ISRCTN43801571 https://doi.org/10.1186/ISRCTN43801571

# Physical activity during cancer treatment (PACT) study

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 17/12/2009 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 26/01/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 17/07/2020 | Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
NTR2138

# Study information

### Scientific Title
A randomised clinical trial of physical exercise during cancer treatment: the PACT study

### Acronym
PACT

### Study objectives
We hypothesise that early physical exercise 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.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Medical Ethics Committee of the University Medical Centre Utrecht, 27/02/2008, ref: 07/271/O

### Study design
Multicentre pragmatic randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Quality of life

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied
Breast cancer/colon cancer

### Interventions
During an intake, patients will be included, baseline measurements will be taken and patients will be randomly allocated to the intervention or control group. Participants assigned to the intervention group will receive usual care in combination with an 18-week supervised group exercise program. They will be encouraged to attend the exercise program two times a week supervised by a physiotherapist.

Participants who will be assigned to the control group will receive usual care, i.e., no exercise intervention.

We will assess the short term as well as the long term effects. Short-term effects will be measured 18 weeks after inclusion (at the end of the program) and long term effects will be measured 9 months after inclusion.

### Intervention Type
Behavioural

### Primary outcome measure
Measured at baseline, 18 weeks and 9 months:
1. Fatigue
2. Health service utilisation and sick leave

### Secondary outcome measures
Measured at baseline, 18 weeks and 9 months:
1. Health related quality of life
2. Anxiety and depression
3. Physical fitness
4. Body composition
5. Cognitive behavioural aspects
6. Physical activity level

### Overall study start date
01/01/2010

### Completion date
31/12/2012

## Eligibility

### Key inclusion criteria
1. Recently diagnosed with breast or colon cancer (stage M0): histological diagnosis of cancer less than six (breast cancer) or ten (colon cancer) weeks ago
2. Treated with chemotherapy
3. Aged 25 - 75 years, either sex
4. Able to read and understand the Dutch language
5. Karnovsky Performance Status of 60 or higher
6. Able to walk 100 metres or more

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
300

### Total final enrolment
92

### Key exclusion criteria
1. Treated for cancer in the past five years (except basal skin cancer)
2. Contraindications for physical activity (Revised Physical Activity Readiness Questionnaire)

### Date of first enrolment
01/01/2010

### Date of final enrolment
31/12/2012

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Universitair Medisch Centrum Utrecht**
Utrecht
Netherlands
3508 GA

## Sponsor information

### Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

### Sponsor details
Laan van Nieuw Oost Indië 334
Den Haag
Netherlands
2593 CE
-
rossum@zonmw.nl

### Sponsor type
Research organisation

### Website
http://www.zonmw.nl/

### ROR
https://ror.org/01yaj9a77

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Netherlands Organisation for Health Research and Development

**Alternative Name(s)**
Netherlands Organisation for Health Research and Development

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
Netherlands

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 09/06/2010 | | Yes | No |
| Results article | results | 08/06/2015 | | Yes | No |
| Results article | results | 01/05/2016 | | Yes | No |
| Results article | results | 08/05/2019 | 10/01/2020 | Yes | No |
| Results article | follow up results | 16/04/2020 | 17/07/2020 | Yes | No |