Effectiveness of physical exercise during chemotherapy to improve physical fitness and reduce fatigue: A randomized trial

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

Summary

ID

NL-OMON32716

Source
ToetsingOnline

Brief title
PACES: Physical exercise during Adjuvant Chemotherapy Effectiveness Study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer en colon cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut

Source(s) of monetary or material Support: KWF Kankerbestrijding;via de Alpe d'HuZes stichting (onderdeel KWF Kankerbestrijding)

Intervention

Keyword: During adjuvant chemotherapy, Fatigue, Physical exercise, Physical fitness

Outcome measures

Primary outcome

The primary outcomes will be physical fitness as assessed with objective performance indicators, and self-reported fatigue.

Secondary outcome

Secondary study outcomes will include self-reported physical activity and physical functioning, mood state and HRQL. Additionally, compliance and satisfaction with the interventions will be evaluated by self-report.

Potential moderating variables, including pre- and post-illness lifestyle, and health- and exercise-related attitudes, beliefs and motivation, will also be assessed.

Study description

Background summary

Cancer chemotherapy is frequently associated with a decline in general physical condition, exercise tolerance, and muscle strength, and with an increase in fatigue. While accumulating evidence suggests that physical activity and exercise interventions during chemotherapy treatment may contribute to preservation of physical fitness and strength, the results of studies conducted to date have not been entirely consistent. Additional research is needed to determine the optimal intensity of exercise training programs, in general, and in particular the relative effectiveness of supervised, outpatient (clinic- or

physical therapy practice-based) versus home-based programs.

Study objective

This study will evaluate the efficacy of: a low intensity, home-based, self-management physical activity program, and a moderate intensity, structured, supervised exercise program, in maintaining or enhancing physical fitness (cardiorespiratory fitness and muscle strength), in minimizing fatigue, and in enhancing the health-related quality of life (HRQL) of patients undergoing adjuvant chemotherapy for breast cancer or colon cancer.

Study design

This multicenter, prospective, randomized trial will compare two interventions with usual care.

Intervention

Onco-Move is a relatively low intensity, home-based, individualized, self-managed physical activity program based on the *Every Step Counts* program of Mock. It uses self-management principles to maintain physical condition and prevent fatigue. Nurses encourage patients to pursue an active lifestyle, including walking, cycling, fitness or swimming, 30 minutes per day (at Borg level 12-14), throughout the chemotherapy treatment. Training with weights is not encouraged. In this program, general information (both verbal and written) is provided about physical activity training.
OnTrack is a relatively intensive, structured, individualized and supervised physical exercise program supervised by a physical therapist in an outpatient or general practice setting. It comprises exercises to maintain or increase cardiorespiratory fitness, and exercises to maintain or increase muscle strength. The cardiorespiratory exercises are done twice a week, 30 minute per session, with an intensity of 60% to 80% of the estimated maximal heart rate, or a score of 12 to 14 on the Borg scale of perceived exertion. The muscle strength program is also practiced twice a week (during the same sessions), 20 minutes per session, starting with 2 series of 15 repetitions at 50%1RM per exercise and increasing gradually to less repetitions at higher load. The participants are also encouraged to be physically active for at least 30 minutes per day at Borg level 12-14. The OnTrack program starts with a baseline assessment before the first cycle of chemotherapy and continues until 3 weeks after the last cycle of chemotherapy.
Usual care will vary according to hospital guidelines and doctors* and patients* preferences, but will not involve routine, systematic exercises.

Study burden and risks

In total, 360 consenting patients will be randomized to one of the two

intervention groups or to a usual care control group. All patients will be asked to undergo performance tests and to complete self-report questionnaires prior to randomization (T0), at the completion of chemotherapy (T1), and at 6 month follow-up (T2).

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

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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 histologically confirmed primary breast or primary colon cancer who are scheduled to undergo adjuvant chemotherapy with curative intent.

Exclusion criteria

Patients with comorbid conditions that would contraindicate participation in a physical activity/exercise program.
This includes patients with serious orthopedic conditions that would hamper functional recovery, and patients with serious cardiovascular or cardiopulmonary conditions (or risks) who would not be able to train at the intensity level required by the programs. Patients suffering from malnutrition as evidenced by a BMI < 18 kg/m2, unintended weight loss of more than 5% per month, or more than 10% unintended weight loss during the previous 6 month period will be considered poor candidates for physical condition training and thus will not be eligible for participation. Patients judged to have serious psychiatric or cognitive problems that would preclude them from program participation will be excluded from the study. For assessment purposes, study participants will need to have basic fluency in the Dutch language. Patients participating in concurrent studies or rehabilitation programs containing elements of physical activity or exercise will also be considered ineligible for the study.

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:	Recruitment stopped
Start date (anticipated):	15-03-2010
Enrollment:	360
Type:	Actual

Ethics review

Approved WMO

Date:	14-01-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL30093.031.09