Patient and Partner *Empowerment* Protocol in Idiopathic Pulmonary Fibrosis

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To evaluate the effect and feasability of a short support program for patients with IPF and their partners. The secondary objective is to explore if hair cortisol, as a measure of chronic stress, is a feasible biomarker for Quality of Life in IPF.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON42031

Source
ToetsingOnline

Brief title
PPEPP

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Idiopathic Pulmonary Fibrosis, scarring of the lung

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Idiopathic Pulmonary Fibrosis, Patient support groups, Quality of Life

Outcome measures

Primary outcome

To evaluate the effect of a short educational program for patients with IPF and their partners on quality of life measured with K-BILD.

Secondary outcome

-to explore if hair cortisol values change before and after the program

-to explore if changes in perceived stress and anxiety measured with questionnaires correlate with hair cortisol values

-to explore if outcomes of the questionnaires focusing on quality of life, health status, anxiety and depression and stress change before and after the program.

-to assess if there is there a learning effect evaluated by IPF specific questions.

Study description

Background summary

Idiopathic Pulmonary Fibrosis (IPF) is a specific form of pulmonary fibrosis of unknown etiology. IPF has a progressive and irreversible course and the mean survival is 2.5-3.5 years after diagnosis. No curative medication exists and life expectancy is short. At the moment, there is only one registered medicine that appears to slow the disease progression. For a small group of patients, lung transplantation can prolong survival. Therefore, interventions focused on improving Quality of Life are an important aspect of clinical care in IPF.
A short support program focusing on education on IPF, psychosocial support and physiotherapy for patients and partners could lead to a better QoL, by improving knowledge about the disease and eliminating uncertainties. Chronic

diseases with great impact on QoL are often accompanied by high perceived stress levels. Chronic stress has been associated with high cortisol levels. However, cortisol levels in blood, saliva and urine are highly variable during the day and therefore findings only show real time information. Cortisol levels measured in scalp hair provide a marker for long-term cortisol exposure and are not subject to the limitations of time-point measurements. Using this relatively novel method, chronically increased cortisol has been linked to stress exposure and decreased mental health.

Study objective

To evaluate the effect and feasability of a short support program for patients with IPF and their partners.
The secondary objective is to explore if hair cortisol, as a measure of chronic stress, is a feasible biomarker for Quality of Life in IPF.

Study design

Prospective intervention pilot study

Intervention

Support program for patients with IPF and their partners.

Study burden and risks

Participants will be asked to attend 3 afternoons, each with a duration of 3 hours, in the hospital for an educational program. Also, participants will be asked to fill in a set of questionnaires at 4 designated moments. For patients this set consists of 5 questionnaires, for partners this set contains 3 questionnaires. Before and after the program, knowledge about IPF is tested, using 10 IPF specific questions. After the program, a hair sample of approximately 150 hairs (20mg) will be collected from all participants that consented. This will be done in such way that it is not or barely visible where the sample was taken. This procedure will take 5 minutes. Hair samples can be taken during a regular scheduled outpatient clinic visit or the researcher can come to the participators at home. Attending the program, filling in questionnaires and taking hair samples is not expected to change the course of the disease or cause side effects.The advantage is that patients and partner receive extra education and coaching during these meetings. The participants will have the opportunity to continue the support groups after the program has ended. The control group will be asked to fill in a set of questionnaires (same as the patients and partners attending the program) at 4 designated moments. Filling in questionnaires is not expected to change the course of the disease or cause side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For patients only:
- Diagnosis of IPF according to the guidelines of 2011
-Forced Vital Capacity (FVC) >=45% from predicted, and if available diffusion capacity for carbon monoxide (DLCO) >= 25% from predicted;For patients and partners (a partner is defined as a marital partner, family member or other close contact):
-Willing and able to attend three afternoons in the outpatient clinic and to complete questionnaires.
-Able to speak, read and write in Dutch
-Written informed consent

Exclusion criteria

For patients only:
- Estimated life expectancy less than 1 year;For patients and partners (a partner is defined as a marital partner, family member or other close contact)
- Unable to provide informed consent
- History of severe psychiatric disease
- If consent for hair sampling is given: use of steroids (systemic, inhalation, intra articular etc.) in the past year.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2014
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-08-2015

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48553.078.14