De haalbaarheid van een beweegprogramma tijdens behandeling van hoofd-halskanker

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27597

Source
NTR

Brief title
Move-FIT study

Health condition

Treatment of advanced Head and Neck Cancer with 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.

Sponsors and support

Primary sponsor: University Medical Center Utrecht and Netherlands Cancer Institute
Source(s) of monetary or material Support: World Cancer Research Fund

Intervention

Outcome measures

Primary outcome

Feasibility: Main outcome: Adherence to supervised and home-based sessions will be monitored throughout the programme (maximum: 6 sessions per week x 10 weeks) in a CRF (physiotherapist;one supervised session per week) and an exercise log/fitness tracker (patient; five home-based sessions per week).

 Compliance with the exercise protocol (intensity and duration) will be registered in a CRF (physiotherapist) and an exercise log (patient).

 Recruitment rate; registered in study file

 Retention rate; registered in study file. Reasons of patients who drop-out during the intervention will be registered.

Secondary outcome

Secondary study outcomes: include physical fitness, nutritional status and energy needs that will be assessed by objective physical and nutritional performance indicators and questionnaires. 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).

Study description

Background summary

Rationale: 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.

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 HRQoL, physical performance, muscle
strength, body composition, total energy expenditure and nutritional status 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, total energy
expenditure, nutritional status, HRQoL outcomes, and qualitative methods (semi-structured interviews) to
gain insight into the participants' perspectives on feasibility and satisfaction.

Study population: Thirty-seven patients will be recruited in UMC Utrecht and Netherlands Cancer
Institute. Patients eligible for this study must be HNSCC patients older than 18 years of age who are
scheduled for CRT, able to write and read Dutch, have a Karnofsky Performance status >60, able to walk
≥60 m without a mobility aid, and have no contraindication for physical activity.

Intervention: The exercise intervention combines endurance and resistance training, and starts one week
prior to 7 weeks of CRT and continues for 2 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.

Main study outcomes: 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.
Secondary study outcomes: include physical fitness, nutritional status and energy needs that will be
assessed by objective physical and nutritional performance indicators and questionnaires. 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).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Burden: Visits scheduled for physical assessment and exercise intervention will be combined with
treatment-related visits if possible.

The patient will be asked three times to spend, at most, 30 minutes completing questionnaires and two
times to spend at most 90 minutes performing physical and nutritional tests and keep a food diary (two
times three days) and an activity diary (weekly) and to participate in semi-structured interviews (45
minutes). These tests, diaries and questionnaires have been used in exercise interventions studies in
other cancer patients (e.g. in patients with oesophageal cancer) and are well tolerated by the patients.
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.

Study objective

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. Head and Neck cancer (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.

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

Study design

Evaluation measurements will be performed at each research center at baseline, i.e. 1 week

before CRT (week 0) and after the exercise intervention (week 12). Midway (week 5) only quality of life and fatigue will be measured. The interviews will be done before the start and after completion of the exercise intervention, either on the day of the evaluation measurements or on a separate day.

Intervention

The exercise intervention combining endurance and resistance training will start one week before the 7 weeks of CRT and continues for 2 weeks after completion.The exercise training will be individualized, and intensity will be continuously adjusted as needed throughout the program.

Endurance training

Participants will be encouraged to perform 15 minutes moderate-intensity endurance physical activity by means of brisk walking at six days per week. Additionally, patients will be instructed to perform 15 minutes of physical activity of their own choice (e.g. biking). For all endurance activities a Borg rate of rated perceived exertion (RPE) between 12 and 15 and a heart rate of at least 60% of the estimated maximum will be targeted. A fitness tracker with a daily step count goal will be used to motivate patients and provide them with feedback during their home-based sessions.

Resistance training

Patients will perform six strength exercises targeting all large muscle groups: arms, legs, shoulders, and trunk, using body weight and elastic bands with varying resistance, on at least three days per week. At least one of the three exercise sessions will be supervised by a physiotherapist, who will adjust the exercise type and intensity to the participant's capacity based on pragmatic 15-repetition maximum (RM) testing, and instruct the participant on proper performance. The strength exercises, using body weight and elastic bands with varying resistance, will be of moderate intensity (50-70% 1RM as determined by pragmatic 15RM testing": progression of exercise intensity/difficulty will be considered for patients who exceed the prescribed 15 repetitions for an exercise during the supervised sessions, and will be achieved by increasing the resistance used (elastic bands or body weight) or by progressing to a more challenging exercise.

Exercises will be chosen according to patients’ abilities and preferences, and will be reconsidered at each visit with the physiotherapist. Each patient will receive a personalized detailed exercise prescription.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- HNSCC Patients who are scheduled for CRT

- Patients ≥18 years of age

 -Patients with sufficient Dutch writing and reading skills

- Karnofsky Performance status >60

 Able to walk ≥60 m without a mobility aid

 -No contraindication for physical activity (assessed by their physician)

Exclusion criteria

There are no exclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017
Enrollment:	37
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47819
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7100
NTR-old	NTR7305
CCMO	NL61408.041.17
OMON	NL-OMON47819

Study results