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

Published: 03-02-2016
Last updated: 19-04-2024

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-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders NEC
Study type	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