Cohort multiple Randomized Controlled trial in pediatric asthma: infrastructure to assess the long- and short-term effects of (eHealth) interventions

Published: 15-02-2024
Last updated: 02-12-2024

CIRCUS cohort:This study aims to provide a framework to assess the effect of (eHealth) interventions and generate short- and long-term data on clinical and patient-reported outcomes of asthmatic children using a cohort multiple Randomized Controlled…

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

Summary

ID

NL-OMON56556

Source
ToetsingOnline

Brief title
CIRCUS

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, bronchial hyperreactivity

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Dit onderzoek is eigen-geïnitieerd en zal daarom door MST worden gefinancierd. Aanstelling hoofdonderzoeker is gefinancierd door Reggeborgh Research Fellowship fonds (binnen dit fellowship wordt dit onderzoek uitgevoerd;maar het bedrijf is geen opdrachtgever voor het onderzoek)

Intervention

Keyword: care evaluation, cohort studies, Pediatric asthma, telemedicine

Outcome measures

Primary outcome

Primary outcome measures are Quality of life(QoL), asthma outcomes(asthma

control, lung function), quality of care, self-management capacity, healthcare

use, and therapy compliance.

Secondary outcome

CIRCUS study:

n/a

MIME study:

The secondary endpoint is the inhalation technique score within the

intervention group.

Study description

Background summary

CIRCUS cohort:
Testing of eHealth interventions seems crucial since eHealth provides possibilities to obtain a real-time and objective view of asthma symptoms. Traditional randomized controlled trials(RCTs) face challenges in evaluating the effect of multiple eHealth components separately and in the long process of translating intervention ideas into funded research protocols, which may risk the eHealth intervention becoming outdated.

MIME study:
Asthma is one of the most common chronic diseases in childhood. One of the problems that can lead to poor symptom control is inadequate inhaler technique. Despite these few studies reporting on the short term effect of remote observation of therapy, no studies report on long term effects of remote inhaler technique training. The research gap therefore lies in the follow-up of inhaler technique and asthma outcomes after a remote inhaler technique intervention.

Study objective

CIRCUS cohort:
This study aims to provide a framework to assess the effect of (eHealth) interventions and generate short- and long-term data on clinical and patient-reported outcomes of asthmatic children using a cohort multiple Randomized Controlled Trial (cmRCT) design.

MIME study:
This study aims to evaluate the long-term effects of video Directly Observed Therapy (vDOT) compared to regular care on the asthma control in children with asthma.

Study design

CIRCUS cohort:
The CIRCUS study is a cmRCT designed to test multiple eHealth interventions in eligible asthmatic children (4-18 years old, treated in MST) within a cohort. Observational clinical data is collected of these children and both the children and their parents regularly complete questionnaires. In addition, a random selection of eligible children is approached for participation in interventions while the non-selected children remain in the control group.

MIME study:
This study is a randomized study, designed as the first intervention of the CIRCUS cohort multiple randomized controlled trial. Children in the intervention group start with an observational week of inhalation recording. Thereafter they receive 6 weeks of intervention, followed by 3 months without intervention. Further follow-up will continue within the CIRCUS cohort. The control group consist of other cohort participants and is blinded

Intervention

Intervention 1 of the cmRCT: (attached as appendix protocol C):
video Directly Observed Therapy (vDOT). The intervention consists of taking recording of daily inhalation use and receiving four feedback sessions of an

asthma nurse based on these home recordings.

Study burden and risks

CIRCUS study:
Children and parents fill out questionnaires on a monthly and half-yearly basis. The questionnaires include: (C)-ACT, PAQLQ, CSQ-4, and PAM-13. In consultation with the patient panel we chose the shortest validated questionnaires to reduce the study burden. Other data (for example healthcare use) is collected by the researchers. No relevant risks were found in the risk analysis. We chose to use this group of children in this study as asthma management in children differs from that in adults.

MIME study:
Asthma is the most common chronic disease in childhood. And within this population incorrect inhalation technique of required maintenance medication (or reliever medication) is of frequent occurrence, causing undertreatment, uncontrolled asthma and higher risk of exacerbations. Moreover, asthma characteristics in children differ from those in adults. It is therefore important to investigate the inhalation technique, try to improve it and try to maintain a good inhalation technique throughout childhood. Moreover, individual children may benefit from the extra attention and education with regards to the inhaler technique. The burden of this study includes the recording of medication intakes for six weeks once daily (10*7=70x +-10seconds * 15minutes), 10 times filling in the (c)-ACT questionnaire (10*3min=30min), and 4 online feedback sessions of 15minutes (1hour). These measurements are non-invasive and no risks are associated with participation.

Contacts

Public
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512KZ
NL
Scientific
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512KZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

CIRCUS cohort (n=300)
-4 to 18 years old
-patient at the children*s department at Medisch Spectrum Twente at moment of inclusion
-diagnosed with asthma by a pediatrician following the Global Initiative for Asthma(GINA) guidelines 2022:

Medical history fitting asthma diagnosis:
Based on (typical) symptoms: (nighttime) wheezing, dyspnea, coughing (triggered by either viral infections, exercise, allergens or weather changes)
(Possibly) supplemented with a family history/atopy

AND

Spirometry variable expiratory airflow limitation by at least one of these criteria:
FEV1/FVC reduced compared to lower limit of normal(Z-score <= -1.64)
Positive bronchodilator responsiveness(increase FEV1>12%)
Positive Exercise Challenge Test (ECT)(decrease FEV1>= 13%)
Excessive variation in lung function (LF) between tests from different dates (variation FEV1>12% pred)

For the MIME intervention (n=106, of which 30 intervention group, 76 control group):
• Participating in CIRCUS cohort & consented willingness to participate in interventions.

• ACT <20
• Using controller inhalation therapy through one of the most common inhaler device types for children (aerosols with spacer, breath actuated aerosol (Redihaler or Autohaler), dry powder inhalator (Nexthaler, Diskus or Ellipta) for asthma at least once daily.

Exclusion criteria

For the CIRCUS cohort:
The child and/or parent(s) has/have insufficient command of the Dutch language resulting in the insufficient ability to understand and/or answer questions

For the MIME study:
• An appointment with the asthma nurse for inhalation instruction has already been scheduled.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-03-2024
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	15-02-2024

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2024
Application type:	Amendment
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
ClinicalTrials.gov	NCTvolgt
CCMO	NL85668.100.23