# OncoRev study.

No registrations found.

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

## Summary

### ID

NL-OMON22705

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

cancer

### Sponsors and support

**Primary sponsor:** KWF
Universiteit Maastricht
**Source(s) of monetary or material Support:** Josephine Nefkens Stichting (Erasmus MC)

### Intervention

### Outcome measures

**Primary outcome**

Quality of life.

**Secondary outcome**

1. Fatigue;

2. Self-efficacy (sense of control);

3. Moderating variables focussing at predictors for success (social-demographics variables, disease and treatment related items, psycho-social variables, process variables, social support and use of medical services and medication);

4. Illness perceptions;

5. Self-management/empowerment;

6. Physical condition: maximal: maximal oxygen uptake, maximal heart rate, total work time, HR at steady state, muscular force;

7. Level of activity.

# Study description

### Background summary

The purpose of the present study is to evaluate the effectiveness of a standardised multi-dimensional rehabilitation program for (ex-)patients with cancer on quality of life when compared to physical exercise and a waiting list control group.

After baseline testing, the multidisciplinary and physical rehabilitation group participate in the rehabilitation program for twelve weeks. Halfway and after completion of the rehabilitation program, baseline testing will be repeated.
To determine the long-term effectiveness of the rehabilitation, the questionnaires will be assessed three and nine month after the end of the rehabilitation program.

### Study objective

Multidisciplinary oncological rehabilitation program has a greater effect on quality of life as compared to physical training and no treatment directly after intervention and in the long term.

### Study design

N/A

### Intervention

1. Multidisciplinary oncological rehabilitation program: pysical training combined with psycho-education (12 weeks);

2. Physical training (12 weeks);

3. Waiting list control group (12-24 weeks).

# Contacts

**Public**
University Medical Center Utrecht (UMCU),
Julius Centrum, STR. 6.131,
P.O. Box 85060
A.M. May-deGroot
Utrecht 3508 AB
The Netherlands
+31 (0)30 2539308
**Scientific**
University Medical Center Utrecht (UMCU),
Julius Centrum, STR. 6.131,
P.O. Box 85060
A.M. May-deGroot
Utrecht 3508 AB
The Netherlands
+31 (0)30 2539308

# Eligibility criteria

## Inclusion criteria

1. Age over 18;

2. Diagnosis of cancer (all types included);

3. Last treatment minimally two month;

4. Life expectation of minimally one year;

5. Minimally three times the answer “yes” on the following questions:

a. Physical complaints like aching muscles, problems with coordination, headache, nausea, heart palpitations, shortness of breath;

b. Reduced physical capacity as compared to before the illness, e.g. less able to walk, cycle

or walk;

c. Psychological problems like increased level of anxiety, depression, uncertainty, shortage of energy or nervousness;

d. Increased level of fatigue;

e. Sleep disturbances;

f. Problems of coping with reduced physical and psychosocial functioning due to cancer;

6. Knowledge of the Dutch language.

### Exclusion criteria

1. Category 3 or 4 of the scheme of Winningham (Winningham 1991);

2. Inability of travelling independently to the rehabilitation centre;

3. Cognitive disorder that might impede the participation in the rehabilitation program (for example: subjects who are unable to be instructed, to think in three dimensions, to fill in questionnaires);

4. Emotional instability that is expected to possibly impede the participation in the rehabilitation program (for example getting divorced at the moment, death of a loved one);

5. Certain restricted risks due to the disease and/or serious co-morbidity (cardiovascular disease, history of long pathology (COPD), diabetes, rheumatoid arthritis;

6. History of and/or actual serious psycho-pathology, psychotic complaints or alcohol abuse;

7. Restricted side-effects of medication (e.g., psycho-pharmaca in high doses);

8. Need for intensive medical treatment or rehabilitation;

9. Participation in any other clinical trial that measures quality of life or physical functions (exception: follow-up evaluation of clinical trials).

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-03-2004 |
| Enrollment: | 225 |
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 09-09-2005 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL255 |

| Register | ID |
| --- | --- |
| NTR-old | NTR293 |
| Other | : N/A |
| ISRCTN | ISRCTN 68530111 |

# Study results

**Summary results**
N/A