

# Qualitative study on experiences of COPD patients on ICU admission because of exacerbation and the impact on quality of life.

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Primary objective: The primary objective is to answer the question: How do COPD patients experience intensive care unit admission because of exacerbation and what is the impact on their quality of life. This study aims to understand the perspective...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Lower respiratory tract disorders (excl obstruction and infection)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON41178

### Source

ToetsingOnline

### Brief title

The ICU QOL-study

### Condition

- Lower respiratory tract disorders (excl obstruction and infection)

### Synonym

COPD and Chronic Obstructive Pulmonary Disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente

**Source(s) of monetary or material Support:** Eigen middelen longgeneeskunde

## Intervention

**Keyword:** Exacerbation of COPD, Patientperspective, Quality of life, The ICU QOL-study

## Outcome measures

### Primary outcome

Het primary outcome measure consists of answering the question: how do COPD patients experience intensive care unit admission because of exacerbation and what is the impact on their quality of life?

### Secondary outcome

The secondary outcome measure consists of answering the questions:

1. What are the experiences of patients with ICU admission because of exacerbation of COPD?
2. What is the impact of this ICU admission on the quality of life in people with COPD?
3. How did patients experience the treatment during ICU admission?
4. How do patients experience the information about possible ICU admission and treatment?

## Study description

### Background summary

Even though there is a relationship between frequent exacerbations of COPD, hospitalization and health related quality of life, there is little research on the impact of ICU admission for this group of COPD patients. Up to now, researches focused mainly on mortality within hospitals. Quality of life and utilization of health services received scant attention.

Treatment of this exacerbation in the ICU has an impact on patients. Feelings of fear, panic en loss of control due to the mask can occur in non-invasive ventilation. Mechanical ventilation has a high morbidity, associated with ventilator pneumonia, and mortality. Several studies have been published in which standardized quality of life questionnaires were used to measure the impact of ICU admission. Several studies have reported low quality of life due to ICU-admission but there were also conflicting results.

Research focused on the perceptions of patients en their caregivers about the severity of COPD in life and the perception of ICU admission. Until now, no literature that considers the experiences of COPD patients with ICU admission because of exacerbation and its impact on the quality of life has been found. Therefore, this study aims to investigate this research topic.

## **Study objective**

Primary objective:

The primary objective is to answer the question: How do COPD patients experience intensive care unit admission because of exacerbation and what is the impact on their quality of life. This study aims to understand the perspective of COPD patients\* admission and treatment, and to gain insight in the perspective of the impact that ICU admission, due to COPD exacerbation, has on health related quality of life. Also, the study may contribute to the provision of information on possible ICU admission and treatment in Medisch Spectrum Twente.

Secondary objective:

In the future, this would provide information on the treatment, support and care of this patient population which promotes their quality of life.

## **Study design**

This study uses a cross-sectional design involving an in-depth interview. A total of 8 patients will undergo an in-depth interview for approximately 60 minutes. In development of the in-depth interview, the existing Hierarchical Quality of Life Model of Spilker and Revicki has been used. The ICU-QOL study is conducted in Medisch Spectrum Twente, Enschede.

## **Study burden and risks**

It may be emotional for patients to think of ICU admission, treatment and impact on quality of life. The patient may become tired and emotional in response to the interview. Other adverse events during and after interviews are not expected. If a patient suffers severe adverse events, he can contact the general practitioner and lung physician.

Patients do not directly benefit from this research. For the future, the research can provide useful information. The research may improve health care in the field of ICU admission for people with exacerbation of COPD. Patients will be interviewed at their own place, spending approximately 60 minutes on participating in the study. No financial compensation is involved.

## Contacts

### Public

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Enschede 7500 KA

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Inclusion:

1. Patients who have had a ICU admission in the period from September 2012 to January 2014;
2. Patients whose ICU admission indication was exacerbation of COPD;
3. Patients who are able to speak in understandable Dutch.

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## Exclusion criteria

Exclusion:

1. Patients with severe psychiatric morbidity, noticeable in the personal file of the patients. The interview may be stressful for this group.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-07-2014

Enrollment: 8

Type: Actual

## Ethics review

Approved WMO

Date: 05-06-2014

Application type: First submission

Review commission: METC Twente (Enschede)

## 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
Other	17858
CCMO	NL48897.044.14