Improvement of physical fitness, muscle strength, aspects of quality of life and decrease of fatigue in children on dialysis

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The purpose of this study is to show that participation in an exercise programme will increase the exercise tolerance, musle power and health-related quality of life and will diminish the degree of fatigue in children on dialysis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON31624

Source
ToetsingOnline

Brief title
Improvement of physical fitness in children on dialysis; Balance - study

Condition

- Nephropathies

Synonym
end stage renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: children dialysis, physical fitness, training

Outcome measures

Primary outcome

Fatigue

Maximal exercise testing

Secondary outcome

Age

Anthropometrics

Functional exercise capacity

Muscle strength

Functional ability

Aspects of Quality of life

Activities of daily living

Study description

Background summary

Adults with end stage renal disease who are on haemodialysis report decreased exercise tolerance, muscle stength, increase in fatigue and decrease in daily activities. Intervention programs do improve these topics as well as aspects of quality of life.
No intervention programs in children on haemodialysis/peritoneal dialysis have been performed regarding increasing exercise tolerance, muscle strength, functional ability and decreasing fatigue.
Fatigue is a major problem in children with chronic renal failure influencing daily activities. This was recently reported by a study by TNO. The department of pediatric physical therapy and pediatric exercise physiology WKZ/UMCU has experience in designing and conducting exercise programs in children with chronic conditions, leading to a more active lifestyle and improvement of ability and participation with eventually decrease of fatigue.

Study objective

The purpose of this study is to show that participation in an exercise programme will increase the exercise tolerance, musle power and health-related quality of life and will diminish the degree of fatigue in children on dialysis.

Study design

1. To assess in children (n=23) treated with haemodialysis/peritoneal dialysis in the academic hospitals of Nijmegen, Amsterdam (UMCA), Rotterdam (Erasmus MC), Antwerpen, en Utrecht (UMCU) the amount of fatigue, anthropometrics, muscle strength, exercise tolerance, physical ability and aspects of quality of life with valid and reliable instruments and questionnaires.

2. The design of an intervention program, primarily aimed at improvement of physical fitness, muscle strength and decrease of fatigue.

3. Conducting an intervention program at home by instructed pediatric physical therapists.The intervention lasts 6 months.

4. To assess the consequences of this program regarding these before mentioned topics after the intervention and after 6 months after intervention.

5. After the expected improvement to stimulate participants in sport activities.

In these 23 children on haemodialysis/peritoneal dialysis the following measurements will be performed:

Fatigue
Anthropometrics
Maximal exercise testing
Functional exercise capacity
Muscle strength
Functional ability
Aspects of Quality of life
Activities of daily living

Measurements are performed 3 months before intervention, just before intervention, after intervention and 3 months after intervention

Intervention will be performed by well instructed and trained pediatric physical therapists in the city were the child lives.

The intervention program is based on earlier studies we performed and also based on the guidelines of the American College of Sports Medicine.

Intervention

Based on a child-friendly fitness program, physical fitness and muscle strength will be trained. This program has been used in the study 04/311 University Medical Center Utrecht and is well-appreciated by the participating pediatric physical therapists as well as children and their parents.

Study burden and risks

Extent of burden: time: during the whole study 4 assessments of 2 hours. The exercise tests will be performed at the hospital where the child is treated

The child participates in an intervention program during 6 months (intervention 1.5 hours per week)

The risk is estimated to be nihil

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

children with end stage renal disease on hemodialysis - peritoneal dialysis

Exclusion criteria

mental retardation, unable to perfom a maximal exercise test.
additional disorders which limit motor activity

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2007
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-01-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL14070.041.06