# Home monitoring in Idiopathic Pulmonary Fibrosis; improving use of anti-fibrotic medication and quality of life

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In this study we will investigate whether a home monitoring program improves disease-specific HRQOL for IPF patients through appropriate medication use and subsequently results in better objective and subjective outcomes.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Lower respiratory tract disorders (excl obstruction and infection) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46643

**Source**
ToetsingOnline

**Brief title**
IPF online

### Condition

- Lower respiratory tract disorders (excl obstruction and infection)

**Synonym**
idiopathic pulmonary fibrosis, lung fibrosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** e-health, home monitoring, idiopathic pulmonary fibrosis, quality of life

## Outcome measures

### Primary outcome

The primary outcome is the difference in the change in total score of K-BILD (Health-related quality of life) between the home monitoring group and the standard care group at 24 weeks.

### Secondary outcome

- Costs and cost-effectiveness

- Patient expectations and satisfaction with medication

- Patient satisfaction with care process

- Number of patients who discontinue use of medication

- Amount of contacts with healthcare providers and number of visits per patient

- FVC decline at 24 weeks

- Personal goal of patient defined at start of study

- Home monitoring values compared to in hospital values of lung function.

- Relation between FVC measurements and PROMs.

- Effect of home monitoring on different parameters of (HR)QOL

# Study description

### Background summary

IPF is a chronic disease with progressive scarring of the lung tissue (fibrosis), resulting in a poor prognosis and a devastating impact on the lives of patients and their families. Progressive shortness of breath, cough and fatigue are major factors influencing health-related quality of life (HRQOL) in

patients with IPF. Recently two anti-fibrotic drugs became available that slow down disease progression. The availability of effective drugs for this devastating disease has importantly changed daily care and research in IPF. Currently, one of the major challenges in daily IPF care is the evaluation of how individual patients objectively and subjectively experience treatment and benefit from treatment. The use of information communication technology in health care, also named e-health, is a promising solution to improve the quality of care. E-health allows remote exchange of data between patients and health care professionals which enables monitoring, research and management of long term conditions. Also communication between patients and physicians, and physicians mutually, becomes more accessible. This creates an opportunity for earlier intervention by health care professionals, which may prevent a hospital admission. This might improve quality of life and reduce costs. Patients easily get access to up-to-date and tailored information, in an interactive way. By providing these tools, patients may better understand their health conditions and become actively involved in management of their own health care, which may lead to a better health status. We have developed an *internet tool* for patients with IPF, providing information and enabling them to keep track of their own symptoms, HRQOL scores, medication use and lung function results.

## Study objective

In this study we will investigate whether a home monitoring program improves disease-specific HRQOL for IPF patients through appropriate medication use and subsequently results in better objective and subjective outcomes.

## Study design

This is a prospective randomized clinical multi-centre study.

## Intervention

The intervention of this study consists of a home monitoring program added to standard care. Control group will receive standard care alone.
The home monitoring program consists of 1) the use of a previously developed interactive internet tool to coach patients and enhance self-management 2) home-based pulmonary function testing with a handheld spirometer and 3) recording of patient reported outcomes (PROs).

## Study burden and risks

Patients will be asked to use the home monitoring program, fill in questionnaires and perform home spirometry. There will be no risk and the burden is acceptable. Participants in the intervention group may directly benefit from this study, because the comprehensive home monitoring program promotes disease self-management and offers extra information and advices about

the disease, medication and side-effects. This may help patients to feel more in control and improve their quality of life.

# 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

All patients with a diagnosis of IPF according to the ATS 2011 criteria and HRCT/pathology criteria of the Fleischner Society (White paper November 2017), about to start on anti-fibrotic treatment (either nintedanib or pirfenidone) will be invited to participate.

## Exclusion criteria

not able to speak, read or write in Dutch,
not able to comply with the study protocol according to the judgement of the patient and/or investigator

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-01-2018 |
| Enrollment: | 90 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 19-10-2017 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 09-03-2018 |
| 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 | NL62925.078.17 |