The effect of using a walk-bike on quality of life and exercise capacity in patients with idiopathic pulmonary fibrosis.

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

Samenvatting

ID

NL-OMON26039

Bron
Nationaal Trial Register

Verkorte titel
Walk-bike IPF

Aandoening

Idiopathic pulmonary fibrosis (IPF), walk-bike, quality of life, exercise capacity

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center, Department of Pulmonary Medicine
Overige ondersteuning: Longfibrose patienten vereniging (Dutch Lung Fibrosis Patients Association)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in total score in health-related quality of life questionnaire SGRQ

Toelichting onderzoek

Achtergrond van het onderzoek

IPF is a devastating progressive disease with limited treatment options. Dyspnea and fatigue lead to a reduction of daily physical activities, exercise tolerance, muscle strength and quality of life. Problems reported by IPF patients are social isolation, increased level of dependency and immobility.We hypothesized that use of this walk-bike in daily life extends the range and everyday mobility of IPF patients, thereby decreases the level of dependency and social isolation, factors that are associated with quality of life. If, with this low-cost intervention, daily activities of IPF patients increase, exercise capacity might improve too. The objective of this pilot study is to assess the efficacy of the ¡°walk-bike¡± on quality of life and exercise capacity in IPF patients. In this crossover pilot study participants will be randomly allocated to either an 8 weeks-exercise intervention (using a walk-bike) or receive standard treatment only. After the follow-up visit at week 9 patient will cross-over to the other group.

Doel van het onderzoek

Use of this walk-bike in daily life extends the range and everyday mobility of IPF patients, thereby decreases the level of dependency and social isolation, factors that are associated with quality of life. If, with this low-cost intervention, daily activities of IPF patients increase, exercise capacity might improve too.

Onderzoeksopzet

There are three study visits:

-Baseline measurements before randomly allocation to either intervention group (use of walk-bike) or control group.

-Post measurements at week 9

-Crossover to other group.

-Post measurements at week 18.

Onderzoeksproduct en/of interventie

Use of a walk-bike in daily life during 8 weeks, with a minimum of 1 hour per day. The patient will be asked to record the time using the walk-bike in a diary. At baseline instructions will be given and a training under supervision.
The control group will receive standard treatment only.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-IPF patients

-Diagnosis of IPF, including probable and possible diagnosis according to ATS/ERS criteria

-Written informed consent

-TLCOc ¡Ý 30%(pred) and FVC ¡Ý 50% (pred)

-6MWD ¡Ý 150 m

-Being clinically stable

-Absolute decline in TLCOc and FVC should be less than 10% in the past 6 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Participation in a formal rehabilitation program within 4 months of start of study

-Musculoskeletal disorders

-Severe cardiac diseases (ejection fraction < 30%, daily angina, or otherwise specified by treating cardiologist)

-Unable to understand informed consent

-Other conditions that hamper the use of a walk-bike

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-07-2015
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	NL5186
NTR-old	NTR5334
Ander register	NL45411.078.14 : MEC- 2014-047 Erasmus MC

Resultaten