Effects of Exercise in Children with a chronic illness: Inflammatory Bowel Disease

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON49222

Source
ToetsingOnline

Brief title
Exercise study

Condition

- Congenital cardiac disorders
- Gastrointestinal inflammatory conditions
- Musculoskeletal and connective tissue disorders congenital

Synonym
Amendement 1 Pompe's disease, Amendement 2 Fontan circulation, Amendement 3 BPD, Inflammatoiry Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Vrienden van Sophia

Intervention

Keyword: children, chronic illness, exercise training, physical activity

Outcome measures

Primary outcome

1) Endurance: measured by the maximum exercise test (VO2 peak).

Secondary outcome

1. Physical functioning in daily life: measured on the basis of quality of life questionnaires (CHQ questionnaires parents and child, PedsQol MFS, IMPACT-III) and volume of physical activity.

2. Endurance: measured on the basis of the maximum and sub-maximal exercise tests (Wattage, ventilation threshold, MET) and the distance ran on the 6-minute walk test (6 MWT).

3. Muscle strength: measured with a dynamometry (Cytec handheld dynamometer (HHD) and manually by means of the Medical Research Council (MRC) score.

4. Energy balance: Caloric intake and diet composition, resting metabolic rate measured by indirect calorimetry.

5. Body composition: measured with a BODPOD® and using physical examination (biometrics and skin fold measurement).

6. Fear of exercise: measured with the TAMPA scale for kinesiophobia and mid-structured interview with separate questions for children and parents

7. Safety: measured by blood tests before and after the maximum exercise test.

For IBD patients only:

8. Degree of disease: measured by the degree of active inflammation by calprotectin in stool and the degree of clinical disease activity: PCDAI (for Crohn's disease) and PUCAI (for ulcerative colitis) scores.

For Fontan patients only:

8. Cardiac function measured with an Echo heart and MRI Cor: Cardiac output, maximum speed: in the ascending aorta, in right upper pulmonary vein, over the mitral valve and tricuspid valve, deceleration time of the peak speed over the mitral valve and tricuspid valve and systolic rash the annular plane.

Study description

Background summary

Inflammatory bowel disease (IBD) is one of the most common auto-immune diseases, including the ulcerative colitis and Crohn's disease. In the Netherlands 2,500 to 3,000 children live with IBD and around 250 children are diagnosed each year. Children with IBD have lower levels of physical activity and are also limited in their endurance compared to healthy children.

Pompe's disease is a rare metabolic disease that affects 1 in 40,000 people. Children with Pompe's disease have progressive muscle weakness, causing problems with walking, climbing, playing and eventually they develop respiratory problems. Whether children with Pompe disease are less active in daily life compared to healthy children has not been investigated yet, we do know that children with Pompe's disease are severly limited in their endurance.

Children with a Fontan circulation are born with a heart defect in which only one heart chamber functions. This occurs in about 3 in 10,000 births. Children with a Fontan circulation have a reduced quality of life, tire more quickly and often develop cardiac arrhythmias and heart failure later in life. It is also known that these children exercise less and have a reduced exercise capacity.

Children with BPD are (premature) born with underdeveloped lungs, leading to

permanent lung damage. The lungs of children with BPD stay very vulnerable. Children with BPD therefore often suffer from respiratory infections and continue to have reduced lung function compared to healthy children. Levels of physical activity have not been investigated yet in this patient group, we do know that children with BPD have a reduced exercise capacity

Study objective

The study focuses on children and young people with IBD from 6-18 years old. These children have lower levels of physical activity and a limited endurance compared to healthy children. Through this research we want to improve the endurance of children with IBD, so that these children may also become more active in daily life. To achieve this, it will first have to be investigated why children with IBD are less active and have limited endurance. For this we research the daily (exercise) activities and quality of life and we measure body composition, disease activity, endurance, muscle strength and energy balance. On the basis of this data, we make a customized training intervention, possibly supplemented with dietary advice and psychological guidance. The primary aim of our study is to measure the effect of this training intervention on the exercise capacity
of children with IBD. We also check whether the training program can be followed safely and has no negative influence on the activity of the disease and we measure the effect of the training program on physical functioning in daily life, muscle strength, fear of exercise, body composition and resting metabolism.

Children and young people with Pompe*s disease have lower levels of physical activity and a limited endurance compared to healthy children. This research focuses on Children and young people with Pompe*s disease from 6-18 years old. Through this research we want to improve the endurance of children with Pompe*s disease, so that these children may also become more active in daily life. To achieve this, it will first have to be investigated why children with Pompe*s disease are less active and have limited endurance. For this we research the daily (exercise) activities and quality of life and we measure body composition, disease activity, endurance, muscle strength and energy balance. On the basis of this data, we make a customized training intervention, possibly supplemented with dietary advice and psychological guidance. The primary aim of our study is to measure the effect of this training intervention on the exercise capacity of children with Pompe*s disease. We also check whether the training program can be followed safely and has no negative influence on the activity of the disease and we measure the effect of the training program on physical functioning in daily life, muscle strength, fear of exercise, body composition and resting metabolism.

Children with a Fontan circulation have lower levels of physical activity move less in daily life and and a limited endurance compared to healthy children. This research focuses on Children and young people with a Fontan circulation of

6-18 years. Through this research, we want to improve the exercise capacity of children with a Fontan circulation, so that these children may also become more active in daily life. To achieve this, it will first be necessary to investigate why children with a Fontan circulation are less active and have a lower exercise capacity. For this we research the daily (exercise) activities and quality of life and we measure body composition, disease activity, endurance, muscle strength and energy balance. On the basis of this data, we make a customized training intervention, possibly supplemented with dietary advice and psychological guidance. The primary aim of our study is to measure the effect of this training intervention on the exercise capacity of children with a Fontan circulation. We also check whether the training program can be followed safely and has no negative influence on the activity of the disease and we measure the effect of the training program on physical functioning in daily life, muscle strength, fear of exercise, body composition and resting metabolism.

