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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
17/09/2008

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.oncorev.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer

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

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Quality of life

Secondary outcome measures
1. Fatigue
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

Overall study start date
15/03/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
225

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)

Sponsor details
P.O. Box 75508
Amsterdam
Netherlands
1070 AM

Sponsor type
Charity

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration