AmbuLatory Pediatric Asthma CAre: The effect of online monitoring and communication on the quality and quantity of pediatric asthma care.

Published: 11-08-2022
Last updated: 05-04-2024

Evaluate the effect of pediatric asthma eHealth care on the healthcare utilization, asthma outcomes and quality of life.

Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON52871

Source
ToetsingOnline

Brief title
ALPACA: AmbuLatory Pediatric Asthma CAre:

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Asthma

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Eigen financiering afdeling

kindergeneeskunde (stichting pediatrisch onderzoek) + Philips research

Intervention

Keyword: Asthma, Child, Monitoring, Telemedicine

Outcome measures

Primary outcome

This study aims to evaluate the effect of pediatric asthma eHealth care on the amount, type and costs of healthcare utilization. The essence of this study is to evaluate the difference in healthcare utilization by the use of eHealth.

Secondary outcome

1) To evaluate the effect of pediatric asthma eHealth care on the asthma outcomes and quality of life.

2) To assess how long the learning effects of the healthcare utilization, asthma outcomes and quality of life effects after 3 months of follow up in theof eHealth interventions compared to the control groupon asthma outcomes. healthcare utilization last and to assess the time to first healthcare events in the follow-up period in both the intervention and control group. (survival analysis).

3) To assess the effect of eHealth interventions (i.e. education on self-management, treatment change or providing a personalized action plan) on the asthma outcomes, such as lung function and asthma control score.

4) To assess the effect of personalized real-time monitoring and education of inhalation (based on objective smart inhaler data) on the inhalation technique/adherence.

5) To investigate the effect of (via eHealth communication) supervised

nebulizer therapy (with Sami the Seal). (amount of events, % solved at home, % that still result in referral to hospital)

6) To correlate monitoring parameters (nocturnal symptoms, lung function, oxygen saturation, cough/wheeze, medication use and air parameters (indoor + outdoor + pollen) univariately and multivariate with reported symptoms and asthma control.

7) To assess the perception of dyspnea in children by correlating the self-reported dyspnea with the visual analogue scale versus home-measured lung function.

8) To analyze the preluding period before an asthma exacerbation for predictors in the home-measured signals using predictive modelling.

9) To explore the feasibility and acceptance of the monitoring devices for home-use in children.

10) To identify the patient characteristics of children with successful eHealth care outcomes.

Study description

Background summary

Asthma is one of the most common chronic diseases in children. Pediatric asthma management is focused on control of asthma symptoms, enabling patients to fully participate in daily life. The Dutch lung alliance states that regular follow-up of asthma control is needed to prevent disease deterioration and boost quality of life. Previous home-monitoring & eHealth studies show potential in ambulatory pediatric asthma care, however one-by-one could not always provide a good correlation with asthma control for all asthmatic children. The primary objective of the ALPACA study is to combine the most

potential home-monitoring measures and the optimized eHealth approaches to evaluate the effect of pediatric asthma eHealth care on the healthcare utilization asthma outcomes and quality of life.

Study objective

Evaluate the effect of pediatric asthma eHealth care on the healthcare utilization, asthma outcomes and quality of life.

Study design

The ALPACA study has a prospective randomized control interventional design, including a follow-up period to evaluate learning effect. The study is divided into two phases of 3 months; In the first phase subjects are randomized to either eHealthcare and observational home-monitoring or only observational home-monitoring during regular care. The second phase is a follow-up period of 3 months to evaluate the follow-up effects of eHealth care compared to the control group and how long these effects can last (survival analysis). The study makes use of an intention-to-treat analysis.

Intervention

eHealth home-monitoring of respiratory physiology and online communication.

Study burden and risks

This study is designed in a way to optimize the trade-off between maximizing the diagnostic value and to minimize the burden. The monitoring devices are chosen based on their feasibility in children, size and unobtrusiveness. This study asks participants to actively blow a lung function and fill in the short C-ACT questionnaire weekly for a period of 6 months. Other monitoring does not require their attention or is performed as needed. Moreover parents and children are interviewed about their experiences. This research does not have any significant safety risks for the subjects. Both the participants and the healthcare professionals have the option the pre-maturely end the participation if any risk may arise (due to i.e. non-compliance to monitoring, loosing contact, failure of technology or any other reason). Moreover children and parents can always use the escape route, which is the regular path of healthcare. Participants may benefit from gaining more insight into their asthma control and increased self-management. The study is group-related as it specifically investigates the effect of eHealth on pediatric asthma outcomes and it could therefore not be conducted without the participation of subjects belonging to the group in question.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

o Children with moderate-to-severe asthma.
o Children in the age group from 4 up to and included 11 years old.
o Children living in a house with WIFI

Exclusion criteria

o Prior participation in eHealth care trial.
o Children/Parents with an inability to understand or speak Dutch.
o Children with divorced parents or other reasons that causes them to be less than 80% on the same living address.
o Children of whom family members have already participated in this trial.
o Children using an inhaler that is not compatible with the FindAir smart

inhaler cap, which cannot be replaced by a compatible alternative.
o Children for whom it is not possible to perform at least one of the two discontinuous dyspnea assessment (lung function/pulse oximetry).
o Children with chronic diseases other than asthma (i.e. inflammatory bowel disease, behavioral disorders, mental retardation).
o Children with currently displaying COVID-19-related symptoms, namely a fever, cough and/or difficulty breathing (during inclusion) or being infected with COVID-19 in the past 14days.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2022
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Airnext spirometer;Pulox 210b pulse oxymeter;Findair smart inhaler
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-08-2022
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL74559.100.22