Home-monitoring of physical activity and vital parameters of pediatric patients following admission due to pneumonia, bronchiolitis or asthma.

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- To determine a mean recovery period for patients admitted with pneumonia, bronchiolitis, preschool wheezing and asthma by using data obtained during admission and via home-monitoring of a two week period following admission and control period and…

Ethical review	Approved WMO
Status	Completed
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON48685

Source
ToetsingOnline

Brief title
Home-monitoring after acute pediatric lung disease

Condition

- Respiratory tract infections

Synonym
asthma, lung disease

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research

Source(s) of monetary or material Support: CHDR

Intervention

Keyword: asthma, bronchiolitis, home-monitoring, pneumonia

Outcome measures

Primary outcome

- Physical activity level (step count) during admission, directly after admission and one month after admission.

Secondary outcome

- Hours of sleep and sleep pattern

- Mean heart rate during admission and at home, data collected via smartwatch

- Daily temperature using Nokia Thermo (children with preschool wheezing and lower respiratory tract infection)

- Daily FEV1/PEF/FVC measurements via portable spirometer (patients with asthma)

- Daily questions / symptom scores via smartphone app:

a. Asthma control diary (ACD) for patients with asthma

b. Respiratory symptom scores for patients with pneumonia and bronchiolitis

c. Medication use and activity estimation

d. Parent-reported recovery

- Proportion of patients with good compliance to study tasks, stratified by age- and disease groups.

- End-of-study questionnaire for parents and children about the experience and tolerability of this method of data collection.

Study description

Background summary

The past years, the use of smartwatches in medical science has increased. Recent systematic reviews have reported studies that used a smartwatch to measure activity level, eating behavior and seizures, among other things. However, these studies are almost always performed on adults and usually in a lab setting. This way of collecting data thus seems to warrant further validation among children. In the future, CHDR aims to perform clinical trials in pediatric patients using home-monitoring techniques. Clinical research in children is difficult to perform due to the invasive and time-consuming nature of current study protocols. One option to overcome these problems is frequent, non-invasive monitoring of symptoms and disease activity in a home-setting.

CHDR has developed a home-monitoring platform that comprises several devices, one of which is the Nokia Steel HR. This wearable device can monitor physical activity levels, measure pulse rate and analyze sleep pattern and sleep duration. Furthermore, the platform consists of a Nokia thermometer, Nokia scales that can measure weight and body composition and an in-house developed smartphone app that collects and transmits the data, adds a questionnaire function and which can utilize other android phone functions. Several other devices will be added to the platform in the future. In the last year, a pilot study has been performed in the Children*s hospital in Basel, during which the CHDR home-monitoring platform has been improved.

Further home-monitoring research, aimed at quantifying disease-activity, will be performed at the Juliana Children*s Hospital in the Hague. Community acquired pneumonia, bronchiolitis, preschool wheezing and asthma are common diagnoses that are characterized by respiratory complaints and often warrant admission. When patients are stabilized and do not need oxygen therapy, discharge follows swiftly. However, there is very little evidence available on the impact on daily life after discharge and the time till full recovery. In the past, studies have relied on parent-reported recovery via phone interview, but objective data is generally not available. This study aims to investigate this, while also validating the CHDR home-monitoring platform further to make it suitable for future clinical trials.

Study objective

- To determine a mean recovery period for patients admitted with pneumonia, bronchiolitis, preschool wheezing and asthma by using data obtained during admission and via home-monitoring of a two week period following admission and control period and 40 days after admission.
- To investigate physical activity levels during and after a hospital admission due to community acquired pneumonia, bronchiolitis or asthma in a pediatric

population
- To compare the calculated mean recovery time to parent reported recovery time.
- To identify baseline or treatment factors that correlate with a longer recovery time (e.g. oxygen therapy, abnormal x-ray, treatment with steroids for pre-school wheezing and asthma)
- To determine correlations between low activity levels and symptom scores, heart rate and other collected data.
- To determine the feasibility, quality and quantity (wear time) of data collection in different age groups.
- To evaluate the ePro questionnaire and notifications app.

Study design

Observational case-control study to determine recovery time after a hospital admission due to community acquired pneumonia, bronchiolitis or asthma and to validate the CHDR home monitoring program in Juliana Children*s Hospital.

Study burden and risks

The burden for study participants is estimated to be low and consists of the continuous wearing of the Nokia Steel HR watch and a once to twice (asthma subjects) daily questionnaire and daily temperature measurement (children with preschool wheezing and lower respiratory tract infection) for the duration of the study period. Furthermore, for patients with asthma, an additional daily spirometry assessment is part of the study. No invasive procedures are included in this study. There are no significant health risks associated with the study assessments. Furthermore, we do not expect any risks regarding the psychological or social state of study participants. With the exception of the smartwatch assessments, for which data will be collected continuously, all study mandated actions can be performed at the subjects* home or hospital room. Collected digital data will pass through adequately protected data servers, which will prevent privacy infractions. Furthermore, the study assessments will not be used to influence the clinical decision process.

The proposed study can only be performed in this group of paediatric patients as described above. Performing this study in an adult population would yield major difficulties since behaviour and recovery in adult patients is significantly different when compared to children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Signed informed consent from both parents prior to any study-mandated procedure.
2. Admission to the pediatric ward of Juliana Children*s Hospital, determined by the attending physician at the time of admission to be due to:
a. Community acquired pneumonia or bronchiolitis (lower respiratory tract infection) (Age 2-12)
b. Preschool wheezing (Age 2-6)
c. Asthma exacerbation with a previous history of asthma (Age 6-12)

Exclusion criteria

1. (interstitial) Lung disease other than infection, asthma or preschool wheezing, cardiac disease, neuromuscular disease, diabetes or any other chronic condition that is associated with impaired activity level.
2. Children that have a mental or motor impairment.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-11-2018
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	31-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-01-2019
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-12-2019
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

ID: 21683
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66432.098.18

Study results

Date completed:	23-03-2020
Results posted:	13-01-2021

Summary results
Trial ended prematurely

First publication
21-12-2020