OncoRev study: effect of a multi-disciplinary rehabilitation program for cancer patients on quality of life - a randomised controlled multicentre trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/12/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/12/2005 Last Edited	Completed Condition category	Results		
		Individual participant data		
17/09/2008	Cancer	Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr A M May-de Groot

Contact details

University Medical Center Utrecht Julius Centrum STR. 6.131 P.O. Box 85060 Utrecht Netherlands 3508 AB +31 (0)30 2539308 a.m.may@umcutrecht.nl

Additional identifiers

Protocol serial number

NTR293

Study information

Scientific Title

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, single blind, placebo controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer

Interventions

- 1. Multidisciplinary oncological rehabilitation program: physical training combined with psychoeducation (12 weeks)
- 2. Physical training (12 weeks)
- 3. Waiting list control group (12 24 weeks)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Ouality of life

Key secondary outcome(s))

- 1. Fatique
- 2. Self-efficacy (sense of control)
- 3. Moderating variables focusing 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, heart rate (HR) at steady state, muscular force

7. Level of activity

Completion date

31/12/2006

Eligibility

Key inclusion criteria

- 1. Aged over 18 years
- 2. Diagnosis of cancer (all types included)
- 3. Last treatment minimally two month
- 4. Life expectation of minimally one year
- 5. Minimum of three answer yes to the following questions:
- 5.1. Physical complaints like aching muscles, problems with coordination, headache, nausea, heart palpitations, shortness of breath
- 5.2. Reduced physical capacity as compared to before the illness, e.g. less able to walk, cycle or walk
- 5.3. Psychological problems like increased level of anxiety, depression, uncertainty, shortage of energy or nervousness
- 5.4. Increased level of fatigue
- 5.5. Sleep disturbances
- 5.6. Problems of coping with reduced physical and psychosocial functioning due to cancer
- 6. Knowledge of the Dutch language

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key 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 lung pathology [chronic obstructive pulmonary disease], 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)

Date of first enrolment

15/03/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation

Dutch Cancer Society and Maastricht University (The Netherlands)

ROR

https://ror.org/02jz4aj89

Funder(s)

Funder type

Charity

Funder Name

Josephine Nefkens Foundation (Josephine Nefkens Stichting) (The Netherlands) - Erasmus Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes