Home-monitoring in pediatric chronic disease

No registrations found.

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

Summary

ID

NL-OMON21018

Source
Nationaal Trial Register

Brief title
CHDR1811

Health condition

Severe overweight, fatigue, sickle cell disease, asthma, cystic fibrosis

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

- Daily physical activity level (step count)

Secondary outcome

Baseline information

Baseline questionnaires:
Arm A: Pediatric Quality of Life Inventory (PedsQL) 4.0, pedsQL multidimensional fatigue scale, Pediatric Functional
Assessment of Chronic Illness Therapy-Fatigue (peds-FACIT-F), Revised Children's Anxiety and Depression Scale (RCADS),
Children's Somatization Inventory (CSI), PROMIS pediatric pain
Arm B: pedsQL 4.0, CSI, RCADS
Arm C: pedsQL 4.0, pedsQL pain quality, PROMIS Pediatric pain,
Arm D: pedsQL 4.0, modified standardized pediatric asthma quality of life questionnaire (MPAQLQ(S)), modified asthma control
questionnaire (MACQ), cystic fibrosis questionnaire (CFQ), respiratory symptom scores

Sleep:
Hours of sleep, time deep sleep, time shallow sleep

Heart rate:
Mean heart rate, max heart rate, min heart rate

Weight and body composition (bioimpedance analysis):
Arm A: baseline and end-of-study weight and body composition
Arm B: weekly weight and body composition

Symptom scores via smartphone app:
Arm A: Daily: fatigue score, sleep quality score, self-reported activity score, parent reported activity score, screen time score.
Weekly: peds-FACIT-F, PROMIS Pediatric pain
Arm B: Daily: self-reported activity score, parent-reported activity score, screen time score, sleep quality score
Arm C: Daily: pain intensity score, pain limits activity score, number of painful areas, parent-reported activity score, self-reported
activity score, screen time score, sleep quality score. Weekly: PROMIS Pediatric pain
Arm D: Daily: asthma control diary (subjects with asthma only), respiratory symptom scores (subjects with cystic fibrosis only),
parent-reported activity, self-reported activity, screen time score, sleep quality score

Daily environmental data:
Arm C: local air quality (NO_2, NO, O_3, PM_{10}, $PM_{2.5}$), weather conditions (mean temperature, max temperature, min
temperature, mean wind speed, mean air humidity, sun exposure duration, amount of rain)
Arm D: local air quality, pollen count, weather conditions

Lung function:
Arm C: baseline and end-of-study NuvoAir spirometry (FEV1, FVC, FEV1/FVC, PEF)
Arm D: baseline hospital spirometry, baseline and daily home NuvoAir spirometry (FEV1, FVC, FEV1/FVC, PEF)

Blood pressure:
Arm A: daily blood pressure measurements

Arm B: daily blood pressure measurements

Compliance:
Proportion of patients with > 70% compliance to study tasks

Unplanned visits or admissions during study period

Labs or diagnostic procedures, obtained as part of standard of care if deemed necessary by treating physician, for example:
Arm A: complete blood count, thyroid screening, C-reactive protein
Arm B: DEXA-scan, thyroid screening

Arm C: hemoglobin, leukocytes, irreversibly sickled cells, reticulocytes
Leftover blood samples will be stored

End-of-study questionnaires:
General: questionnaire for parents and children about the experience and tolerability of the methods of data collection.
Arm A: pedsQl 4.0, peds-FACIT-F, pedsQL multidimensional fatigue scale, RCADS, CSI
Arm B: pedsQl 4.0, RCADS, CSI
Arm C: pedsQL 4.0, pedsQL pain quality, PROMIS Pediatric pain
Arm D: pedsQl 4.0, asthma control questionnaire (subjects with asthma only), cystic fibrosis questionnaire (subjects with cystic fibrosis only)

Study description

Background summary

Treatment, follow-up and execution of clinical trials of children with chronic disease is challenging. Often, there is a considerable
time interval between outpatient clinic visits and patients' and parents' ability to recall the severity of symptoms is often suboptimal and subjective. Furthermore, clinical trials are often quite invasive and time-consuming for children. One option to overcome these problems is frequent, non-invasive monitoring of symptoms and disease activity. An example of non-invasive monitoring is by using smartwatch technology. Recent systematic reviews have reported studies that used a smartwatch to measure activity level, eating behavior and seizures, among other things. It has been hypothesized that these devices can also be used to monitor various other conditions. However, past 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 at home.
CHDR has developed a home-monitoring platform that comprises of 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, with the NuvoAir spirometer, subjects can collect full spirometry data with their smartphone. Several other devices,

like the Nokia Body+ Scales, Nokia Blood Pressure Monitor, are also part of the platform. In the future, home-monitoring research, aimed at quantifying disease-activity, will be performed at the Juliana Children's Hospital in the Hague. This study aims to evaluate the feasibility of home-monitoring in patients with fatigue (arm A), obesity (arm B), sickle cell disease (arm C) and chronic lung disease (arm D). Furthermore, it aims to compare activity levels of patients to healthy controls and to evaluate correlations between physical activity, heart rate, environmental factors and symptoms.

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

Day 1-28

Contacts

Public
Centre for Human Drug Research
Adam Cohen

+31 71 5246 400
Scientific
Centre for Human Drug Research
Adam Cohen

+31 71 5246 400

Eligibility criteria

Inclusion criteria

General
1. Signed informed consent from both parents or the legal guardian prior to any study-mandated procedure.
2. Patients undergoing treatment in the outpatient clinic of Juliana Children's Hospital.
3. Age 6-16
Arm A.
- Patients are referred by their general practitioner due to complaints of general malaise, fatigue or tiredness.
Arm B.
- Patients are diagnosed with obesity
Arm C.
- Patients are diagnosed with sickle cell disease
Arm D.
- Patients are treated for cystic fibrosis or
- Patients have controlled or difficult to control asthma at the time of inclusion.
o Difficult to control asthma defined by Asthma Control Questionnaire cutoff score of 1.5 or fulfilling ≥ 3 Global Initiative for Asthma (GINA) criteria for partly/uncontrolled asthma

Exclusion criteria

1. Evidence or history of lung disease, cardiac disease, neuromuscular disease, diabetes or any other chronic
condition other than the studied disease, that might impair activity level.
2. Children that have a mental and/or motor impairment.
3. Inability to wear or use the wearable device.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2018
Enrollment:	180
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: 48867
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7611
CCMO	NL66457.098.18
OMON	NL-OMON48867

Study results