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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

Protocol serial number
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

Study type(s)
Quality of life

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(s)
Measured at baseline, 18 weeks and 9 months:
1. Fatigue
2. Health service utilisation and sick leave

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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?
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
Protocol article	protocol	09/06/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes