Evaluation of myAirCoach self-management support compared with usual care in asthma: a pragmatic randomized controlled trial

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Primary objectiveTo assess whether self-management support by the myAirCoach system as an adjunct to usual care improves asthma control in patients with asthma, compared to usual care.Secondary objectives* To determine whether the myAirCoach system…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON46602

Source
ToetsingOnline

Brief title
myAirCoach: evaluation campaign

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, CARA

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: EU Horizon 2020

Intervention

Keyword: eHealth, mHealth, personalised, sensors

Outcome measures

Primary outcome

Primary objective

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

Secondary outcome

Secondary objectives

* To determine whether the myAirCoach system improves quality of life, asthma exacerbations and FeNO and lung function level

* To determine whether the myAirCoach system improves adherence to medications and asthma self-management

* To determine users* acceptance of the myAirCoach system and identify potential issues to the implementation of the system

* To assess cost-effectiveness and organisational impact of the myAirCoach system, compared to usual care

* To determine whether the Philips Air Purifier improves asthma control, quality of life and exacerbation rate

Study description

Background summary

With the advances in technology, mHealth systems can now integrate physiological, behavioural and environmental information which is relevant for patients to improve self-management behaviour in order to achieve and maintain good asthma control and quality of life. To this purpose the myAirCoach project was started. Preceding the current study, we assessed the patients view on the use and necessity of mHealth and which components it should consist of, through focusgroups and a subsequently developed questionnaire (Simpson et al. ERJ 2016).In the quantification campaign a wide range of physiological, behavioural and environmental data was collected using current mHealth and home-monitoring systems, environmental databases and patient characteristics, to determine to what extent asthma control and the occurrence of asthma exacerbations can be predicted (Honkoop et al. BMJ open 2016). Simultaneously, technicians developed an add-on to respiratory inhaler devices. For the current study we have developed a system that is capable of supporting patients in important self-management aspects and tasks. Good self-management means that patients need to understand the purpose of asthma medications and be able to use medication and devices correctly, appreciate the importance of environmental influences, including lifestyle, need to recognise factors that make the condition worse and understand the value of self-monitoring and be able to recognise and treat worsening symptoms or function and know when to seek urgent medical attention (Reddel et al. Int J Tuberc Lung Dis 2014).
The myAirCoach system provides patients better insight into their condition and how it is affected by their environment and behaviour. In addition, myAirCoach supports asthma patients and their health care professionals in setting self-management goals and facilitates more personalised recommendations on asthma management based on a patients* medical history and continuous/regular monitoring of environmental, physiological and behavioural factors that are known to affect asthma control and to cause asthma exacerbations.
The myAirCoach system provides feedback on the concentration of pollen and dust particles in the outside environment. However, indoor pollen and dust might prove to be just as important, especially concentrations in the bed-room where patients spend many hours. With the advent of air purifiers, this provides with another target for improvement of asthma outcomes of our patients. However, for the current study, if the air purifier would be added from the start, it would be impossible to determine the separate effect on outcomes of the myAirCoach system and of the air purifier. Therefore we added a second randomisation procedure, with an additional one month follow-up, to assess the (additional) effect of the Philips air purifier in both the intervention and control group.

Study objective

Primary objective
To assess whether self-management support by the myAirCoach system as an adjunct to usual care improves asthma control in patients with asthma, compared

to usual care.

Secondary objectives
* To determine whether the myAirCoach system improves quality of life, asthma exacerbations and FeNO and lung function level
* To determine whether the myAirCoach system improves adherence to medications and asthma self-management
* To determine users* acceptance of the myAirCoach system and identify potential issues to the implementation of the system
* To assess cost-effectiveness and organisational impact of the myAirCoach system, compared to usual care
* To determine whether the Philips Air Purifier improves asthma control, quality of life and exacerbation rate

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 (variable follow-up length; see figure below) plus 1 month of environmental monitoring; A sequential phased study so that patients will therefore be involved for a minimum 4 months, up to a maximum 10 months.
Number and type of subjects: 90 asthmatic patients
Study Outcomes: Primary: Asthma Control (assessed through the ACQ)
Secondary: Asthma exacerbations, lung function, quality of life, costs
Start date: 01.09.2017
End date: 30.06.2018
The follow-up will end on the same calendar date for all participants in order to observe sufficient occurrences of asthma exacerbations during the study period. This results in a variable follow-up duration.
UK Centre: Royal Brompton Hospital
Netherlands: Leiden University Medical Center

Staggered enrolment
To prevent that major technical issues with the myAirCoach system inflicts too many participants and thereby possibly leading to quitting the study, participants will be enrolled in cohorts corresponding to myAirCoach version releases (minor updates).

Intervention

Usual care vs myAirCoach intervention

myAirCoach intervention

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.

Additional 1 month Philips Internal environmental monitoring
We will provide participants with two Philips Air Purifier devices. This system measures and displays the indoor air quality (particulate matter). We will ask participants to place one in the bedroom and one in the living room. The purifier operates quietly, the sound of a gentle breeze, and dims its light at night, so it won*t disturb sleep. We will supply devices to half in each group (Intervention vs. Control) who will use the Philips home air purifier machine and half will not (see Figure 1). Participants receiving these devices will receive an additional £15 to cover the cost of electricity consumption. The internal environment Philips monitoring device tells patients about indoor pollutants, which empowers them to act upon that.

Study burden and risks

Potential risks and burdens for research participants
We do not consider this study to have any significant risk to the participants. The skin prick test/peripheral blood test for allergies and the bronchial challenge are potentially performed at baseline, if participants did not undergo a recent allergy test, or if they did not have a confirmed diagnosis of asthma. Although these tests are invasive and might cause discomfort, they will also be of aid to the individual patient, since it will improve understanding of potential allergies and/or increase certainty about whether or not the patient is suffering from asthma. We do not anticipate that our research will cause any upset to the participants, since all sensors and devices are non-invasive. There are no known serious adverse effects when using any of the sensors or devices. However, these sensors and devices will provide participants with several results of continuous monitoring, such as pulse, activity, breathing rate, FeNO measurements and exhaled breath temperature and will give patients feedback on inhalation technique and medication adherence. These results may be experienced as uncomfortable by some patients, or even cause anxiety, especially if the scores are out of the ordinary.
To manage this concern we have taken several steps:
* Patients will be informed upon the purpose of the research at several stages of the process, including* the study advert, the participant information sheet, during the consent process and at the start of the study.
* Patients will be reassured that they have the right to withdraw anytime, that the data obtained will remain anonymous and will be handled in adherence with the data protection act.
* We have assigned an independent pulmonary physician who is available for questions
This research does constitute a significant burden on the time of participants.

Potential for benefit to research participants
As a result of participation in the research, patients are assisted in their self-management of asthma and improve their inhalation technique, adherence, knowledge about potential triggers for loss of asthma control or asthma attacks and potentially improve their asthma control and quality of life. In the long term, the results may assist the development/design of the next generation of 'user centred' mHealth systems, that may improve the way asthma is managed and thus be of help to the participants as well.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

maximal 60 patients with asthma in NL (and minimal 30 patients in UK)
* Age 18+

* Clinician diagnosis of asthma
* Asthma treatment step 2-5 - need for regular controller medication (*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 (Android operating system)

Exclusion criteria

* Unable to understand Dutch or English, as appropriate

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-02-2018
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	myAirCoach mobile app;inhaler adapter and biomonitor device
Registration:	No

Ethics review

Approved WMO Date:	15-12-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-02-2018
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

ID: 23774
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62699.058.17
OMON	NL-OMON23774