Motivational coaching to improve physical activity behaviour following a supervised 10-week exercise rehabilitation program in cancer patients

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

Summary

ID

NL-OMON55808

Source
ToetsingOnline

Brief title
Motivational coaching following supervised cancer rehabilitation

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer, Oncology

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cancer, Exercise guidelines, Motivational Coaching, Physical activity

Outcome measures

Primary outcome

The main endpoints are minutes of moderate- to- vigorous physical activity (MVPA) per week, assessed using an accelerometer and PA diary

Secondary outcome

Secondary endpoints are the VO2peak and other outcomes on the CPET (like maximal heart rate (HRpeak) and maximal work rate (Wpeak), heart rate (HR), work rate (W) and oxygen uptake (VO2) at the ventilatory anaerobic threshold (VAT) and the respiratory compensation point (RCP); anthropometrics; muscle strength; physical activity; Health Related Quality of Life (HRQoL); fatigue; anxiety and depression symptoms, return to work (RTW) rates (%), exercise participation, the experiences of participants with the transition from supervised exercise rehabilitation to community-based exercise and the acceptability of the coaching intervention. All measurements will be performed at baseline and at six months follow-up, except for the semi-structured interview which will only take place once, during the follow-up measurement. Furthermore, patient characteristics, medical treatment, attrition to other rehabilitation modalities and exercise history will be extracted from electronic patient dossiers (EPD).

Study description

Background summary

Due to improved diagnosis and treatment modalities, cancer survival rates are increasing. Consequently, the population of cancer-survivors is growing and there is an urgent need for evidence-based survivorship-care to mitigate or prevent side-effects. It has been well-established that a cancer rehabilitation program that contains exercise training, positively affects these side-effects, but less is known about the long-term effects. The existing evidence suggests that cardiorespiratory fitness (CRF) does not further increase after completing oncological rehabilitation and that cancer survivors often do not meet current exercise guidelines. Motivational coaching for exercise adherence could be effective to improve physical activity (PA) levels, CRF and other outcomes in participants after completing oncological rehabilitation.

Study objective

The main objective of this study is to examine the effect of motivational coaching following oncological rehabilitation in cancer patients, on minutes of moderate- to- vigorous physical activity (MVPA) measured after six months, with an accelerometer (MOX) and an activity diary.

Study design

Randomized Controlled Trial (RCT) with two parallel groups.

Intervention

The coaching program is called *Beweeg Bewust* and is guided by the organization *Maastricht Sport*. The objective of the coaching program is to motivate the patients to participate in exercise and to be sufficiently active according to current exercise guidelines.

In this motivational coaching program, each patient will be linked to an individual coach, who is a trained sports college student and will guide them to stay physically active. During an intake assessment, the coach will give individually tailored exercise advice, based on performance tests, personal motivation and personal preferences. The coach will help them to choose a sports activity that personally fits. Participants are offered the possibilities to attend to the groups sessions of the organisation, to go to other sports clubs or to perform exercise independently (like walking, cycling etc.) After the intake, the program mainly contains electronic coaching (e-coaching). Motivational coaching will be based on the COM-B model. In the first twelve weeks, the coach will approach the participant weekly, by e-mail,

or when preferred by telephone. In this way, the coaches will stimulate the participants to attend the sports activities. In the twelfth week , there will be an evaluation appointment to give the coach and participant insight into the progress of the participant. Intensity and frequency of coaching in the last three months, will be based on this evaluation.

Study burden and risks

Risks associated with participation in this study are considered negligible. Participants will be asked to visit the hospital once, to undergo two performance tests at follow-up. These performance tests are safe in this population, and could only result in some exhaustion or muscle soreness. Furthermore, participants will be asked to wear an accelerometer for seven consecutive days at baseline and follow-up. The accelerometer will be attached with an anti-allergic plaster, so the risk for allergic reactions is low. Participants are instructed to remove the plaster, when experiencing any itch or redness. At baseline, participants fill in three questionnaires as a part of usual care and two short structured interviews are added for the study. At follow-up these three questionnaires and structured interviews will be repeated. Furthermore, a subsample of the participants will participate in a semi-structured interview about the experiences with with the transition from supervised exercise rehabilitation to community-based exercise. This means participants have to fill in 3 extra questionnaires and will undergo 4 or 5 extra interviews for the study. During the 7-day wearing time of the accelerometer at both time points, participants have to fill in a PA diary. In total, participants of this study will be asked to spend maximal four hours of their time for all measurements.

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

- Patients who are histologically confirmed with the diagnosis of cancer
- Patients who are aged >= 18 years
- Patients who undergo / completed treatment with curative intent
- Patients who completed the oncological exercise rehabilitation program at MUMC+

Exclusion criteria

- Patient who are scheduled to undergo chemotherapy, radiotherapy or surgery in the next 6 months
- Patients with cognitive disability, who are not able to understand instructions and /or are not able to fill in the questionnaires.
- Patients who are unable to speak, understand and read the Dutch language
- Patients who are not able to perform basic activities of daily living (such as walking) or patients who are suffering from other disabling comorbidity that seriously hamper physical exercise (like severe heart failure, chronic obstructive pulmonary diseases, neurological disorders or severe polyneuropathy)
- Patients who have an increased risk of falling, as assessed on the *4-Stage Balance Test* (46).

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2019
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	01-12-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL68040.068.18