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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

## **Summary**

### ID

NL-OMON20853

Source NTR

Brief title IMT in children and adolescents with Cystic Fibrosis

#### **Health condition**

inspiratory muscles (inademhaling spieren) training Cystic Fibrosis (taaislijmziekte) exercise capacity (inspanningsvermogen)

### **Sponsors and support**

**Primary sponsor:** University Medical Center Utrecht, The Netherlands **Source(s) of monetary or material Support:** Koninklijk Nederlands Genootschap Fysiotherapie (KNGF)

### Intervention

### **Outcome measures**

#### **Primary outcome**

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Peak workload attained during cardiopulmonary exercise testing.

#### Secondary outcome

- 1. Exercise capacity;
- 2. Respiratory muscle function;
- 3. Peripheral muscle function;
- 4. Habitual daily activity;
- 5. Rate of perceived excertion;
- 6. Patients preferred ocupational performance;
- 7. Spirometry;
- 8. Anthropometry;
- 9. Use of medication and other care;
- 10. Health related quality of life.

# Study description

#### **Background summary**

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).

#### Study objective

A home-based peripheral muscle training program (Five Basic Exercises program (5BX)) is

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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).

#### Study design

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

#### Intervention

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.

# Contacts

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# **Eligibility criteria**

### **Inclusion criteria**

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

### **Exclusion criteria**

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".

# Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	60

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Type:

Anticipated

# **Ethics review**

Positive opinionDate:04Application type:Fir

04-11-2009 First submission

# **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
NTR-new	NL1975
NTR-old	NTR2092
Other	METC UMC Utrecht : 09-114/K
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# **Study results**

Summary results N/A