Home-monitoring of disease activity in pediatric chronic disease.

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General- To compare physical activity levels of pediatric patient subjects with healthy control subjects.- To compare mean heart rate and variation in heart rate during the day of patients and healthy controls.- To compare sleep duration of patients...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48867

Source
ToetsingOnline

Brief title
Home-monitoring in pediatric chronic disease

Condition

- Other condition
- Blood and lymphatic system disorders congenital
- Bronchial disorders (excl neoplasms)

Synonym
asthma, cystic fibrosis, fatigue, severe overweight, sickle cell disease

Health condition

obesity, chronic fatigue

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: internally funded CHDR study

Intervention

Keyword: chronic disease, fatigue, home-monitoring, obesity

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

General
- To compare physical activity levels of pediatric patient subjects with healthy control subjects.
- To compare mean heart rate and variation in heart rate during the day of patients and healthy controls.
- To compare sleep duration of patients and healthy controls
- To evaluate adherence to study tasks in pediatric subjects
- To determine the tolerability, feasibility, quality and quantity (wear time) of the employed methods of data collection in different age groups.
- To evaluate the ePro questionnaire and notifications app.

Arm A, patients with fatigue.
- To identify factors in the collected data (physical activity, heart rate), the patients* medical history, physical examination or demographics that correlate with the presence of physical illness.
- To compare daily blood pressure measurements of pediatric fatigue patients to healthy controls

Arm B, patients with obesity.
- To identify a correlation between physical activity and weight loss or weight gain during the study period.
- To compare daily blood pressure measurements of pediatric obesity patients to healthy controls

Arm C, patients with sickle cell disease.
- To find correlations between the presence of symptoms, obtained via questionnaire data, and collected data (mean heart rate, physical activity, sleep duration).
- To find correlations between the presence of symptoms and air quality and weather conditions.
- To evaluate correlations between physical activity and impaired lung function
- To gather data regarding physical activity and heart rate before, during and after a vaso-occlusive crisis, if such an event occurs during the study period.
- To validate the NuvoAir spirometer in pediatric patients

Arm D, patients with chronic lung disease.
- To evaluate the tolerability, compliance and intrasubject variability of daily lung function monitoring.

- To assess correlations between the presence of symptoms and asthma control and collected data (mean heart rate, physical activity, lung function, sleep duration, pollen counts, air quality, weather conditions).
- To gather data regarding physical activity, heart rate and lung function before, during and after an asthma exacerbation or pulmonary cystic fibrosis exacerbation, if such an event occurs during the study period.
- To validate the NuvoAir spirometer in pediatric patients

Study design

Prospective observational case-control study to monitor symptoms and behavior in pediatric patients with different chronic diseases in a home-setting.

Study burden and risks

The burden for study participants is estimated to be low and consists of several baseline study assessments, the continuous wearing of the Nokia Steel HR watch, daily spirometry or blood pressure measurements, weekly weighing, and daily or weekly questionnaire assessments for the duration of the study period. The assessments have been designed to be as unobtrusive as possible and are outlined in tables 1-4. 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. Except for the smartwatch assessments, for which data will be collected continuously, all study mandated actions can be performed at the subjects* home or at the outpatient clinic. 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 disease behaviour 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

General
1. Signed informed consent from both parents or the legal guardian prior to any study-mandated procedure and from subjects aged older than 11 years old.
2. Patients undergoing treatment by a pediatrician
3. Age 6-16 years for subjects in arm A, B and D. Age 5-17 for subjects in arm C., 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 (excluding: CF-associated diabetes in arm D, diabetes type 2 associated with obesity in arm B) 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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-11-2018
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	09-10-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-08-2019
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: 21018
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66457.098.18

Study results

Date completed: 08-10-2020

Results posted: 13-01-2021

Summary results
Trial ended prematurely

First publication
11-01-2021