

Development of an optimal program for the rehabilitation of cancer patients after chemotherapy

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Ethical review	-
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31213

Source

ToetsingOnline

Brief title

Development of an optimal program for cancer patients after chemotherapy

Condition

- Other condition

Synonym

cancer, deconditioning, side effect

Health condition

nieuwvormingen, (1)bijwerkingen inherent aan de behandeling: chemotherapie en bestraling.
(2)Deconditionering

Research involving

Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum

Source(s) of monetary or material Support: Stichting "Bevordering gezondheidszorg Veldhoven" Secretaris dhr. HW Heijmans", Kleine Dreef 41, 5304 LG, Veldhoven, Stichting Onderzoek en Stimulatie Sport en Bewegen bij kanker

Intervention

Keyword: cancer, chemotherapy, quality of life, rehabilitation

Outcome measures

Primary outcome

Physical capacity (muscle strength and condition), body composition, fatigue, quality of life and feeding.

Secondary outcome

not of application

Study description

Background summary

cancer is an invasive disease. This disease and his treatment have invasive consequences on the quality of life of the patient. Research shows that 75-96% of all cancer patients treated with chemotherapy and 75-100% of cancer patients treated with radiotherapy have complaints of fatigue. This fatigue has influence on the daily functioning. The causes of fatigue are complex and multifactorial. Psychological and physical factors that follows after cancer plays a role. A greater part of medical doctors prescribed rest for optimal recovery. According to recent understandings this appears not the good advice. Recent studies demonstrate that physical training has a significant effect of the quality of life and cancer related fatigue. De physiological changes after training are poor understood. In the Netherlands experience has gained from the "integraal kankercentrum Limburg in revalidation clinic Hoensbroek and Hornerheide" with a revalidation program for (ex)cancer patients called "Herstellen Balans". This program was very positive judged by patients and their trainers.

Study objective

The goal of this study is to develop an optimal training program that had good physiological explanations and on the other hand the limitations experienced by the patients has to be studied. With positive findings, this program can be embedded in the regular treatment of cancer patients. With this research, understandings about physiological parameters and changes due to training are gained, which can result in optimization of the training program in the future. Second, understandings about the appearance of limitations on cardiopulmonary and muscular level are gained, which exist as side effects of chemotherapy. Third, understanding in body compensation changes in cancer patients after chemotherapy before and after physical training are gained. From literature is known that body compensation after chemotherapy improved significantly. By training intervention and guidelines for healthy foods, this program tries to change the body compensation positively.

Study design

Intervention research with as intervention a physical training program during 18 weeks under supervision of a specialized physiotherapist. Indication for intervention: cancer patients treated with chemotherapy and/or radiotherapy. The program focusses on improving fatigue, cachexia, deconditioning and obesity. A control group without intervention is applied, because no physical training existed or was offered at the time of diagnosis.

Intervention

The intervention consists of a physical part during 18 weeks and a psychological part. First 12 weeks the accent lies on strength training with exercises for different muscle groups. From week 13 until week 18 patients train once a week under supervision of a physiotherapist, with accent on more condition, hold the muscle strength and pleasure in sports.

Study burden and risks

not of application

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with cancer with curative treatment with chemotherapy in Maxima Medical Centrum Veldhoven.

Chemotherapy at least 6 weeks and maximal 52 weeks

Motivated to follow the program

Be able to follow the program under professional supervision

Logistic possible to follow the program

age 18-65 years, treated with chemotherapy from 2001, no co-morbidity

Exclusion criteria

In general daily life dependent of care

Low physical capacity (sitting, laying and under 100 meter walking)

Cognitive disturbances or emotional very weak

Severe side effects of medication

Other severe diseases responsible for physical activity intolerance

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2008
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO	
Date:	01-05-2004
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	20-08-2007
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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

CCMO

ID

NL18846.015.07