

UMBRELLA Fit

Gepubliceerd: 07-12-2015 Laatste bijgewerkt: 13-01-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20644

Bron

NTR

Verkorte titel

UMBRELLA Fit

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: UMC Utrecht

Overige ondersteuning: NWO-VENI

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Quality of life

- Fatigue

- Anxiety and depression

- Physical activity level and sedentary time

Toelichting onderzoek

Achtergrond van het onderzoek

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 to 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 to 18 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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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)

Onderzoeksproduct en/of interventie

- 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

Contactpersonen

Publiek

UMC Utrecht, Julius center - kamernummer 6.119

Roxanne Gal
Huispostnummer Str. 6.131 - Postbus 85500

Utrecht 3508 GA
The Netherlands
T +31 (0)88 75 696 24

Wetenschappelijk

UMC Utrecht, Julius center - kamernummer 6.119

Roxanne Gal

Huispostnummer Str. 6.131 - Postbus 85500

Utrecht 3508 GA

The Netherlands

T +31 (0)88 75 696 24

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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 to 18 months post diagnosis
- Primary cancer treatment completed (except for hormonal treatment)
- Physically inactive lifestyle (<150 min per week moderate to intensive activities (\geq MET4))

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contra-indications for exercise

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	14-11-2015
Aantal proefpersonen:	260
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	07-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47246
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.