# Trial at home healthy children database with wearables

Gepubliceerd: 18-03-2019 Laatst bijgewerkt: 15-05-2024

Protocol to establish the intra- and intersubject variability of several wearables and devices in a home-setting. Protocol to provide control subjects to the studies CHDR1810, CHDR1811.

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

## Samenvatting

### ID

NL-OMON20776

**Bron**
Nationaal Trial Register

**Verkorte titel**
CHDR1817

**Aandoening**

Healthy subjects, children

### Ondersteuning

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

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

- Daily step count

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

Protocol to establish the intra- and intersubject variability of several wearables and devices in a home-setting.
Protocol to provide control subjects to the studies CHDR1810, CHDR1811.

### Onderzoeksopzet

Day 1-21

# Contactpersonen

### Publiek

Centre for Human Drug Research
Adam Cohen

+31 71 5246 400

### Wetenschappelijk

Centre for Human Drug Research
Adam Cohen

+31 71 5246 400

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Enkelblind |

| | |
|---|---|
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-09-2018 |
| Aantal proefpersonen: | 150 |
| 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: 48686
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7612 |
| CCMO | NL66574.098.18 |
| OMON | NL-OMON48686 |

# Resultaten