Protocol for gathering data for the pediatric control groups of various CHDR trial@home studies with wearable technology and smart-phone applications.

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Last updated: 10-01-2025

- To determine the tolerability, feasibility and quality of the employed methods of data collection in different age groups. - To investigate inter-subject variability and normal-values regarding step count, heart rate, sleep duration, blood...

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

Summary

ID

NL-OMON48686

Source
ToetsingOnline

Brief title
Trial@home gathering data with wearable technology

Condition

- Other condition

Synonym
children, Healthy subjects

Health condition

Alternatieve methode voor vitale functie metingen bij kinderen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Control, Devices, E-health, Pediatric

Outcome measures

Primary outcome

- Daily step count

Secondary outcome

- Baseline information: including age, weight, length, school and city

- Daily heart rate data

- Biweekly temperature

- Daily sleep duration

- Questionnaire data (see above table)

- End-of-study questionnaire for parents and children about the general

experience, tolerability, and feasibility of this method of data collection.

- Proportion of participants with good compliance (> 70%) to study assessments

- Biweekly lung function (FVC, FEV1, PEF)

- Daily blood pressure

- weekly weight and body composition

- Daily smartphone use data (app use, screentime)

Study description

Background summary

Chronic diseases impairs the daily life and routine of a child and adolescent. These children are treated over a long time. The child is prone to visit the hospital or any other treatment center more frequently than his/her peers. This could be just for simple tests to assess the vitality of the child but with disproportional impact. With the current technology a lot of these vital parameters (e.g. physical activity, weight, blood pressure, temperature, pain and general well-being) could be assessed at home using wearables and smart phone applications.

The use of wearable devices (e.g. Fitbit, Garmin and Nokia) is increasing in clinical research. The normal daily life behavior of a child is currently unknown to a medical specialist. The specialist relies on clinical tests and subjective recall to assess if certain treatments have worked. In combination with accompanying questionnaire applications these wearables are able to monitor the behavior of its wearer in an at home setting[!]. This feature could be of benefit to monitor patients with a chronic disease over a longer period of time without it being invasive to the patient. Especially children could benefit from at home monitoring with wearables, since a doctor could monitor himself if a behavior is normal and if a child is required to go the hospital for a check-up.

This study is part of the first phase of the trial@home project. If the wearables are assessed as valid and feasible enough to be used in paediatrics, then different interventions could be researched and the real life conditions of a child could be monitored. Therefore the goal of this study is to demonstrate the feasibility of using wearable technology in an at home setting for healthy/undiagnosed children. In addition the study is designed in such a way that the results of this study can be used as control groups in other studies of the trial@home project, such as CHDR1810 and CHDR1811 where wearables are used to monitor paediatric patients to minimize the burden and number of subjects.

Study objective

- To determine the tolerability, feasibility and quality of the employed methods of data collection in different age groups.
- To investigate inter-subject variability and normal-values regarding step count, heart rate, sleep duration, blood pressure, body composition and smart phone use of healthy children in an at home situation.
- To evaluate adherence to study tasks in paediatric subjects.
- To evaluate correlations between collected data and questionnaire output.
- To compare collected data of healthy subjects with paediatric patient

subjects of related projects CHDR1810 and CHDR1811.

Study design

Observational prospective non-invasive study of data gathering in an at-home situation. The children will be followed for a period of 21 days. There are three groups of children. The groups and their respective device combination are comparable with the subject groups of CHDR studies 1810 and 1811.

Study burden and risks

There is no direct health benefit for the participants, there is only a small compensation with a gift certificate. There is also minimal risk for the participants, since all the devices that are used by the children, have a CE brand and therefore eligible for consumer use. All the data is pseudonymized according to the GDPR laws and therefore the privacy of the participants and their parents is maintained

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

Age 2 to 16 years old
Signing of informed consent form by both parents and when older as 11 child also

Exclusion criteria

Not physically able to wear or use the devices
Evidence or history of chronic lung disease, cardiac disease, neuromuscular disease, diabetes or any other chronic condition that might impair activity level.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-11-2018
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2018
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:	24-01-2019
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: 20776
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66574.098.18

Study results

Date completed: 19-02-2020

Results posted: 13-01-2021

First publication
21-12-2020