 weeks after completion of CRT. Related to high-frequent hospital visits and the willingness to do exercises in daily life, a combined supervised and home-based, moderate-intensity exercise programme is planned.

Study burden and risks

Visits scheduled for physical assessment and exercise intervention will be combined with treatment-related visits if possible.
The patient will be asked threetimes to spend, at most, 30 minutes completing questionnaires, to perform physical tests and to undergo measurements of body composition and resting energy expenditure. Furthermore, the patient is asked to wear an activity tracker, to keep an activity diary and (for two times three days) a food diary. The patient is also asked to participate in semi-structured interviews (45 minutes). As in any exercise situation, injuries due to exercise can occur; to minimize the risk the intensity of the exercise program will be

gradually increased during the study and the program will be supervised by a physiotherapist. The estimated extra risk for the patient while participating in this study is low.
Benefits: Possible benefits for participants are a reduction in fatigue and an increase of physical fitness possibly leading to prosperous recovery and better HRQoL.

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

head neck cancer patients who are scheduled for chemoradiotherapy or bioradiotherapy (cetuximab and radiotherapy)
<=> 18 years of age
sufficient Dutch writing and reading skills

no contra indication for physical activity

Exclusion criteria

na

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2018
Enrollment:	37
Type:	Actual

Ethics review

Approved WMO Date:	16-11-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	02-08-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-10-2018
Application type:	Amendment
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

ID: 27597
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61408.041.17
OMON	NL-OMON27597