Innovative healthcare delivery for patients with asthma using digitally supported self-management: A pilot study in secondary care

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To investigate whether Astmakompas is feasible, acceptable, easy and safe to use in a secondary care context for both patients and healthcare professionals (HCPs), as well as to investigate its potential effects in improving health and healthcare...

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

Summary

ID

NL-OMON53444

Source
ToetsingOnline

Brief title
Astmakompas

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Asthma, eHealth, Secondary care, Self-management

Outcome measures

Primary outcome

Primary study parameters include the Feasibility of Intervention Measure (FIM), the Acceptability of Intervention Measure (AIM, only administered in HCPs), objective user patterns of Astmakompas, the Client Satisfaction Questionnaire-8 (CSQ-8, only administered in patients), the System Usability Scale (SUS, administered in both HCPs and patients), and adverse events (assessed in patients). Qualitative assessment in patients and HCPs will give a more in-depth understanding of feasibility, acceptability, usability and safety of Astmakompas.

Secondary outcome

Secondary study parameters, all assessed in patients, include asthma control (assessed using the Asthma Control Questionnaire [ACQ] and the weekly monitoring questionnaire that is part of Astmakompas), lung function as assessed by the spirometer, illness-related quality of life as assessed by the Respiratory Illness questionnaire-Monitoring 10 (RIQ-MON10), generic quality of life as assessed by the EuroQol 5 dimensions 5 levels (EQ-5D-5L), the Perceived Control of Asthma Questionnaire (PCAQ), and direct and indirect costs as assessed by items from the iMTA Productivity Cost Questionnaire (iPCQ) and iMTA Medical Consumption Questionnaire (iMCQ). Additionally, qualitative assessment in patients and HCPs will give a more in-depth understanding of direct and

indirect costs.

Study description

Background summary

Asthma is a major chronic disease that is estimated to affect approximately 262 million people worldwide. Asthma control is often suboptimal, with approximately 50% of patients having (partially) uncontrolled asthma. These patients have a higher risk of asthma exacerbations, asthma-related hospitalization and emergency department visits, resulting in high healthcare and societal costs. Poor asthma control is furthermore a major contributor to impaired health-related quality of life. Although the literature shows promising results of (digital) supported self-management interventions in improving asthma control and other important health outcomes, relatively little is known about the cost-effectiveness of such supported digital interventions delivered on a smartphone in comparison to usual care. Furthermore, no cost-effectiveness research is been conducted in a secondary care. The proposed pilot study is needed to establish whether Astmakompas is considered feasible, acceptable, easy and safe to use in a secondary care context by both patients and HCPs, as well as its potential of improving health and healthcare outcomes, before commending a large-scaled cost-effectiveness study.

Study objective

To investigate whether Astmakompas is feasible, acceptable, easy and safe to use in a secondary care context for both patients and healthcare professionals (HCPs), as well as to investigate its potential effects in improving health and healthcare outcomes.

Study design

A mixed-method study consisting of a multi-center, single-arm, pre-post intervention study with a duration of 12 weeks. The quantitative part consists of a survey providing insights on the feasibility, acceptability, usability, safety, and preliminary effects of Astmakompas. The explanatory qualitative part consist of semi structured focus groups/ individual interviews for patients, and individual interviews for HCPs, which will complement the quantitative results.

Intervention

Astmakompas is a CE-certified eHealth application for patients with asthma. The platform consists of a patient app, a portal for HCPs, and a wireless

spirometer connected to the patient app. The patient app combines monitoring with self-management tools, and provides a portal to present these data as well as to communicate with their HCP. The monitoring enables patients to monitor their asthma control on a weekly basis using a standardized Patient Reported Outcome Measure (PROM) questionnaire, and additionally with a spirometer that assesses, amongst others, FEV1 and FVC. Patients* monitoring data is linked to their personalized digital action plan, including self-management strategies and treatment recommendations based on the latest international treatment guidelines. The action plan aims to increase patients* awareness of their symptoms and/or the severity of their symptoms, as well as their corresponding adverse effects. The action plan subsequently supports patients to intervene in a more timely manner, thereby preventing worsening of symptoms. When patients* monitoring results show a deterioration of asthma control, HCPs receive smart notifications by means of algorithms. Patient data can thereby serve as direct input in the consultations with the HCP, or they can proactively offer as-needed support. By means of the communication portal between patient and HCPs, patients are able to ask non-critical asthma-related questions to their HCP through a chat function of the application.

Study burden and risks

Regarding time investment, all participating asthma patients will be asked to complete a questionnaire at baseline, taking approximately 15-20 minutes, and at post-intervention (i.e., 12 weeks after baseline), taking approximately 25 minutes. Furthermore, part of the Astmakompas intervention is completing a weekly questionnaire taking approximately 2-3 minutes to complete, and weekly spirometer assessments (i.e., approximately 1-5 minutes each). In addition, a subsample of patients (n = 8 to 12) will participate in an online focus group / individual interview lasting approximately 90 minutes, which will be reimbursed with a gift voucher of 25 euro. In line with the experiences of two previous small pilot studies, we do not expect any health risks to be associated with the use of Astmakompas. Potential benefits include increased asthma control and self-management of the disease, as well as more efficient care by means of among others increased access to medical staff. Hence, the potential benefits are expected to outweigh the burden of the study.
The participating four HCPs will participate in an individual interview lasting 60 minutes, which will be reimbursed with a gift voucher of 100 euro.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Being aged 18 years or older
• Not having used Astmakompas before
• Having a physician diagnosis of asthma
• Having uncontrolled asthma as defined by a score of >= 1.5 on the Asthma Control Questionnaire
• Being able to understand, read and speak the Dutch language (i.e., based on self-report)
• Having access to the Internet and a smartphone

Exclusion criteria

• Having a respiratory disease other than asthma
• Having a non-reversible airway obstruction

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2022
Enrollment:	23
Type:	Actual

Medical products/devices used

Generic name:	Astmakompas
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-06-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-02-2023
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	NL80559.058.22