UMBRELLA Fit

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1. We hypothesize that exercise training in breast cancer survivors positively affects patients quality of life, on the short- and longterm.2. We hypothesize that the cohort multiple Randomised Controlled Trial (cmRCT) is a more suitable design for...

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20644

Source
NTR

Brief title
UMBRELLA Fit

Health condition

Breast cancer

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: NWO-VENI

Intervention

Outcome measures

Primary outcome

- Quality of life
- Fatigue
- Anxiety and depression

- Physical activity level and sedentary time

Secondary outcome

- Contamination
- Participation
- Retention
- Composition of the study population

Study description

Background summary

Rationale: 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 comprising a selected group of relatively young, and 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. Moreover, it hampers generalization of results. 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. 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. In addition, we will evaluate the concept 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 population: Breast cancer patients participating in the UMBRELLA cohort who meet the following criteria: 1) UMBRELLA informed consent for randomization to future research/ intervention studies; 2) 18-75 years of age; 3) 12 months to18 months post diagnosis, 4) primary cancer treatment completed (except for hormonal treatment), and 5) a physically inactive lifestyle.

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.

Main study parameters/endpoints: The primary endpoints for this study are: quality of life (primary patient-related outcome), fatigue, and physical activity levels on the long-term. Secondary outcomes are methodological: i.e. contamination, participation, retention and the composition of the study population.

Study objective

1. We hypothesize that exercise training in breast cancer survivors positively affects patients quality of life, on the short- and longterm.
2. We hypothesize that the cohort multiple Randomised Controlled Trial (cmRCT) is a more suitable design for exercise-oncology trials.

Study design

- Baseline (start exercise programme)
- 12 weeks (end exercise programme)
- Questionnaires at regular intervals within the UMBRELLA cohort (after diagnosis, 6, 12, 18, 24, 36, 48, etc. months)

Intervention

- Intervention group: 12-week structured exercise programme with two combined strength- and endurance trainingssessions a week under supervision of a physiotherapist. In addition, patients will be asked to increase physical activity outside the program and reduce sedentary behaviour.
- Control group: care as usual

Contacts

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Eligibility criteria

Inclusion criteria

- Adult women with breast cancer visiting the radiotherapy department of the University Medical Center Utrecht
- Mentally able to understand and sign informed consent
- Able to speak, read and understand Dutch
- UMBRELLA informed consent for randomization to future research/ intervention studies
- 18-75 years of age
- 12 months to18 months post diagnosis
- Primary cancer treatment completed (except for hormonal treatment)
- Physically inactive lifestyle (<150 min per week moderate to intensive activities (>= MET4))

Exclusion criteria

Contra-indications for excercise

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2015

Enrollment:	260
Type:	Actual

Ethics review

Positive opinion
Date: 07-12-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47246
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5381
NTR-old	NTR5482
CCMO	NL52062.041.15
OMON	NL-OMON47246

Study results

Summary results
Gal R, Monninkhof EM, Groenwold RHH, van Gils CH, van den Bongard DHJG, Peeters PHM, Verkooijen HM, May AM. The effects of exercise on the quality of life of patients with breast cancer (the UMBRELLA Fit study): study protocol for a randomized controlled trial. Trials. 2017;18:504. doi:10.1186/s13063-017-2252-5.