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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22822

Source
Nationaal Trial Register

Brief title
QLIM

Health condition

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

Sponsors and support

Primary sponsor: VU university medical center
Wilhelmina Children's Hospital, UMC Utrecht
Source(s) of monetary or material Support: The RoParun, VONK and possibly the Dutch Cancer Society (via Alpe D'HuZes Foundation)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Fatigue

2. Body composition

3. Daily physical activity levels

4. Depression

5. Health-related quality of life

6. Self-perception

7. Behavioral problems

Ad1) Fatigue will be assessed by the 18-item PedsQL Multidimensional Fatigue Scale Acute Version. This instrument is a module of the PedsQL 4.0 Generic Core Scale. The module encompasses 3 subscales: 1) general fatigue (6 items), sleep/rest fatigue (6 items), and cognitive fatigue (6 items).

Ad 2) Body composition (fat mass, muscle mass, bone mineral density (total and at the lumbar spine)) will be assessed by whole body dual energy X-ray (DEXA) scanning. In addition, body mass index (kg/m2) will be determined by dividing weight to the nearest 100gr by height to the nearest 0.5 cm. Furthermore, short-term changes in bone formation and bone resorption, as well as possible abnormalities in hormonal and biochemical metabolism of the bone are determined by serum levels of bone turnover markers. Next to minerals as calcium, phosphate and magnesium, procollagen type 1 C-terminal peptide (P1CP), the cross-linked telopeptide of type 1collagen (1CTP), parathyroid hormone (PTH), 25-hydroxyvitamin D (25OHD) and the growth hormone IGF-1 are being analysed.

Ad 3) Daily physical activity levels will be monitored by the Actical accelerometer. The accelerometers will be initialized to collect data at 15 second intervals during 4 days, including 1 weekend day. Output (activity counts) will be downloaded to a PC after the monitoring period. In addition, a physical activity questionnaire will be administered. The final choice of questionnaire will be made during the preparatory phase of the study, based on careful review of literature and consultation with experts in physical activity measurement.

Ad 4) Symptoms of depression will be assessed by the Children’s Depression Inventory (CDI).

Ad 5) Health-related quality of life (HrQOL) will be assessed by child self-report and parent-proxy report using two questionnaires, the PedsQL 4.0 Generic Core Scale and the the PedsQL 3.0 Cancer module.

Ad 6) Self-perception, an intervening variable directly affecting HRQOL, will be assessed by the Dutch version of the Self Perception Profile for children (CBSK) and adolescents (CBSA). The questionnaire assesses the
self-perception of scholastic competence, social acceptance, physical appearance, behavioral conduct, global self-worth and close friendships.

Ad 7) Behavioral problems will assessed using the Dutch translated and validated Child Behavior Checklist (CBCL). In addition, the Youth Self Report (YSR) assesses internalizing and externalizing behavior problems reported by children of 11 to 18 years old.

Other study outcomes:

Compliance with the physical and psychosocial intervention programs will be assessed by self-report and by objective assessments by trainers and psychologists involved. Non-responders and drop-outs will receive a short questionnaire to assess the reasons for non-participation or dropping out of the study.

Satisfaction with the intervention will be assessed. Patients in the intervention group will be asked to complete a brief questionnaire addressing the perceived efficacy of and satisfaction with the intervention program, whether they would suggest any changes to the program, and if they would recommend it to other patients undergoing childhood cancer treatment.

Sociodemographic and clinical data are obtained by means of a questionnaire at baseline and from medical records respectively. Data include (parental) education, living situation, medication use, life-style variables, sex, pubertal status, diagnosis, date of diagnosis, treatment protocol, type and dose of chemotherapeutics and/or radiotherapy, and adverse events during treatment. During follow-up, data on disease status and any additional treatment will be recorded.

Moderating variables. A series of questions will be developed to assess a number of potential moderating variables and variables that may predict compliance with the intervention program. These questions will address pre-illness life style (frequency, nature and intensity of physical activity and exercise behavior), current attitudes towards and beliefs about exercise, in general, and during treatment in particular. Attitudes towards and beliefs about exercise, as well as physical activity patterns, will also be assessed in parents and siblings since this may be correlated with a positive attitude towards physical activity in childhood cancer patients. These questions will be administered at baseline only.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	12-11-2008
Application type:	First submission

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	ID
NTR-new	NL1462
NTR-old	NTR1531
Other	METc VU medisch centrum : 08/208
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A