A randomized controlled trial to evaluate the effectiveness and cost-effectiveness of exercise interventions after chemotherapy on physical fitness, fatigue and quality of life.

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This present study aims to investigate the effectiveness and cost-effectiveness of a high intensity exercise program, a low-to-moderate intensity exercise program and a waiting list control group on physical fitness (cardiorespiratory fitness and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON39339

Source
ToetsingOnline

Brief title
REACT

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, cervix cancer, colon cancer, ovarian cancer, testis cancer or lymphomas cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: after chemotherapy, fatigue, physical exercise, physical fitness

Outcome measures

Primary outcome

Cardiorespiratory fitness, muscle strength and fatigue.

Secondary outcome

Secondary outcome variables include body composition and bone mineral density,

health-related quality of life, physical activity

level, satisfaction with the intervention, mood disturbances, sleep quality,

functioning in daily life and return to work.

Study description

Background summary

Cancer chemotherapy is frequently associated with a decline in general physical fitness and severe symptoms of fatigue. While accumulating evidence suggests that physical activity and exercise interventions after chemotherapy may contribute to preservation of physical fitness and reduction of fatigue. However, evidence-based recommendations regarding the optimal training approach and training intensity in cancer patients are still lacking.

Study objective

This present study aims to investigate the effectiveness and cost-effectiveness of a high intensity exercise program, a low-to-moderate intensity exercise program and a waiting list control group on physical fitness (cardiorespiratory fitness and muscle strength) and fatigue in cancer patients who completed chemotherapy.

Study design

This multicenter, prospective, randomized trial will compare two exercise programs and a waiting list contole group.

Intervention

A. High intensity exercise program

Patients allocated to the high intensity exercise program will train in groups twice a week for 12 weeks under supervision of a physiotherapist. One training session takes one hour. The high intensity exercise program includes high intensity endurance and resistance exercises. In addition, daily physical activity is stimulated using behavioural motivational techniques.

B. Low-to-moderate intensity exercise program

Patients allocated to the low-to-moderate intensity exercise program will train in groups twice a week, for 12 weeks under supervision of a physiotherapist as well. One training session takes one hour. The low-to-moderate exercise program includes the same endurance and resistance exercises compared to the high intensity exercise program, but differs in training intensity. In addition, daily physical activity is stimulated using behavioural motivational techniques.

Study burden and risks

In total, 280 consenting patients will be randomly assigned to either a 12-week high intensity exercise program or a low-to-moderate intensity exercise program. Next, patients from both groups will be randomly assigned to immediate training or waiting list (i.e. waiting list control group). After 12 weeks, patients of the waiting list control group will start with the exercise program they have been allocated to.

Both exercise programs, the high intensity exercise program and the low-to-moderate intensity exercise program, consist of 12 weeks of training, twice a week (24 h.). Furthermore behavioural motivational counselling sessions (3 h.) will be provided during and after the exercise programs to stimulate daily physical activity.

All patients participating in the randomized trial will be asked 3 times to undergo a physical fitness examination (1.15 h.) and to complete self-report questionnaires (60 min.), 4-6 weeks after chemotherapy, after completion of the exercise program and after 12 months follow-up. In addition, all patients will

be invited for a DXA scan two times (30 min.) and will be asked to complete a cost diary every three months (30 min.).

Relevance: If demonstrated to be effective, the availability of such exercise intervention programs will be a welcome addition to the standard program of care offered to cancer patients after chemotherapy treatment.

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 with histological confirmed primary breast, colon, ovarian, cervix, testis cancer or lymphomas with no indication of recurrent or progressive disease, who completed ((neo)adjuvant) chemotherapy with curative intention, are eligible for this study.

Exclusion criteria

Patients who are not able to perform basic activities such as walking or biking, who show cognitive disorders or severe emotional instability, who are suffering from other disabling comorbidity that might hamper physical performance capacity (e.g. heart failure, chronic obstructive pulmonary disease (COPD), orthopaedic conditions and neurological disorders), and patients who are unable to understand and read the Dutch language will be excluded from the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2011
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	14-10-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2011

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL32880.015.10