A-CaRe study 3: Exercise intervention after stem cell transplantation.

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Stem cell transplantation survivors who received the high-intensity strength and interval training program will (1) have an improved physical fitness, (2) report lower levels of fatigue, (3) report less mood disturbances, higher levels of daily…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25999

Bron
Nationaal Trial Register

Verkorte titel
EXIST

Aandoening

Physical exericse, Physical fitness, Fatigue, Stem cell transplantation

Ondersteuning

Primaire sponsor: Dept of Hematology, Academic Medical Center Amsterdam

Overige ondersteuning: Dutch Cancer Society, Alpe d’HuZes Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Cardiorespiratory fitness;

2. Muscle strength;
3. Fatigue.

Ad 1) Cardiorespiratory fitness is measured during a VO2max test on a cycle ergometer under supervision of a sport physician. A ramp test design will be applied, after 4 minutes of unloaded cycling; the load will be gradually increased till exhaustion. Throughout the test ECG and pulse oxymetry will be monitored and heart rate, blood pressure and gas exchange variables will be measured. Among the variables that will be determined are the VO2peak, maximal heart rate, maximal work rate, maximal minute ventilation, VO2 uptake at ventilation threshold, and the maximal respiratory exchange ratio.

Ad 2) Upper extremity muscle strength of adults is measured using a grip strength dynamometer. Lower extremity muscle strength is tested by the functional 30s chair stand test, according to a standardized measurement protocol.

Ad 3) Two self-report questionnaires will be used to assess fatigue: the Multidimensional Fatigue Inventory (MFI) and the Fatigue Quality List (FQL). The MFI consists of 5 subscales based on different dimensions: general fatigue, physical fatigue, reduced activity, reduced motivation and mental fatigue. The FQL consists of 25 adjectives describing the fatigue experience, organized into 4 subscales: frustrating, exhaustion, pleasant and frightening.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Physical exercise interventions after stem cell transplantation can have positive effects on physical fitness, fatigue and quality of life in hematologic patients who have undergone high dose chemotherapy and autologous stem cell transplantations. However, the trials conducted so far were of poor to moderate quality. Also data on cost-effectiveness of these interventions are not available. Hence there is a need for a rigorous, appropriately controlled assessment of the (cost-)effectiveness of exercise programs in these patients.

Purpose:

The study is part of a larger research program (A-CaRe) which is sponsored by the Alpe D'HuZes foundations and coordinated by the EMGO institute in Amsterdam. The objectives of the current study are: (1) to determine the effectiveness of a state-of-the-art individualized high intensity strength and interval training program with respect to physiological and psychological status in patients with multiple myeloma and (non-)Hodgkin’s lymphoma who have recently undergone HDC followed by ASCT and (2) to evaluate the cost-effectiveness of

this exercise program.

Plan of investigation:

Following a small pilot study to evaluate feasibility of the process of training and assessments according to a detailed manual, a prospective, randomized controlled trial will be performed in 120 patients with multiple myeloma or relapse (non-)Hodgkin's lymphoma who have undergone induction chemotherapy followed by high-dose chemotherapy and autologous stem cell transplantation. Patients will be randomized to either the intervention group or the control group.

The intervention will start 6-12 weeks after SCT and will consist of an 18 weeks supervised high intensity exercise program (2x/wk for the first 12 weeks and 1x/wk for the last 6 weeks; aerobic and resistance exercise). 3 booster sessions at increasing (4, 10, 18 weeks after completion of the intervention program) will be held during which patients are trained and counselled and motivated to continue exercising and maintain active lifestyle in general. The control group will receive standard care. Patients will be followed until 12 months after the end of the intervention program or a comparable time after SCT in the control group.

The primary outcome variables are fatigue, cardiorespiratory fitness and muscle strength. Secondary outcome measures include adherence and compliance, health-related quality of life, physical activity, mood disturbance and return to work. A cost-effectiveness analysis will be performed.

Relevance:

If demonstrated to be effective, the availability of the intervention will be a welcome addition to the standard care of patients with of haematological cancer patients treated with high dose chemotherapy and autologous stem cell transplantation.

