



PACES: Physical exercise during Adjuvant Chemotherapy Effectiveness Study

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Background

Cancer chemotherapy is frequently associated with a decline in general physical condition 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.

Aim

To evaluate the effectiveness and cost-effectiveness of
1) a moderate intensity, home-based, physical activity program
2) a high intensity, structured, supervised exercise program
in patients undergoing adjuvant chemotherapy for breast cancer or colon cancer.

Methods

Study design: This multicenter, prospective, randomized trial will compare two interventions (Onco-Move and OnTrack) with usual care.

Study population: Patients undergoing adjuvant chemotherapy for breast cancer or colon cancer (n=360)

Intervention

Onco-Move: Moderate intensity, home-based, self-management physical activity program

Patients receive encouragement and general information (both verbal and written) by oncology nurses.

- Daily 30 minutes of activity
- Walking, cycling, swimming, ..
- Training with weights is not encouraged

Usual care will vary according to hospital guidelines and doctors' and patients' preferences, but will not involve routine, systematic exercises.

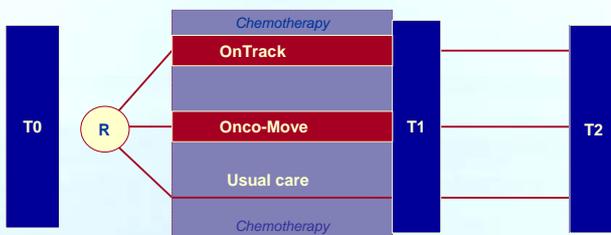
OnTrack: High intensity, structured, exercise program supervised by a physical therapist

- 2 sessions per week:
 - Muscle strength exercises
 - 20 minutes per session
 - 2 x 15 rep. 50%1RM increasing to higher load
 - 6 exercises (large muscle groups)
 - Aerobic exercises
 - 30 minutes (minimal 15 min. per exercise)
 - 60% to 80% of maximal heart rate
- Daily 30 minutes of activity

Research Design and Study Outcomes

In total, 360 consenting patients will be randomized (R) to one of the two intervention groups or to the 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).

Figure 1. Design and measurements



Main study outcomes:

- Cardiorespiratory fitness
 - Steep ramp test and Exercise endurance
- Muscle strength
 - Upper extremity: JAMAR® grip strength, microFET®
 - Lower extremity: 30s chair stands test, microFET®
- Self-reported fatigue (questionnaires)
 - Multidimensional Fatigue Inventory (MFI)
 - Fatigue Quality List (FQL)

Secondary study outcomes: will include self-reported physical activity (PASE), measured physical activity level (Accelerometer) and functioning in daily life (IPA), mood state (HADS), health-related quality of life (EORTC QLQ-C30) and quality of sleep (PSQI), chemotherapy completion rates and anthropometric measures (skinfold + waist-hip). At T1 compliance and satisfaction with the interventions will be evaluated by self-report.

Results

The project will have a total duration of 4 years.

Twelve hospitals in the broader Amsterdam region of the Netherlands are participating in this trial. Patient recruitment has had a staggered start since April 2010, and will continue until January 2012.

To date, 19 patients have been recruited into the trial.

Discussion

This large, multicenter, randomized clinical trial will provide additional empirical evidence regarding the effectiveness of physical exercise during adjuvant chemotherapy in maintaining or enhancing physical fitness and minimizing fatigue.

If demonstrated to be effective, exercise intervention programs will be a welcome addition to the standard program of care offered to patients with cancer undergoing chemotherapy.

