

# Home-monitoring in pediatric chronic disease

No registrations found.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Positive opinion           |
| <b>Status</b>                | Recruiting                 |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | 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<sub>2</sub>, NO, O<sub>3</sub>, PM<sub>10</sub>, PM<sub>2.5</sub>), 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 (FEV<sub>1</sub>, FVC, FEV<sub>1</sub>/FVC, PEF)

Arm D: baseline hospital spirometry, baseline and daily home NuvoAir spirometry (FEV<sub>1</sub>, FVC, FEV<sub>1</sub>/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  $\geq 3$  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