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Investigating the clinical utility of wearable motion sensors to guide therapy in children with cerebral palsy

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Abstract

Background: Children with cerebral palsy (CP) experience a wide range of motor impairments and rarely achieve the recommended level of daily physical activity. To recognise environmental barriers and facilitators, clinicians depend upon an objective evaluation of performance in daily life. Wearable inertial sensors (Physilog®) have recently been developed to measure meaningful spatio-temporal gait parameters. In this study, we investigated the clinical utility of wearable sensors to guide therapy in children with CP.

Methods: 9 patients with CP wore inertial sensors at baseline (= week 0), at pre- (= week 4) and post-intervention (= week 8) and follow-up (= week 12). Physiotherapists were asked to develop the intervention phase (i.e., a training plan integrated in their patient's daily routine) according to the sensors outcomes. To assess the clinical utility of inertial sensors, we designed three different questionnaires for the patients, caregivers and physiotherapists, respectively. The answers were recorded using a visual analogue scale (VAS; 0 representing the worst score, 100 representing the best score; ≤30 not satisfied, 31–69 average, ≥70 satisfied) and comments were noted down during the interviews. Furthermore, technical problems and training plans were gathered in a case report form.

Results: Overall, patients were satisfied with the sensors (mean 70.6 - 87.4) but experienced tiredness (mean 53.4) during the month of personal training. Caregivers found the sensors useful (mean 77.4) and six out of eight parents noticed an improvement of their child's physical performance. All physiotherapists would consider using sensors in their practice (mean 82.0) even though they scored their usefulness as average (mean 66.0). Despite having a better representation of patients' physical activities with sensors (mean 70.0), physiotherapists had trouble adapting the exercises proposed to their patients (mean 49.0).

Conclusion: Despite some technical issues, Physilog® sensors presented fairly good acceptability and practicability. Nevertheless, several physiotherapists faced difficulties in adapting existing therapy according to sensor outcomes. Therefore, the implementation of the sensors in clinics to guide therapy will require further adaptations of the setting to increase its relevance.

Keywords: Clinical utility, Inertial sensors, Cerebral palsy, Performance, Personalized training.

Introduction

With a prevalence of 2.23 per 1000 live births in Switzerland, cerebral palsy (CP) is the most common cause of motor disability in childhood (1). This condition is defined as “a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain” (2). Given the wide range of motor impairments encountered with CP, a standardized description has been developed using the Gross Motor Function Classification System (GMFCS) (3). This classification ranges from level I (highest level of gross motor functioning) to level V (lowest level of gross motor functioning). Motor impairments are rarely the sole manifestations of CP. Indeed, there are several other health conditions associated with it, including learning disabilities, epilepsy, dysarthria, sensory impairments, chronic pain, low visual acuity, gastrointestinal and feeding issues (4).

In order to understand the needs of each patient, a clear picture of the term ‘disability’ is required. With the International Classification of Functioning, Disability and Health (ICF), the World Health Organization (WHO) proposed a bio-psycho-social model for disability (5). In this classification, the term ‘functioning’ encompasses the body functions and structures, activities (execution of a task by a person) and participation (involvement in daily life). It is connected to environmental and personal factors in a complex and dynamic manner. Activity and participation are further qualified using ‘capacity’ (execution of a task at the highest probable level of functioning) and ‘performance’ (execution of a task in daily environment).

According to this model, the assessment of children with CP must take into account every component of the ICF system. Yet, currently the evaluation is mostly based on impairment of body structures and functions and limitations of activities, which are well described by specific classification systems. Clinicians assess body structures and functions as they perform a physical examination that includes joint range of movement, muscle strength and spasticity. Based on this examination, they are able to categorize motor abnormalities as spastic, dystonic, athetotic or ataxic (6). When required, medical imagery offers additional information on body structures.

Several tools are validated to assess the ‘capacity’ of walking including standardized physical tests (*e.g.,* gross motor function measure (GMFM), 6-minute walk test) as well as three-dimensional instrumented gait analyses. Regarding ‘performance’, assessment instruments

can be divided into two categories: subjective and objective. Subjective tools include questionnaires, interviews, proxy reports (performance estimated by a parent or therapist) or diaries. In a review, Trost et al. found those instruments had an acceptable validity in typically developing children (7). Furthermore, Capio et al. confirmed that different questionnaires (ASKp, CAPE) used to measure physical activity demonstrated good validity and reliability in children with CP (8). Recently, Ammann-Reiffer et al. demonstrated that a therapist's reports of a child's inpatient performance with the Functional Mobility Scale (FMS) or the Gillette Functional Assessment Questionnaire – walking scale (FAQ) corresponded to the performance score reported by parents at home (9). Available self or proxy report measures offer an overall picture of a child's performance, but they are limited by observer and recall biases and cannot substitute for an objective measurement tool. To overcome these limitations, instruments are being developed to measure physical activity (PA). There are four different parameters to monitor when evaluating PA: frequency, duration, intensity and type. PA also differs according to the context of activity (domain) such as leisure-time PA or in-school PA. An ideal measurement tool should provide information about all these characteristics (7). The available tools that demonstrate good validity include heart rate monitors, pedometers and accelerometers (7). In a systematic review of the performance measurement instruments in adolescents with CP, Clanchy et al. stated that accelerometers provide quantitative information regarding frequency, intensity and duration of PA (10). However, accelerometers are not sensitive to every type of movement and activities such as climbing stairs, cycling or lifting cannot be assessed (7). Furthermore, the reliability of accelerometers has not been documented for children with CP (10). Finally, there is no classification available to rate participation and environmental factors, and thus both remain difficult to measure as they rely mostly on self-report or proxy report instruments (11).

Clinicians and therapists often assume that 'capacity' reflects 'performance' despite the distinction in the WHO classification. Yet, Holsbeeke et al. established that children with the same level of motor capacity demonstrated large ranges of motor performance, which supports the idea that performance cannot be reduced to capacity (12). Along the same line, Bloemen et al. highlighted in their systematic review the wide range of parameters associated with performance in physical activity that are not present when assessing motor capacity (13).

Consequently, clinicians are still taking therapeutic decisions based mainly on impairments

and limitations of activities, as confirmed in a review by Novak et al. (14). The authors identified 51% of therapeutic interventions as directed towards an improvement at the body structures and functions level, and 30% as directed towards the activity level against only 5% directed towards the participation level, and 6% directed towards the environment level. Currently, a child with CP may benefit from proven effective interventions such as anticonvulsants, botulinum toxin injections, bisphosphonates, casting, diazepam, fitness training, hip surveillance, pressure care and selective dorsal rhizotomy to improve body structures and functions (14). With respect to activity level, specific trainings with physical and occupational therapists, including bimanual training, constraint-induced movement therapy, context-focused therapy, goal-directed training/functional training and home programmes, are also reported as being effective (hence they are often called “green-light” interventions) (14). Novak et al. highlighted the absence of green-light interventions focusing on participation or environmental levels of the ICF model (14). Anaby et al. came to the same conclusion in their own review and pointed out the lack of integration of the ‘participation’ component of the ICF into practice (15).

Ultimately, the goal of every therapeutic intervention is to improve quality of life. Maher et al. established that physical activity was associated with an increase in quality of life and happiness in children with CP (16). Nevertheless, despite the elaboration of specific recommendations concerning PA for patients with CP (17), the majority of children with CP do not reach the recommended level of daily PA (18,19). Considering that life expectancy, well-being, participation, mental and physical health in adults with CP are inferior compared to general population, Colver queried the effectiveness of rehabilitation plans for children with CP (20). To enhance participation, Bjornson et al. suggested that rehabilitation programs should focus on improving activity performance (*i.e.*, what children are able to do in daily life) as it positively influences children’s participation in daily life, regardless of their activity capacity (*i.e.,* what children are able to do in clinical setting) (21). Along the same line, Reedmann et al. pointed out the limited effects of capacity-focused interventions for increasing participation (22).

Therefore, there is an urge for progress in rehabilitation to enable children with CP to reach the recommended level of PA and thus achieve better adult outcomes. However, such progress is not conceivable without a precise measurement of a child’s day-to-day PA performance. Furthermore, measuring performance in daily life will enable clinicians to

recognise environmental barriers and facilitators, and monitor response to treatment. Additionally, it will also provide information about the four dimensions of PA. In order to overcome the lack of reliable tool to measure performance in daily life, new wearable motion sensors are being developed in the context of the Leenaards project (23). This large project is divided into three parts. The first part aimed at developing wearable motion sensors that are compact and offer a precise estimation of most clinically relevant spatio-temporal gait parameters, together with algorithms capable of analysing those data. The second part, which is still on-going, consists in validating technically and clinically the inertial sensors as a reliable tool for measuring mobility and gait performance in children with CP in their daily environment. Finally, the third part of the project aims at evaluating the ability of these inertial sensors to guide therapy in children with CP.

Even though wearable motion sensors are widespread in different settings, the “clinical utility” of this new technology has to be verified in practice. In academic publications, this term often includes clinical effectiveness and cost-effectiveness without taking into account practitioners’ needs in their clinical practice. Toomey et al. added to that narrow definition of clinical utility the point of view of the therapist on the usefulness of a tool (24). Furthermore, Smart described a multi-dimensional model characterized by four factors: appropriateness, accessibility, practicability and acceptability (25).

The goal of this study is to explore the clinical utility of wearable motion sensors as a new tool for guiding therapy in children with CP. Therefore, we will follow the model described by Smart. Firstly, we need to enquire about the effectiveness and the relevance of including information provided by the motion sensors in the existing treatment plan in order to establish their appropriateness. Secondly, we have to consider the costs and availability of the product in order to assess its accessibility. Thirdly, practicability relates to the functioning of the device and the suitability (*e.g.,* does it work properly in daily life situations? Is it easy to use?). Another aspect of the practicability is the implementation in practice for the physical therapist with very concrete notions of ease of understanding and adequacy of time to interpret the results. Finally, to be acceptable, there should not be any ethical, legal, social or psychological concern from patients, families or clinicians. To gather information about the components of this model, Smart recommends the use of qualitative research methods such as interviewing and observation.

Methods

Participants

The recruitment of patients started after the approval by the Commission cantonale d'éthique de la recherche sur l'être humain (CER-VD) in Lausanne. Physicians of the Paediatric Neurology and Neurorehabilitation Unit, CHUV, Lausanne, examined the eligibility criteria of their patients and informed the study investigator about potential participants. Patients attended either a public school or a special needs school for children with motor and/or sensory deficits. Participants fulfilled the following inclusion criteria: 1) diagnosis of CP, 2) GMFCS level I-III, 3) aged 7 to 18 years, 4) informed consent. GMFCS level I corresponds to a child who walks without limitation, level II to a child who experiences difficulty walking long distances and balancing and level III to a child who walks indoors using a hand-held mobility device(3). Participants were excluded for the following 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), 4) known or suspected non-compliance, 5) inability to follow the procedures of the study, *e.g.*, due to language problems, psychological disorders, 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 less than 7 years, 11) severe visual impairments. If the child was eligible, the study investigator contacted the caregiver to explain the goal of the study and invite them to take part. If the caregiver and the potential participant were interested, further information was sent and written informed consent was obtained from the legal guardians of every child participating in the study. Participants older than 14 years of age signed a written informed consent, while younger ones provided oral agreement.

Inertial sensors

This study aimed to assess the clinical utility of the Physilog® inertial sensors. Physilog® sensors are small wireless devices capable of measuring barometric pressure as well as angles, velocities and accelerations in 3-dimension. They were given to caregivers in a solid

suitcase containing 5 sensors. An information notice with instructions for the recording and contact numbers was also provided to caregivers. The sensors are placed on specific parts of the body (ankles, thighs, trunk) using self-adhesive PALstickies™ (dual layer hydrogel) and securing them with a tight garment (socks, leggings or the lycra cuffs provided in the kit). Patients and caregivers also received verbal instruction on how to fix, turn on and turn off the sensors. As soon as the sensors were switched on and fixed to the body, the patients were asked to lie down and stand still for 30 seconds to help calibrate the device. The recording was planned on an ordinary school day, for at least 10 consecutive hours. The Physilog® inertial sensors measured daily life gait performance, which includes gait parameters (stride length, foot clearance, stride velocity, joint angles, gait cycle time, gait asymmetry) and stair climbing. They recorded the four dimensions that characterize daily physical activity: type, intensity, duration and frequency.

Personalized physical training

Each participant had to wear the inertial sensors at baseline (week 0), pre intervention (week 4), post intervention (week 8) and follow-up (week 12). The intervention consisted of an individualized community-based training program based on the measurement at baseline. A human movement scientist discussed the results of the baseline measurement with the habitual physiotherapist of each participant. The goals were set according to patients' preferences and using the Goal Attainment Scale (GAS) to measure individual progress (26). The physiotherapists performed the GAS at baseline, after they discussed the sensor outcomes. They also had the possibility to complete the GAS before the explanation in order to appreciate the difference between the goals set with and without sensor outcomes. Finally, they performed the GAS at post intervention to quantify individual progress. Physiotherapists developed a training plan that was integrated in their patient's daily routine. The training plan aimed at increasing the walking periods and/or enhancing the physical activity intensity and/or the quality of movement. During the month of community-based training, patients kept going to their usual physiotherapy sessions and therapists were asked to focus on the same goals that were set for the individualized training plan.

Data collection

This study had a cross-sectional design. The data collection began in September 2017 and ended in June 2018. A specific questionnaire was designed for each group of participants (patients, caregivers, physiotherapists). With the help of a study investigator, participants

answered the survey after the end of the personalized physical training. It consisted of 19, 13 and 9 questions for the physical therapists, caregivers and children, respectively. The answers were recorded mostly using a simple visual analogue scale (VAS) and additional space to write down comments or justifications for the answer. Multiple-choice questions were used when the VAS was not a suitable option.

The VAS was represented as a 100 millimetres line anchored at each end by words expressing opposing ideas or extremes of a feeling. The worst score was always situated at the left anchor (0 mm). Participants were asked to mark that line at the point that best reflected their answer. The investigator was present during the completion of the questionnaire to ensure a correct comprehension of questions and ask for justifications when not provided spontaneously. This prevented missing values and questionnaires completed incorrectly, as this is a risk when using VAS (27). Questions were elaborated to cover the different aspects of clinical utility such as rehabilitation experience, expectations and outcome perceptions. This scale seemed the most appropriate for our study as it "might capture aspects that are beyond the reach of the Likert index" (28). Moreover, VAS showed good validity and reliability with a paediatric population aged 8 years and older (29). To facilitate the interpretation of the results, the VAS was used for the three groups of participants.

Another source of information was the case report form. It gathered information regarding practicability, such as technical problems encountered with the sensors or number of support requests, and acceptability, such as adverse effects. It also contained the list of exercises proposed by physiotherapists for the month of intensive therapy.

Data analysis

Questionnaire data was exported into an Excel file for analysis. Descriptive statistics were calculated to summarize the answers. VAS scores were divided into three groups using the same method as Gerber et al. (30); answers of 30 or less were considered as "not satisfied"; answers between 31 and 69 as "average"; and those of 70 or more as "satisfied". To complement those results, comments were studied in detail and divided into categories with the same themes. Answers considered as relevant or with a mean VAS score below 70 were discussed. Certain questions were deleted before the analyses because they were not relevant (*e.g.,* results were not always explained to patients, therefore the related question

was deleted). The complete questionnaires are available on the appendix. French answers and questions were translated into English. The relationship between VAS scores and patients' age, GMFCS level and physiotherapists' years of experience was examined by the Spearman correlation coefficients for non-normal distributed data. Related samples comparisons were analysed using the Wilcoxon signed rank-test for non-normally distributed data. The level of correlation was determined using the following definitions; 0-0.25 (no or little relationship), 0.25-0.50 (fair degree), 0.50-0.75 (moderate to good relationship), 0.75-1.00 (very good to excellent) (30). Comparisons between public and special need school patients were assessed using unpaired *t*-test for normally distributed data.

All statistical analyses were performed using SPSS software (Version 25). Pairwise deletion was used for missing data. The results were significant with $p < 0.05$, except for the multiple comparisons with the Spearman's rho test in which case the Bonferroni correction was used resulting in a significance level of $p < 0.02$.

Results

Patient characteristics are shown in Table 1.

We obtained the informed consent from 11 families, of which one patient withdrew because of social issues before the study onset and another one did not follow the intensive physical therapy because his physiotherapist went on medical leave and was therefore excluded from the study. Nine patients were included in the analyses of which five attended a special needs school. All parents answered the questionnaire except for one patient (ID 07). This patient lived in a boarding school, and therefore their parents were not involved in the study. The other caregivers of children attending the special need school were also less involved in the study because they did not have to attend physiotherapy sessions and therefore, it was more difficult to meet them. Seven physiotherapists were involved in the study, two of them took care of more than one patient; they completed separate questionnaires for each patient.

Table 1: Patient characteristics

ID	Age [y]	Gender	GMFCS [1-3]	Type of CP	School
01	11.8	F	3	Diplegic	Public
02	9.0	F	1	Hemiplegic	Public
04	8.3	M	3	Quadriparetic	Public
05	9.4	F	2	Tetraparetic	Public
06	8.7	M	3	Tetraparetic	Special needs

07	17.2	F	3	Diplegic	Special needs
08	15.5	F	1	Quadriparetic	Special needs
10	16.4	M	1	Hemiplegic	Special needs
11	16.5	F	1	Hemiplegic	Special needs

Abbreviations: *ID* identification, *GMFCS* gross motor function classification system, *CP* cerebral palsy

Patient questionnaires

VAS scores given by patients are listed in Table 2.

Some patients reported discomfort with the sensors (they were itchy). One patient had difficulty getting undressed because of the sensors fixed on the thighs. One patient scored his motivation for training as low (VAS of question 8 ≤ 30) and the eight other patients scored the motivation as high (VAS of question 8 > 70). Seven out of nine patients noticed some difference in their physical performance after the intervention (walked a longer distance, walked without assistance, better balance, increased strength).

Table 2: Patient questionnaires

Questions							**# Answers in VAS category**		
0= negative end, 100= positive end		**N**	**Min.**	**Max.**	**Mean**	**SD**	**≤ 30**	**31-69**	**≥ 70**
1	Did you find the sensors uncomfortable to wear an entire day?	9	45	100	83.5	20.0	0	2	7
2	Were you more motivated to follow your training, as you knew your physical activity would be recorded before and after the intensive therapy?	9	4	100	81.3	33.0	1	0	8
3	Were you stressed or anxious about the therapists looking at your physical activity at home?	9	50	100	87.4	19.0	0	1	8
4	Do you think you will progress more thanks to the sensors?	9	47	100	70.6	25.1	0	4	5
5	Did you feel pain during or after the intensive therapy? (Note: 0 = extremely painful, 100 = not painful at all)	9	11	100	82.0	31.7	1	1	7
6	Were you tired during the intensive therapy? (*Note*: 0 = extremely tired, 100 = not tired at all)	9	0	100	54.6	37.1	2	3	4

Abbreviations: *Min* minimum, *Max* maximum, *SD* standard deviation, VAS score categories, ≤ 30 unsatisfied, 31-69 average, ≥ 70 satisfied

Caregiver questionnaires

VAS scores given by parents are illustrated in Table 3.

One parent did the questionnaire on the phone and told the investigator where to tick on the VAS scale. The answers were extreme (0 or 100) but were consistent with the explanation given and therefore those results were included in the study. One parent perceived no benefit of the sensors for her child's therapy (VAS of question 2 ≤ 30) and said, "*my child is almost 17 years old, I don't need sensors to see where her strength and weakness are, I already know that very well*". The others found the sensors useful (VAS of question 2 ≥ 70). One mother said, "*it was useful to see how little my child was moving at school because I usually used to ask him less than his siblings when he came back home, but now I see that he is static during school and needs to move more at home*". Caregivers' answers of question 3 (improvement of physical capacity thanks to sensors) diverged greatly. On the one hand, parents believed the sensors would highlight areas for improvement and therefore lead to progress. On the other hand, some caregivers believed the sensors were not responsible for any improvement because firstly, sensors are just collecting data for the study not for their child's therapy and secondly, progress is related to the intensive therapy, which could be made without sensors. One parent declared that the sensors were not a motivation for her, as she did not feel comfortable having the responsibility of the training program at home (VAS of question 11 ≤ 30). There was no significant difference between parents' motivation and children's motivation ($Z = -1.15$, $p = 0.25$).

Furthermore, one parent did not understand the purpose of the sensors despite the explanation given by the investigator. Moreover, five parents did not understand the link between sensors and the physical training program. They did not notice any difference between the exercises made according to sensors' results and the type of exercises their child does in habitual physiotherapy sessions. Six out of eight caregivers noticed a difference in their child's physical performance (walked without assistance, better balance, going up the stairs, less time seated, easier to get dressed up, better endurance). Three parents had to contact the investigators because of technical issues with the sensors (one or more sensors did not turn on).

Table 3: Parent questionnaires

Questions							# Answers in VAS category		
0= negative end, 100= positive end		**N**	**Min.**	**Max.**	**Mean**	**SD**	**≤ 30**	**31-69**	**≥ 70**
1	Do you think the sensors are useful for your child's therapy?	8	0	100	77.4	32.9	1	0	7
2	Do you think the physiotherapist's training is more efficient thanks to the sensors?	8	0	100	68.3	33.6	1	2	5
3	Do you expect an improvement of your child's physical capacity thanks to the sensors?	8	0	100	67.5	32.1	1	3	4
4	Were the explanations on sensors' user guide sufficient?	8	54	100	93.3	16.1	0	1	7
5	Were the physiotherapists' instructions sufficient?	8	77	100	94.8	8.4	0	0	8
6	Did you have any issues with the sensors?	8	52	100	91.8	17.1	0	1	7
7	Was it easy to contact the investigator when needed?	8	98	100	99.8	0.7	0	0	8
8	Is using the sensors a motivation for **your child**?	8	0	100	65.0	39.2	2	1	5
9	Is using the sensors a motivation **for you**?	8	0	100	61.4	41.8	2	1	5
10	Do the sensors make you more attentive to the physiotherapist's training program?	8	0	100	73.4	40.5	2	0	6

Abbreviations: *Min* minimum, *Max* maximum, *SD* standard deviation, VAS score categories, ≤ 30 unsatisfied, 31-69 average, ≥ 70 satisfied

Physiotherapist questionnaires

VAS scores given by therapists are shown in Table 4.

