Home-monitoring in pediatric chronic disease

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21018

Bron
NTR

Verkorte titel
CHDR1811

Aandoening

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

Ondersteuning

Primaire sponsor: N.A. (Collaboration Juliana Children’s Hospital & CHDR)
Overige ondersteuning: CHDR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Daily physical activity level (step count)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Day 1-28

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48867
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten