

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### Source

NTR

### Brief title

myAirCoach EC

### Health condition

Patients with a doctors-diagnosis of asthma from outpatient clinics and from general practices in the region of London and Manchester in the UK and Leiden in The Netherlands

### Sponsors and support

Primary sponsor :	Leiden University Medical Center
Source(s) of monetary or material Support :	European Union Horizon 2020

### Intervention

### Outcome measures

### Primary outcome

Asthma Control assessed through the Asthma Control Questionnaire (ACQ)

## Secondary outcome

Asthma exacerbations, lung function, FeNO, quality of life, patient utilities, costs, user acceptance

## Study description

### Background summary

#### DESIGN

Multi-centre, pragmatic randomized control trial

#### AIMS

To assess the myAirCoach system in a real life environment and determine whether it provides clinical benefit (improvements in asthma control) to patients with asthma.

#### OUTCOME MEASURES

Primary: Asthma Control (assessed through the ACQ)

Secondary: Lung function, asthma exacerbation, quality of life, Symptoms, costs

#### POPULATION

Maximal 60 subjects in the Netherlands, minimal 30 subjects in the UK, 90 subjects in total

#### ELIGIBILITY

Adult patients with uncontrolled asthma

#### TREATMENT

myAirCoach intervention

#### DURATION

3-9 months (variable follow-up length); A sequential phased study so that patients will therefore be involved for a minimum 3 months, up to a maximum 9 months

## Study objective

Self-management support by the myAirCoach system as an adjunct to usual care improves asthma control in patients with asthma, compared to usual care.

## Study design

Type of study: Multi-centre, pragmatic randomized controlled trial, in which participants will be randomized in a 1:1 ratio to myAirCoach self-management support as an adjunct to usual care (myAirCoach group) or to usual care alone (usual care group).

Duration: 3-9 months (staggered enrolment with variable follow-up duration). A sequential phased study so that patients will therefore be involved for a minimum 3 months, up to a maximum 9 months.

## Intervention

Usual care group

Patients in the usual care group will be provided with regular (face-to-face) care with their health care professionals.

myAirCoach group

In addition to usual care patients in the myAirCoach group will be provided with self-management support via the myAirCoach system. This system consists of the several devices and mHealth and web-applications for patients as well as a web-application for health care professionals.

## Contacts

### Public

Leids Universitair Medisch Centrum<Br>

Postzone J-10<br>

Postbus 9600

Jacob K. Sont

Leiden 2300 RC

The Netherlands  
+31 (0)71 5269111

**Scientific**

Leids Universitair Medisch Centrum<Br>

Postzone J-10<br>

Postbus 9600

Jacob K. Sont

Leiden 2300 RC

The Netherlands

+31 (0)71 5269111

## Eligibility criteria

### Inclusion criteria

- Age 18+
- Clinician diagnosis of asthma
- Asthma treatment step 2-5 - need for regular controller medication ( $\geq 6$  months of the year), this equates to 2 or more ICS prescriptions per year
- Poor asthma control ( $ACQ > 0.75$ ) and/or one-or-more exacerbations or hospital visit in the previous year due to asthma
- Ownership of a mobile phone compatible with the myAirCoach system

### Exclusion criteria

- Unable to understand English or Dutch, as appropriate

## Study design

### Design

Study type :	Interventional
Intervention model :	Parallel
Allocation :	Randomized controlled trial

Masking :	Open (masking not used)
Control :	N/A , unknown

## Recruitment

NL	
Recruitment status :	Recruiting
Start date (anticipated) :	16-02-2018
Enrollment :	90
Type :	Anticipated

## Ethics review

Positive opinion	
Date :	02-05-2018
Application type :	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 46602  
Bron:  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL6944
NTR-old	NTR7200
CCMO	NL62699.058.17
OMON	NL-OMON46602

## Study results