# eVita COPD; Patient Centered Care through eHealth Solutions

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Congenital respiratory tract disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44920

**Source**
ToetsingOnline

**Brief title**
eVita COPD

### Condition

- Congenital respiratory tract disorders

**Synonym**
COPD, respiratory symptoms

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** stichting Zorg Binnen Bereik

## Intervention

**Keyword:** COPD, eHealth, selfmanagement

## Outcome measures

### Primary outcome

The main study parameter is change of health status (CCQ) of primary care COPD patients who received an online supported self-management program, with different implementation methods. We expected that higher levels of personal assistance will result in better selfmanagement and improve health stuatus .

### Secondary outcome

Secondary outcomes are the effects of different implementation methods of the selfmanagement program on general quality of life, health care use and actual use of the online patient portal.

# Study description

### Background summary

The number of patients in need of COPD management is increasing. Self-management may help to provide accessible health care but costs are high due to ineffective health care processes. Evidence based improvements of efficiency and quality in health care processes and in clinical outcomes have been reported for online automated monitoring systems (patient portals). However, sustainable realization in daily practice stays behind. Insights in optimal implementation methods in large real-life primary care populations are needed for successful integration in practice.

### Study objective

The main aim is to investigate clinical effects of different implementation methods of online supported self-management for COPD patients in primary care. Secondary objectives include effects on well-being, health care use and actual use of the portal. Differences in users* satisfaction will be investigated as tertiary goals. Patient characteristics will be investigated as determinants

for actual use of the portal.

## Study design

This study encludes a parallel cohort design. The clinical effects will be measured according to interrupted time series (ITS) design.

## Intervention

Participants who wish to start with self-management will be supported with an online platform for group A and B, called eVita COPD patient platform. This platform enables patients to manage their own health and disease. The COPD platform is integrated in a patient platform (eVita platform) for chronic diseases (diabetes, heart failure and COPD) that is developed by health care professionals, ICT professionals and (COPD) patients. Patients in group A and B will be randomly divided in 2 subgroups after inclusion. Patients in subgroup A1 and B1 will be individually supported to use the online patient portal by an account manager in face-to-face (A1) or telephone contacts (B1). Subgroups A2 and B2 will not receive additional support from an account manager. For COPD patients in group C a more simple portal will be provided by Saltro Diagnostic Centre, with basic information of COPD and individualized test results.

## Study burden and risks

General Practitioners in the three primary care cooperations that will parcticipate in this study provide COPD care since many decades. The care programs are grounded on evidence based national guidelines and have received objective quality labels. Professionals of the primary care cooperations are in control of the safety of all patients on daily base: deviations in CCQ, medication or other determinants are automatically and daily sent to the professionals to guarantee safety of all patients. Comparable self-management programs are broadly accepted and being used by other professionals without report of adverse events, despite lack of evidence based support.

For research goals, patients are asked to fill in questionnaires every three months during a period of 15 months. The questionnaires will be provided online and take between 10-20 minutes to complete. After replying the first and last set of questionnaires, participants will receive gift cards (¤30 in total) as a reward. This study is important as current care processes can be improved in favor of patients by its results.

Patients who do not wish to start with self-management continue to receive regular care. Participants are free to withdraw from the study any moment without specification of reasons. This will not affect continuity of care. Furthermore, professionals within the cooperations can decide to withdraw

subjects from the study for urgent medical reasons.

## 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

COPD patients according to GOLD criteria (post-bronchodilator FEV1/FVC<0.7)

### Exclusion criteria

patients who are unable to fill in questionnair
patients that have no access to internet
patients with terminal illness

severe immobile patients
patients with severe substance abuse

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

## Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-02-2014 |
| Enrollment: | 225 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 15-07-2013 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 13-07-2016 |
| Application type: | Amendment |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

# 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 | NL44486.058.13 |

# Study results

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| Date completed: | 01-11-2016 |
| Actual enrolment: | 215 |