

Inspiratory muscle training prior to peripheral muscle training in children and adolescents with Cystic Fibrosis.

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A home-based peripheral muscle training program (Five Basic Exercises program (5BX)) is more effective in [a] increasing exercise capacity (e.g. peak work rate) and [b] patients' preferred occupational performance when it is preconditioned by...

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

Samenvatting

ID

NL-OMON20853

Bron

Nationaal Trial Register

Verkorte titel

IMT in children and adolescents with Cystic Fibrosis

Aandoening

inspiratory muscles (inademhaling spieren)

training

Cystic Fibrosis (taaislijmziekte)

exercise capacity (inspanningsvermogen)

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, The Netherlands

Overige ondersteuning: Koninklijk Nederlands Genootschap Fysiotherapie (KNGF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Peak workload attained during cardiopulmonary exercise testing.

Toelichting onderzoek

Achtergrond van het onderzoek

Cystic fibrosis (CF) primarily affects the respiratory and digestive systems in children and young adults. Due to the continual bronchial airway obstruction a chronic hyperinflation of the thorax develops, thereby decreasing the efficiency of inspiratory muscle work and increasing work of breathing (WOB) in rest and during exercise. The increased WOB and the corresponding fatigue of the inspiratory muscles (diaphragm and supportive inspiratory muscles) are thought to induce a so called 'respiratory muscle induced metaboreflex' causing a reflex vasoconstriction of the locomotor muscle blood vessels. It is feasible that this decreased blood supply to the locomotor muscles will limit exercise capacity.

The hypothesis of this study is therefore: A home-based peripheral muscle training program (Five Basic Exercises program (5BX)) is more effective in [a] increasing exercise capacity (e.g. peak work rate) and [b] patients' preferred occupational performance when it is preconditioned by inspiratory muscle training (IMT).

Doel van het onderzoek

A home-based peripheral muscle training program (Five Basic Exercises program (5BX)) is more effective in [a] increasing exercise capacity (e.g. peak work rate) and [b] patients' preferred occupational performance when it is preconditioned by inspiratory muscle training (IMT).

Onderzoeksopzet

1. $t = 0$ (baseline);
2. $t = 6$ weeks;
3. $t = 12$ weeks;
4. $t = 18$ weeks;
5. $t = 24$ weeks.

Onderzoeksproduct en/of interventie

Both groups receive inspiratory muscle training (IMT) or sham (placebo)-IMT based on randomization. IMT last for 6 weeks, 5 days a week, 11 minutes a day.

After IMT or sham-IMT, both groups receive a standardized peripheral muscle training programme (5 Basic eXercises (5BX)) for 6 weeks, 5 days a week, 11 minutes a day.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Ambulant patients with CF;
2. Age: range from 12 to 18 years of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Gastro-intestinal or pulmonary exacerbation (extra oral or intravenous antibiotics for the past four weeks) at inclusion;

2. Oxygen saturation (SpO₂) < 90% (without O₂ supply);
3. Ineligible to perform CPET;
4. Not familiar with the Dutch language;
5. Pneumothorax;
6. Participation in study "MOVIT" less than one year ago. Patients can enter the protocol one year after finishing participation in "MOVIT".

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	04-11-2009
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	NL1975
NTR-old	NTR2092
Ander register	METC UMC Utrecht : 09-114/K
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A