The effect of exercise on breast cancer patients* quality of life using the cmRCT design: The UMBRELLA Fit trial

Published: 26-05-2015
Last updated: 13-01-2025

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON47246

Source
ToetsingOnline

Brief title
UMBRELLA Fit trial

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Jullius Centrum voor Gezondheidswetenschappen en Eerstelijnsgeneeskunde
Source(s) of monetary or material Support: ZonMw VENI subsidie

Intervention

Keyword: breast cancer, cmRCT, exercise, quality of life

Outcome measures

Primary outcome

The primary endpoints for this study are: quality of life (primary patient-related outcome), fatigue, and physical activity levels on the long-term.

Secondary outcome

Secondary outcomes are methodological: i.e. contamination, participation, retention and the composition of the study population.

Study description

Background summary

The evidence for beneficial effects of exercise training in breast cancer survivors is growing, however, the long-term effects of structured exercise programmes are not clear yet. Furthermore, former trials have been performed in a highly controlled lab setting and included patients comprised a selected group of relatively young, high educated women who were physically active before diagnosis. Inclusion of this selected group might have led to contamination (i.e. control participants adopt the exercise intervention) in these trials which might have diluted results and explain part of the small effect sizes found. Exercise-oncology trials also suffer from difficult accrual since eligible patients do not want to be randomized to the control group. To overcome these problems, the cohort multiple Randomised Controlled Trial (cmRCT) is hypothesized be a more suitable design for this field. In a cmRCT, the intervention study is performed embedded in an on-going prospective cohort study with regular follow-up measurements. This design also provides an excellent opportunity to gain long-term results.

Study objective

Aim of this study is to assess the effects of exercise intervention on breast

cancer patients* quality of life on the short (6 months) and long-term (24 months) according to the cmRCT design and to test the utility of the cmRCT design in the field of exercise oncology.
Study design: Randomized controlled trial, nested within a prospective cohort (UMBRELLA) according to the *cohort multiple randomized controlled trial* (cmRCT) design. UMBRELLA is a prospective cohort study including all breast cancer patients visiting the UMC Utrecht department of Radiotherapy .

Study design

The cohort multiple Randomised Controlled Trial (cmRCT) design

Intervention

A 12-week structured exercise programme, consisting of two one-hour supervised fitness group sessions at a physiotherapist centre per week. The training programme is a combination of high intensity endurance training and strength training.

Study burden and risks

Burden and risk: Patients randomized to the intervention group will be invited twice for a 2-hour visit to the research center for filling out extra questionnaires, a physical examination, and several physical tests (at baseline and at 12-weeks follow-up). Furthermore, patients in the intervention group are invited to participate in a 12*week exercise program of 2 hours twice weekly. The estimated extra risk for the patient while participating in this study is low. To minimize the risk of injuries during exercise, the intensity of the exercise program will be gradually increased during the study and the program will be supervised by a physiotherapist. We will try to reduce the burden of travelling to the training facilities by offering the exercise program by physiotherapists nearby the patients* home.
Benefit: We expect that the exercise program will have a beneficial effect on the patients* health status. After study cessation, we will sent all UMBRELLA participants the results of the study accompanied with an exercise advice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject should first be included in UMBRELLA. The inclusion criteria of the UMBRELLA cohort are:
- adult women with primary curatively treated breast cancer (stage I-III) visiting the radiotherapy department of the University Medical Center Utrecht
- mentally component to sign informed consent
- able to speak, read and understand Dutch;Specific citeria for the UMBRELLA Fit trial
- 18-75 years of age
- 12 months-18 months after inclusion in the UMBRELLA cohort
- finished primary breast cancer treatment (except hormal therapy)
- an inactive lifestyle
- informed consent given in UMBRELLA for being invited for future research/ intervention studies;An inactive lifestyle is determined as <150 minutes per week performing moderate to intensive (><= 4 MET) leisure time and sports activities/exercise (based on the SQUASH questionnaire).

Exclusion criteria

- contra-indications for exercise, e.g. neurological problems (balance, dizziness), arrhythmias, walking problems and uncontrolled high blood pressure.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2015
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	26-05-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-02-2016
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-05-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20644
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52062.041.15
OMON	NL-OMON20644