Children with BPD have limited endurance compared to healthy children. This research focuses on Children and young people with BPD of 6-18 years. Through this research, we want to improve the exercise capacity of children with BPD, so that these children may also become more active in daily life. To achieve this, it will first be necessary to investigate if children with BPD are less active in daily life. For this we research the daily (exercise) activities and quality of life and we measure body composition, disease activity, endurance, muscle strength and energy balance. On the basis of this data, we make a customized training intervention, possibly supplemented with dietary advice and psychological guidance. The primary aim of our study is to measure the effect of this training intervention on the exercise capacity of children with BPD. We also check whether the training program can be followed safely and has no negative influence on the activity of the disease and we measure the effect of the training program on physical functioning in daily life, muscle strength, fear of exercise, body composition and resting metabolism.

Study design

The study is a cross-over intervention study. Each patient group will be randomized in to two groups. At start, each group will have two assessment days. Following these assessments a tailor-made training programs will be made, taking in to account on which of the domains (e.g. 1) endurance, 2) muscle strength, 3) core stability, 4) inspiratory muscle strength, 5) psychosocial functioning and/or fear for children and/or their parents and 6) caloric intake) score less compared to healthy peers or desire advise. One group will start with 12 weeks of training until assessment 2, and will have a resting period between assessment two and three. The other group will start with the resting period and will train between assessment two and three.

Intervention

During 12 weeks the children will follow a tailor made training program. These trainings will take place 2-3 times a week for an hour and will supervised by a local physiotherapist.

The cross-over design was chosen to make sure all children will be able to participate in the training program and because less patients will be needed while every child is its own control.

Group 1:
M1 12 weeks training M2 12 weeks *rest* M3
|--|----------|--|----------
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Group 2:
M1 12 weeks *rest* M2 12 weeks training M3
|--|----------|--|----------
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At M1 the volume of physical activity and the possible cause of a decreased physical functioning will be examined. Depending on the results training programs will be made. Focus will be on a decreased outcome and the needs of the patients for: 1) endurance, 2) muscle strength, 3) core stability, 4) inspiratory muscle strength, 5) psychosocial functioning and 6) caloric intake. Depending on the results of M1 and earlier research in adult patients training programs:
We expect to focus on endurance training possibly with strength training
When needed dietary advise and psychosocial training will complete the training programs.

Study burden and risks

Earlier research in children and adults with different chronic diseases have shown that supervised exercise training has beneficial effects on health. Previous study showed that adults with IBD had increased exercise capacity and quality of life scores after training. Patients probably may benefit from our study. We expect that the quality of life and physical activity will increase.

Previous studies in adults with Pompe disease have shown that supervised training led to an increased quality of life and better endurance. This has not yet been investigated in children. Patients are likely to benefit from participating in this study. We expect that both the quality of life and the physical functioning of the children will increase.

Previous studies in children with lung diseases have shown that supervised training led to an increased quality of life and better endurance. This has not yet been investigated in children with BPD. Patients are likely to benefit from

participating in this study. We expect that both the quality of life and the physical functioning of the children will increase.

Assessments are divided over 3 moments, each moment consisting out of 2 visitis, 4 hours per visit. In between each visit the patients have to answer questionnaires (n=4, total time 45 minutes taken into account at the assessment time). Furthermore the patient have to wear an accelerometer for three days, which isn't uncomfortable. They have to keep a diary on activity for these three days (30 minutes in total, taken into account in the assessment days)

Risks of the assessments:
- blood sample: vein punction might be painfull, cause hematomas and bleedings
- bicycle ergometer test: can reveal hart rhythm disorders. Heart rhythm and blood pressure will be monitored by a trained supervisor. The test will be stopped in case of a heart rhythm disorder or when the supervisor thinks it isn't safe to continue. Patients can get fatigued or have muscle soreness after the test.
- 6 minute walk test: can cause fatigue
- indirect calorimetry and BODPOD and MRI wil take place in a small device. Claustrofobic children might feel uncomfortable.

We don't expect any complications due to the exercise training based on existing literature. Patients with contra-indications for sport activities will be excluded. It is always possible to get injured during physical activity but the risks in this study are reduced due to the supervision of the physiotherapist. Patients might get fatigued or muscle soreness due to the exercise training. The training program takes time from children and parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1) Patients need to be diagnosed with inflammatory bowel disease
2) Age between 6 and 18 years old
3) A signed informed consent of the patient and/or their parents or legal guardian in case of age <16years
4) patients participating in the substudy EXERCISE Pompe disease need to be diagnoses with Pompe disease and should fulfill inclusion criteria 2 and 3.
5) Patients participating in the substudy EXERCISE Fontan circulation need to be diagnoses with a Fontan circualtion and should fulfill inclusion criteria 2 and 3.
6) Patients participating in the substudy EXERCISE BPD need need to be diagnoses with BPD and should fulfill inclusion criteria 2 and 3.

Exclusion criteria

1) height <120cm
2) physically not able to perform a ergometer test
3) participating in other exercise training programs
4) contra-indication for exercise

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2019
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	26-11-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-06-2020
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27466
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70912.078.19
OMON	NL-OMON27466