Home-monitoring after acute pediatric lung disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21683

Source
NTR

Brief title
CHDR1810

Health condition

Lung disease, asthma

Sponsors and support

Primary sponsor: N.A. (Collaboration Juliana Children’s Hospital & CHDR)
Source(s) of monetary or material Support: CHDR

Intervention

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

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 trial methods. One option to overcome these problems is frequent, non-invasive monitoring of symptoms and disease activity in a home-setting. For example, by using smartwatches and other devices.

Study design

Admission – 14Day recovery period – 25Day break period – 10 day healthy period.

Contacts

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Eligibility criteria

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:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2018
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48685
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7610
CCMO	NL66432.098.18
OMON	NL-OMON48685

Study results