Quality of Life in Motion: A combined physical exercise and psychosocial training program to improve physical fitness in children with cancer.

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1. Childhood cancer patients who follow the QLIM intervention program will: a. achieve significantly higher levels of physical fitness after the 12 week intervention compared to patients in the control group, as assessed by objective performance...

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

Samenvatting

ID

NL-OMON22822

Bron
Nationaal Trial Register

Verkorte titel
QLIM

Aandoening

Physical activity, physical fitness, muscle strength, fatigue, obesity, bone mineral density, mood, health-related quality of life, chemotherapy, radiotherapy, childhood cancer. Lichamelijke activiteit, uithoudingsvermogen, kracht, vermoeidheid, botdichtheid, overgewicht, kwaliteit van leven, kinderkanker, chemotherapie, radiotherapie

Ondersteuning

Primaire sponsor: VU university medical center
Wilhelmina Children's Hospital, UMC Utrecht
Overige ondersteuning: The RoParun, VONK and possibly the Dutch Cancer Society (via Alpe D'HuZes Foundation)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1) Cardiorespiratory fitness
2) Muscle strength

Ad 1) Cardiorespiratory fitness will be assessed by the peak oxygen consumption (VO2-peak), peak work load (Wmax) and peak heart rate from a graded exercise test on an electronically braked cycle ergometer. After 1 minute of cycling without resistance, the workload is increased by 10, 15 or 20 Watts every minute according to the Godfrey protocol. The highest achieved workload (Wmax) will be recorded. The patients will breathe through a facemask connected to a calibrated metabolic cart. Breath-by-breath minute ventilation, oxygen consumption, carbon dioxide production, and the respiratory exchange ratio will be calculated from conventional equations. Heart rate will be measured continuously during the aerobic exercise test by a bipolar electrocardiogram or heart rate monitor. VO2-peak will be calculated as the average value over the last 20 sec before subjective exhaustion. Prior to the aerobic exercise test pulmonary function will be assessed at rest by measuring the forced air expiratory volume in 1 second and the forced vital capacity using a portable spirometer. The best out of 3 forced expiratory flow-volumes (in upright position) will be recorded. In addition, systolic and diastolic blood pressure will be measured in upright sitting position using an automatic device.

Ad 2) Muscle strength of the proximal and distal muscles in the upper and lower extremities will be measured by a calibrated hand-held dynamometer both at the right and left side of the body. Three consecutive measurements will be performed using the ‘break method’. The highest value will be registered. In the upper extremity, grip strength and strength of the shoulder abductors and the wrist extensors will be measured. In the lower extremity the muscular strength of the hip flexors and the knee and dorsal foot extensors will be measured. All within subject tests will be performed by the same assessor using the same hand held dynamometer to prevent inter-instrument and inter-observer bias. Test-retest reliability in hand-held dynamometry in children has been established previously.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:
Advances in treatment of childhood cancer have dramatically increased long-term survival. As a result, the numbers of childhood cancer survivors (CCS) are growing. A recent study has shown that approximately 75% of CCS have at least one adverse health effect after a median

follow-up of 17 years. Prevention or reduction of acute and long-term adverse health effects should be pursued in order to maintain or improve health-related quality of life (HrQOL). Physical fitness has been shown to be reduced both during and after childhood cancer with physical inactivity being one of the most prominent causes. Physical inactivity may lead to obesity, fatigue, a poor skeletal and/or mental health, and ultimately a compromised HrQOL. Therefore, prevention of inactivity-related health problems by increasing physical fitness both during and following treatment is essential. Rehabilitation programs in adult cancer patients report positive effects on physical fitness and HrQOL and have been introduced as standard care. However, such a program does not exist for childhood cancer patients (CCP). Limited evidence suggests that it is safe for CCP to engage in physical activities and that physical exercise programs are capable of increasing physical fitness both during and following treatment. However, study groups were small, restricted to children with acute lymphoblastic leukemia, and effects on health outcomes and HrQOL are rarely assessed. In addition, the interventions included a physical exercise program only, thus not addressing the psychosocial factors affecting physical activity in CCP.

