

# Burden of Obstructive Lung Disease

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The BOLD initiative is designed to provide a means to collect high-quality, country-specific data on the prevalence and social and economic burden of chronic obstructive pulmonary disease (COPD) using strictly standardized, tested methods. BOLD data...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Bronchial disorders (excl neoplasms)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30709

### Source

ToetsingOnline

### Brief title

BOLD

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

COPD, emphysema and chronic bronchitis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** COPD, Prevalence, risk factors

## Outcome measures

### Primary outcome

Prevalence of COPD

### Secondary outcome

None

## Study description

### Background summary

COPD prevalence is generally higher than is recognized by health authorities because prevalence estimates have mostly relied on self-reported doctor-diagnosis, a notoriously unreliable source of information for COPD. There is an urgent need for reliable prevalence data obtained from population-based surveys using carefully standardized methods.

### Study objective

The BOLD initiative is designed to provide a means to collect high-quality, country-specific data on the prevalence and social and economic burden of chronic obstructive pulmonary disease (COPD) using strictly standardized, tested methods. BOLD data will enable governments and the private sector to make policy decisions on how to provide adequate and appropriate care for those suffering from COPD.

### Study design

The initiator of this project is the Kaiser Permanente Centre for Health Research in Portland, Oregon (USA). Many hospitals in several countries join the project. E.g. China, Turkey, Iceland, South-Africa, Austria, Poland, Norway, Australia, U.K. and Germany. In the Netherlands the University Hospital in Maastricht will participate in the study.

BOLD is designed primarily as a COPD prevalence survey among non-institutionalized adults aged older or equal to 40 years. Individuals in this age range will be asked to complete a questionnaire covering respiratory symptoms, health status, activity limitation, and exposure to potential risk factors, such as tobacco smoke.

### Study burden and risks

People are asked to come to the University Hospital in Maastricht or the former Hospital Annadal once. This visit will approximately take 1 tot 1,5 hours. They will be interviewed following 5 structured questionnaires regarding health and habits. They will also be asked to provide measurements of lung function before and after administration of a short-acting bronchodilator.

## Contacts

### **Public**

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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

Adults older than or equal to 40 years.

## Exclusion criteria

People who are institutionalized for chronic (mental) illness, military and prisoners

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 12-09-2007

Enrollment: 600

Type: Actual

### Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 26-02-2007

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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	NL14657.068.06