

# myAirCoach \* The use of home-monitoring and mHealth systems to predict asthma control and the occurrence of asthma exacerbations

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Respiratory disorders NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON43950

### Source

ToetsingOnline

### Brief title

myAirCoach first quantification campaign

### Condition

- Respiratory disorders NEC

### Synonym

asthma, asthmatic bronchitis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Europese Unie. Horizon2020

## Intervention

**Keyword:** asthma, mHealth, self-management, sensor

## Outcome measures

### Primary outcome

The degree to which the various measurements, alone or in combination, can predict loss of control on asthma during phase one, and the occurrence of (severe) exacerbations during phase two.

### Secondary outcome

- User acceptance of mHealth and home-monitoring systems, as determined by user adherence to measurements and the After-Scenario Questionnaire (ASQ) feedback
- The influence of seasonality (different seasons) on our primary parameters/endpoints

## Study description

### Background summary

Asthma is a variable lung condition whereby patients experience periods of controlled and uncontrolled asthma symptoms. Poor asthma control is associated with an increased risk of exacerbation, impaired quality of life, increased use of healthcare services and reduced productivity. Therefore, the ability to determine and to predict the level of asthma control is useful for patients and their healthcare teams, and may assist in the management of the condition.

### Study objective

Therefore, the aim of the myAirCoach project is to develop and evaluate technologies that assist patients with asthma. To this purpose we developed a one year observational quantification campaign in which we will identify potentially relevant self-monitoring procedures, including sensor devices and environmental data and we will evaluate their effectiveness in predicting

asthma control.

## Study design

Observational study divided in two phases. Patients will be provided with mHealth and home-monitoring systems. Phase 1 involves one-month of daily measurements using these systems. Phase 2 is a follow-up phase of 11 months, with weekly measurements. A further two weeks period of daily monitoring randomised between 2-9 months will also be conducted in Phase 2, to assess potential seasonal influences.

## Study burden and risks

This is an observational study in which no interventions take place. Therefore the risks of participation are limited to local side effects of the sensors and possible anxiety related to the feedback of vital signs. This research constitutes a considerable burden to patients, especially in phase 1, since it requires regular measurements and filling in questionnaires. The benefit for participants will be an increased awareness of relations between deterioration of asthma and environmental stimuli and bodily signs.

## Contacts

### Public

Leids Universitair Medisch Centrum

albinusdreef 2  
Leiden 2300 RC  
NL

### Scientific

Leids Universitair Medisch Centrum

albinusdreef 2  
Leiden 2300 RC  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

\* Confirmed diagnosis of asthma by either:

o Reversibility of 12% and/or 200ml in a spirometry

o Peak flow monitoring of one week showing \*

o Positive bronchial challenge;\* Use of regular asthma treatment, minimal 6 months in the previous year

\* Age 18+

\* A course of oral prednisone for a minimum of three days, or an emergency department visit/hospitalisation for asthma, in the previous twelve months. Or currently experiencing uncontrolled asthma, based on the result of the Asthma Control Questionnaire

### Exclusion criteria

\* Well-controlled and without treatment most of the year

\* Comorbidities that cause overlapping symptoms such as breathlessness, wheeze, cough or other interfering chronic condition

\* Unable to understand English, Dutch

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 26-07-2016

Enrollment: 50  
Type: Actual

## Ethics review

Approved WMO  
Date: 03-02-2016  
Application type: First submission  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 16-11-2016  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## 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	NL54495.058.15