Purpose:
The proposed study is part of a larger KWF program proposal: the Alpe d'HuZes Cancer Rehabilitation Research Program (A-CaRe) coordinated by the EMGO Institute. The aim of the study is to evaluate the short- and long-term effectiveness of a combined physical exercise and psychosocial intervention program, implemented during or shortly after treatment, in improving the physical fitness of CCP. In addition, it will be determined whether positive effects on physical fitness will attenuate or even prevent inactivity-related health problems (i.e. fatigue, obesity) and improve HrQOL.

Plan of investigation:

The proposed study is a multi-center randomized clinical trial. Eligible CCP are between 8 and 18 years at time of inclusion into the study, diagnosed with any type of childhood malignancy, treated with chemo- and/or radiotherapy, and no longer than 12 months off treatment. In total, 100 consenting patients will be randomized to either the intervention or the control group after being stratified according to type of malignancy, age group, and moment of inclusion into the study (during/after treatment). Randomization will occur as soon as the clinical condition of the patient enables him/her to participate in the intervention program.

The 12-week intervention consists of a combined physical exercise (2x/week) and psychosocial support program followed by a 1 day booster session. The physical exercise program includes both cardiorespiratory and muscle strength training, and the psychosocial support program (6 child and 2 parent sessions) contains psycho-education and cognitive-behavioral therapy. The control group will receive care as usual. All patients will be asked to undergo performance tests and complete a battery of questionnaires prior to randomization (T=0), after 12-14 weeks (T=1) and at 12 month follow-up (T=3). At T=2 (6-9 months from baseline) only the questionnaires will be administered. The primary outcome of the study is physical fitness (=cardiorespiratory fitness and muscle strength) as assessed by objective

performance indicators. Secondary outcomes will be fatigue, body composition, daily physical activity levels, depression, HrQOL, self perception and behavior.

Scientific/social relevance:

If the intervention program demonstrates to be effective, it may lead to short- and long-term health benefits and may, therefore, be a welcome addition to the standard care of CCP. In addition, it may contribute to a healthier adult life-style since the intervention is implemented during a period of life where the basis for adult behavior, life style and health status is established.

Doel van het onderzoek

1. Childhood cancer patients who follow the QLIM intervention program will:

a. achieve significantly higher levels of physical fitness after the 12 week intervention compared to patients in the control group, as assessed by objective performance tests.

b. achieve a significantly higher muscle mass, lower fat mass and higher BMD after the 12 week intervention than patients in the control group, as assessed by objective measurements.

c. achieve significantly higher levels of daily physical activity after the 12 week intervention, compared with patients in the control group, as assessed by accelerometers.

d. report significantly lower levels of fatigue and depression, and higher levels of HrQOL after the 12 week
intervention than patients in the control group.

e. maintain significantly higher levels of physical fitness, daily physical activity, HrQOL and lower levels of
fatigue and depression than patient in the control group, nine months after completion of the intervention program.

2. The changes in physical fitness will, in part, mediate the beneficial effect of exercise on inactivity- related adverse health outcomes, mood, and HrQOL.

Onderzoeksopzet

T=0: at baseline (prior to randomization)

T=1: after 12-14 weeks

T=2: on the day of the booster session for patients and on an equivalent moment in time for controls. Only the outcomes obtained by questionnaires will be assessed

T=3: after a follow-up of 12 months from baseline

Onderzoeksproduct en/of interventie

The QLIM intervention consists of a combined physical exercise (a) and psychosocial support (b) training program followed by a 1 day booster session (c).