Doel van het onderzoek

Stem cell transplantation survivors who received the high-intensity strength and interval training program will (1) have an improved physical fitness, (2) report lower levels of fatigue, (3) report less mood disturbances, higher levels of daily activities and an improved health-related quality of life, (4) have a higher partial and full return to work rate compared to stem cell transplantation survivors who received standard care only.

In addition, the high intensity strength and interval exercise program is more cost-effective compared to current standard care.

Onderzoeksopzet

1. T=0: Baseline, 6-12 weeks after SCT and prior to randomisation;

2. T=1: At completion of the 18-week intervention;

3. T=2: 12 weeks months after ending the intervention.

Onderzoeksproduct en/of interventie

Besides the standard care patients in the intervention arm follow an 18-weeks exercise. This program consists of high-intensity resistance and interval training. Before the start of the program, a sport physician will screen the patient and, where necessary adapt the program. Training takes place twice a week (first 12 weeks) and later once a week in physical therapy practices supervised by physical therapists. Patients will train on specialized resistance training equipment and on bicycle ergometers. Furthermore, the physical therapist will coach the patient to maintain an active lifestyle from week 10 onwards.
Resistance exercise consist of six exercises targeting the large muscle groups: (1) vertical row; (2) leg press; (3) bench press; (4) pull over; (5) abdominal crunch; (6) lunge. Indirect one repetition maximum (1-RM) measurements will be performed every 4 weeks for all six exercises. In the first 12 weeks, the resistance exercise consists of two sets of 10 repetitions at 65 to 80% of the 1-RM. From week 12 onwards it comprises of more repetitions (20 repetitions per set) at a lower resistance (35-40%).
Before and after the resistance exercise patients cycle two times eight minutes with alternating resistance. To determine right resistance a steep ramp test will be performed every 4 weeks. With this test the subject is instructed to cycle at a speed between 70 and 80 rpm, starting at a work rate f 25 Watt for 30 seconds. Hereafter the load is increased by 25 watt every 10 seconds till exhaustion. Maximal short exercise (the maximal workload, MSEC) is recorded. In the first 8 weeks, blocks of 30 seconds at 60% will be alternated with blocks of 60 seconds at 30%. From week nine onwards, the duration of the latter block is reduced to 30 seconds.
The counselling is based on the Onco-Move program ('Every Step Counts). Patients will be encouraged to achieve and maintain a physically active lifestyle including moderate to vigorous activities for a period of at least 30 minutes 4 to 6 days per week. An information folder wherein information about physical activity and desired intensity based on the Borg Scale of perceived exertion will be given to the patient. During the counselling sessions, the physical therapist will verbally explain the information. Besides for providing information, the sessions will be used for filling out the activity diary of the previous weeks, evaluate experienced difficulties with being active and formulate objectives for the coming period.

Both the patients in the intervention arm and the patients in the control arm receive standard care. However, since currently the usual care is not standardized, the care will vary according to doctors’ and patients’ preferences. Patients in the control arm are allowed to participate in sports.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosed with multiple myeloma in first line or with (non-)Hodgkin's lymphoma in first relapse and treatment with HDC and autologous SCT 6 to 12 weeks ago;

2. Age between 18 and 65 year;

3. Sufficiently recovered from the stem cell transplantation and having peripheral blood recovery;

4. Ability to cycle on a bicycle ergometer against a load of at least 25 watt;

5. Ability to walk at least 100 meters independently without crutches, canes or walking frame;

6. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Tandem autologous-allogenic stem cell transplantation;

2. Severe cognitive impairment;

3. Severe emotional instability;

4. Insufficient mastery of the Dutch language;

5. Presence of extensive osteolytic lesions with risk of fracture;

6. Serious cardiopulmonary and cardiovascular conditions;

7. Other disabling comorbidity interfering with the intervention program or influencing outcome parameters (a.o. having a pacemaker, epileptic seizures and poorly regulated diabetes mellitus);

8. Severe infections;

9. Relapse/progression of disease.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	125
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-05-2010
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	NL2216
NTR-old	NTR2341
Ander register	METC AMC : 10/106
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A