Through the sensors, the majority of physiotherapists considered having a better representation of their patient's physical activities in daily life (mean VAS score of question 3 ≥ 70). None of the physiotherapists found the results completely unexpected (no VAS score of question 2 ≤ 30). Nevertheless, 6 out of 9 therapists were surprized by some aspects of their patient's daily activities (6 VAS score of question 2 between 31 and 69). One therapist said, "*I was surprized to see that my patient was walking and standing more than I had imagined but I expected the results concerning body's asymmetry*". Another one stated, " *I*

imagined my patient more active, especially at home". However, few therapists modified their training program according to the results gathered by the sensors (mean VAS of question 5 between 31 and 69). A therapist said, " *I changed 1 out of 4 goals after taking note of the sensor outcomes. I asked the patient to increase the endurance when walking*". Another therapist explained, *"after taking into account the results, I said to my patient that instead of walking more during the day, I wanted him to walk for a longer period without stopping (in concrete terms; to walk during a 10 minutes period several times a day)".* Besides, when they changed the exercises, it was sometimes in favour of unspecific goals such as increasing walking pace or endurance. A therapist that did not change her training program stated, "*I couldn't add any physiotherapy exercises in his everyday life because my patient is already doing a lot*". Furthermore, another therapist said, "*I have changed some exercises according to the results of the sensors because I was asked to, as part of the study, but my goal as a physiotherapist is to improve the quality of movement. In my workplace, increasing the global physical activity of patients is delegated to healthcare assistants*".

All physiotherapists needed the explanations of the investigator to understand the results. One therapist stated: "*without the explanation of the investigator, lots of outcomes and measures would have been very difficult to understand*" and another one "*the results are way to complicated to understand without explanation*". Nevertheless, the therapists found the results comprehensible with the help of the investigator (8/9 VAS score of question 5 $\geq$ 70). The time needed by the investigator to explain the results to physiotherapists varied from 10 minutes to more than 20 minutes. One therapist said "*it took more than 20 minutes for the investigator to explain and highlight the main outcomes, but it would have taken much longer without his help*". The majority of therapists mentioned that using the sensors would increase their workload (mean VAS score of question 6 between 31 and 69). Indeed, even though, during the current study they were not responsible for analysing data and explaining the results to parents or for cleaning and charging the sensors, they expected these tasks to take a large amount of time. Three therapists expected the sensors not to increase their workload (VAS score of question 6 $\leq$ 30) and one explained, "*if we need more time to analyse the data, the employer should provide time for that*". Physiotherapists were moderately motivated by their work with sensors (mean VAS score of question 9 between 31 and 69), mainly because no formal evidence of the validity, reliability and usefulness of sensors was available.

All therapists agreed that the sensors would be useful for the initial evaluation of the patient

and before/after a medical intervention (botulinum toxin injection, surgery…). One therapist said, "*the sensors could be a way to justify an intervention in order to get costs covered by insurances*". 5/9 would use the sensors once a year. A therapist said "*it would be useful for the follow-up of chronic patients*" and another one stated "*having a measurement every year is important during the rapid growth phase of childhood*". 4/9 would use it once every two years. 5/9 would use the sensors for an entire week as it gives, according to therapists, a global view of the patient. A therapist that would use the sensor for an entire week said, "*the day when the patient is wearing the sensors is not necessarily representative of his habits and the fact that he is wearing them can already influence his physical activities*". 2/9 therapists would use the sensors two days: one school day and one during the weekend. They expect the weekend days to be very different from school days and that this information would be useful. 2/9 therapists would use the sensors during one school day only. Those therapists, who are in favour of a single day of recording, claimed that the weekend days are too random to bring valuable information. Regarding the price of the system, the majority of therapists would purchase it for 2'500 CHF, considering that the device can be used for several patients. However, they presumed there would be no extra costs for yearly software update, which was not declared by the sensors' supplier. Therapists that are not interested in buying the sensors mentioned the lack of evidence and the need for more parameters.

According to physiotherapists, the main interests of the sensors were the long period of recording (ca. 10 hours) when compared with physiotherapy sessions (usually 1 hour or less), a more realistic representation of physical activity and an objective way to measure change. The therapists also highlighted the main drawbacks which are 1) they lack some gait parameters concerning the quality of movement, 2) the sensors did not provide the information required to have a precise view of patients' physical activity during the day, 3) it is time-consuming, 4) the lack of evidence. The motion sensors were judged as not useful (VAS of question 1 $\leq$ 30) by one therapist because of their lack of precision.

Finally, all therapists would consider including the sensors in their work practice (VAS score of question 10 $\geq$ 70) although they would not use them as a device to guide their physiotherapy program. One therapist's statement on the sensors was "*it is a tool for measuring progress and for the follow-up of patients but not a good tool for individualizing therapy*". Conversely, a therapist said, "*I did a better coaching thanks to the sensors. It gave me ideas for stimulating the patient's physical activity".* The therapist of a patient with

GMFCS III (ID 04) said "*it was complicated to set goals according to the sensors given the important motor limitations of the child*". The therapist in charge of a patient with GMFCS-I (ID 08) said "*the sensors are not useful for a patient like her with high functional capacity whereas the 3D gait analysis is very useful because it is very precise*".

Table 4: physiotherapist questionnaires

Questions							# Answers in VAS category		
0= negative end, 100= positive end		**N**	**Min.**	**Max.**	**Mean**	**SD**	**≤ 30**	**31-69**	**≥ 70**
1	How useful was the evaluation of physical activity by the sensors?	9	20	91	65	20.5	1	6	2
2	Did you expect such results for your patient?	9	38	99	62	25.3	0	6	3
3	Through the results, do you have a better representation of your patient's physical activity in daily life?	9	4	98	70	27.5	1	2	6
4	Was the interpretation of the results easy?	9	61	97	79	10.1	0	1	8
5	Was the training program different because of sensors' results?	9	4	99	49	35.1	3	3	3
6	Is the use of the sensors increasing your workload?	9	3	89	46	29.6	3	5	1
7	Through the sensors, do you feel more confident regarding the choice of the training program?	9	3	84	44	28.7	3	3	3
8	If the sensors were available for 2500 CHF, would you buy it?	9	4	85	63	27.3	1	2	6
9	Is using the sensors a motivation **for your work**?	9	22	87	67	20.1	1	2	6
10	Is including the sensors into your work practice worth considering?	9	70	100	82	9.6	0	0	9

Abbreviations: *Min* minimum, *Max* maximum, *SD* standard deviation, VAS score categories, ≤ 30 unsatisfied, 31-69 average, ≥ 70 satisfied

Results for correlations are shown in Table 5.

We examined the relationships between VAS scores of question 1, 3 and 7 and patients'

age, GMFCS level and physiotherapists' years of experience. There was no correlation found between how useful the physiotherapists rated the sensors and children's age, patients' GMFCS level or physiotherapists' years of professional experience. There was no correlation between the representation physiotherapists might have about their patients' daily physical activity after interpreting the sensor outcomes and patients' age nor physiotherapists' years of experience. There was no correlation between the physiotherapists' rating of the level of confidence with regard to the choice of exercise for the training program and children's age, GMFCS level and therapists' years of experience. There was no difference found between patients in public and special needs school concerning the usefulness of sensors (rated by physiotherapists) (p= 0,42), the representation of daily activity after analysing the sensor outcomes (p= 0,77), and the confidence the physiotherapists might have in creating the training plan (p= 0,42). The descriptive statistics are shown in Table 6.

Table 5: Correlations

			Patients' age	GMFCS	Years of experience
Spearman's rho	Usefulness of sensors rated by physiotherapists (question 1)	Correlation coefficient	0.27	0.41	-0.34
		Sig. (2-tailed)	0.49	0.27	0.38
	Representation of patients' daily activity (question 3)	Correlation coefficient	- 0.05	0.67	-0.30
		Sig. (2-tailed)	0.90	0.05	0.44
	Confidence regarding exercises' choice (question 7)	Correlation coefficient	-0.42	0.37	0.19
		Sig. (2-tailed)	0.27	0.33	0.62

Spearman's rho test using the Bonferroni correction of the alfa level ($p < 0.02$).

Table 6: Difference between types of school

	School	N	Mean	SD	Std. Error Mean
Usefulness (question 1)	Public	4	72.0	11.5	5.7

	Special need	5	60.0	25.8	11.5
Representation (question 3)	Public	4	73.3	14.4	7.2
	Special need	5	67.2	36.6	16.4
Confidence (question 7)	Public	4	53.8	33.8	16.9
	Special need	5	37.0	25.3	11.3

Abbreviations: *N* number, *SD* standard deviation, *Std*. standard

Usability

Information regarding usability was taken from the case report forms. There was no serious side effect reported during the study. The mean time for donning the sensors was 7.4 minutes (SD = 3.3) and the mean time for doffing was 4.4 minutes (SD = 2.4). Caregivers were in charge of mounting the sensors when the children were in a public school and investigators mounted the sensors when the patients attended a special needs school, as the parents were less involved in the study in those cases. The sensors were used 36 times during the study (4 times for each patients). During that period, the patients experienced 10 technical problems, among which 3 sensors switched off during the day of recording, 4 sensors fell off, one sensor was blinking again a couple of hours after he was turned off. One sensor at the ankle was causing pain to the patient and had to be removed prematurely. The sensors at the ankle had to be fixed above the appropriate level because the patient was wearing boots during the day of recording. The case report forms gathered also the exercises proposed by physiotherapists during the month of intensive therapy. The types of exercises are listed in Table 7.

Table 7: Type of exercises

Integrated into everyday life	**Enhancing physical capacity**	**Not specific**
To use only one walking stick	Sideway shifting	To increase the walking distance
To climb the stairs without holding the handrail	Stand up - sit - stand up	To increase walking pace
To go down the stairs without help	Stand up - walk - come back	To increase racing pace
To do the washing-up (stand up right for 20 minutes)	10 minutes of treadmill per day	To increase the endurance when walking

To make longer steps when using the walking frame	Series of squatting	
To stay less seated between 4 and 5pm	Series of dorsal flexion of the feet	
To make less shifting on the ground	Series of hip flexion	
To make at least 2 walking periods of 5 minutes per day	To hold the walking stick with two hands and lift it above the eyes	
To make more than XX steps per day	Trunk rotation while sitting on a ball	
To stand up on one foot while brushing the teeth	Series of stepping up and back on the floor	
To dress up (the top) while standing up straight	To run 10 minutes in a row	
To use less the walking frame in school	To go up 10 floors per day	
To go from classroom to physiotherapy without aid	To pass over an obstacle at knee level	
To improve the walking when hold by one hand	To hold a “chair position” against the wall	
To push the food trolley towards the kitchen		

Discussion

This study aimed at evaluating the clinical utility of wearable motion sensors to guide physiotherapy for children with cerebral palsy.

Patient questionnaires

As all mean VAS, except for one, were in the “satisfied” range we can conclude that the sensors are well accepted by patients. Nevertheless, there is room for improvement. Indeed, some patients complained about discomfort due to the sticker used to fix the sensors. Therefore, it would be worth finding an alternative method for fixing the device. The only question with a mean VAS on the “average” range concerned the tiredness during the month of physiotherapy. As shown in Table 7, physiotherapists included some exercises, which were integrated into everyday life or directed towards improving physical capacity such as series of squatting or period on a treadmill. Those exercises, in addition to physiotherapy

sessions and school, can surely induce fatigue. Nonetheless, almost all patients were motivated during the study and the majority experienced some improvement in their physical activity.