A) The FITstrong physical training program

Since childhood cancer therapy has been associated with a loss of both aerobic capacity and muscle strength, the 12-week physical training program includes a combination of both cardio-respiratory and muscle strength training (2 x 45 minutes per week at a (FITkids) sports center as near to the child's residential address as possible). Training is performed individually under the supervision of an experienced (pediatric) physical therapist who will receive a paper version of the training program, and an instruction session to guarantee uniformity of the training program. The FITstrong training program consists of 3 phases of one month each (appendix 1).
The main goal of the 1st phase is to increase muscle strength while the 2nd phase primarily aims to increase cardio-respiratory fitness. The 3rd phase aims to further increase both cardio-respiratory fitness and muscle strength through interval training.
In
order to improve compliance with the program all sessions have varying contents. The duration and intensity of the sessions gradually increases throughout the study. The training intensity is assessed by monitoring the heart rate during the training session. Progression will be monitored by field tests (23,63,64) at the start and end of each phase by the therapists in the local sports centers.

In week 6-12, children will be instructed to perform (at least twice a week) 5 additional exercises at home with increasing intensity and frequency to enhance strength, flexibility an aerobic fitness (65). This aims to introduce physical exercise into their daily routine to encourage an active life-style after the FITstrong program has been completed. During the program, patients are not restricted to perform additional (social) activities such as school or leisure sports. The intervention to be evaluated in this study has already been developed and pilot-tested. During the first 6-months preparatory stage of the study, Intervention Mapping (IM) will be used as a checklist to optimize (fine-tune) the design and contents of the intervention. IM is a protocol that describes a stepwise process for theory and evidence-based development of health promotion programs (66). A fuller description of IM is provided in the proposal of the 'A-CaRe subprogram 1: clinical research.

B) The psychosocial training program

The psychosocial training program implemented in this study includes six child sessions of 60 minutes (once every two weeks) and two parent sessions (see below). The program contains

two important elements:

1) psycho-education

2) cognitive-behavioral therapy.

Psycho-education includes disease-related topics, for example physical changes and family relations. For adolescents, sexual orientation and growth and development topics will also be included. Cognitive-behavioral interventions are incorporated in the program to intensify awareness of hidden feelings, thoughts, behavior and their consequences, and to enhance coping strategies. The intervention will be provided by a trained pediatric psychologist in the treatment center of the child. The content of the program, psycho-educational information and exercises are written in an instruction manual. To enhance the effects of the psychosocial training for the individual patient, the manual is divided into several modules with different topics (see appendix 2).

All topics will be discussed, but the amount of exercises within the topics will differ per patient. Choices will be made according to the clinical evaluation of the pediatric psychologist in the process of the training, and according to a weighted judgment by parents and patient on several statements about the topics at the start of the training (first parent session and first child session). An independent psychologist will attend randomly selected sessions to evaluate whether the therapists still work according to the manual.

Because there is a strong impact of parent support on the physical activity of children (67), two parent sessions will be included in the program: at T=0 and T=1. By increasing the parental knowledge of the child's abilities during and after childhood cancer, the parent sessions aim to increase parental support, in order to improve compliance and endurance. In the first session the parents are educated about the principals of the program so they can encourage and support their child. The last session includes an evaluation (see appendix 2). Both the parents and the therapist will give their impression of the child's functioning and possible changes observed during the program.

C) The booster session

All patients in the intervention group will be invited for a one day booster session, 3-6 months after completion of the 12-week intervention period, which entails a group sports clinic and a psychosocial session. QLIM-participants will engage in physical activities in age-matched groups and will talk about what they have learned during both elements of the QLIM intervention.

Contactpersonen

Publiek

VU University Medical Center, Department of Pediatrics,
P.O. Box 7075
K.I. Braam
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4449110 / +31 (2)20 4442420

Wetenschappelijk

VU University Medical Center, Department of Pediatrics,
P.O. Box 7075
K.I. Braam
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4449110 / +31 (2)20 4442420

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children who are:

1. 8-18 years at the time of intervention

2. Diagnosed with any type of childhood malignancy

3. Treated with chemo-and or radiotherapy

4. No longer than 12 months off treatment

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Children who:

1. Require a bone marrow transplantation

2. Require growth hormone treatment

3. Depend on a wheelchair

4. Are unable to “ride a bike”

5. Are not able to read, or write

6. Are not able to self-reflect, and/or follow instructions

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2008
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	NL1462
NTR-old	NTR1531
Ander register	METc VU medisch centrum : 08/208
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A