UMBRELLA Fit trial
An exercise intervention study within UMBRELLA

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Previous exercise-oncology studies

OncoRev \(\rightarrow\) randomization to control not possible

Pilot PACT \(\rightarrow\) adapted Zehlen design
Pilot PACT study (n=64)

- Modified Zelen design with consent to postponed information
- Problems:
  - Drop-out intervention group > d-o control group
  - Patients met each other
  - Difficulty with blinding during campaign/inclusion

→ PACT study: conventional randomization

- Velthuis MJ, May AM, Monninkhof EM et al. Alternatives for randomization in lifestyle intervention studies in cancer patients were not better than conventional randomization; J.Clin.Epidemiol. 2012
Previous studies

OncoRev → randomization to control not possible

Pilot PACT → design not feasible

PACT study: 3% contamination in the control group

New design is needed!
Exercise-oncology TwiCs

Challenges
• Immediate drop out?
  • Intervention is time consuming
  • Motivation for exercise
• Compliance during intervention?

→ Feasibility study and methodology
Informed consent:

1) Collection of clinical data & patient reported outcomes (90%)

Optional:
2) To be invited for future interventional studies (87%)

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PROSPECTIVE COHORT

Random selection

Exercise group
Control group

Subpopulation

Re古代测量

Diagnosis (Radiotherapy)  6-m  12-m  18-m  24-m  36-m  48-m  ...

UMBRELLA FIT inclusion and follow-up

Repeated measurements

UMC Utrecht Julius Center
UMBRELLA Fit trial

• ~ 150 patients with breast cancer
  (75 pts participating in the exercise intervention)

• 12-week supervised exercise intervention

• QoL, fatigue, physical fitness assessment at BL and 12-week in the intervention group
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• Outcome:
  • Compliance – PA level (intervention and control)
  • Participation rate and intervention-compliance (intervention)
  • Drop-out (intervention and control)

• Short- and long-term QoL, fatigue

UMBRELLA Fit trial - Methodology

- BL&12-week measurements vs regular cohort measurements
- Ongoing sampling until 75 participants who accept the intervention are included?
- Predict compliance in the control group (IV analyses)
- Replacement of control group participants who drop out?

- Simulation studies on acceptance rate needed to detect effects
- Sample size calculation