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

No registrations found.

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

Summary

ID

NL-OMON26039

Source
Nationaal Trial Register

Brief title
Walk-bike IPF

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center, Department of Pulmonary Medicine
Source(s) of monetary or material Support: Longfibrose patienten vereniging (Dutch Lung Fibrosis Patients Association)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

-Change in exercise capacity measures
(distance (m) during 6-minute-walk-test and average steps per day)

-Change in scores in health-related quality of life questionnaires K-BILD and GAD-7

-Change in component scores (symptoms, activity and impact) in health-related quality of life measured with SGRQ.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

-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.

Exclusion criteria

-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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2014
Enrollment:	22
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-07-2015
Application type:	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	NL5186
NTR-old	NTR5334
Other	NL45411.078.14 : MEC- 2014-047 Erasmus MC

Study results