A cluster Randomised Controlled Trial of the effectiveness, usability and acceptability of a smart inhaler programme in asthma patients: the ACCEPTANCE study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28450

Source
NTR

Brief title
ACCEPTANCE

Health condition

Asthma

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: AstraZeneca

Intervention

Outcome measures

Primary outcome

Difference in medication adherence over twelve months between the smart inhaler programme group and control group measured by electronic monitoring

Secondary outcome

1. Asthma control (ACQ-5 score) at all time points
2. Reliever use (SABA dispense data)
3. Asthma-related quality of life (mini-AQLQ score) at all time points
4. Exacerbations
5. Usability and technology acceptance of the smart inhaler programme from a patient's and health care professional's perspective, measured by the System Usability Scale (SUS) and Technology Acceptance Questionnaire (TAQ)
6. Use of the smart inhaler programme as measured by log data
7. Total costs of health care utilisation
8. Absenteeism and presenteeism (WPAI)
9. Patient characteristics: attitude and self-efficacy (KASE-AQ), beliefs about medicine (BMQ-S), illness perception (B-IPQ), eHealth Literacy (eHLQ)

Study description

Background summary

Self-management-based eHealth interventions are promising in increasing medication adherence and maintaining asthma control. Evidence on long-term benefits and acceptability is scarce. In this open-label cluster randomized controlled trial of 12 months in general practices in the Netherlands, the effectiveness of a smart inhaler based asthma self-management programme on medication adherence will be assessed in adults with partially controlled or uncontrolled asthma with evidence of non-adherence. The primary outcome is medication adherence over twelve months. Secondary outcomes include asthma control, quality of life, exacerbations and SABA use. Furthermore, the study will investigate who would benefit most based on patient characteristics, collect health utilization data to inform a cost-effectiveness analysis and evaluate the programme on usability and acceptability.

Study objective

A smart inhaler-based self-management programme will improve medication adherence in adults with partially controlled or uncontrolled asthma.

Study design

Start run-in period of 6 weeks (T-1), baseline (T0), 3 months (T3), 6 months (T6), 9 months (T9) and 12 months (T12)

Intervention

- Intervention group: Participants in the smart inhaler based self-management programme group will use an electronic monitoring device (EMD) attached to their regular maintenance inhaler, which will be connected to an application on the participant's smartphone. The application will give reminders and feedback about the participants' medication use and participants will be able to document their asthma symptoms and triggers on a daily basis with a symptom and trigger-tracking feature. Health care professionals will have access to the data on medication adherence via a health care portal.

- Control group: Participants in the control group will be given the EMD, which will objectively monitor their inhalation actuations, without them being able to the view their medication adherence data or receive reminders ('silent electronic monitoring').

Both groups will receive usual care according to the Dutch National primary care asthma Guidelines.

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Eligibility criteria

Inclusion criteria

1. Doctor-diagnosed asthma (when recruited via general practices or public channels), self-reported asthma diagnosis (when recruited via pharmacies - asthma diagnosis will be confirmed by GP at study end (T12))
2. Partially controlled or uncontrolled asthma, defined as an ACQ-5 score ≥0.75 at the first visit T-1
3. Use of Symbicort® Turbuhaler® as maintenance therapy for at least eight weeks before entering the run-in period

4. Being non-adherent during the run-in period, defined as an adherence rate of below 80% over the third and fourth week of the run-in period. Adherence is defined as the number of adherent days as a proportion of the total number of days during the third and fourth week of the run-in period.
5. In possession of a smartphone
6. Written informed consent

Exclusion criteria

1. Age < 18 years
2. Use of SMART regimen (Symbicort Maintenance And Reliever Therapy) by taking Symbicort as reliever in response to symptoms
3. Change in inhaled corticosteroids (ICS) dose in the 4 weeks prior to the run-in period
4. Use of systemic corticosteroids in the 4 weeks prior to the run-in period, including maintenance therapy
5. Current use of biologics, including anti-IL-5 (mepolizumab, reslizumab, benralizumab) or anti-IgE (omalizumab)
6. Diagnosis of COPD, interstitial lung diseases, bronchiectasis or other significant respiratory condition
7. Malignancy with life expectancy < 1 year
8. Pregnancy
9. Inability to understand Dutch
10. Any other condition which, at the GPs and/or investigator’s discretion, is believed may present a safety risk or impact the study results

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-08-2019

Enrollment:	242
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	03-07-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52658
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7854
CCMO	NL69909.056.19
OMON	NL-OMON52658

Study results

Summary results

N/A