# Adaptive Computerized COPD Exacerbation Self-management Support (ACCESS): a randomized controlled trial.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Respiratory tract infections |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON42056

**Source**
ToetsingOnline

**Brief title**
ACCESS study

### Condition

- Respiratory tract infections

**Synonym**
Chronic Obstructive Pulmonary Disease (COPD)

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Chronic Obstructive Pulmonary Disease (COPD), exacerbations, IT application, self-management

## Outcome measures

### Primary outcome

Primary aim: to improve the number of exacerbation-free weeks.

### Secondary outcome

Secondary aims: to improve exacerbation self-management,

exacerbation-management related self-efficacy, and quality of life. To decrease

ER visits, hospital admissions and COPD related costs.

# Study description

### Background summary

COPD exacerbations considerably affect patients* health status and contribute to COPD related costs. Patients often have problems in recognizing and responding promptly to exacerbations. Tools that support patients in exacerbation self-management such as paper exacerbation action plans and telemonitoring systems have shown some positive results on exacerbation related outcomes. However, many patients appear not to adhere to their action plan instructions. Besides, existing telemonitoring tools rely heavily on the input of healthcare professionals which makes it difficult to assess the true effects and cost effectiveness of telemonitoring systems.
Recently, we have developed the *Adaptive Computerized COPD Exacerbation Self-management Support* (ACCESS) system. This system is far more advanced than existing telemonitoring systems. It integrates the outcomes of objective parameters, such as spirometry, pulse-oximetry, temperature, and self-reported symptom worsening into a Bayesian network model resulting in a weighted exacerbation risk prediction. Patients are able to monitor themselves at any given moment. The ACCESS system not only predicts whether an exacerbation is imminent, but also provides ad hoc tailored advice without interference of a healthcare professional.

### Study objective

Our primary aim is to assess the (cost-)effects of the ACCESS system in the support of exacerbation self-management of patients with COPD.

## Study design

This study is a multicenter, pragmatic, two-arm, randomized controlled trial with a follow-up of 12 months per patient.

## Intervention

After a short self-management educational session on exacerbations, patients are randomized to either 1) exacerbation self-management support through the use of a paper exacerbation action plan (control group); or 2) exacerbation self-management support through the use of the ACCESS system (intervention group).
Participants in the intervention group receive the instruction to use ACCESS when they notice a change in COPD symptoms. Patients in the control group receive the instruction to use their paper action plan when they notice a change in COPD symptoms.

## Study burden and risks

Burden
Before the start of follow-up and after informed consent, all enrolled patients participate in a 1 hour group meeting addressing early recognition and prompt treatment of exacerbations. In the intervention group patients receive instructions from their practice nurse/pulmonary nurse on the use of the ACCESS system. Patients are asked to use ACCESS whenever they experience acute symptom worsening. An ACCESS entry takes about 5 minutes. In the control group, patients receive instructions from their practice nurse/pulmonary nurse on the use of a paper exacerbation action plan as recommended by current national COPD guidelines. At three months patients in both groups visit their practice nurse/pulmonary nurse to evaluate their exacerbation self-management.
For outcome measurements both groups have weekly phone calls from an automated telephone system (TEXAS) for one year, scheduled on the day and time of the patient*s preference. This phone call takes about four minutes. All questionnaires are filled in at baseline and at 12 months of follow-up, except for COPD specific quality of life and generic quality of life which are also filled in at three, six and 9 months. At six and nine months a member of the research team contacts the patients in both groups for research purposes, i.e. evaluating the questionnaires and the use of the automated exacerbation assessment system TEXAS.

Risks
The risks in this study are limited. To all participants care as usual is continued.

Benefits
All participants may benefit from participation, because all patient receive support in exacerbation self-management. Participants in the intervention group receive the ACCESS system in addition to usual care. Participants in the control group receive a paper action plan, which is the recommended care by current COPD guidelines.

## 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

- age >= 40 years;
- confirmed diagnosis of COPD by spirometry (post-bronchodilator FEV1/FVC < 0.70);
- at least 2 self-reported exacerbations in the previous 12 months, i.e. a change for >= 2 consecutive days in either >= 2 major symptoms (dyspnea, sputum purulence, sputum

amount) or any 1 major symptom plus any >= 1 minor symptoms (colds, wheeze, sore throat, cough)

### Exclusion criteria

- self-reported co-morbid conditions that prohibit participation;
- unable to communicate in the Dutch language;
- severe difficulties using a smartphone

## 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: | Pending |
| Start date (anticipated): | 01-04-2015 |
| Enrollment: | 86 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | a new software application called ACCESS |
| Registration: | No |

## Ethics review

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| Approved WMO Date: | 08-04-2015 |
| Application type: | First submission |

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| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 15-04-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 09-06-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 16-06-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 21-07-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 23-09-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 27-10-2015 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 08-01-2016 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 13-01-2016 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 01-04-2016 |
| Application type: | Amendment |

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| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 30-05-2017 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL49741.091.14 |