Follow You intervention study: Effectiveness of a multidisciplinary training program on daily physical functioning in children and young adolescents with a hereditary connective tissue disorder: a feasibility study

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1) Improving the (physical) daily functioning of children with HCTD2) Testing feasibility of intervention for child / parents and therapists

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON50966

Source
ToetsingOnline

Brief title
FY intervention study on daily (physical) functioning

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
extreme flexibility, Heritable Connective Tissue Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: SIA RAAK PRO

Intervention

Keyword: Children and adolescents, Heritable Connective tissue disorder, physical functioning, training

Outcome measures

Primary outcome

The Goal Attainment Scaling (GAS) determines the extent to which a treatment goal has been achieved. A goal for the treatment is set in accordance with parents and child. The main goal is included in the analysis. On the basis of that goal, a 6-point GAS scale is established on which the extent to which this goal has been achieved can be evaluated. GAS is a generic, evaluative tool that can describe change per person or in groups with good validity and reliability

The endurance is determined with the Fitkids Treadmill Test. This is a maximum exercise test. During the test, heart rate is measured with a Polar heart rate monitor. The degree of fatigue is measured with the OMNI scale. The degree of pain, whether present or not, is measured with a Visual Analogue Scale (VAS). The Fitkids Treadmill test has been developed for children with chronic conditions, is very applicable and has good validity and reliability.

Secondary outcome

Motor functioning and physical capacity

The Bruininsk-Oseretsky Test of Motor Proficiency-2 (BOTMP-2) is used to

measure motor functioning. The test consists of 8 subtests; 4 for gross motor skills (bilateral coordination, balance, sprint speed and strength and dexterity) and 4 for fine motor skills. The test has good validity and reliability.

The Muscle Power Sprint Test (MPST) determines the anaerobic endurance, shown as Peak and Mean Power. The MPST is a sprint test where 6 x 15 meters is sprinted as fast as the child can. There is a 10-second rest between sprints. The time of every 15 meter sprint is registered to 0.1 second with a stopwatch. The power (power) is then calculated with the time, body weight and distance traveled. The test has good validity and reliability.

Agility during intensive movement is measured with the 10 x 5 meter sprint, shown in seconds. The 10 x 5 meter sprint is completed as fast as the child can. The test has good validity and reliability.

The Childhood Health Assessment Questionnaire (CHAQ-38) is used to measure limitations at the activity level. The CHAQ-38 was developed and validated by Lam et al (2004) and consists of 38 items divided into 9 subscales with daily skills (such as dressing, walking, school activities). This assessment evaluates 3 components: (a) difficulty to perform activity on a 4 point scale, (b) use of special tools, and (c) assistance needed to perform the activity. The CHAQ is a valid, reliable and sensitive measuring instrument to measure functional disability and has been validated and translated for use in the

Netherlands.

fatigue

The degree of fatigue experienced is measured using the Promis questionnaire. The Promis short form Fatique V2.0 is for children aged 8 and older. The Parent proxy report (V2.0-Parent proxy) is taken from the parents / guardians of children 6 and 7 years old. Promis Fatique is a questionnaire based on the item response theory to measure the degree of perceived fatigue in children. Promis Fatique short form is a valid, reliable and sensitive measuring instrument for children with chronic disability. The Dutch and Flemish translation of the Promis Fatique short form items were tested and found to be reliable and takes about 10 minutes.

Physical examination

Date of birth, diagnosis, height (cm), weight (kg) (Tanita MC780), body mass index (BMI), will be collected for all participants. Joint mobility will be assessed by the Beighton score, Upper limb assessment and the Lower limb assessment..

Study description

Background summary

Connective tissue disorders (CTD) is a collective term for diseases or disorders generally characterized by systemic problems affecting the cardiovascular, muscular and pulmonary systems, hypermobility, extreme skin flexibility and tissue fragility. Three known types of CTDs are Ehlers-Danlos

Syndromes (EDS), Marfan Syndrome (MFS), and Loeys-Dietz Syndrome (LDS). The incidence is low, about 1-3 per 10,000 children are diagnosed with a CTD.

Health problems related to the disease can be various and have a profound impact on physical, social and psychosocial functioning and health-related quality of life. Joint hypermobility in children will often result in injuries and pain. This may lead to reduced physical activity, increased absenteeism and reduced physical and psychosocial functioning.

In a previous study, we examined the impact of the disease in a large group of children with CTD using a survey and various physical tests. Based on these two studies we designed an intervention study which is in line with the physical limitations obtained and experienced by the children and individual needs for tailored training.

Study objective

1) Improving the (physical) daily functioning of children with HCTD
2) Testing feasibility of intervention for child / parents and therapists

Study design

This is a (not controlled, not randomised) intervention study, feasibility study.

- T0 Baseline measurement (AMC)
- Training
- 12 weeks 3 times a week training for 45 minutes at the local pediatric physical therapist
- 3 information meetings at Reade (2 hours each)
- T1 measurement

Intervention

An intensive trainings period of 12 weeks, 3 times a week 45 minutes consist of High intensity training or Power training and tailored to individual needs.
in addition, there are information meetings about how to deal with complaints and limitations in daily living.

Study burden and risks

Intensity of the intervention is comparable to a Gym class at school, regular pediatric physical therapy training or intensive playing outside. The cardiologist's permission is required for participation in the study.

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 and adolescents (6-18 years old) who are diagnosed with either Marfan syndrome, Ehlers-Danlos Syndromes or Loeys-Dietz syndrome, who are treated in the Amsterdam University Medical Center, location AMC or Reade Amsterdam. The origin of the children/adolescents and their parents can be of every country and/or ethnicity .

Exclusion criteria

Children/ adolescents who, next to the Marfan syndrome, Ehlers-Danlos Syndromes or Loeys-Dietz syndrome, have another prominent chronic disease affecting their

physical functioning, or children who are seriously cognitive impaired or completely wheelchair dependent.
In addition, for children with MFS, LD and EDS-vascular type permission from the cardiologist is required for participation in this study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	18-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL76844.018.21