OncoRev study.

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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.

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

Samenvatting

ID

NL-OMON22705

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

cancer

Ondersteuning

Primaire sponsor: KWF
Universiteit Maastricht
Overige ondersteuning: Josephine Nefkens Stichting (Erasmus MC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-03-2004
Aantal proefpersonen:	225
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL255
NTR-old	NTR293
Ander register	: N/A
ISRCTN	ISRCTN 68530111

Resultaten

Samenvatting resultaten

N/A