ISRCTN11365830 https://doi.org/10.1186/ISRCTN11365830

Measuring physical activity and gait parameters during daily life with wearable motion sensors to guide therapy in children with cerebral palsy

Submission date
19/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cerebral palsy is the general term for a number of conditions caused by problems in the brain and nervous system that affect movement and co-ordination. The condition can occur if the brain develops abnormally or is damaged before, during or shortly after birth. Clinicians need a feasible and precise evaluation of motor (movement) impairments, as well as their causes and their consequences for daily life, not only to establish treatment strategies but also to measure the effectiveness of treatment. The aim of this study is to measure the motor performance of children during their daily life using portable and unobtrusive movement sensors. On the basis of these measures, specific goals are set, an individualized treatment plan is made, and the treatment outcome is measured for each participant.

Who can participate?
Children and adolescents aged 7-18 with a diagnosis of cerebral palsy

What does the study involve?
All participants are tested on four occasions. The first evaluation (week 0) is carried out over two days. On the first day, the participant is equipped with the movement sensors and carries them for 10 hours. On the second day, the participant's motor capacity is tested and goals are set on what the participant would like to achieve. The second evaluation (week 4) includes another 10 hour measurement with the sensors. In the same week, the participant receives an individualized treatment plan with exercises and behavioural patterns they should perform during the following 4 weeks. This treatment plan is followed at home and in the community with the goal to increase the time spent walking and/or the level of physical activity and/or gait (walking) quality. The third evaluation (week 8) is again performed on two days. The first assessment is another 10 hour measurement with the sensors, while the second assessment comprises the motor capacity test (same as week 0) and the attainment of the goals set at week 0. At the last evaluation (week 12), participants again wear the sensors during one day (10 hours) and the attainment of the goals is checked a second time.

What are the possible benefits and risks of participating?
The results will show whether data from the movement sensors are appropriate for motivating participants and for making individualized physical training programs that improve participants' physical performance in daily life. There is only minimal risk associated with this study, there are no known undesirable effects with inertial sensors, and there is no pain involved in this study. However, potential unknown risks cannot be excluded. The risk of unauthorized data access and /or unwanted identification of participants is very low, as all the data will be encoded.

Where is the study run from?
Centre Hospitalier Universitaire Vaudois (CHUV) (Switzerland)

When is the study starting and how long is it expected to run for?
February 2017 to January 2019

Who is funding the study?
Fondation Leenaards (Switzerland)

Who is the main contact?
Dr Corinna Gerber
corinna.gerber@chuv.ch

Contact information

Type(s)
Scientific

Contact name
Dr Corinna Gerber

ORCID ID
http://orcid.org/0000-0002-3353-0038

Contact details
CHUV
UNRP, Hôpital Nestle
Lausanne
Switzerland
1011

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016-01831

Study information

Scientific Title
Performance during daily life assessed with wearable motion sensors to guide therapy in children with cerebral palsy: a pilot study

Acronym
CP_Perform

Study objectives
An effective training plan can be developed based on the results of the baseline performance, measured with inertial sensors. Furthermore, the improvements due to the intervention are measurable with the same assessment method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commission cantonale d'éthique de la recherche sur l'être humain (CER-VD), Switzerland - Cantonal ethics committee for research with human beings, Vaud, Switzerland, 20/02/2017, ref: 2016.01831

Study design
Single-center longitudinal multiple single-case ABA design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
All participants will be tested on four occasions (six visits): Baseline (week 0), pre (week 4), post (week 8), follow-up (week 12). Between the baseline and the pre, as well as between the post and the follow-up, participants will follow their usual treatments. In the middle of the study, from week 5 until the end of week 8, participants will perform an individualized treatment plan in their community setting additionally to their usual treatments.

Assessments:
The study will take place over 12 weeks with four evaluation time-points including six visits. The first evaluation (week 0) will be done on two days. The first day, the patient will be equipped with the inertial sensors and carry them for 10 consecutive hours. On the second day, the participants motor capacity will be tested with the Gross Motor Function Measure (GMFM, lasting about 45 minutes) and goals will be set on what the patient would like to achieve with the help of the intervention (duration approximately 15 minutes).
The second evaluation (week 4) will include the repetition of the 10 hours measurement with the inertial sensors. In the same week, the participant will receive an individualized treatment plan with exercises and desired behavioral patterns they should perform during the following four weeks.
The third evaluation (week 8) will again be performed on two days. The first assessment will be again a repetition of the 10 hours measurement with the inertial sensors, while the second one comprises the GMFM (same at week 0) and the control of attainment of the goals set at baseline (week 0).
At the last evaluation time-point (week 12), participants will again wear the inertial sensors during one day (10 hours) and the attainment of the goals set at baseline (week 0) will be checked a second time.

