Evaluatie van het myAirCoach zelf-management ondersteuningssysteem voor mensen met astma in vergelijking met gebruikelijke zorg: een pragmatisch gerandomiseerd onderzoek (myAirCoach: evaluation campaign).

Gepubliceerd: 02-05-2018 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23774

Bron
NTR

Verkorte titel
myAirCoach EC

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: European Union Horizon 2020

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Asthma Control assessed through the Asthma Control Questionnaire (ACQ)

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Unable to understand English or Dutch, as appropriate

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-02-2018
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-05-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46602
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten