# PACES: Physical exercise during Adjuvant Chemotherapy Effectiveness Study.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20755

**Source**
Nationaal Trial Register

**Brief title**
PACES

**Health condition**

breast cancer, colon cancer, borstkanker, darmkanker

### Sponsors and support

**Primary sponsor:** Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI AVL)
**Source(s) of monetary or material Support:** Dutch Cancer Society

### Intervention

### Outcome measures

**Primary outcome**

1. Cardiorespiratory fitness;

2. Muscle strength;

3. Self-reported fatigue.

**Secondary outcome**

1. Mood disturbance;

2. Self-reported physical activity level;

3. Functioning in daily life;

4. Health-related quality of life;

5. Quality of sleep;

6. Measured physical activity level;

7. Chemotherapy completion rates;

8. Complaince;

9. Statisfaction with intervention;

# Study description

**Background summary**

Background:

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.

Objective:

This study will evaluate the efficacy and cost-effectiveness 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.

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).

Study population:

In total, 360 consenting patients undergoing adjuvant chemotherapy for breast cancer or colon cancer.

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.

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, HRQL, Quality of sleep, Measured physical activity level and Chemotherapy completion rates. 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.

Relevance:

If demonstrated to be effective, the avialability 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.

**Study objective**

The primary research hypotheses are:

1. Patients who follow the Onco-Move program will achieve better physical fitness levels, as assessed by objective performance tests, and will report less fatigue than patients in the usual care control group;

2. Patients who follow the OnTrack program will achieve better physical fitness levels, as assessed by objective performance tests, and will report less fatigue than patients in the

usual care control group.

The secondary research hypotheses are:

3. Patients who follow the Onco-Move or the OnTrack program will report less mood disturbance, higher levels of physical activity and functioning in daily life, and better health-related quality of life than patients in the usual care control group;

4. Patients who follow the OnTrack program will maintain and/or achieve more muscle strength than patients who follow the Onco-Move program. The OnTrack program is also expected to achieve greater gains in cardiorespiratory fitness than the Onco-Move program. However, the magnitude of these differences is expected to be smaller than those observed between the OnTrack program and the usual care control group. No differences are expected between the two programs in self-reported outcomes during treatment. However, it is hypothesized that, at the 6 month follow-up, patients who participated in the OnTrack program will report less fatigue, and higher levels of physical activity and functioning than those who participated in the Onco-Move program.

Baseline assessments of (self-reported) activity levels, lifestyle, attitudes and beliefs regarding physical activity and fitness may be helpful in identifying subgroups of patients for whom the two intervention programs are more or less appropriate/effective. However, the core evaluation of program effectiveness will be based on the intact groups; subgroup analyses will be of an exploratory nature (see also the paragraph on statistical analysis).

**Study design**

All primary outcomes will be assessed at baseline (prior to randomization) (T0), at completion of chemotherapy (T1), and at 6 months follow-up after completion of chemotherapy (T2). Patients will follow different chemotherapy regimens of varying length, resulting in a varying time from baseline to the measurement at T1.

**Intervention**

1. Onco-Move;

2. OnTrack.

1. 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.

2. 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.

The control group will recieve usual care. Usual care will vary according to hospital guidelines and doctors' and patients' preferences. Although usual care can not be standardized, it will not involve routine, systematic exercises.

## Contacts

**Public**
Plesmanlaan 121
H. Waart, van
Amsterdam 1066 CX
The Netherlands
+31 (0)20 5122474
**Scientific**
Plesmanlaan 121
H. Waart, van
Amsterdam 1066 CX
The Netherlands
+31 (0)20 5122474

## Eligibility criteria

### 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

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-02-2010 |
| Enrollment: | 360 |

| | |
|---|---|
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 11-01-2010 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL2042 |
| NTR-old | NTR2159 |
| Other | PTC09.2711/P09PHY (METc NKI-AVL) : NKI 2009-4299 (KWF) / NL30093.031.09 (CCMO) / |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

## Study results

**Summary results**
N/A