Intervention:
On the basis of the capacity (GMFM) and performance (inertial sensors) measures at baseline (week 0), the patient's habitual physiotherapist will elaborate an individual treatment plan for the patient. This treatment plan will be followed at home and in the community with the goal to augment the time spent walking and/or the level of physical activity and/or gait quality. Participants will follow this treatment plan during four weeks (weeks 5-8). During this treatment phase, participants will follow the usual quantity of therapies. However, during usual these therapies, the physiotherapists will focus on the same goals that were established individually for each patient at the baseline measure of the study.

Intervention Type
Other

Primary outcome measure
1. Daily life gait performance corresponding to the individual goals of each participant (e.g. improvement in gait symmetry)
2. Physical activity levels (i.e. amount of time spent walking and/or in moderate to intensive physical activity)
Both measured using a 10h measurement of daily activity using inertial motion sensors, the Physilog(R) 4 sensors (GaitUp, Switzerland), at baseline (BL) (week 0), pre (BL + 4 weeks), post (BL + 8 weeks), follow-up (BL + 12 weeks)

Secondary outcome measures
1. Gross motor capacity, measured using the Gross Motor Function Measure 66 (GMFM-66) at BL and post
2. Goal attainment, measured using Goal Attainment Scaling (GAS) at BL, post and follow-up
3. Time taken for donning and doffing of sensors, recorded in the CRF at all four time-points (baseline, pre, post, follow-up)
4. Sensor data analysis within the two weeks after the baseline measurement of each patient
5. Feasibility of using the Physilog® inertial sensors for treatment planning in an outpatient setting, assessed with a semi-structured interview with physiotherapists after the follow-up measurement

Overall study start date
20/02/2017

Completion date
25/01/2019

Eligibility

Key inclusion criteria
1. Informed consent as documented by signature (Appendix Informed Consent Form)
2. Diagnosis of cerebral palsy
3. Gross Motor Function Classification System (GMFCS) level I-III
4. Aged 7 to 18 years

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
14

Key exclusion criteria
1. Surgery at the trunk or lower limb level within the last six months
2. Botulinum toxin injection in the trunk or lower limbs within the last three months
3. Other clinically significant concomitant disease states (e.g., renal failure, hepatic dysfunction, cardiovascular disease, etc)
4. Known or suspected non-compliance
5. Inability to follow the procedures of the study, e.g. due to language problems, psychological disorders etc of the participant
6. Participation in another study including intensive therapy of the lower limbs within the 30 days preceding and during the present study
7. Intensive gait therapy within the 30 days preceding and during the present study
8. Inpatient rehabilitation stay aimed at improving gait within the 30 days preceding and during the present study

9. Previous enrolment into the current study
10. Mental age < 7 years
11. Severe visual impairments

Date of first enrolment
23/03/2017

Date of final enrolment
20/10/2017

Locations

Countries of recruitment
Switzerland

Study participating centre
Centre Hospitalier Universitaire Vaudois
Lausanne
Switzerland
1011

Sponsor information

Organisation
Centre Hospitalier Universitaire Vaudois (CHUV)

Sponsor details
Hôpital Nestlé CHUV
Lausanne
Switzerland
1011

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05a353079

Funder(s)

Funder type
Charity

Funder Name
Fondation Leenaards

Alternative Name(s)
Leenaards Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
The trialists plan to publish the results of the trial in a high-impact peer reviewed rehabilitation journal by the end of 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
As these are patient related data and patients as well as their legal guardians only give informed consent to use data for this specific study, the trialists cannot provide any study data. All data will be stored at the Department Woman-Mother-Child at CHUV in Lausanne.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	11-13 years	20/03/2017	21/03/2017	No	Yes
Participant information sheet	14 years and older	20/03/2017	21/03/2017	No	Yes
Participant information sheet	caregivers	20/03/2017	21/03/2017	No	Yes
Results article		16/10/2020	14/11/2022	Yes	No