Caregiver questionnaires

The questions related to the use of sensors (question 4 and 6) had a mean VAS in the "satisfied" category. This means that the user guide provided to caregivers was clear enough. Despite technical issues with sensors (they turned off, fell off…), parents were still satisfied with them. One parent (ID 11) thought the sensors were not useful as her child is almost a grown-up and they are already aware of her strength and weakness. However, other caregivers of adolescents (ID 7-8-10) found the sensors useful. A possible explanation for that divergence of opinion could be that, according to her caregiver, patient with ID 11 is already very active, benefits from a personal trainer at home and her parents are extremely involved in her physical training. In this case, information provided by sensors might be less informative. All parents, except for ID 11, believed that the sensors are useful with a mean VAS score of question 1 in the "satisfied" category. Nevertheless, the mean VAS of the questions about the efficiency of the training program and the expected improvement of their child's physical capacity fell into the "average" category. This discrepancy might be explained by a misunderstanding of the purpose of the sensors. Indeed, during the interviews it became evident that some caregivers did not completely understand the aim of the sensors. Thus, some parents believed that inertial sensors were research tools that aimed at gathering data about the physical activity of patients with cerebral palsy in general. Moreover, several parents did not understand the link between sensors and the personalized training program. This misunderstanding might be explained 1) by the setting: the sensors were used within the scope of a study, which might lead parents to believe we gathered data for science's benefit and not directly to improve their child's personal therapy, and 2) by lack of a comprehensive explanation about the link between the data collected with sensors and the training program. This last point reflects the low motivation scored by one parent who did not understand the purpose of the sensors. Furthermore, another caregiver lacked motivation because she felt under pressure with the training program at home. This suggests that instructions concerning the personal training program were not completely understood by physiotherapists. Indeed, therapists sometimes just added physiotherapy exercises to be done at home under parental supervision, without incorporating those exercises into daily

routine. This manner of implementing the community-based exercises differed from the instructions given to physiotherapists when they were included in the study. Moreover, Lillo-Navarro et al. highlighted the factors associated with low adherence to home-based training supervised by parents (31). Among those factors, the amount of exercises and physiotherapists' lack of instructions concerning the incorporation of the exercises into daily life represented barriers to good adherence. Additionally, caregivers of children with CP asserted the negative impact of applying pressure to comply with home-based training (32). However, most caregivers were motivated by the sensors and were interested about seeing an improvement of their child's performance.

Physiotherapist questionnaires

The physiotherapists were asked to adapt patients' daily physical activities according to the results gathered by motion sensors in order to promote a more active lifestyle. Despite having a better representation of patients' physical activities with sensors, physiotherapists had trouble adapting the exercises proposed to their patients and when they changed those exercises, they were not always integrated in children's daily life. Given those results and Table 7, we might suppose that physical therapists did not understand the real purpose of the sensors in our study, which was not to add physiotherapy exercises at home but to adapt children's daily physical activities. There are many possibilities to explain this discrepancy. Firstly, the results were difficult to understand without the help of an investigator. There was a lot of information given at the same time and physiotherapists did not modify the therapy program directly after the explanations were given. Despite the comprehension of the results rated as good by physiotherapists, the large amount and the complexity of the data together with a delay in using that information might have led to a loss of relevant outcomes that were essential to develop the training plan. Secondly, some therapists complained about the lack of parameters assessing the quality of movement, yet there were several parameters related to the quality of movement, such as stride length, swing duration, stance duration, knee, thigh and shank angles, limp, double support and symmetry of movements. Consequently, those parameters were either not comprehensible for physiotherapists despite the explanation of a study investigator or they were not sufficiently relevant for their training plan. In a study by Borisov et al., physiotherapists were asked to rate the usefulness of gait parameters recorded by motion sensors (33). According to those therapists, the most useful parameters for planning therapy were sit-to-stand duration, walking speed and cadence.

However, sit-to-stand duration was not assessed with the Physilog®. Additionally, during the interviews in our study, physiotherapists requested specifics gait parameters for their patient, which were not recorded by sensors. Indeed, as patients presented different level of functional limitations, the relevance of the parameters reported by sensors might not be the same for each patient. Therefore, even though gait parameters describing the quality of movement were part of sensor outcomes, other metrics were probably desired by physiotherapists to plan the training program. However, our study confirms that physiotherapists are considerably focused on quality of movement. This is in line with the findings of Anaby et al., who highlighted some gaps between recommended and current practice among physiotherapists and the lack of evidence for such rehabilitation approaches focusing on the impairment-level of the ICF framework (15). Thirdly, the physiotherapists involved in this study were in charge of their patient for a long time, several years sometimes, and they were used to set long-term goals for their patient. This might be an explanation for the difficulty faced with setting goals and planning a training program for a 4-week period. Besides, the difficulties in developing a therapeutic plan that is embedded in patients' daily life are encountered by many physiotherapists outside the scope of our study (15). To sum up, the complexity of the data gathered with sensors, the lack of relevant parameters assessing the quality of movement and the difficulty in setting short term goals that are embedded in patients' daily life led physiotherapists to misuse the sensor outcomes.

In order to define the type of patients that would benefit the most from motion sensors, we examined the correlations between patients' age and patients' GMFCS level and 1) the usefulness of sensors (rated by physiotherapists), 2) physiotherapists' representation of their patients' daily physical activities and 3) physiotherapists' confidence regarding the development of a training program. As none of those correlations were significant, it did not appear that sensors would benefit more to a specific patient's profile. Additionally, given the small sample of participants and the large heterogeneity among them, significant correlations were not expected. Furthermore, despite the large range of years of professional experience (from 1 year to 30 years), there was no correlation found between physiotherapists' years of experience and 1) the perceived usefulness of sensors, 2) the representation of patients' physical activity and 3) therapists' confidence in their exercises' choice. This suggests that despite important professional expertise, sensors might bring additional information to therapists. Furthermore, Borisov et al. collected feedbacks of therapists with a professional experience of 11.86 years (SD= 12.56 years) who worked with wearable sensors and those

interviews confirmed that the majority of therapists were comfortable with new technology and interested in using it (33). Additionally, in our study all physiotherapists considered that motion sensors could be used in clinical practice. Indeed, even though, according to physiotherapists, the sensors might not be the ideal system for guiding the personal training, all therapists agreed that sensors would be useful for initial evaluation and follow-up of their patients' physical activity. Therefore, as suggested by physiotherapists and scientific literature, sensors might be used as an objective tool to assess patient's physical activity before and after an intervention (botulinum toxin injection, ankle-foot orthoses…) (34). This follows the same lines as the article by Kane et al., which emphasised the need for a reliable and standardized tool to evaluate the impact of orthoses on patients' participation and that such a device may promote confidence and consistency across physiotherapists as well as improve outcomes (35). Moreover, wearable motion sensors are already being used to assess gait outcomes after surgery (36).

