Physical Activity during Cancer Treatment study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26673

Source
NTR

Brief title
PACT

Health condition

physical exercise; cancer; adjuvant treatment; fatigue; cost-effectiveness

Sponsors and support

Primary sponsor: Comprehensive Cancer Center Middle Netherlands
Comprehensive Cancer Center Limburg
University Medical Center Utrecht
Maasticht University
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Fatigue;

2. Health service utilization;

3. Sick leave.

Secondary outcome

1. Health related quality of life;

2. Physical fitness (aerobic peak capacity, muscle strength);

3. Body composition;

4. Self-efficacy.

Study description

Background summary

Physical Activity during Cancer Treatment (PACT) Study: a randomised clinical trial of physical exercise during cancer treatment.

Rationale for the study:

Cancer related fatigue is one of the major problems of cancer patients. Sixty% - 96% of the cancer patients report high levels of fatigue during or after cancer treatment. We hypothesise that early physical exercise will increase physical fitness and thereby diminish complaints of fatigue. This may result in a decrease of healthcare related expenditures by reducing healthcare utilisation and production loss due to sick leave.

Research questions:

1. Is an 18-week group wise supervised exercise programme during adjuvant cancer treatment effective in reducing complaints of fatigue and health service utilisation and sick leave (primary outcomes) and in improving health related quality of life, physical fitness, body composition and self efficacy (secondary outcomes)?

Study design:

Randomised controlled clinical study.

Study population:
A total of 300 newly diagnosed patients with breast or colorectal cancer admitted for adjuvant cancer treatment including chemotherapy.

Intervention:
The intervention group will receive an 18 week supervised group exercise programme including principles of Bandura's social cognitive theory (SCT) during cancer treatment. The exercise programme will start earliest one week after surgery and < 6 weeks after definite diagnosis. The control group will receive care as usual (no exercise programme).

Outcome:
Exercise is supposed to reduce fatigue and health service utilisation and sick leave. Primary and secondary outcomes will be assessed immediately after ending the intervention (after 18 weeks: short term) and after 9 months (long term).

Primary outcomes: Fatigue (Multidimensional Fatigue Inventory), health service utilisation, sick leave.

Secondary outcomes: Health related quality of life (EORTC QOL C30, EQ5D), physical fitness (aerobic peak capacity, muscle strength), body composition and self efficacy.

Sample size calculation and data analysis:
A sample size of 150 participants for each cancer type, 300 in total, will be required to detect a significant reduction in complaints of fatigue (p=0.05, 80% power). Data will be longitudinally analysed, using mixed linear regression models.

Economic evaluation:
The goal of the economic evaluation is to assess the balance between (in)direct costs and (long term) effects of the exercise programme versus no exercise programme during cancer treatment. We will generate incremental cost-effectiveness ratios (ICER) to capture the added value of the exercise programme.

Study objective

We hypothesize that physical exercise during cancer treatment by reducing complaints of fatigue will lead to a reduction in sick leave and production losses. Altogether we expect that physical exercise during cancer treatment will be cost-effective.

Study design

Baseline, 18 weeks and 9 months after inclusion.

Intervention

The intervention group will receive an 18 week supervised group exercise program based on Bandura’s social cognitive theory (SCT) during cancer treatment. The exercise program will start earliest one week after surgery and at least within six weeks (breast cancer) or ten weeks (colon cancer) after definitive cancer diagnosis. The control group will receive care as usual (no exercise program).

Contacts

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Eligibility criteria

Inclusion criteria

Patients diagnosed with breast or colon cancer (M0) who will be treated with chemotherapy.

Inclusion criteria are:

1. Histological diagnosis of cancer < 6 weeks ago;

2. Adjuvant treatment including chemotherapy;

3. Age 25-75 years;

4. Able to read and understand the Dutch language;

5. Karnofsky Performance Status ¡Ý 60;

6. Able to walk ¡Ý 100 meter.

Exclusion criteria

Exclusion criteria are:

1. Treatment for cancer during the past five years (except basal skin cancer);

2. Contra-indications for physical activity (R-PARQ).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-12-2009
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	NL2021
NTR-old	NTR2138
Other	ZonMw / METC UMC Utrecht : 171002202 / 07/271/O
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A