Finally, even though the sensors in our study did not appear to be appropriate to guide physiotherapists' training plan, another possibility to benefit from the sensors in the clinical setting would be to make the sensors available to other healthcare workers. Indeed, a physiotherapist mentioned the healthcare assistant as being in charge of improving global physical activity. To our knowledge, there is no research concerning physical activity programs made by healthcare assistants or exercise-referral to a healthcare assistant. According to the Swiss *Secrétariat d'Etat à la formation, à la recherche et à l'innovation,* one of healthcare assistants' skills should be to « support the clients in their mobility » (37) without further description of their tasks. There is a lack of evidence to support the idea of delegating a training program to healthcare assistants. However, the concept of exercise-referral is being developed with the emergence of specialists in adapted physical activity (38). The main goals of those professionals, according to the *French society of professional in adapted physical activity*, are to "optimise the capacities of people with specific needs in bio-psycho-social domains through physical, sport and artistic activities" and "create personalized intervention programs for people with specific needs" (39). Besides, these health workers are also entitled to practise in the rehabilitation field. Therefore, given their qualifications, it might be more relevant to recommend the use of sensors by specialists in adapted physical activities.

Usability

With regard to sensors' usability, the questionnaires revealed a need for improvement. Indeed, there are significant technical issues with the sensors, which need to be addressed before their clinical implementation. Regarding the interpretation of the results, it would have been difficult for therapists to understand the results without the help of the investigator. In order to be used independently in clinical practice, the data gathered by sensors should be clear and easily understood by therapists. A possible idea to overcome this problem would be to create a user guide with detailed explanations on how to interpret such results, to offer a training session when the sensors are purchased and to improve data visualisation. Furthermore, there is no consensus among physiotherapists regarding the duration or the frequency of recording, but the majority of physiotherapists are in favour of an entire week of monitoring. According to the recent recommendation for PA monitoring in children with CP, a minimum of 3 days of reliable recording is indispensable to reflect adequately habitual PA (40). However, another wearable accelerometer was used for the monitoring (StepWatch®) and a total of 7 days of monitoring was necessary to be certain of achieving those 3 required days. Therefore, the timeframe required to achieve 3 days of recording might be different with Physilog® sensors. Additionally, as mentioned by some physiotherapists and confirmed in literature, PA differs on weekdays and weekends (18). Therefore, weekdays and weekends should be included if possible and therapists should note if the recording was made during a weekday or not as patients tend to be more active during school days (40). According to physiotherapists, sensors would be useful for the initial evaluation of a patient and before/after an intervention. In case no intervention was required for a patient, an assessment would be requested every one to two years.

Clinical considerations

To assess the clinical utility of the wearable motion sensors used in this study, we followed the multi-dimensional model described by Smart (25). As the sensors are being developed, there is still a lack of evidence regarding sensors' effectiveness. Moreover, implementing the sensors in a clinical setting in order to guide therapy might not be relevant, as some physiotherapists faced difficulties in adapting existing therapy according to sensor outcomes. Therefore, the appropriateness of motion sensors to this effect has not been proven. Considering their accessibility, it appears with the questionnaires that sensors' costs would be reasonable if no extra costs were added (e.g. software updates). However, this study did

not assess sensors' cost-effectiveness. The wearable motion sensors functioned, despite some technical issues inherent to the development of a new device. Nevertheless, parents were not concerned about those technical problems and considered the sensors as easy to use. Additionally, all physiotherapists would consider including motion sensors in their work practice, even though outcomes are not understandable enough, as currently presented, and the time needed to interpret the results without the help of an investigator might be significant, at least during the first few uses. Given these results, we suggest that wearable motion sensors demonstrate good practicability, as long as support is provided to therapists to interpret the results. Finally, as there were no ethical, legal, social or psychological concerns from study participants, we assume that motion sensors are acceptable. Although wearable motion sensors presented fairly good acceptability and practicability, using the sensors to guide patients' therapy lacks clinical relevance. Furthermore, other aspects of clinical utility such as effectiveness and cost-effectiveness could not be assessed and accessibility needs to be clarified.

Limitations and Outlook

This study was part of a pilot study concerning the wearable motion sensors and consequently presented a small sample of participants, especially when looking at sub-groups for our statistical analyses. Therefore, the strength of the statistical analyses based on VAS results remains low. Moreover, standard deviations were often large, reflecting that answers from participants diverged considerably and therefore it was difficult to generalise the findings. Additionally, as the statistical analyses concerning the reliability of sensor measurements were still on-going, we did not have any information regarding potential reliability issues with the data collected by sensors. In this study, we showed that it was difficult for physiotherapists to guide therapy according to sensor outcomes. Therefore, for future studies, we suggest that other health workers should be involved in the project (e.g. adapted physical activity specialists). Additionally, it would be worth including a larger sample of participants and using the sensors in a different setting (for example as an evaluation tool before and after a medical intervention). Finally, another research possibility would be to assess the sensors for a longer period of recording (36) and eventually to develop a standardized recording protocol with Physilog sensors (40).

Conclusion

Despite enabling physiotherapists to assess physical activity more objectively and over a longer period of time than a therapy session, wearable inertial sensors, such as Physilog®, were not considered by therapists to be an appropriate device to guide physiotherapy for children with cerebral palsy. This is strongly contrasted with the perception of both children and their parents who clearly held a more positive view of the sensors' usefulness, regarding both its impact on therapy and on expected progress, when participating in the same programme.

Wearable sensors seems meaningful for the affected children and their families, are easy to use, present good acceptability and practicability. Therefore, they could be used with different goals, such as an evaluation tool for patients' follow-up or to assess outcome after a medical intervention, or with professionals more attuned to daily life performance, such as adapted physical activity specialists.

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