2016•2017
FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN
master in de revalidatiewetenschappen en de kinesitherapie

Masterproef

The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis

Promotor :
Prof. dr. Peter FEYS

Copromotor :
Prof. dr. JEAN MANCA

Gertjan Bervoets , Sander Liekens
Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie

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KNOWLEDGE IN ACTION

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ACKNOWLEDGEMENT

This master thesis is written as part of our master studies rehabilitation sciences and physiotherapy at the University of Hasselt. The writing and testing took place from November 2016 till June 2017. This master thesis encompasses in a broader research and development group, MS-X-Move. This research group tried to answer a question of a multiple sclerosis patient, David Seffer: “Can you develop a walking aid by which I can walk longer and further and that can transport me when I’m tired?”

At first we want to thank our promotor, prof. dr. Peter Feys, and the University of Hasselt, who involved us in this master thesis. We thank all members of the research group MS-X-Move for the achievements within the R&D project: David Seffer, prof. dr. Jean Manca (co-promotor), Michel De Roeve, prof. dr. Kristof Vaes, Laurette Van Aert, Nicolas Van Der Wee, Geert Palmers and prof. dr. Peter Feys. We also want to thank the national MS center of Melsbroek, prof. dr. Stephan Ilsbroukx, Benoit Gebara, Pascal Van Der Beeten and Johan Van Nieuwenhoven, who helped us with patient recruitment and the possibility to test at their site and Msc Maarten Coemans who helped with data-analysis. We want to thank the participants of this study to help us investigate our research question.

At last we want to thank our parents, who gave us the opportunity to start and finish these studies and who were there for us when needed, our friends and family for all the useful advice and our girlfriends for their patience. This all made us bring this master thesis to a successful conclusion.

Gertjan Bervoets

Geneikenstraat 103, 3560 Lummen, June 6, 2017

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CONTEXT OF THE MASTER THESIS

This master thesis fits in the domain of neurological rehabilitation. Patients who suffer from neurological conditions like multiple sclerosis (MS), stroke or spinal cord injury (SCI) have different kinds of impairments. An example of these impairments is a decline of their cognitive skills for MS and stroke patients. This decline can also interfere with their motor capacities and other daily life functional tasks. For example, walking to the fridge or more important, just standing. For stroke patients, the impairments are related to a specific region of the brain. Stroke patients' impairments are mostly unilateral. This is different for spinal cord patients. Spinal cord patients may also experience unilateral loss of function but this function loss may also be bilateral depending on the kind and location of lesion. Beside these two groups, people with multiple sclerosis (pwMS) also belong to the neurological patients. David Seffer, a MS patient, has been testing different walking aids for quite a while and he describes them on his online blog (http://nieuwhulpmiddel.blogspot.be/). This way other people can inform themselves and find out how the different walking aids are experienced by a real patient. David himself experiences difficulties when walking in an outdoor setting. There for he has been searching and testing for years to find the best walking aid that helps him in these outdoor settings. Unfortunately he hasn't find the perfect walking aid to help him, that's why he contacted specialists to find an answer on the next question: 'Can you make me some kind of device that enables me to walk further distances outdoors?'.

Around this question a team of specialists was put together including prof. dr. Jean Manca, professor in physics at University Hasselt, Mr. Michel De Roeve, technical expert in physics at University of Hasselt, prof. dr. Peter Feys, professor in Rehabilitation sciences and physiotherapy at University Hasselt. Beside these specialists a master student product design from the University of Antwerp, Nicolas Van der Wee and his promotor prof. dr. Kristof Vaes joined the team. The product design department of LUCA school of arts at Genk (represented by Barbara Kok) and Geert Palmers, CEO of 3E completed the tiger team. In September 2016, Laurette Van Aert, a master student product design from the University of Antwerp joined the team. Together, these people formed the MS-X-Move team and this team hoped to be able to come up with a solution to help David.

This study can have an important impact for many patients, not only those with MS. By using the prototype and thereby reducing fatigue, people will be able to regain some form of independence and self-confidence in their lives. Therefore, David would not be the only person with MS who would benefit from a powered walker as walking aid. A lot of persons, with MS, Amyotrophic lateral sclerosis or just elderly need something between a walker and a wheelchair. Something they can walk themselves and are not obligated to sit. Especially in pwMS, where walking is almost always affected, it could be useful to walk with a powered walker. Being able to walk further and longer has a positive impact on self-confidence, independence and quality of life in general (Larocca, 2011). PwMS were chosen because David, a MS patient himself, asked for the adapted walking aid and the specific needs of pwMS. At the long term, a powered walker combined with an unique design can lower the stigma that hangs around the use of a walker. Nowadays people are still a bit holding back to immediately use a walker if advised. The use of this device is often associated with older people, a high level of dependency and patronizing thoughts by bystanders.

During fall of 2015 the main focus was based on the designs and sketches form Nicolas Van Der Wee. After different conversations with David, the main goal of Nicolas was to design a prototype walker that was less stigmatizing and on the other hand still functional and meeting the requirements of David. Nicolas first designs were very diverse. He drew designs ranging from a bike on which you can lie to futuristic walkers (Appendix 1). Professor Doctor Peter Feys, Sander Liekens and Gertjan Bervoets focussed mainly on important aspects like; posture when the person was walking with the prototype, safety measurements, functionality on different terrains and other import body-related aspects based on characteristics of pwMS. The most difficult part for Nicolas and his design was to create a prototype walker that could be transformed in a powered wheelchair that the user could operate and ride with. Therefore he created a central axis that was on the one hand very firm to provide enough stability when using the prototype and on the other hand very easy to operate when the switch had to be made from walker to wheelchair mode. During spring 2016 Nicolas tested with a very basic prototype (Appendix 2) made from steel pipes and basic wheels to learn more about the different dimensions of the walker. The tests with this rudimental prototype where mainly important for the design of the handlebars. If handlebars were located close to the sides of the body and not in front of the user like most existing walkers on the market, it is more

comfortable for the user. From this basic prototype Nicolas developed during summer of 2016 his final design for the prototype (Appendix 3). By modern designs, shapes and colours he tried to make this prototype less stigmatizing. Unfortunately this design was never actually developed due to very complicated technical aspects.

After Nicolas completed his Master thesis in the summer of 2016, Laurette Van Aert joined the team during fall of 2016. The main goal of the team now was to develop an actual working prototype that Sander and Gertjan could use to test within the context of this particular master thesis. Laurette came with the idea to use bamboo for the prototype. Bamboo has several potential features when developing a walker (lightweight, rigid, stiff and hollow).

During several meetings (winter 2016 to spring 2017) the team searched for new designs and ways to actuate the prototype. Feedback about pwMS, body-related factors and geometry was given. Besides these physiotherapy-related aspects the physiotherapists also helped with the choice of materials, wheels, tires and actuating system. At the end of spring 2017 a prototype (Appendix 4) was developed by Michel De Roeve. This prototype was based on a regular walker (Appendix 5) but the back wheels were replaced by hover board wheels (Appendix 6) and actuated. The amount of actuation could be controlled by the user by the handlebars (Appendix 7). With the present knowledge about MS, walking speeds of pwMS and differences in fine motor skills, important input was given to Michel for the correct adjustments and settings of the actuation system to fit persons with MS. This was the actual prototype that was used during the experimental tests of this study.

During the development phase of the prototype in the first months of 2017 Professor Peter Feys, Sander Liekens and Gertjan Bervoets focussed on drafting all the documents needed for the approval of the ethics committee. Their approval was needed to perform our tests with the prototype walker. We asked for permission of the ethics committee of the University of Hasselt, the University of Leuven and the National Ms Center Melsbroek. Following documents were submitted to the ethics committees: protocol, informed consent and submission document (Appendix 8). The documents were multiple times adjusted to meet feedback and requirements of the three ethics committees. Last version was submitted in April 2017 and received approval. Design and methods of the study, submission to ethics committee, communication with National MS Center, data-aquisition and analysis and writing were all independently done by the master students with feedback from the promotor.

THE EFFECT OF A POWERED WALKER ON MOTOR FATIGABILITY DURING A SIX-MINUTE WALK TEST AND ON AN OUTDOOR COURSE IN PERSONS WITH MULTIPLE SCLEROSIS

ABSTRACT

Background: this master thesis is situated in a research project named MS-X-Move which is made up of the MS Tiger Team. **Objectives:** In this study researchers investigated the effect of a powered walker on motor fatigability during a six-minute-walking test (6MWT) and an outdoor course in persons with Multiple Sclerosis (pwMS). **Participants:** six individuals diagnosed with Multiple Sclerosis with an EDSS-score between 5.5 and 6.5. **Measurements:** for the 6MWT the following measurements were taken: the total distance (measured in meters), the average heart rate per every minute (bpm), the percentage change in distance walked (distance walked index, DWI) was calculated for every minute compared with minute 1, BORG dyspnea level, RPE for overall fatigue and specifically for leg fatigue. For the outdoor course the total time (measured in seconds) and section times (measured in seconds) where measured, also the Quebec user evaluation of satisfaction with assistive technology, VAS for usefulness and BORG dyspnea level, RPE for overall fatigue and specifically for leg fatigue. **Results:** no significant differences were found between a regular and powered walker. Results closest to significant for the 6MWT were: RPE – leg fatigue ($p=0.12$) and for the outdoor course: RPE – overall fatigue ($p=0.12$). **Conclusion:** this study failed to show a significant difference on motor fatigability when comparing a regular with a powered walker, probably related to the relative low number of test subjects. Some pwMS however showed some benefit from a powered walker when executing these tests. Therefore, more tests should be performed to get reliable conclusions.

INTRODUCTION

Multiple Sclerosis is a neurodegenerative disease that affects the conduction of myelinated neurons in the brain and spinal cord. It is a demyelinating and degenerative disease in which the myelin, the insulating cover around neurons, disappears (Compston & Coles, 2002). MS patients can experience an acute loss of function during a relapse but in general the disease has a more chronic, progressive character. These patients experience a progressive loss of strength and endurance most prominent in the lower limbs. The main difficulties for walking are related to balance, strength and endurance. Especially endurance, what can be measured by a 6MWT (Crapo et al., 2002), is affected in MS as C. Leone et al. (2016) described that there is a continuous decline in walking speed during the 6MWT, this can be defined as 'motor fatigue'. Recent research showed that this decline in walking speed was most prevalent in the more disabled pwMS and in the progressive phenotype of MS (C. Leone et al., 2016). Phan-Ba et al. (2012) found during a 500 meter walking test that more disabled pwMS, who have a higher EDSS-score, declined more in walking speed during the test in comparison with pwMS with a lower EDSS-score. Chaudhuri and Behan (2004) described fatigue in neurological disorders as the inability or difficulty to initiate or sustain a voluntary activity. Besides motor fatigability and fatigue it is important to note the difference with 'performance fatigability'. This is defined as 'an objective decrement in performance induced by continued activity' (Kluger et al., 2016). The difference with 'motor fatigability' is the fact that 'motor fatigability' is specifically directed to the decline in walking speed where 'performance fatigability' is directed to a general decline in performance during continuous exercise or activities.

There are many walking aids available; walkers, crutches, canes, knee ankle foot orthoses (KAFO), passive or active exoskeletons. Finlayson, Peterson, and Asano (2014) described the use of walking aids by pwMS. They reported a use of at least two walking aids by 60% of patients and an increase in falls the more different walking aids a person used. They reported two reasons why there was an increase in falls in pwMS who used multiple walking aids. The first reason described the fact that people who use more walking aids, are more likely to be people who have more problems with balance and coordination. Besides a higher fall prevalence, walking aids also have been proven to be positive for the user. A study from 2013 in an elderly population concluded that assistive devices, especially walking aids are safe and effective (Sonn, Davegårdh, Lindskog, & Steen, 1996).

Within the domain of the walker many innovations have been done the last years. The design has changed to more modern frames, which are lighter in weight by using more modern materials like aluminum or carbon fiber. Nowadays some models can be transformed to a kind of wheelchair where another person can still transport the patient when he starts to get tired. Progress was also made in the department of the tires selected for the walker. The first walkers available on the market were fitted with plastic, rather hard tires. Nowadays mostly rubber tires are used with a lot of different types available. People can choose for slick versions, mainly used in a city environment, or for tires with a rougher surface for the outdoor settings (forest, gravel roads, grass roads, hills,…).

The main objective of this part of the study was to investigate whether people with multiple sclerosis (pwMS) are able to walk with a powered walker and if the use of a powered walker can reduce the motor fatigue during a six minute walking test (6MWT) and/or on an outdoor course. Until now, we found only one existing powered walker made by ello®(https://www.ello-info.de/#vorteile). This study was the first to conduct tests on an outdoor course and during a 6MWT with a powered walker compared to a regular walker.

METHODS

Research question

The primary research question is; 'What are the effects of a powered walker in pwMS on motor fatigue during a six-minute walking test and during an outdoor course including daily life obstacles and off-road sections?' (RQ1) This research question is strongly dependent on whether or not the participants are able to walk with and handle the powered walker. The hypothesis was that pwMS, who experience lower motor control levels, stability and coordination problems (Compston & Coles, 2008), have some kind of trouble handling the actuating mechanism on the prototype. Four secondary research questions (RQ) were formulated:

- How does the use of the prototype influence the walking speed when completing an outdoor course in comparison of a regular walker? (RQ2)
- What is the influence of the use of a powered walker on perceived performance fatigue (BORG perceived exertion) during an outdoor course with daily life obstacles? (RQ3)
- What is the influence of the use of a powered walker on perceived performance fatigue (BORG perceived exertion) and distance during a six-minute-walking test? (RQ4)
- What is the influence of a powered walker on the level of ease of use measured by the Quebec user evaluation of satisfaction with assistive technology (Dutch version) questionnaire (Demers, Weiss-Lambrou, & Ska, 1996)? (RQ5)

Based on the research questions above, the following hypotheses (H) were formulated;

- The use of a powered walker will decrease the experienced motor fatigue measured by the walking index (C. Leone et al., 2016) during a six-minute walking test and an outdoor course. (H1)
- The use of a powered walker will reduce the time needed to complete an outdoor course including daily life obstacles and off-road sections. (H2)
- The use of a powered walker will reduce the perceived exertion during an outdoor course including daily life obstacles and off-road sections. (H3)
- The use of a powered walker will have a beneficial effect on the distance, measured by the walking index (C. Leone et al., 2016) and total distance, covered during a 6MWT as will diminish the perceived performance fatigue during the test. (H4)

- The use of a powered walker will be feasible in pwMS during an outdoor course with daily life obstacles or during a 6MWT. (H5)

To find answers on these research questions and hypotheses the effect of a powered walker was tested in pwMS on motor fatigue during a 6MWT and an outdoor course that mimics daily life obstacles. All tests were done at the site of the National MS center Melsbroek in Belgium. This center is specialized in rehabilitation for MS-patients and offered the perfect resources and location for testing the prototype.

Study design & participants

The tests of this pilot study with a crossover randomized controlled design were executed in the National MS Center of Belgium, in Melsbroek. It's a pilot study to investigate the possible positive effect of a powered walker. Six participants diagnosed with MS were recruited from the NMSC Melsbroek, Belgium. Participants had to be diagnosed with MS by the criteria of McDonald (Polman et al., 2011), their EDSS-score had to be between 5.5-6.5 and they had to be able to hold a walker with both hands while walking. Subjects were excluded if they met any of the following criteria:

- They had major orthopaedic problems, upper or lower extremity.
- They had been diagnosed with any cardiovascular complication.
- They had a relapse within the last month.
- They were participating in a different study.
- They didn't speak Dutch.
- They were younger than 18 years old.
- They were or became pregnant.

Recruitment & procedure

The participants were recruited in the National MS Center of Melsbroek under supervision of dr. S. Ilsbroukx (rehabilitation physician) and Johan Van Nieuwenhoven (physiotherapist). After recruitment the following procedure was used. In total, tests were executed over three test days. On day one, two 6MWT were executed by only one patient. The first test was done with the regular walker in the morning. To make sure there was enough rest time, the second test with the powered prototype walker was done in the afternoon. The second test day another five participants were tested during two 6MWT. Two of these participants began with the prototype walker in the morning and performed their second 6MWT with the regular walker in the afternoon. The other three participants started with the regular walker in the morning for their first 6MWT and performed the second 6MWT with the prototype in the afternoon. On the third test day all five participants performed their tests on the outdoor course. One participant did his/her first test on the outdoor course with the prototype in the morning and the second test was done with the regular walker in the afternoon. All four other participants executed their first test on the outdoor course with the regular walker in the morning and performed their second test in the afternoon on the outdoor course with the prototype powered walker. It is important to note that there were two identical walkers used during the tests. The only difference between the two models was the fact that one model was powered by an extern actuating system and was modified with special actuated wheels. The two models were perfectly identical except for weight, handlebars and back wheels. The powered prototype weighed 5.60 kg more than the control, the handlebars were modified so the person who uses the prototype could control the amount of actuation and the back wheels were different due to the actuating component. It's important to note that both walkers were adjusted to fit the participant as best as possible. Settings were saved for every participant to make sure that both walkers were adjusted exactly the same each time for the participant.

Important to note is that all descriptive outcome measurements came out of the participants file. Most recent data or tests were used. For some patients some descriptive data were missing and therefore executed. This way all descriptive data were equally available for all participant.

Allocation

Allocation was done by sealed envelope principle. Two allocations were done: the kind of walker to start with in 6MWT and the kind of walker to start with during the outdoor course. In both occasions there are two possibilities, starting with the powered walker or starting with the regular walker.

Outcomes

The outcome variables were divided into descriptive variables, being the baseline characteristics to describe the participants, and experimental outcome variables, being the investigated variables compared between both walkers.

Descriptive outcome variables

To describe the baseline characteristics of the participants following descriptive variables were taken:

- Type of MS, time since onset and last relapse
- Multiple sclerosis functional composite (MSFC): a test consisting of three sub-tests: the Nine Hole Peg Test (NHPT), the Timed 25feet Walk Test (T25WT) and the Paced Auditory Serial Addition Test (PASAT). The MSFC is a specific test for MS to describe specific skills: arm/hand function, cognitive function and leg function. It's a reliable test to document disease progression used in a descriptive manner (Meyer-Moock, Feng, Maeurer, Dippel, & Kohlmann, 2014).
- Expanded Disability Status Scale (EDSS): a scale to define the degree of progression of MS based on ambulation. A score between 0 and 10 with steps of 0.5 where 0 stands for no influence of MS and 10 for dead because of MS. The EDSS-score is a worldwide used score to define the degree of neurological impairment in pwMS (Kurtzke, 1983).
- Symbol Digit Modalities Test (SDMT): a test to detect brain damage or cognitive impairment. A study from 2008 showed that the SDMT has perfect reproducibility over repeated testing and is valid when used in pwMS (Benedict et al., 2008).
- At the start of every test day there was asked for fatigability level of the past week by a Visual Analog Scale (VAS). Following question was asked, "How tired are you today?" (appendix 9). A study showed that the VAS is a moderately reliable, though valid and

useful tool to screen rapidly for fatigue impact in pwMS (Kos, Nagels, D'hooghe, Duportail, & Kerckhofs, 2006).

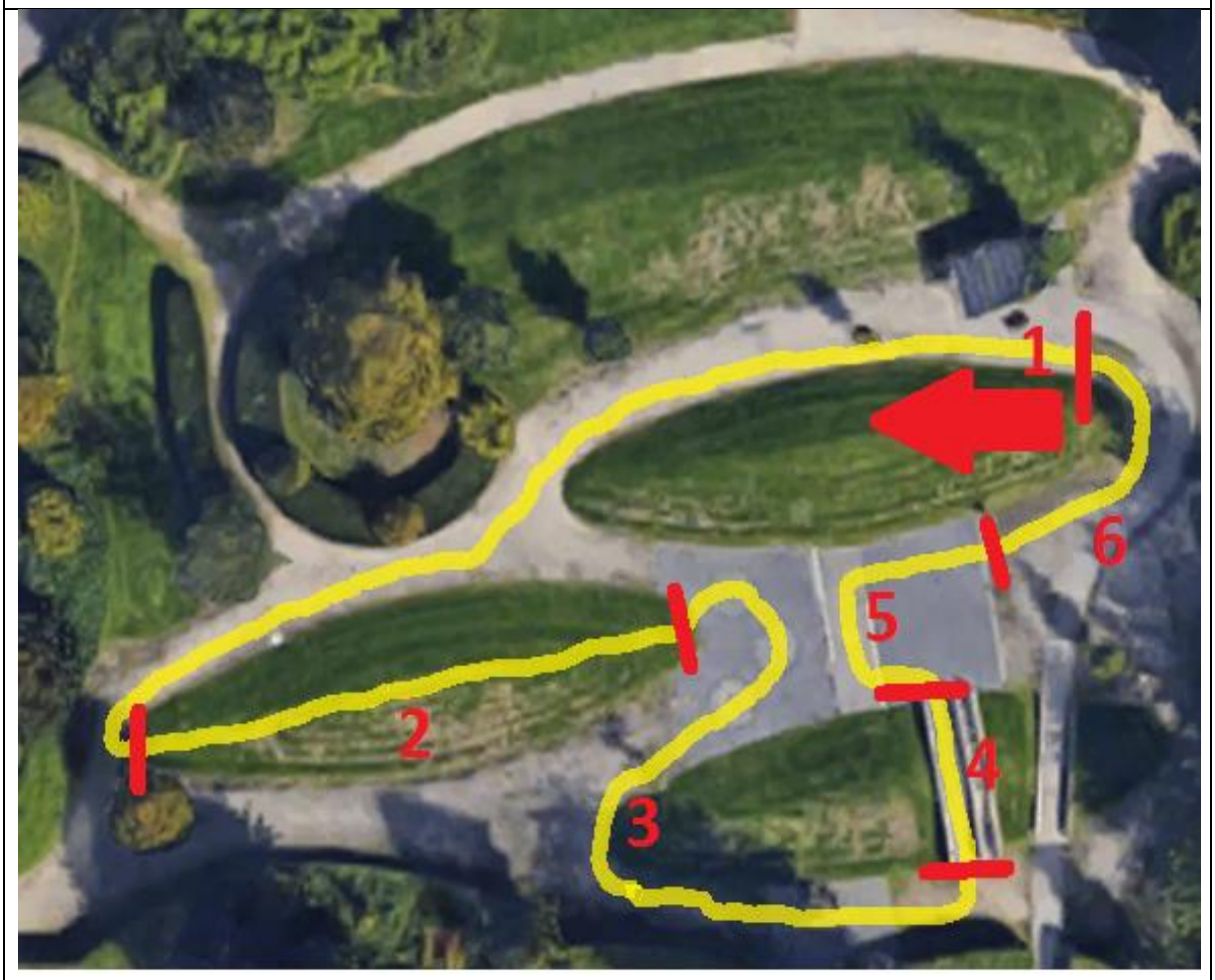
Experimental outcome variables

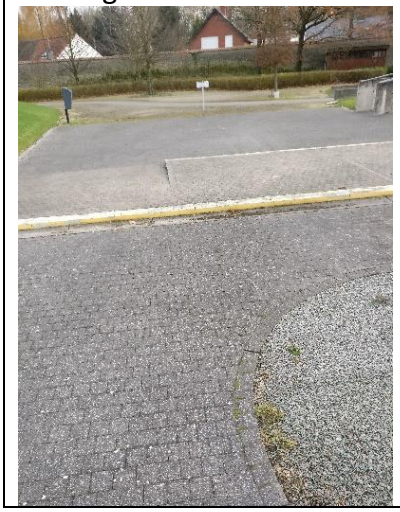
To measure the effect of the intervention versus the control following outcomes measures were set:

Outdoor course

An outdoor course was set up (details see box below) to mimic daily life/outdoor situations. The course includes gravel roads, pavement, a small grass hill, a paved slope a typical street curb and gutter. The distance was 204 meters in total.

Overview of the outdoor parkour (Google Maps©)



1. Gravel road A (68m) Flat gravel stretch from start point to begin grass hill. 	2. Grass Hill (37m) 4% Uphill and downhill slope on grass surface. 
3. Gravel road B (52m) Pavement and gravel without gradient, containing cobblestones	4. Paved slope (11m) 9% slope on paved surface both uphill and downhill 
5. Curb & gutter (17m) Concrete surface containing curb (10cm) and street gutter 	6. Last part to the finish (19m) Flat gravel road without gradient

Primary outcome measures – outdoor course:

- Total time that is needed to complete the course (measured with a stopwatch in seconds).

Secondary outcome measures – outdoor course:

- Time that is needed to complete different parts of the course (measured with a stopwatch in seconds). The course will be divided into six different parts; the gravel road from the start until the grass hill (1), the grass hill itself (2), pavement and gravel section (3), the paved slope (4), the curb and street gutter section (5) and lastly the final part to the finish (6)
- Ease of use of the walker (measured by the Quebec User Evaluation of Satisfaction with Assistive Technology (Dutch version) questionnaire (Demers et al., 1996)). This was reported for the outdoor course in general. (Appendix 10)
- The level of usability (measured by a Visual Analoge Scale (VAS))
  The level of usability was reported for every part of the outdoor course as mentioned above. (Appendix 11)
- The level of experienced fatigue (BORG RPE) after the test (measured by the rate of perceived exertion scale (Brice T Cleland, Benjamin A Ingraham, Molly C Pitluck, Douglas Woo, & Alexander V Ng, 2016). Used ranges were 6-20 (Appendix 12). The general feeling of fatigue was specifically asked for after the test for this BORG RPE.
- The level of dyspnea (BORG) after the test (Appendix 13). The BORG dyspnea scale ranging from 0-10 was chosen because research has shown that measuring dyspnea by the BORG scale results in more stable measurements in comparison with a VAS-scale for dyspnea (Wilson & Jones, 1989).
- The level of leg fatigue (BORG RPE) after the test (Appendix 12). For this BORG the patients were specifically asked to answer considering only their experienced leg fatigue but the same RPE score-range was kept as the general fatigue BORG RPE (6-20).

Six minute walk test

This test was conducted in the hallway of the National MS Center Melsbroek. A standardized protocol was applied to make sure both researchers gave the same instructions to every participant. A study from 2008 showed that the 6MWT is a feasible, reproducible and reliable measure in pwMS (Goldman, Marrie, & Cohen, 2008). The participants were instructed to cover a maximal distance walking on maximal walking speed during the six minutes. The distance between turning points measured 30 meters and both turning points were marked with a cone. Before the test subjects were clearly instructed to turn around the two cones.

<u>Primary outcome measures – six minute walking test:</u>

- Total distance covered in six minutes by the subject (measured in meters by a roller meter).

<u>Secondary outcomes measures – six minute walking test:</u>

- Minute per minute distance (measured by the walking index (C. Leone et al., 2016)) The walking index measures the decline in distance walked in the first to all following minutes during a 6MWT. This was calculated by the Distance Walked Index (DWI) and the next formula:

  DWI = ([Distance walked at minute n – Distance walked at minute 1]/Distance walked at minute 1) × 100.

  The DWI was calculated for every minute of the 6MWT to achieve an overall view of drop of walked distance during every minute of the 6MWT.
- The level of experienced fatigue (BORG RPE) after the test (measured by the rate of perceived exertion scale (Brice T Cleland et al., 2016). Used ranges were 6-20 (Appendix 12). The general feeling of fatigue was specifically asked for after the test for this BORG RPE.
- The level of dyspnea (BORG) after the test (Appendix 13). The BORG dyspnea scale ranging from 0-10 was chosen because research has shown that measuring dyspnea by the BORG scale results in more stable measurements in comparison with a VAS-scale for dyspnea (Wilson & Jones, 1989).
- The level of leg fatigue (BORG RPE) after the test (Appendix 12). For this BORG the patients were specifically asked to answer considering only their experienced leg

fatigue but the same RPE score-range was kept as the general fatigue BORG RPE (6-20).

- The average heartrate during each minute. The heartrate is measured by a Polar® band and watch and logged to Polar Flow® (www. https://flow.polar.com). The average heartrate was extracted for each minute of the 6MWT.

Data-analysis

The small sample size implicated that all data were non-parametrically tested and that the descriptive data would probably be normally distributed when tested. But when testing non-parametrically, this is not necessary.

All experimental variables were non-parametrically tested between the two walkers with paired tests when possible (Wilcoxon signed rank test). For 6MWT following tests were conducted (Table 3): comparison of total distance, comparison of total average heart rate, comparison of experienced fatigue scales (BORG RPE, BORG dyspnea and BORG legs). The DWI during 6MWT was analyzed by a Cochran-Mantel-Haenszel method. Every minute of the index was compared by this method. For the outdoors course all data were tested by a Wilcoxon signed rank test. Following data were compared between both walkers within each subject (Table 5): total time of the course, time of the six different sections, the Quebec user evaluation of satisfaction of assistive technology (Dutch version) adapted for the total course, VAS-scores for each section and a comparison of the experienced fatigue scales (BORG RPE, BORG dyspnea and BORG legs). All analyses were performed in SAS® 9.4 (SAS Institute Inc).

RESULTS

Participants (Table 1)

In total six MS patients were included in this study (four men and two women). All participants had an EDSS-score between 5.5 and 6.5 and met the previous established inclusion criteria. Time of MS diagnose ranged between 2002 and 2010 with ages between 39 and 61. Five of the six test subjects used an AFO in combination with any other walking aid (crutch, cane, knee-extension brace). One patient (E) had severe spasticity that had a big influence on walking. Five of the six subjects were tested on the same dates. All tests on the outdoor course were done on the same day (May 26, 2017) for all of the five subjects. As far as the 6MWT was concerned, five subjects executed the test on the same day (May 23, 2017) and one participant executed the 6MWT on May 18, 2017. For a schematic overview see table 1 below. For privacy reasons the names of the participants were replaced with letters (A-F).

Table 1: Patient characteristics

PATIENT CHARACTERISTICS

PATIENT	**A**	**B**	**C**	**D**	**E**	**F**
GENDER	male	Male	male	female	male	female
AGE	46	59	44	44	39	61
DATE MS DIAGNOSE	October 2008	January 2002	April 2002	April 2010	February 2007	April 2002
TYPE OF MS	Relapse-remitting	Relapse-remitting	Relapse-remitting	Relapse-remitting	Primary progressive MS	Relapse-remitting
DATE LAST MS RELAPSE	December 2009	May 2014	May 2016	2013	Na.	2014
EDSS-SCORE	6	6.0-6.5	6.0	6.0	6.5	6.0
WALKING AIDS	Hip flexion assist right, AFO right and Cane right	Knee extension brace (left) & AFO (left and right)	AFO left	AFO right & crutch left	AFO right	Cane left
9HPT	left: 26.55 right: 19.41	left: 25.70 right: 22.20	left: 30.15 right: 39	left: 27.30 right 30.07	left: 22.65 right 16.44	left: 26.78 right 21.20
25FTWT	5.5”	11.7”	9.11”	8”	51”	10.3”
DATE TEST DAY 6MWT	18 May 2017	23 May 2017	23 May 2017	23 May 2017	23 May 2017	23 May 2017
DATE TEST DAY OUTDOOR COURSE	26 May 2017	26 May 2017	26 May 2017	26 May 2017	26 May 2017	26 May 2017

Six minute walk test

This study did not aim to find strong significant results due to only five participants completed the outdoors course and six participants completed the 6MWT.

Total distance (Appendix 14)

In total six participants performed the 6MWT. Two of the participants performed their first 6MWT in the morning with the powered walker and tested with the regular walker in the afternoon. The other four participants started with the regular walker in the morning and performed their second 6MWT in the afternoon with the powered walker. Four out of six participants walked a greater distance during the 6MWT with the powered version in comparison with the regular walker. Two participants covered less distance with the powered version. There was no significant ($p=1.00$) difference between the regular and powered walker in total distance covered during the 6MWT. The median covered distance for the regular walker was 284.5 meters in comparison with 241 meters with the powered walker. Individual results can be found in appendix 14.

Distance per minute (m) (Appendix 15 & 16)

With the regular walker, three of the six participants showed a clear drop in covered distance as they further advanced in the test. This can be seen in appendix 15. When comparing the same participants when using the powered walker, no clear drop can be seen and the covered distance per minute stays fairly constant. For an overview see appendix 15 and 16.

Distance walked index (DWI) per minute (Appendix 17 & 18)

Two out of six participants were able to increase their DWI (%) during the last minute both with 6% when comparing with the first minute of the 6MWT. The other four participants dropped distance matching with a DWI (%) of -34%, -4%, -82% and -11% during their last minute of the 6MWT when using the regular walker. Compared with the last minute of the 6MWT when using the powered walker all six participants covered more distance in the last minute. For example comparing the two last minutes of the 6MWT of subject one, this participant, with the regular walker dropped from 68 meters covered during the first minute to 41 meters and 45 meters covered during the last two minutes when using the regular walker. Comparing this with the two last minutes using the powered walker covering 60

meters the first minute and 55 meters and 53 meters the two last minutes. This matches a DWI (%) during the last two minutes of -8% and -12%. The graph of the distance covered per minute (Appendix 15 & 16) by the regular and powered walker shows a smaller decrease with the powered walker.

Table 2: 6MWT DWI (%) comparison per minute per participant for the regular walker Vs. powered walker

	DWI (%) PER MINUTE									
	60”-120”		120”-180”		180”-240”		240”-300”		300”-360”	
PARTICIPANT:	Regular	Powered	Regular	Powered	Regular	Powered	Regular	Powered	Regular	powered
A	-9%	-8%	-26%	0%	-37%	-3%	-40%	-8%	-34%	-12%
B	0%	-18%	-3%	-13%	6%	-27%	-3%	-24%	6%	-22%
C	-2%	6%	-11%	3%	-7%	6%	-22%	14%	-4%	49%
D	2%	7%	4%	-2%	-2%	-10%	-2%	-2%	6%	5%
E	-9%	-20%	-18%	-10%	-27%	-30%	-55%	0%	-82%	0%
F	-2%	0%	-2%	-13%	-9%	-9%	-13%	-6%	-11%	2%

Another import finding can be seen in appendix 19. This figure shows the average DWI (%) per minute comparing the powered and regular walker. There is a clear drop, when using the regular walker, of DWI when participants advanced further in the test, especially after minute four of the six. When using the powered walker participants also drop in DWI until minute four during the 6MWT but are able to deflect this negative evolution into an increase in distance covered during minute five and six. This difference in drop of covered distance between the regular and powered walker was not significant (p=0.28).

Average heart rate (bpm) (Appendix 20)

Four of the six participants had a lower average heart rate during the 6MWT when walking with the powered walker. Two other participants showed a 10 beats per minute increase when walking with the powered version compared to the regular walker. Important to note is that out of the two participants who showed an increase in average heart rate when using the powered walker, one participant covered a greater distance when compared with the regular walker. The other participant who showed an increase in average heart rate with the powered

walker covered a smaller distance using this walker in comparison with the regular walker. The median heart rate for the regular walker was 124 bpm and 122 bpm for the powered walker. The median heart rate of the powered walker was 1.6% lower than the regular walker, yet there was no significant difference (p=0.68) found between the regular walker and powered walker.

BORG-scale and RPE: Dyspnea, general fatigue and leg fatigue (Appendix 21)

Level of dyspnea:

The level of dyspnea was assessed at one minute after completing the 6MWT by a BORG-scale between zero (no dyspnea at all) and ten (maximal dyspnea) and is displayed in appendix 21 in green. Two participants showed an increase in dyspnea level when using the powered walker and four participants reported the same level of dyspnea. The median BORG-score for dyspnea for the regular walker was 3 compared with 5 for the powered walker indicating a 66.6% difference. Yet no significant difference (p=0.50) was found between both walkers.

Level of general fatigue:

The level of general fatigue was assessed one minute after completing the 6MWT by a RPE-scale between six (absolutely no fatigue) and twenty (maximal fatigue) and is displayed in appendix 21 in blue. All six participants scored a median RPE of general fatigue from 14.5 when using the regular walker. For the powered walker the median RPE of general fatigue was 12. This is equal to a 17.2% decrease in general fatigue when using the power walker. Yet this difference was not found to be significant (p=0.56).

Level of leg fatigue:

The level of leg fatigue was assessed one minute after completing the 6MWT by a RPE-scale between six (absolutely no fatigue) and twenty (maximal fatigue) and is displayed in appendix 21 in red. Important to note is that to assess the level of leg fatigue, researchers asked the participants specifically to only report their leg fatigue. Six participants showed a median RPE for leg fatigue of 16 when using the regular walker compared with an median RPE of leg fatigue of 13.5 when using the powered walker. This shows a decrease (-15.6%) in RPE specifically for leg fatigue when using the powered version. This difference was found to be closest to significant (p= 0.12).

These three BORG-scales together show that the level of dyspnea isn't largely affected by using a powered walker instead of a regular one. However, the use of a powered walker has a slight positive effect on the RPE for general and especially leg fatigue. Both average RPE of general fatigue and leg fatigue were lower when using the powered walker in comparison with the regular walker. Note that all three outcomes were not significant when comparing the regular with the powered walker.

Table 3. 6MWT results including number of participants, P-values, median results for the regular and powered walker and % difference (All negative % outcomes should be interpreted as an average score in favour of the powered walker except for the total distance)

COMPARISON	NUMBER OF PARTICIPANTS	P-VALUE	MEDIAN REGULAR WALKER	IQR REGULAR WALKER	MEDIAN POWERED WALKER	IQR POWERED WALKER	% DIFFERENCE
6MWT							
TOTAL DISTANCE (M)	6	ns	284.5	84	241	37.3	-15.2%
DWI (%)	6	ns	-8	0.2	-5	14.16	-37.5%
AVERAGE HEART RATE (BPM)	6	ns	124	26.3	122	35	-1.6%
BORG-SCALE: DYSPNEA (0-10)	6	ns	3	3.75	5	4	66.6%
RPE – GENERAL FATIGUE (6-20)	6	ns	14.5	8.25	12	3.75	-17.2%
RPE – LEG FATIGUE (6-20)	6	ns	16	2.25	13.5	2.5	-15.6

Outdoor course

As with the 6MWT, there were only five participants in total which made it not possible to apply parametric data-analyzation. Therefore significant differences were not expected between the regular and powered walker.

Total time (Appendix 22)

In total five participants completed the course. Important to note is that one subject experienced severe spasticity in the lower extremities. Taking into account the fact that this participant only walked a distance of 54 meters in his best 6MWT and knowing that the entire outdoor course is 204 meters long, it was decided to let this participant complete only one section of the course (gravel road B). When comparing the powered walker with the regular walker, three participants completed the entire course faster with the powered version. The other two participants walked faster with the regular walker. Important is the fact that one of these two participants who walked faster with the regular walker was the one subject who experienced severe spasticity. The median time needed to complete the outdoor course with the regular walker was 300 seconds. When using the powered walker the median time was 311 seconds to complete the entire outdoor course. This is equal to a 3.6% increase in total time needed to complete the course with the powered walker. Yet this difference was found not to be significant (p=0.43) when comparing the regular with the powered walker.

Section times (Appendix 23 to 28)

Gravel road A (Appendix 23):

In total four of the five participants completed the first section 'gravel road A'. Appendix 23 shows that all four participants needed more time to complete this first section when using the powered walker. The median time needed to complete this section with the regular walker was 86 seconds and 94 seconds for the powered walker. This corresponds with a 9.3% increase in time needed to complete the first section when using the powered walker. P-value for the difference in time was 0.25.

Grass hill (Appendix 24):

Four of the five participants completed the second section 'grass hill'. In total of this four participants, three completed the grass hill section faster when using the powered walker and one participant was slower when using the powered walker. The median time that was needed to complete the grass hill section with the regular walker was 74 seconds. When using the powered walker the median time for the grass hill section was 69.5 seconds. This means that when using the powered walker the participants were 6.1% faster in time compared to the regular walker but this difference was not significant (p=0.87).

Gravel road B (Appendix 25):

In total five participants completed this section. Three of the five participants completed this section faster with the powered walker as displayed at appendix 25. The other two participants needed more time to complete this section when using the powered version. Important to note is that one of these two participants was the one who experienced the severe spasticity in the lower extremities. Median times needed to complete this section of the course were 91 seconds for the regular walker and 85 seconds for the powered walker. This corresponds with a 6.6% decrease in time needed to complete this section when using the powered walker. Yet this difference was not significant (p=0.81) after data-analyses.

Paved slope (Appendix 26):

This section was completed by four participants in total. Displayed in appendix 26 is a reduction in time by two of the four participants when using the powered walker. One participant needed more time to complete the paved slope section when using the powered walker and one participant completed this section in the same time with both walkers. Median time for the regular walker was 25 seconds compared with 26 seconds when using the powered walker. This corresponds with a 4% increase in time when using the powered walker but no significant difference (p=0.75) was found.

Curb & gutter (Appendix 27):

Four participants completed this section of the course. Three of the four participants were faster when completing this section with the powered walker in comparison with the regular walker. One participant needed two seconds more to complete this section with the powered walker. The median time to complete the curb & gutter section with the regular walker was 36.5 seconds. When using the powered walker the median time was 32 seconds which made the powered walker 12.3% faster in time than the regular walker in this section without a significant difference (p=0.37).

Last part to the finish (Appendix 28):

As displayed in appendix 28, four participants completed the last section of the outdoor course. Two participants were faster when using the powered walker, one participant showed the same time with the powered and regular walker and one participant was slower when completing this section using the powered walker. Median times for the regular and powered walker were respectively 25 seconds and 26.5 seconds. This made the powered walker 6%

slower on the last section of the outdoor course but this difference was found not to be significant (p=0.75).

Ease of use

The Quebec user evaluation of satisfaction with assistive technology (Dutch version) (adapted) (Appendix 29):

The Quebec user evaluation of satisfaction with assistive technology (Dutch version) was adapted to the relevant information. Therefor only question one to nine were asked. For a detailed description of all asked questions see appendix 10. In total all five participants answered two adapted Quebec user evaluation of satisfaction with assistive technology (Dutch version) questionnaires. One for the regular walker and one for the powered version. These questions were asked within 5 minutes after ending the outdoor course. After adapting the questionnaire the possible maximal score was 45. Out of the five participants, two participants showed a higher score with the powered version. All other three participants showed higher scores when using the regular walker. The median score of the regular walker for the adapted The Quebec user evaluation of satisfaction with assistive technology (Dutch version) was 37/45, for the powered walker the median score was 33/45 points. There was no significant difference (p=0.43) found in The Quebec user evaluation of satisfaction with assistive technology (Dutch version) scores between both walkers.

Visual Analog Scale – usefulness (Appendix 11):

For every section of the course; gravel road A, grass hill, gravel road B, paved slope, curb & gutter and the last part to the finish, a VAS regarding usefulness of the regular and powered walker on that particular section of the outdoor course was asked.

Median VAS for usefulness comparison per section (Appendix 30 & 31):

In total four participants filled a VAS for usefulness for every section of the course. For the section ‘gravel road B’ were five results available because this section was also completed by the participant who suffered severe spasticity in the lower extremities. What becomes clear in the figure from appendix 30 is that the average VAS for usefulness is lower for every section of the course when using the powered walker. This also becomes clear if looked at appendix 31 were the difference of VAS-score of the regular walker with the powered walker for every

individual participant per different section of the course is considered (all p-values for the different VAS-levels can be found in table 5). This figure has to be interpreted as follows: a score of zero means that this participant gave the same VAS-score for the regular walker as for the powered walker for that particular section of the outdoor course. (The sections of the course are listed from section one to six from left to right on the figure in appendix 31). Also note that a negative score means that this participant gave a higher VAS-score for the regular walker as for the powered walker (with the difference displaying on the figure as a negative number). As seen with the average VAS-scores per section, two participants scored mainly higher when using the regular walker instead of the powered walker. This is seen in participant two and three. Participant one gave six same scores for the regular as for the powered walker. Important to note is that participant four is the one who experienced severe spasticity and only completed section three of the outdoor course. Therefore section one, two, four, five and six are scored as zero. This participant also scored zero on the completed section three of the course meaning he gave the same VAS-score when using the regular and powered walker.

BORG-scales and RPE: Dyspnea, general fatigue and leg fatigue (Appendix 32)

Level of Dyspnea:

The level of dyspnea was assessed at one minute after completing the outdoor course by a BORG-scale between zero (no dyspnea at all) and ten (maximal dyspnea) and is displayed in appendix 32 in green. Two participants scored the same levels of dyspnea for the regular and powered walker, two participants gave a lower level of dyspnea when using the powered walker and one participant gave a higher dyspnea score when using the powered version. Median BORG-score for dyspnea for the regular walker was 4 and also 4 for the powered walker. No significant difference (p=1.00) was found between both walkers on the level of dyspnea.

Level of general fatigue:

The level of general fatigue was assessed one minute after completing the outdoor course by a RPE-scale between six (absolutely no fatigue) and twenty (maximal fatigue) and is displayed in appendix 32 in blue. Four of the five participants gave a higher score of general fatigue after using the powered walker and one participant gave the same score for the regular and powered walker. The median RPE for general fatigue was 10 for the regular walker and 12 for

the powered walker indicating a 20% difference. Yet no significant difference (p=0.12) was found.

Level of leg fatigue:

The level of leg fatigue was assessed one minute after completing the outdoor course by a RPE-scale between six (absolutely no fatigue) and twenty (maximal fatigue) and is displayed in appendix 32 in red. Important to note is that to assess the level of leg fatigue, researchers asked specifically to name the leg fatigue. Two participants gave the same leg fatigue score for both walkers, two participants gave a higher score when using the powered walker and one participant gave a lower score for the powered walker. A median RPE for leg fatigue of 13 was found for the regular walker and a median RPE for leg fatigue of 13 for the powered walker indicating 0% difference. No significant difference (p=0.75) was found.

Table 5. Outdoor course results including number of participants, P-values, median results for the regular and powered walker and % difference (All negative % outcomes should be interpreted as an average score in favour of the powered walker with exception for the scores of the Quebec user evaluation of satisfaction with assistive technology (Dutch version) and VAS-levels for usefulness).

COMPARISON:	NUMBER OF PARTICIPANTS:	P-VALUE:	MEDIAN REGULAR WALKER	IQR REGULAR WALKER	MEDIAN POWERED WALKER	IQR POWERED WALKER	MEDIAN % DIFFERENCE
OUTDOOR COURSE							
TOTAL TIME(S)	4	ns	300	62	311	71	3.6
SECTION TIME – GRAVEL ROAD A	4	ns	86	22.7	94	23	9.3
SECTION TIME – GRASS HILL	4	ns	74	24.5	69.5	25.7	-6.08
SECTION TIME – GRAVEL ROAD B	5	ns	91	50	85	26	-6.6
SECTION TIME – PAVED SLOPE	4	ns	25	11.2	26	9.5	4
SECTION TIME – CURB & GUTTER	4	ns	36.5	22.7	32	11.2	-12.3
SECTION TIME – LAST PART TO THE FINISH	4	ns	25	5.5	26.5	6.7	6
THE QUEBEC USER EVALUATION OF SATISFACTION WITH ASSISTIVE TECHNOLOGY (DUTCH VERSION) ADAPTED	5	ns	37	6	33	2	-10.8
SECTION VAS – GRAVEL ROAD A	4	ns	8.5	1.2	6.7	4.3	-21.2
SECTION VAS – GRASS HILL	4	ns	9.5	1.2	8	1.7	-15.8
SECTION VAS – GRAVEL ROAD B	5	ns	8	1	8	2	0
SECTION VAS – PAVED SLOPE	4	ns	9	2	8	1.7	-11.1
SECTION VAS – CURB & GUTTER	4	ns	8	0.5	8	3.2	0
SECTION VAS – LAST PART TO THE FINISH	4	ns	8	0.7	7.7	2.1	-3.7
BORG-SCALE: DYSPNEA(0-10)	5	ns	4	3	4	2	0
RPE – GENERAL FATIGUE(6-20)	5	ns	10	2	12	1	20
RPE – LEG FATIGUE(6-20)	5	ns	13	4	13	4	0

DISCUSSION

On the one hand motor fatigue during exercise is a major problem for pwMS and limits them during activities of daily life (C. Leone et al., 2016). On the other hand there are no real walking aids available for pwMS that are specifically designed for use in an outdoor environment. Consequently pwMS might benefit from a powered rollator during walking in an outdoor environment or during a 6MWT. As mentioned above there were, partly due to the small sample size, no clear results if a powered walker is better than a regular walker. When performing the 6MWT with the powered walker, four of the six participants covered a greater distance during the tests in comparison with the regular walker. Yet no significant difference was found between both walkers considering total distance. As for the distance per minute and the DWI(%) there is a positive effect of the powered walker in the sense of a smaller decrease towards the end of the test. Yet no significant difference was found between both walkers. Further, no significant differences were found in the outcomes from average heart rate, BORG dyspnea level and RPE overall fatigue. The closest results to significance was found in the difference between RPE leg. When comparing the results for the outdoor course three of the five participants completed the course faster with the powered walker without significant difference. There is an average lower score of the powered walker on ease of use, but not significant. This was also the case for the 'VAS-usefulness' results. Further there were no significant difference found in BORG dyspnea, RPE leg fatigue. The difference between both walkers concerning RPE overall fatigue came the closest to being significant but yet wasn't.

Study limitations

First, this study is part of a research and development (R&D) project whereof all persons within the consortium, the MS-X-Move, were unsponsored. This R&D project gave a tight time schedule and therefore, it was only possible to test 6 subjects. Another import aspect is the very large heterogeneity of clinical profiles of pwMS. This means that including test subjects with an EDSS-score between 5.5 and 6.5 may have a large variety in neurological or orthopaedic complications. Due to these reasons the results are less applicable to all pwMS with an EDSS-score between 5.5 and 6.5.

Secondly, only pwMS were tested with an EDSS-score between 5.5 and 6.5. Initially these subjects were chosen because an EDSS-score from 5.5 or above meant that they are dependent of some kind of walking aid. As the intervention existed out of walking with a powered walker (=walking aid) it wasn't possible to test pwMS with an EDSS above 6.5. Helping this group being depended of a wheelchair to walk again with a motorized walker might have been interesting. Furthermore research can focus on investigating the effects of a powered walker on pwMS with a lower EDSS score. Interesting would be to look at the effects of a powered walker during a 6MWT where a powered walker is compared with walking without walking aid.

Bias

In this study it was not possible to control previous physical and/or mental efforts of the test subject the preceding days, which could have biased the results. Secondly, due to the working-mechanism of the prototype, neither the researchers nor the participants were blinded for the different study conditions. It's possible that participants were more motivated when testing with the powered walker because they believed that the actuation would help them to cover a greater distance or set a faster time.

Powered walker

Controls, fine-motor skills and grip strength

The prototype itself also did influence the results because the way the user could control the powered walker was not yet on point. The mechanism to control the level of drive and support from the motorized wheels was not easy to handle for pwMS. The actuation required some fine motor skills in the user's hands. This made interaction between the user and the prototype very difficult and resulted in the fact that the prototype could not optimally adjust to the physical capabilities of the user. Multiple participants reported that they found it very difficult to apply 'three different forces' with their hands. For the actuating system, the user had to grip onto the handle with the thumb, push the handle forward and still hold on to the handle with their whole hand and fingers. A study from 2016 has shown that grip strength is altered in pwMS. Their results showed that pwMS have an exaggerated grip force, especially

when catching something or in rapid movements (Allgöwer, Kern, & Hermsdörfer, 2016). Obviously holding on to the handle of the powered walker does not classify as a rapid movement but it might be the case that, pwMS produce exaggerated grip force to hold on to the handle because their fine motor skill and control in their hands is affected. It might be plausible that they tried to compensate with exaggerated grip force for their affected fine motor skills and control from their hands. In contrary a study from 2016 showed that the handgrip force decreased during exercise but not different than healthy controls however pwMS reported more experienced fatigue in their non-dominant hand (Severijns, Lemmens, Thoelen, & Feys, 2016). It is plausible that this interfered with the results from the powered walker because a similar grip in both hands is needed when walking straight while a careful hand control is needed when cornering to control the actuation. This difference in perceived fatigue might interfere with the handling of the powered walker and the controls over the actuation system.

Weight

It is debatable if the weight of the prototype was an influencing factor. Because of the drive mechanism, batteries and motorized wheels the prototype weighed 5.60kg more than the control walker. This could have masked the potential beneficial effects of the motorization on the fatigue levels. No participants reported that the extra weight of the powered walker asked any extra effort when using it during the 6MWT and the outdoor course. It might be the case that due to the actuation, the extra weight was neutralized and the actuation had no further benefit.

Orthopedic problems

Another point of debate is that pwMS often have multiple orthopaedic problems (Mandell D, 2012) that influence their efficiency during locomotion. PwMS often experience symptoms of a drop foot were KAFO's are often the solution (Hwang, Yoo, An, & Heo, 2013). It's plausible that a drop foot or KAFO's/AFO's interacted with the results. As can be seen in table 1, five of the six participants wore an AFO. Other mobility aids such as a hip flexion assist, a cane, a crutch and a knee extension brace were used by the participants.

Double tasks in pwMS

Further it has been proven that pwMS during cognitive-motor double tasks often perform less than people without MS (Ghai, Ghai, & Effenberg, 2017). It has also been proven that a motor-

motor double task interferes with the balance and gait patterns of pwMS (Dujmovic et al., 2017; Mercan, Kara, Tiftikcioglu, Mercan, & Sertpoyraz, 2016). In this study the subjects had to handle the powered walker during walking. This was even more difficult when they were completing the outdoor course due to different kinds of surfaces and obstacles. Researchers in this study noted this kind of double task as not purely motor-motor because the way the powered walker had to be handled, there was some need of cognitive-motor interference and processing. In a study of 2015 it was shown that a cognitive-motor double task has the greatest impact in pwMS (Carmela Leone, Patti, & Feys, 2015). This raises the theory that this affected cognitive-motor interference might have interfered with the results. Further research might focus on an intervention were one group of pwMS practice for six weeks with a regular walker and another group of pwMS practice with a powered walker. Baseline measurements would be taken before the start of the six weeks of practicing including the same protocol as this study. After six weeks the same tests as this study are repeated were after researchers can look at the difference in motor learning between both walkers.

Powered walker and spasticity

As already mentioned above, one participant had severe spasticity in his lower limbs. Because of this spasticity he always had to place one foot and 'hip hike' the other to place it next to his other foot. During this 'hip hike' phase he needed strong support from his upper body through his arms on the walker. The way that the current handles are made, this participant wasn't able to benefit from the actuation at all. Due to his strong support on the handles from the walker, he pushed the handles backwards which disabled the actuation to the back wheels. When using the regular walker there was no problem at al. During further developments of the powered walker researchers should try to make the actuation system free from the handles and make it easier to control, especially the handlebars.

Powered walker, safety and action slowing in pwMS

In this study researchers didn't specifically tested for safety of the powered walker but there are some reflections to make. Firstly there were no falls from the participants nor when using the powered or regular walker. When looking at the 6MWT first, it was important when turning around the cones that the user released the actuation from the hand on the inside of the turn. This to release the actuation on the inside wheel which allowed the user to make an easier turn by keeping the actuation on the outside wheel. All participants did master this skill

fairly quickly without any falls or near falls. Further no problems were reported when performing the 6MWT.

When the participants performed the outdoor course no falls were reported, nor with the powered or regular walker. One particular part of the course did gave some participants some problems. Participants had difficulties when they were on top of the paved slope and had to switch to zero actuation of the back wheels in order to complete the downhill part of the paved slope. It was difficult to make this switch quickly and this led to the fact that some participants were still actuating the back wheels during the downhill of the paved slope. Due to this difficult switch in actuation two participants had a short moment of imbalance on this part but without any falls. A study from 2010 showed action slowing of pwMS is related to an attentional deficit which results in an inability to maintain high levels of rapid actions and to subtle motor slowing even in patients without motor deficits during clinical examination (Stoquart-ElSankari, Bottin, Roussel-Pieronne, & Godefroy, 2010). This can be a possible explanation for the difficulties that the participants had when they had to switch to zero actuation.

Six-minute walk test

Rest time and fatigue levels

Both for the 6MWT as for the outdoor course it is debatable if the participants were given enough rest time to recover from a maximal effort during the first test. Research on the acute recovery in pwMS is rare. A study found that the degree of intensity is more important instead of the amount of physical activity when considering recovery time. They saw that pwMS needed more time to recover after a high intensity exercise. The same prolongation of recovery time after a longer, moderate intensity exercise was not found (Collett, Meaney, Howells, & Dawes, 2017). Another study found that pwMS experienced a larger degree of leg fatigue after a high-intensity exercise. Also pwMS experienced this feeling of leg fatigue longer than healthy controls (Dawes et al., 2014).

As already mentioned above, this study could not control the variability in fatigue levels (Khan, Amatya, & Galea, 2014) day by day experienced by pwMS. Researchers found that the time of day did not influence the walking capacity in pwMS. They did found a significant difference

between exercise in the morning and noon/afternoon on fatigue that was reported by the Rochester Fatigue Diary. Yet this significant difference in reported fatigue did not interfere with the walking capacity on different times during the day (Feys et al., 2012). All subjects but one were hospitalized in the national MS center in Melsbroek, Belgium. They were rehabilitating for a few weeks. This meant that the patients had different therapies during the day (physical therapy, occupational therapy, hydrotherapy, fitness, …) and experienced more fatigue further in their day because they had therapies between the two tests. Although walkers were randomised per participant, it resulted in more participants started in the morning with the regular walker (N = 4), and thus performed the test with the powered walker in the afternoon. The patients were more exhausted, not due to the time of day but due to all therapies and this may have had an influence on the test results.

Total distance

Looking at the total walked distance during the 6MWT (Appendix 12) this study shows that there was no significant difference found mainly due to two participants who covered both 68 and 59 meters less with the powered walker. Important to note is that one person had severe spasticity which disabled him to cover an equal distance as the other five participants. from the six participants, four did cover a greater distance with the prototype. Three of these who covered a greater distance did executed their best test using the powered walker in the afternoon after all the therapies. One other participant performed better with the powered walker but did her first test with the powered walker in the morning and tested with the regular walker in the afternoon. These two findings obviously are contradictory. There were three participants who performed better in the afternoon when using the powered walker, after undergoing all therapies. These participants might already be more fatigued than in the morning thus lower the score on their 6MWT. Yet they performed a better test with the powered walker. This shows a strong positive effect of the powered walker. On the other hand, when considering the one participant who performed her best test with the powered version in the morning, it might be that this participant performed better with the powered walker because she was already fatigued due to all therapies during the day were after she performed her test with the regular walker.

The two participants who showed a decrease in total distance when using the powered walker both did their first test in the morning with the regular walker and performed their second

6MWT in the afternoon using the powered walker. As mentioned above, fatigue might have had an impact on their second test result being less than with the regular walker.

Outdoor course

Temperature and pwMS

The last test day (May 26, 2017), was a warm day in Belgium, 30°C. Some pwMS may experience difficulties during such warm temperatures (Mollaoğlu & Üstün, 2009) this effect is mainly seen on the visual performance skills, this is known as the Uthoff's sign. On this test day the outdoor course was tested. In the morning, when the temperature was acceptable, three persons tested the regular walker and two the new prototype. In the afternoon, when the temperature had risen to about 30°C the participants performed their second test with the other walker. Although it was not documented, no participant did report any important negative effect on his/her ability to perform the test due to the hot weather so there is no suspicion of interference with the results.

pwMS and outdoor situations

As mentioned above, the outdoor course consisted out of six different sections. This study tried to mimic an outdoor setting as best as possible with the different possibilities on site of the National MS center Melsbroek. The course had different surfaces such as gravel, cobblestones, pavement, grass and concrete. The course also included two different small hills; a grass hill and a paved slope. These two types of "obstacles" can be found in an outdoor setting. Further it might be possible that people come across longer, steeper hills or slopes when walking outside, in a forest or even in an urban environment. When looking at the capital of Belgium as an example, Brussels has many challenges for a pwMS who is using a walker. Besides all curbs, cobbles, uneven pavements and street gutters, this city also has some longer hills which form a big challenge for pwMS or other people who use a walking aid. When walking in a big city like Brussels, you still have to keep focus and concentration on everyone around you, cars, busses, bicycles and other people. Researchers in this study classify walking in these environments (outdoor and urban) as different double-tasks. Because the user of the powered walker has to handle the walker but also has to look out for roots, stones, holes when he is walking in an outdoor setting, as for an urban setting already mentioned. A study from

2015 around dual-task cost described that pwMS experience problems when executing a cognitive-motor task which leads to slowing down of the walking speed. Further the researchers also showed that the impact on dual-task cost is the largest when pwMS combine a cognitive task with a motor-motor double task (Carmela Leone et al., 2015). When extrapolating these results to walking in an outdoor setting, people have to walk and control a powered walker, which classifies as a motor-motor double task. Further the user also has to think about how much actuation he sends to the back wheels by controlling the amount of push on the handles from the walkers. This together with the motor-motor double task already classifies as a cognitive task combined with a motor-motor double task. On top of these tasks, the user has to stay focused on the environment and react to quick changes in his environment as already mentioned. All this together makes it difficult to estimate and speculate about the effect of the powered walker in such busy environments because this study only tested the prototype in a very controlled and quiet setting, thus the result can't be extrapolated to real daily life setting.

CONCLUSION

The present pilot study with a crossover randomized controlled design demonstrates that a powered walker can be helpful for pwMS in an outdoor environment although there were no significant improvements found. This study demonstrated that some pwMS might benefit from a powered walker during a 6MWT and that the use of a powered walker is less feasible for individuals with severe spasticity. Further it demonstrated that pwMS still had some difficulties when using the powered walker (fine motor skills, dual tasks, amount of support, …), especially when controlling the amount of actuation by the handles. This is something that needs to be addressed in further developments and research. Further research in this domain would be recommended with a larger sample size with pwMS and eventually with elderly people who suffer less with dual task cost and have better fine motor skills. To conclude in this study no statistically significant differences between a regular and powered walker were found but important trends were seen that implicate further research on the domain of a powered walker in pwMS.

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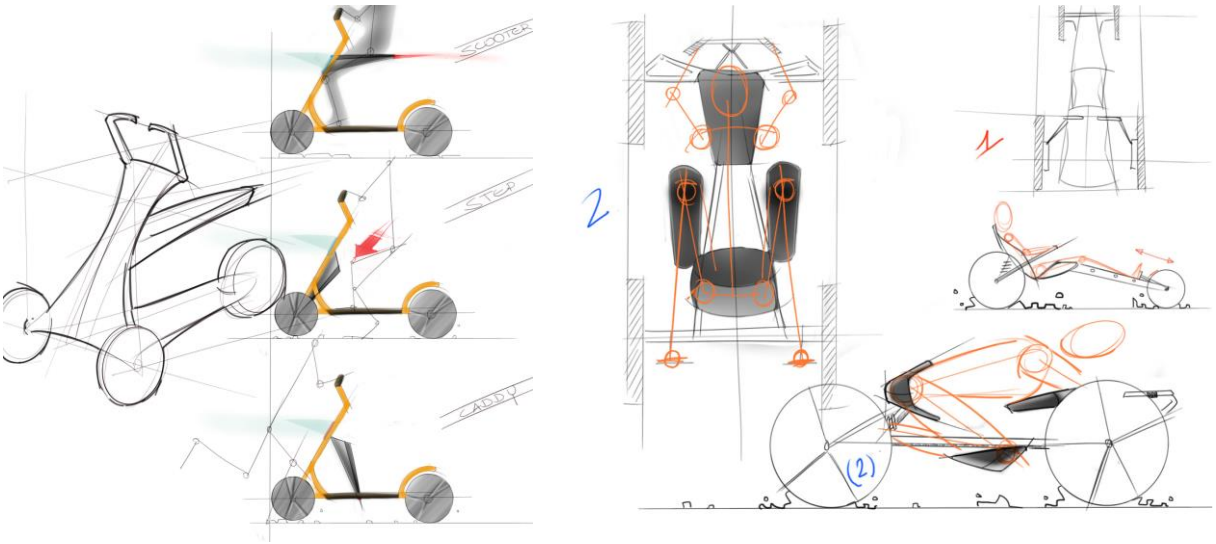
APPENDIX

Appendix 1: First designs from Nicolas Van Der Wee



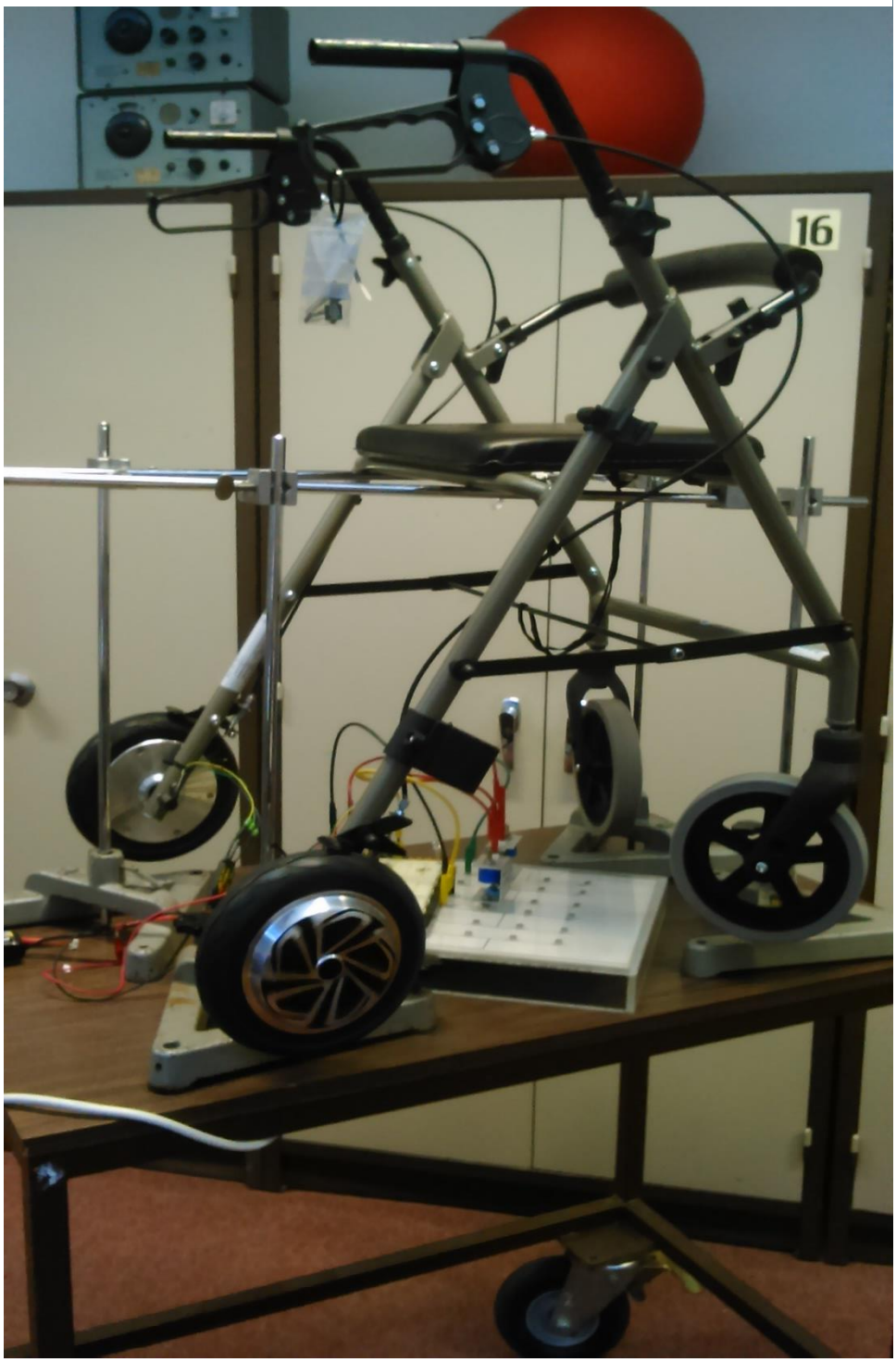
Nicolas Van Der Wee© 2015

Appendix 2: Rudimental prototype from Nicolas Van Der Wee

Nicolas Van Der Wee© 2016

Appendix 3: Final designs from the prototype of Nicolas Van Der Wee

Appendix 4: Prototype powered walker



Appendix 5: Technical details regular walker

Make	Vermeiren
Address	Vermeirenplein 1/15, B-2920 Kalmthout
Type	Rollator
Model	Eco-light
Width	600 mm
Length (unfolded)	760 mm (with basket) 670 mm (without basket)
Length (folded)	410 mm (handgrips mounted) 270 mm (handgrips dismounted)
Maximum height	950 mm
Minimum height	820 mm
Seat height	550 mm
Seat with	410 mm
Seat depth	340 mm
Weight (with basket) Weight (without basket)	7.60 kg 7.00 kg
Wheels	8 x1 ¼ (⌀ 200 mm)
Brakes	Multifunctional brake
Max. inclination forwards	15°
Max. inclination backwards	7°
Max. inclination sideways	5°
Maximum user weight	Max. 120 kg
Maximum basket weight	Max. 5 kg
Turning with	1400 mm
Storage temperature	+5°C - +41°C

https://www.vermeiren.be/web/web.nsf/detailproduct.xsp?CountryVBNLProductGroupLoophulpenSubGroupLichtgewichtSelectedECO-Light

The prototype was perfectly identical to this walker except for the following points. Weight: due to the installation of the actuation system (wheels, battery and electronics) the total weight was 13.2 kg. This is a 5.60 kg difference. Also the standard handlebars were replaced for special produced handlebars to deliver and control the actuation. The standard back wheels were replaced for hover board wheels (6.5 inch). These wheels had the biggest contribution to the increase in weight.

Appendix 6: Hoverboard wheels prototype

Michel De Roeve© 2017

Appendix 7: Handlebars prototype

Michel De Roeve© 2017

Appendix 8: Submission document

Aanvraagformulier
advies voor een experiment op de menselijke persoon
Geldig bij indiening van studies bij de comité's medische ethiek van alle sites waarvan u hierboven het logo alsook de contactgegevens vindt.

Advies voor een experiment op de menselijke persoon

1. Richtlijnen.

De comités voor Medische Ethiek (CME) hebben 25 dagen om dossiers te evalueren en hun advies over te maken. De doelstelling van dit formulier is om op eenvoudige wijze zo veel mogelijk relevante informatie met betrekking tot uw onderzoeksproject weer te geven. Hiermede kan de behandeling van uw dossier door de comités voor Medische Ethiek (CME) zo vlot mogelijk verlopen. Dit is een elektronisch formulier en de ruimte kan naar behoefte aangevuld worden. Algemene opmerkingen voor het CME zijn welkom onder de rubriek 'opmerkingen' (laatste rubriek).

Dit aanvraagformulier, evenals alle overige documenten, dienen ELEKTRONISCH doorgestuurd te worden. De indieningsbrief dient ONDERTEKEND te zijn door de hoofdonderzoeker binnen de betrokken instelling. Dit ondertekende bevestigingsformulier mag zowel per post als elektronisch ingediend te worden.

Specifieke indieningsvereisten.

Het Comité voor Medische Ethiek UHasselt vraagt van een aantal documenten zoals de indieningsbrief, het aanvraagdocument, het protocol, het informatie- en toestemmingsformulier en eventuele vragenlijsten **14 gedrukte exemplaren**.

De Ethische Toetsingscommissie van het Jessa Ziekenhuis vraagt 1 exemplaar van alle documenten en 1 CDRom per post naar Jessa Ziekenhuis, Ethische Toetsingscommissie, t.a.v. Katrien Jaemers, Stadsomvaart 11 te 3500 Hasselt

Voor de elektronische indiening dienen de bestanden in Word-of PDF-formaat opgemaakt te worden. De documenten worden vertrouwelijk behandeld.

Indien de vereiste documenten administratief niet in orde zijn, wordt de studie niet ontvankelijk geacht.

Hieronder vindt u een checklist van de vereiste documenten.

Bij een initiële indiening dienen de dossiers gelijktijdig bij het centrale ethische comité en de lokale ethische comités van de deelnemende sites ingediend te worden.

Aanvraagformulieren dienen samen met het volledige dossier aan het comité voor medische ethiek voorgelegd te worden.

Enkel de punten die van toepassing zijn, dienen ingevuld te worden.

Aanvraagformulieren dienen vergezeld te zijn van de volgende documenten (indien van toepassing):

☒ indieningsbrief (ondertekend)

☒ aanvraagformulier (met vermelding van de opdrachtgever)

☒ patiënteninformatie en toestemmingsformulier (Nederlandstalig)

☒ patiëntendocumenten / vragenlijsten (Nederlandstalig)

☒ verzekeringsattest

☐ Investigator's Brochure

☒ protocol

☐ protocol synopsis

☒ CV van de coördinerende hoofdonderzoeker in België

☒ CV van de hoofdonderzoeker van de lokale site

☐ CV van de lokale onderzoeker van de site

☐ contracten met de onderzoeker (clinical trial agreement)

☐ European clinical trial application form

☐ ontvangstbevestiging Eudract-nummer (interventionele studie met geneesmiddel)

☒ lijst met contactgegevens deelnemende Belgische sites en ethische comités

☐ facturatiegegevens voor het opstellen van een factuur of self-bill

☐ afspraken met diensten (labo, radiologie, nucleaire,…)

Opmerkingen:

1) *Indien het om een niet-contractueel onderzoek in een andere site dan de UHasselt gaat waarbij één van de uitvoerders verbonden is aan de UHasselt, dient het dossier eveneens ingediend te worden bij het comité medische ethiek van de UHasselt.*
2) *Wanneer een studie niet gelijktijdig bij de comités medische ethiek van de deelnemende sites wordt ingediend, behoudt het comité medische ethiek dat het enkel advies verleent zich het recht voor, om de termijn waarop het advies verleend moet worden, te verlengen.*
3) *Voor een studie, waarbij de goedkeuring van de Wetenschappelijke Raad van de Universitaire Biobank Limburg (UBiLim) vereist is, kan pas een advies verleend worden wanneer deze goedkeuring aan het dossier is toegevoegd.*

2. Titel en gegevens mbt de studie.

Titel studie: *The effect of a powered walker on motor performance and fatigue in persons with multiple sclerosis*
Acroniem: /
EudraCT number: /
Protocol nummer: /

Commercieel onderzoek ☐ Niet- commercieel onderzoek ☐ Eindwerk/Doctoraat X

3. Gegevens aangaande de onderzoeker(s) en sites.

Coördinaten opdrachtgever *
Naam: REVAL, Universiteit Hasselt
Adres: Agoralaan, gebouw D, Diepenbeek
Contactpersoon: Prof. Dr. Peter Feys (peter.feys@uhasselt.be) tel: 32-11-292123
(*) Volgens de huidige jurisprudentie, zelfs met schriftelijke toestemming van de deelnemer, is de opdrachtgever/ onderzoeker niet ontheven van zowel strafrechterlijke als burgerlijke aansprakelijkheid.

Coördinaten CRO (bedrijf dat de studie in opdracht van de sponsor uitvoert)
Naam: /
Adres: /
Contactpersoon (e-mailadres): /
aantal onderzoeker(s): /

Coördinaten van de hoofdonderzoeker:
Naam, voornaam: Feys, Peter
Titel: Prof. Dr.
Instelling: Universiteit Hasselt, België
Tel: 0032 11 29 21 23
E-mailadres: peter.feys@uhasselt.be

Coördinaten van lokale onderzoekers per site:
Prof. S. Ilsbroukx
MS centrum Melsbroek
Adres: Vanheylenstraat 16, 1820 Steenokkerzeel
Telefoon: 02 597 80 00

3. Naam van het Leidinggevend ethisch comité dat het uniek advies uitbrengt.

Naam: Commissie Medische Ethiek UZ KU Leuven / Onderzoek
Adres: Herestrat 49, 3000 Leuven
Tel: 016/34.86.00
E-mailadres: ec@uzleuven.be

4. Kenmerken van het farmacon (indien van toepassing)

Niet van toepassing.

5. Protocol (zie eveneens bijlage "Protocol")

Introductie & doel van de studie

Deze masterproef is deel van een overkoepelend inter-disciplinair project dat 'MS-X-Move' noemt. MS-X Move bestaat uit Prof Dr. Peter Feys (Revalidatiewetenschappen en kinesitherapie, UHasselt), Prof Dr. Jean Manca (Phys-X-Lab UHasselt), Dr. Kristof Vaes (Productontwikkeling Universiteit Antwerpen), Prof Dr. Michel De Roeve (Phys-X-Lab UHasselt), Geert Palmers (CEO of 3E), masterstudent productontwikkeling Laurette Van Aert, David Seffer en twee masterstudenten revalidatie wetenschappen; Sander Liekens en Gertjan Bervoets. Dit project is opgezet rond één MS patiënt, David Seffer. Het doel van deze werkgroep is om een nieuw loophulpmiddel te ontwikkelen voor MS patiënten of andere neurologische aandoeningen, dat specifiek ontworpen is voor het wandelen in een 'outdoor'-setting. De huidige hulpmiddelen voldoen niet aan de klinische vereisten van de persoon met MS.

Het doel van de studie is om te onderzoeken of een nieuw ontwikkeld prototype van rollator met zelf-bestuurde aandrijving meer efficiënt is om gedurende langere tijd buitenshuis te kunnen wandelen, en of de patiënt minder vermoeidheid ervaart tijdens het stappen in vergelijking met een reguliere rollator. Meer specifiek gaat het hier over motorische vermoeidheid. Motorische vermoeidheid is het onvermogen om de spieren maximaal neuraal te blijven aansturen tijdens beweging (Zijdewind, Prak, & Wolkorte, 2016). Bij een aanzienlijk deel van de patiënten met MS zien we bijvoorbeeld dat de wandelsnelheid gedurende de 6MWT lineair daalt en er geen stijging komt naar het einde toe zoals dit bij mensen zonder motorische vermoeidheid wel het geval is (C. Leone et al., 2016).

Onderzoeksvraag

Het algemene doel van de studie is om de bruikbaarheid te evalueren bij het wandelen met het nieuwe prototype en of personen met tekenen van motorische vermoeibaarheid bij MS beter presteren wanneer men dit device buiten gebruikt, in vergelijking met een reguliere rollator. Om hierop een antwoord te vinden werden de volgende sub vragen opgesteld;
1: Hoe beïnvloedt het gebruikt van het nieuwe prototype de tijd die nodig is om succesvol een obstakel parcours af te leggen in vergelijking met een normale rollator?
2: Hoe beïnvloedt het gebruik van het nieuwe prototype de ervaren vermoeidheid door de testpersoon, in vergelijking met een normale walker?
3: Hoe beïnvloedt het gebruik van het nieuwe prototype rollator de motorische vermoeidheid ervaren door de testpersoon tijdens een 6MWT, in vergelijking met een reguliere rollator?

Hypotheses

Gebaseerd op bovenstaande onderzoeksvragen, werden drie hypotheses opgesteld, de eerste hypotheses is de primaire, de anderen zijn steeds secundaire hypotheses;

- Het gebruik van het nieuwe prototype heeft een positief effect op de tijd die nodig is om het obstakelparcours af te leggen, in vergelijking met het gebruik van een reguliere rollator.
- Wanneer men het nieuwe prototype gebruikt zal de ervaren vermoeidheid lager zijn dan bij een normale rollator.
- De gemeten motorische vermoeidheid bij het gebruik van het prototype zal minder zijn dan bij een normale rollator.

Methodes

Studie design

Een piloot studie met een cross-sectioneel design zal opgezet worden. Eén deel van de testen zal buiten doorgaan op het wandel en hindernisparcours in het Nationaal MS Centrum te Melsbroek. Ernaast zullen er testen afgenomen worden in een meer klinische setting zoals in een revalidatiecentrum of universiteitslabo waar men de patiënten zal bevragen, en tests zal laten uitvoeren zoals de 6MWT.

Deelnemers

Vijftien testpersonen, gediagnosticeerd met MS, met een EDSS-score tussen 5.5 en 6,5 (afhankelijk van een hulpmiddel om langere afstanden buitenshuis te stappen) zullen participeren in de studie.

Inclusie criteria

Inclusiecriteria zijn: gediagnosticeerd met MS volgens criteria van Poser of McDonald, EDSS-score tussen 5,5 en 6,5. Een score van 6 betekent dat ze altijd afhankelijk zijn van een loophulpmiddel (niet verder bepaald), 7 betekent dat ze in een rolstoel zitten wat impliceert dat ze niet aan de testen zouden kunnen meedoen. Verder zullen de testpersonen in staat moeten zijn om met een rollator met dubbele handensteun te wandelen.

Exclusie criteria

Exclusiecriteria zijn:

- Aanwezigheid van belangrijke orthopedische problemen interfererend met het stappen.
- Gediagnosticeerd met één of meerdere cardiovasculaire ziektes
- Een exacerbatie minder dan 3 maanden voor de studie.
- Participeren in een andere studie.
- Geen kennis van de Nederlandse taal.
- Jonger dan 18 jaar.
- Zwangerschap.

Rekrutering

Testpersonen zullen gerekruteerd worden vanuit het MS centrum te Melsbroek onder supervisie van dr. S. Ilsbroukx (revalidatie-arts).

Allocatie

De proefpersonen zullen gerandomiseerd worden over de volgorde van testing. De helft van de proefpersonen zal eerst de aangedreven rollator testen, de andere helft eerst de standaard rollator. Dit wordt gedaan voor zowel de 6MWT als het obstakelparcours en steeds via het 'sealed envelope' principe.

Experimentele condities & tests

Enerzijds zal er getest worden met een nieuw prototype rollator. Dit prototype zal aangedreven achterwielen bevatten die aangestuurd worden via de handvaten. Ter vergelijking zal er getest worden met een reguliere rollator die identiek is aan het prototype met dit verschil dat er geen aandrijvingsmechanisme op aanwezig is en daarmee tevens lichter in gewicht is.

Studie verloop

Er zullen twee experimentele condities zijn. De eerste is mobiliteit met de normale, reguliere rollator. De tweede conditie zal mobiliteit met het nieuwe, aangedreven prototype rollator zijn. De rollator is ontwikkeld door het MS-X-Move © team. Het oorspronkelijke idee van Nicolas Van Der Wee, master student product design aan de Universiteit Antwerpen, werd vereenvoudigd tot een standaard rollator met aandrijving, gestuurd via de handvaten.
De aandrijving van het prototype zal gebeuren via de handvaten. De normale, reguliere rollator die zal gebruikt worden bevat geen aandrijving en is perfect identiek aan het nieuwe prototype, op uitzondering van het gewicht en de aandrijving. We melden dat er voor de rollator met aandrijving géén CE certificaat voorhanden is.

Idealiter wordt de volgende testprocedure gevolgd; Op dag één worden alle descriptieve tests afgenomen in de voormiddag (exclusief de testen die overgenomen worden vanuit NMSC Melsbroek). Na een middag pauze van 90 minuten zal er een moment voorzien worden ter familiarisatie met het prototype waarna de 6MWT zal afgenomen worden met beide rollators. Tussen de 6MWT zal steeds minimum 90 minuten tijd zitten. Op de tweede testdag wordt er in de voormiddag tevens een familiarisatie moment ingepland betreffende het obstakelparcours waarna de eerste test kan afgenomen worden op het obstakelparcours (rollator 1). Na een middagpauze van 90 minuten zal de tweede testen afgenomen worden op het obstakelparcours (rollator 2).

Prototype aangedreven rollator:

Descriptieve Uitkomstmaten

Na gerekruteerd te zijn zullen de testpersonen een deel descriptieve tests ondergaan en vragenlijsten invullen om een baseline niveau vast te stellen. Een deel van deze testen zullen overgenomen worden vanuit NMSC Melsbroek. Deze testen zullen éénmalig afgenomen worden om een beeld te krijgen van het basisniveau van de patiënt.

- ziekteduur, en type MS
- Modified fatigue impact scale (MFIS): een op de 'Fatigue Impact Scale' gebaseerde test, aangepast via items verkregen uit interviews met MS patiënten om te meten hoe vermoeidheid hun dagelijkse leven beïnvloed. De schaal meet naar effecten op fysiek, cognitief en psychosociaal vlak. Via deze schaal trachten we een algemeen beeld te verkrijgen in hoeverre vermoeidheid het algemeen functioneren beïnvloedt van de testpersoon.
- 4 stage balance test (4SBT): een test om statische balans na te gaan. Vier progressieve moeilijkheidsgraden worden aangeboden. Men begint met de twee voeten langs elkaar, daarna met één voet half langs de andere. Hierna wordt er over gegaan naar het plaatsen van één voet achter de andere en als laatste wordt er gevraagd om op één voet te staan. Elke opdracht moet minstens voor tien seconden volgehouden worden alvorens over te gaan naar de volgende. Het doel van deze test voor ons is om een snel zicht te krijgen op het evenwichtsniveau van de participant.
- Twelve item MS walking scale (MSWS-12): deze schaal vraagt naar de invloed van MS, in de voorbije twee weken, op wandelen. Er worden 12 vragen gesteld aan de participant naar de invloed van zijn MS op balans, uithouding, snelheid, loophulpmiddelen,.. tijdens het wandelen. Via deze schaal trachten we een duidelijker beeld te verkrijgen omtrent de invloed van MS specifiek op het wandelen van de testpersoon.
- Multiple Sclerosis Functional Composite (MSFC): een uit drie delen bestaande test die de status van een MS patiënt beschrijft. De drie deeltesten testen elk een afzonderlijke vaardigheid (been functie/ambulantie, arm/hand functie en cognitie)
    - 9-Hole Peg Test (arm-hand functie)
    - Timed 25-feet walk (been functie/ambulantie)
    - Pasat test (cognitief)

  Via deze testen trachten we informatie te verkrijgen omtrent de invloed van MS op verschillende aspecten zijnde; onderste lidmaat, bovenste lidmaat en cognitie.
- Expanded Disability Status Scale (EDSS): EDSS staat voor 'Expanded Disability Status Scale'. Dit is een tabel om de voortgang van de ziekte te meten en kan enigszins de prognose van het ziektebeloop vormgeven. De EDSS-score loopt van 0 tot 10 met tussenstappen van 0.5, waarbij 0 staat voor totale afwezigheid van enige neurologische klachten of afwijkingen. Bij toenemende invaliditeit kan de score oplopen tot 10. Tot en met EDSS-score 3.5 ondervindt de patiënt in zijn/haar dagelijkse functioneren nauwelijks of geen last. De EDSS score wordt verkregen van de behandelende arts.
- Aan het begin van elke testdag zal gevraagd worden naar het activiteitenniveau en het vermoeidheidsniveau van de afgelopen week. Dit zal gebeuren via een VAS-schaal die op volgende wijze opgesteld zijn:

<u>VAS Activiteiten</u>

0	5	10
Geen activiteiten	=>	Maximale activiteiten

<u>VAS Vermoeidheid</u>

0	5	10
Geen vermoeidheid	=>	Maximaal vermoeid

Experimentele Uitkomstmaten

Obstakelparcours

De testpersonen zullen een obstakelparcours moeten afleggen. Het parcours zal bestaan uit grindweg gecombineerd met klinkers. Het zal een lengte hebben van +- 150m. Verder zal er een helling aanwezig zijn en zal deze ook een stoeprand en een grasveld omvatten. (zie foto's hieronder ter verduidelijking)

Grasheuvel:

Grindweg:

Helling:

Stoeprand:

Primaire uitkomstmaat:

Totale tijd: de totale tijd die nodig is om het obstakelparcours af te leggen (gemeten via stopwatch in seconden).

Secundaire Uitkomstmaten:

Deel tijd: de tijd die nodig is per sectie van het parcours (gemeten via stopwatch in seconden). Op grindweg, grasheuvel, stoeprand

'Ease of use' van de rollator: ervaring van de testpersoon met de rollator tijdens het af leggen van het obstakelparcours, gemeten via de Quebec user evaluation of satisfaction with assistive technology (Demers et al., 1996) die van het parcours (zie boven) zal afgenomen worden. De QUEST is (Engelstalig) is betrouwbaar, valide en toepasbaar op patiënten met multiple sclerosis (Demers, Monette, Lapierre, Arnold, & Wolfson, 2002). De Nederlandstalige versie van de QUEST, de Quebec user evaluation of satisfaction with assistive technology is ook een valide en betrouwbaar meetinstrument (Wessels & De Witte, 2003).
Bovendien zal er een algemene VAS-score gevraagd worden naar het gebruiksgemak van de rollator.

VAS Nuttig

0	5	10
Géén hulp	=>	Volledige hulp

6MWT

Naast het obstakel parcours moeten de testpersonen ook een 6MWT afleggen. Deze zal afgenomen worden in een klinische setting van een ziekenhuis. De 6MWT zal opgezet worden in een vaste omgeving met een gemarkeerde lengte van 40m. De personen zullen dan binnen 6 minuten zoveel mogelijk lengtes moeten afleggen door 180° te draaien op het einde van elke lengte. Één onderzoeker blijft steeds binnen korte afstand van de testpersoon, dit voor de veiligheid van de proefpersoon, terwijl een tweede onderzoeker de afgelegde lengtes bijhoudt.

Primaire uitkomstmaat:

Totale afstand: totale afstand die afgelegd wordt gedurende 6 minuten (gemeten in meters).

Secundaire uitkomstmaten:

Minuut per minuut afstand: gemeten via de walking index (C. Leone et al., 2016).

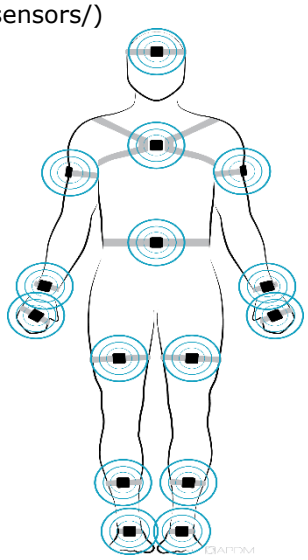
Rate of percieved exertion: de mate van ervaren vermoeidheid door de testpersonen (gemeten via de 'Rate Of Perceived Exertion scale' (BORG), afgenomen elke minuut). De BORG-schaal is een betrouwbare en gevalideerde manier om de RPE te meten bij patiënten met MS (B. T. Cleland, B. A. Ingraham, M. C. Pitluck, D. Woo, & A. V. Ng, 2016). De testpersonen zullen 4 maal bevraagd worden, een eerste keer staande aan de startlijn, een tweede keer vlak na 3 minuten in de 6MWT of in het midden van het obstakelparcours, een derde keer na het volbrengen van de test (6MWT/obstakelparcours) en een laatste keer 5 minuten na het einde van de test. De score-range die gebruikt zal worden is de BORG RPE (Borg, 1998; Noble & Robertson, 1996);

6	Niet vermoeid
7	Extreem licht
8	
9	Zeer licht
10	
11	Licht
12	
13	Gemiddeld
14	
15	Zwaar
16	
17	Zeer zwaar
18	
19	Extreem zwaar
20	Maximaal vermoeid

Heart rate: hartslag gedurende de test (gemeten via polar hartslagmeter, afgenomen elke minuut).

Wandelsnelheid & spatiotemporele parameters: verschil in wandelsnelheid en stappatroon gedurende de 6MWT die zal gebruikt worden om in te schatten of er een effect op de motorische vermoeidheid is. De lineaire daling van de wandelsnelheid zal onderzocht worden omdat deze sterk correleert met de somatische vermoeidheid ($p<0,0001$) (Burschka et al., 2012) Dit alles zal gemeten worden via APDM©-sensoren (http://www.apdm.com).

APDM©-sensoren (http://www.apdm.com/wearable-sensors/)



Overige

De proefpersonen zullen zowel tijdens de 6MWT als tijdens het obstakelparcours gefilmd worden. Deze beelden kunnen achteraf eventueel gebruikt worden ter promotie of ter afstelling van de rollator.

Data-analysis

Vermits het over een kleine sample size gaat, zal er steeds niet-parametrisch getest worden. Er zal steeds een vergelijking gemaakt worden tussen de standaard rollator en de aangedreven rollator. De data zijn steeds afhankelijk van elkaar.

⇨ Wilcoxon signed-rank test

Volgende uitkomstmaten worden vergeleken tussen beide rollators:

- 6MWT
  - Snelheid en afstand per minuut
  - Totale afstand
  - Hartslag
  - Ervaarde vermoeidheid
- Obstakelparcours
  - Totale tijd
  - Tijd per onderdeel
  - Gebruiksgemak
  - Ervaarde vermoeidheid

Time planning

Het prototype zal klaar zijn februari 17'. Tijdens dit proces zal ook al het rekruteren van patiënten al gestart zijn. De tests worden uitgevoerd vanaf goedkeuring van het ethisch comité, optimaal vanaf maart 2017 tot uiterlijk december 2017. Hierna zal data analyse en beschrijving verder verwerkt worden.

Tijd-planning	Jan	Feb	Maa	Apr	Mei	Jun	Jul	Aug	Sep	Okt	Nov	Dec
Afwerking prototype												
Rekrutering patiënten												
Data verzameling												
Data analyse												
Data reportering												
Afwerking												

Bias

Wanneer men zal horen van een aangedreven rollator bestaat de kans dat de testpersonen een overwaardering zullen voelen voor de nieuwe technologie die hen wordt aangeboden. Dit kan als gevolg hebben dat ze het prototype positiever zullen ervaren omdat het een nieuwigheid is. Tevens kan het zo zijn dat de testpersonen een grotere fysieke inzet zullen tonen wanneer ze het prototype gebruiken door de zelf verwachtte positieve invloed.

Verwachte voordelen voor deelnemer en /of wetenschap

Momenteel weten we nog niet of de geplande interventie met een aangedreven rollator daadwerkelijk gunstige effecten heeft op vermoeidheid bij mensen met multiple sclerosis. Indien, uit de resultaten blijkt dat dit een duidelijk positief effect heeft, kan dit een mogelijke nieuwe piste zijn voor het verder ontwikkelen van een aangedreven rollator. Verder kan dit een eerste stap zijn naar het op de markt brengen van een allereerste, aangedreven rollator.

6. Evaluatie van de voorspelbare risico's van de behandeling en/of de procedures van de studie (pijn, ongemak, invasieve handelingen en middelen om deze risico's te verminderen en de eventuele ongewenste effecten tijdens de procedures / buiten de procedures op zich te nemen, mogelijk contact met de onderzoeker, …)

We weten tot op de dag van vandaag nog niet in welke mate het veilig is op met dergelijk soort aangedreven rollator te wandelen. We kunnen op dit moment ook nog niet inschatten hoe de rollator zal reageren en interactie vertonen met de gebruiker. We sluiten op dit moment zeker niet uit dat bepaalde parcoursonderdelen voor specifieke personen onmogelijk zullen zijn of in zekere mate een vergroot risico zal zijn om met een aangedreven rollator te wandelen. Om dit risico te minimaliseren zal de testpersoon bij elke test vergezeld worden van een onderzoeker die bij de testpersoon blijft en zijn veiligheid garandeert in geval er onvoorziene omstandigheden zich voordoen. Daarnaast kan obstakelparcours ingekort worden indien een individu één bepaald onderdeel niet kan uitvoeren.

Verder verwachten we langs een vergroot valrisico geen neveneffecten. Hoewel er voldoende rustpauzes ingelast worden tijdens de testsessies, zou het wel kunnen dat de proefpersonen fysiek vermoeid geraken tijdens de testafnames.

6.1 Uw eigen evaluatie van de risk/benefit balans voorstellen

Zoals eerder aangegeven kunnen we nog niet inschatten of deze interventie daadwerkelijk een positief effect zal hebben. We kunnen onze inschattingen ook niet baseren op eerder onderzoek aangezien, deze specifieke interventie in acht genomen, er nog geen studies gedaan werden in dit domein.

Indien we naar de risk/benefit balans kijken stellen we als risico een vergroot valrisico vast bij de gebruiker. Wij stellen echter dat mits een, op voorhand duidelijke uitleg gepaard gaand met een vrij oefenmoment, de gebruiker al enige mate kan wennen aan de rollator en op deze manier zijn valrisico zal beperken. Verder stellen we ook dat er altijd dichte begeleiding zal nodig zijn tijdens het gebruik van het apparaat om extra te ondersteunen in moeilijke situaties en zo het valrisico te verkleinen.

6.2 Evaluatie van mogelijke schade aan onderzoekers, zijn medewerkers en patiënten

6.2.1 Risico's voor de onderzoekers en voor de medewerkers van de onderzoekers.

X geen ☐ ja hieronder beschreven

……

……

……

……

6.2.2 Risico's voor de patiënten.

☐ neen X ja hieronder beschreven

Vergroot valrisico en een vergroot risico op vermoeidheid.

……

……

……

……

6.2.3 Werden veiligheidsmaatregelen genomen, en zo ja welke?

Informatie moment met uitleg over de werking van de rollator. Volgend hier op een vrij oefenmoment ter gewenning aan het apparaat. Verder zal tijdens deze oefenmomenten én testmomenten altijd extra begeleiding aanwezig zijn bij de test persoon.

Opmerking: *wanneer er, na indienen van een studieprotocol, aanpassingen (amendementen, een nieuwe investigator's brochure, een nieuw informed consent…) gebeuren aan het protocol, gelieve dan een bondige beschrijving te maken van de veranderde tekst. Het is onmogelijk voor de leden van het CME om telkens het volledig aangepaste document door te nemen. Elke aanpassing kan dan grondiger gecontroleerd worden*.

7. Studiestructuur (kruis aan wat van toepassing is)

☐ Studie NIET vallend onder de wet van 07/05/2004 (bv. retrospectieve studie, medical need, compassionate use)

X Studie vallend onder de wet van 07/05/2004

X Niet-commerciële studie

X monocentrisch

☐ multicentrisch

☐ Commerciële studie

☐ monocentrisch

☐ multicentrisch

X Interventioneel ☐ Niet-interventioneel

☐ Fase I ☐ Fase II ☐ Fase III ☐ Fase IV

☐ Dubbelblind X Gerandomiseerd ☐ Placebogecontroleerd

X Nationaal Multinationaal Europees Mondiaal

7.1. Beschrijving van de wervingsprocedure (het hiervoor gebruikte materiaal / documenten toevoegen)

7.2. Beschrijving van de behandeling(en) toegepast op elke deelnemersgroep in de studie.

Aantal groepen : 1

15 proefpersonen zullen onderworpen worden aan 2 testcondities zijnde; testings met een reguliere, niet-aangedreven rollator en anderzijds met een prototype, aangedreven rollator.

Het totaal aantal proefpersonen zal 15 bedragen, allen multiple sclerosis patiënten.

Startdatum van de hier voorgedragen studie: november 2016
Einddatum van de hier voorgedragen studie: mei 2017

8. Beschrijving andere goedkeuringen

Niet van toepassing

9. Bondige beschrijving van de onderzoeksparameter(s).

9.1. Laboratoriumonderzoeken

X neen ☐ ja

Indien ja: de volgende bloedonderzoeken zijn studiespecifiek:

Indien ja: andere, niet studiespecifieke onderzoeken:

9.2. Speciale invasieve en niet-invasieve onderzoeken

X neen ☐ ja

Indien ja: de volgende onderzoeken zijn studiespecifiek:

Indien ja: andere, niet studiespecifieke onderzoeken:

9.3. Inspuitingen van radio-isotopen.

X neen ☐ ja hieronder beschreven

9.4. Klinische parameters

X neen ☐ ja hieronder beschreven

9.5. Bijkomende studiespecifieke parameters hierboven niet vermeld

9.6. Zijn er afspraken met andere diensten (medische beeldvorming, labo…)?

☐ ja, welke?

X neen

9.7. Zijn de diensthoofden van de afdelingen / diensten waar het onderzoek gebeurt op de hoogte?

☐ ja, kopie als bijlage toegevoegd

X neen

10. Beschrijf welke mechanismen de opdrachtgever in werking heeft om studie-specifieke onderzoeken op eigen financiële last te dragen en niet ten laste van het RIZIV

10.1. Laboratoriumonderzoeken

X niet van toepassing
☐ testen (cfr. 8.1) worden enkel in een referentielaboratorium uitgevoerd
☐ testen (cfr. 8.1) worden deels/volledig in het lokale laboratorium uitgevoerd en er werden afspraken gemaakt om de RIZIV-aanrekening te blokkeren.

10.2. Speciale invasieve en niet-invasieve onderzoeken

X niet van toepassing
☐ er werden afspraken gemaakt om de RIZIV-aanrekening te blokkeren.

11. Specifieke faciliteiten nodig voor het uitvoeren van deze klinische proef.

12. Toestemming van de patiënt tot de klinische proef

12.1. Is er een Nederlandstalige patiënteninformatie en toestemmingsformulier voorhanden?

X ja

☐ neen, gezien het een retrospectieve studie is.

12.2. Kunnen er omstandigheden zijn waarin de patiënt zelf niet in staat is om toestemming te verlenen?

X neen, die omstandigheden doen zich niet voor

☐ ja

☐ De patiënt is minderjarig

Voldoet het experiment aan de eisen gesteld door art 7 van de wet van 07/05/2004 experimenten op de menselijke persoon?

☐ neen ☐ ja

Welke maatregelen tot het verkrijgen van de toestemming worden genomen?
…….

Wat is de motivering om deze patiënten te includeren?
…….

☐ De patiënt is meerderjarig en wilsonbekwaam

Voldoet het experiment aan de eisen gesteld door art 8 van de wet van 07/05/2004 experimenten op de menselijke persoon?

☐ neen ☐ ja

Welke maatregelen tot het verkrijgen van de toestemming worden genomen?
…….

Wat is de motivering om deze patiënten te includeren?

…….

☐ De studieopzet vereist uitzondering op basis van hoogdringendheid

Voldoet het experiment aan de eisen gesteld door art 9 van de wet van 07/05/2004 experimenten op de menselijke persoon?

☐ neen ☐ ja

Welke maatregelen tot het verkrijgen van de toestemming worden genomen?
…….

Wat is de motivering om deze patiënten te includeren?

12.3. Bevat de Nederlandstalige patiënteninformatie en toestemmingsformulier informatie over de volgende aspecten (cfr. Wet van 07/05/2004 experimenten op de menselijke persoon):

	ja	neen
het doel van het experiment:	X	
de reden waarom de patiënt wordt gevraagd:	X	
het belang van het onderzoek:	X	
de activiteiten die van de proefpersoon worden verwacht:	X	
de voordelen voor de proefpersoon:	X	

de belasting voor de proefpersoon:	X	
de risico's voor de proefpersoon:	X	
de maatregelen om deze risico's te beperken:	X	
de (eventuele) vergoeding voor de proefpersoon:	X	
de verzekering voor de proefpersoon tegen eventuele schade:	X	
de vertrouwelijkheid van de gegevens:	X	
de deelname aan de studie is vrijwillig:	X	
het recht om deelname te weigeren (zonder gevolgen voor de behandeling):	X	
het recht om zich te allen tijde terug te trekken (zonder verdere gevolgen voor de behandeling):	X	
het op zich nemen van de zorgen na de stopzetting van deelname aan de studie door de deelnemer (wie neemt hiervoor verantwoordelijkheid op?)	X	
de identiteit en bereikbaarheid van de lokale onderzoeker:	X	
de mogelijkheid vragen te stellen aan de lokale onderzoeker:	X	
de mogelijkheid te overleggen met familie/bekenden:	X	
de redenen waarom deelnemers van kwetsbare groepen aangezocht worden (indien dit van toepassing is):	X	
aan de proefpersoon wordt een kopie van het informatie- en toestemmingsformulier meegegeven:	X	

De studie zal geen ethische goedkeuring genieten indien op 1 van bovenstaande vragen neen geantwoord wordt

13. Is er een verzekering afgesloten door de opdrachtgever?

☐ neen (enkel bij retrospectieve studies van toepassing):

☒ ja: kopie of aanvraag als bijlage toegevoegd

14. Financiering en vergoedingen

☒ niet van toepassing

☐ financiering van de studie (IWT, FWO, andere…):

☐ (ontwerp-) overeenkomsten in bijlage toegevoegd

☐ *(*ontwerp)-overeenkomsten NIET in bijlage toegevoegd: reden:…

14.1 Vergoeding(en) aan de proefpersoon:

- Geen vergoeding voorzien, enkel terugbetaling eventuele transportkosten

14.2. Vergoeding(en) aan de onderzoeker:

- Geen vergoeding voorzien

14.3 In geval van contractuele studie, staat er in het contract een bepaling die de publicatie van de resultaten kan tegenhouden of onderwerpen aan voorwaarden?

Niet van toepassing.

15. Aanmelden studie:

Het aanmelden van een studie is sterk aangeraden en noodzakelijk indien u de resultaten wenst te publiceren. Is de studie aangemeld:

☐ ja, via:

X UHasselt (**registration.clinicaltrials@uhasselt.be**)

☐ www.clinicaltrialsregister.eu (enkel voor studies met medicatie)

☐ www.clinicaltrials.gov

☐ http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/

☐ andere:

☒ neen

16. Woordverklaring

BELANGRIJK: De wet op experimenten op de menselijke persoon 7 mei 2004 identificeert de volgende taken:
- Opdrachtgever: legt het protocol voor aan CME ter advies en voorziet een verzekering. NB: ingeval van een niet-commerciële studie is de hoofdgeneesheer de opdrachtgever van de studie.
- Hoofdonderzoeker: inlichten van de deelnemers en verkrijgen van een schriftelijke toestemming alvorens het experiment uit te voeren.
- Comité Medische Ethiek: unieke adviezen worden overgemaakt aan de opdrachtgever, lokale adviezen aan het CME dat het enkel advies levert .

Enkel advies:
het begrip "enkel advies" komt overeen met het begrip"uniek advies". het centrum dat het enkel advies verleent, is het centraal ethisch comité

CRO
Clinical Research Organisation ofwel bedrijf dat de studie in opdracht van de sponsor uitvoert.

Anoniem
Dit zijn gegevens die niet in verband kunnen gebracht worden met een geïdentificeerde of identificeerbare persoon en dus geen persoonsgegevens zijn. Slechts bij uitzondering zijn anonieme gegevens toegelaten.

Gecodeerde gegevens
Dit zijn persoonsgegevens die slechts door middel van een code in verband kunnen gebracht worden met een geïdentificeerde of identificeerbare persoon.

Investigator's Brochure (IB)
De Investigator's Brochure bevat de fundamentele data, verkregen tijdens preklinische en klinische studies over een geneesmiddel in studieverband. De IB is van essentieel belang bij het ontwikkelingsproces van een geneesmiddel en wordt geüpdatet met nieuwe informatie van zodra deze beschikbaar is.

Klinische studie: verschillende fasen
Klinische studies zijn uitgevoerd in fasen.

fase 1 : screening voor veiligheid
Onderzoekers testen een experimenteel geneesmiddel of behandeling in een kleine groep gezonde mensen (20-80) om de veiligheid te evalueren, bepalen van een veilige dosering en bijwerkingen te identificeren.

fase 2 : vaststellen van het testprotocol
Experimentele studiemedicatie of -behandeling wordt gegeven aan een grotere groep mensen (100-300), ditmaal patiënten met de te behandelen aandoening, om efficiëntie en veiligheid uit te testen, eventueel nog de juiste dosis te vinden.

fase 3 : finale testen

Experimentele studiemedicatie of- behandeling gegeven aan grote groepen patiënten (1,000-3,000) om de doeltreffendheid en veiligheid te bevestigen, bijwerkingen te volgen, te vergelijken met gangbare behandelingen.

fase 4 : 'post-goedkeuring' studies

Deze studies gebeuren nadat een medicament of toestel op de markt is gebracht. Zij beogen aanvullende informatie te bekomen over het medicament of toestel.

Interventioneel

Dit omvat elk onderzoek bij de mens (in de wet een "proef" en "experiment" genoemd) waarbij afgeweken wordt van de normale standaarddiagnostiek of standaardtherapie.
Enkele voorbeelden:

- Een extra bloedafname
- Een extra RX
- Een geneesmiddel in een andere dosis of formulering toedienen, voor een andere indicatie, …
- Randomiseren van proefpersonen
- Vragenlijsten
- …

Niet-interventioneel

(*in de wet een "proef zonder interventie" genoemd*):
Onderzoek waarbij de geneesmiddelen worden voorgeschreven op de gebruikelijke wijze, overeenkomstig de in de vergunning voor het in de handel brengen vastgestelde voorwaarden. De indeling van de patiënt bij een bepaalde therapeutische strategie wordt niet van tevoren door een onderzoeksprotocol bepaald, maar maakt deel uit van de gangbare medische praktijk en het besluit om het geneesmiddel voor te schrijven staat geheel los van het besluit om een patiënt te laten deelnemen aan het onderzoek.
De patiënt in kwestie hoeft geen extra diagnostische of controleprocedure te doorlopen en voor de analyse van de verkregen resultaten worden epidemiologische methodes gebruikt.

NB: De wet is van toepassing zowel op interventioneel als op niet-interventioneel onderzoek, met uitzondering van retrospectief onderzoek (zie website ethisch comité "retrospectief onderzoek").

FDA

De ***Food and Drug Administration*** (**FDA**) is in de Verenigde Staten van Amerika een agentschap van de federale overheid dat de kwaliteit en veiligheid van voedsel, toevoegingen daaraan en medicijnen bewaakt, maar ook de behandeling van bloed, medische producten, toestellen met elektromagnetische straling en cosmetica controleert. De FDA dwingt de naleving van gedeeltes van de *Public Health Service Act* af.

EMA

Het **Europees Geneesmiddelenbureau** (**EMA**) is een gedecentraliseerd orgaan van de Europese Unie. Het heeft als belangrijkste taak de gezondheid van mens en dier te beschermen en te bevorderen. Dit doet het door geneesmiddelen voor menselijk en dierlijk gebruik te beoordelen en hierop toezicht te houden.

Nomenclatuur van de geneeskundige verstrekkingen

"De in deze nomenclatuur vermelde geneeskundige verstrekkingen, die worden verleend in het kader van de wet van 7 mei 2004 inzake experimenten op de menselijke persoon en waarvan de uitvoering specifiek in het kader hiervan wordt voorzien in het door voorvermelde wet voorziene protocol mogen niet worden aangerekend aan de verplichte verzekering, noch aan de rechthebbende. Het protocol en de lijst patiënten en controlepersonen opgenomen in de studie zijn ter inzage van geneesheren-inspecteurs van de Dienst voor geneeskundige evaluatie en controle van het Rijksinstituut voor ziekte- en invaliditeitsverzekering."

17. Literatuur

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Appendix 9: VAS fatigue of the day - Dutch version

Naam:

VAS-vermoeidheid aan start testdag 1:

Datum:

0	1	2	3	4	5	6	7	8	9	10
Geen vermoeidheid					=>			Maximaal vermoeid		

Score:

VAS-vermoeidheid aan start testdag 2:

Datum:

0	1	2	3	4	5	6	7	8	9	10
Geen vermoeidheid					=>			Maximaal vermoeid		

Score:

Appendix 10: the Quebec user evaluation of satisfaction with assistive technology adapted version

D-QUEST

iRv, versie februari 2000

Naam cliënt: .....

Hulpmiddel / voorziening: .....

Datum: .....

Tevredenheid over uw hulpmiddel en de bijbehorende dienstverlening

Het doel van deze vragenlijst is na te gaan hoe tevreden u bent over uw hulpmiddel en de bijbehorende dienstverlening.

- Wilt u bij elk van de vragen aangeven hoe tevreden u bent over uw hulpmiddel en de bijbehorende dienstverlening, met behulp van de volgende 5 antwoord-mogelijkheden:

  Totaal niet tevreden
  Niet tevreden
  Min of meer tevreden
  Tevreden
  Zeer tevreden

- Wilt u alstublieft voor elk van de volgende vragen het antwoord aankruisen dat het best bij uw mate van tevredenheid past?
- Wilt u alstublieft alle vragen beantwoorden?
- Indien u niet helemaal tevreden bent, wilt u dan alstublieft de reden daarvan toelichten in de daarvoor bestemde ruimte achter de vraag?

1	Hoe tevreden bent u over de **afmetingen** van uw hulpmiddel? (maat, hoogte, lengte, breedte)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
2	Hoe tevreden bent u over het **gewicht** van uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
3	Hoe tevreden bent u over de **verstel-mogelijkheden** van uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
4	Hoe tevreden bent u over de **veiligheid** van uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
5	Hoe tevreden bent u over de **duurzaamheid** van uw hulpmiddel? (bestendigheid, slijtvastheid)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
6	Hoe tevreden bent u over het **gemak** waarmee u uw hulpmiddel **kunt gebruiken**?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
7	Hoe tevreden bent u over het **comfort van uw hulpmiddel**?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
8	Hoe tevreden bent u over de **effectiviteit** van uw hulpmiddel? (De mate waarin het hulpmiddel doet waarvoor het bedoeld is)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:

Hoe tevreden bent u, **alles bij elkaar genomen**, over uw **hulpmiddel**?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	

9 Hoe tevreden bent u over het **verstrekkingsproces** waarmee u uw hulpmiddel heeft verkregen? (procedures, tijdsduur)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
10 Hoe tevreden bent u over de geboden **reparaties en onderhoud** voor uw hulpmiddel?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
11 Hoe tevreden bent u over de **professionaliteit van de dienstverlening**? (kwaliteit van de informatie en vakkundigheid van de dienstverleners)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:
12 Hoe tevreden bent u over de **service en dienstverlening na aflevering** van uw hulpmiddel? (na-zorg, blijvende ondersteuning, begeleiding)	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	Reden ontevredenheid:

Hoe tevreden bent u, **al deze vier onderwerpen bij elkaar genomen,** over de totale **dienstverlening**?	Totaal niet tevreden Niet tevreden Min of meer tevreden Tevreden Zeer tevreden	

Hieronder is een lijst van dezelfde12 onderwerpen weergegeven.
Wilt u de drie onderwerpen die u het meest belangrijk vindt uitkiezen?

Zet een kruisje voor de **drie onderwerpen** die u het belangrijkste vindt.

Afmetingen	Comfort
Gewicht	Effectiviteit
Verstel-mogelijkheden	Verstrekkingsproces
Veiligheid	Reparaties en onderhoud
Duurzaamheid	Professionaliteit van de dienstverlening
Gebruiksgemak	Service en dienstverlening na aflevering

The Quebec User Evaluation of Satisfaction with assistive Technology adapted version

- How satisfied are you about the dimensions of the assistive device? (size, length, height, width)
- How satisfied are you about the weight of the assistive device?
- How satisfied are you about the adjustment options of the assistive device?
- How satisfied are you about the safety of the assistive device?
- How satisfied are you about the ease of use of the assistive device?
- How satisfied are you about the comfort of the assistive device?
- How satisfied are you about the effectiveness of the assistive device? (does the assistive device do what you expect it to do?)
- How satisfied are you in general about the assistive device?

People had to answer these question with answer options: totally unhappy(1) – unhappy(2) – more or less satisfied(3) – satisfied(4) – very satisfied(5). These answer options were given a score as you can see behind brackets after every option. These scores were added up for every participant. This means every participant had two D-Quest scores, one for the regular walker and one for the powered walker. The reason why we deleted the other question is because these questions asked information about the service of the assistive device; reparation and maintenance, time to delivery, and other services that were irrelevant for our study.

Appendix 11: Visual Analog Scale – usefulness (Dutch version)

Naam:

Hoe nuttig vond u het hulpmiddel op volgende delen van het parcours:

- Op de grindweg?

0	1	2	3	4	5	6	7	8	9	10
Niet nuttig					=>				Heel Nuttig	

Score:

- Op de grasheuvel?

0	1	2	3	4	5	6	7	8	9	10
Niet nuttig					=>				Heel Nuttig	

Score:

- Op de alt. Helling + stoeprand?

0	1	2	3	4	5	6	7	8	9	10
Niet nuttig					=>				Heel Nuttig	

Score:

- Op het laatste deel tot finish?

0	1	2	3	4	5	6	7	8	9	10
Niet nuttig					=>				Heel Nuttig	

Score:

Appendix 12: BORG RPE (rate of perceived (leg) exertion) - Dutch version

BORG RPE (rate of perceived exertion)

Hoe vermoeiend was de afgelopen activiteit?

6	Niet vermoeid
7	Extreem licht
8	
9	Zeer licht
10	
11	Licht
12	
13	Gemiddeld
14	
15	Zwaar
16	
17	Zeer zwaar
18	
19	Extreem zwaar
20	Maximaal vermoeid

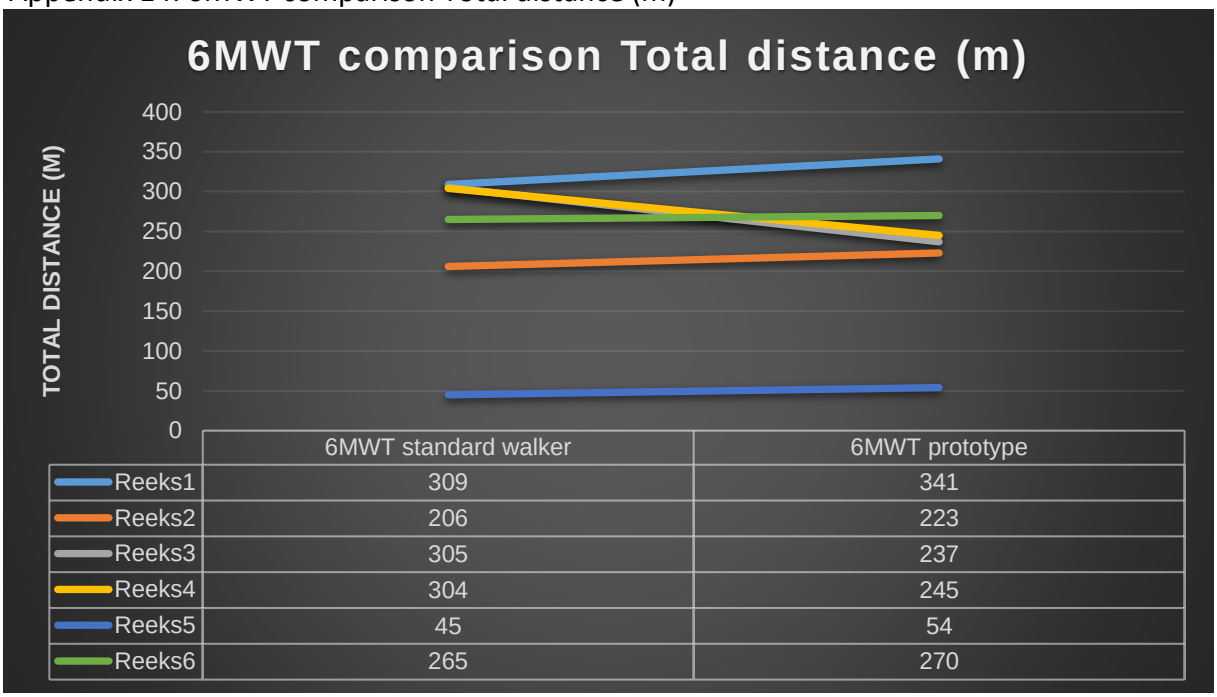
Appendix 13: BORG level of Dyspnea - Dutch Version

BORG Kortademigheid

Hoe moeilijk is het om te ademen?

0	Niet vermoeid
0.5	Extreem licht
1	Zeer licht
2	Licht
3	Gemiddeld
4	Enigszins ernstig
5	Ernstig
6	
7	Zeer zwaar
8	
9	Extreem zwaar
10	Maximaal

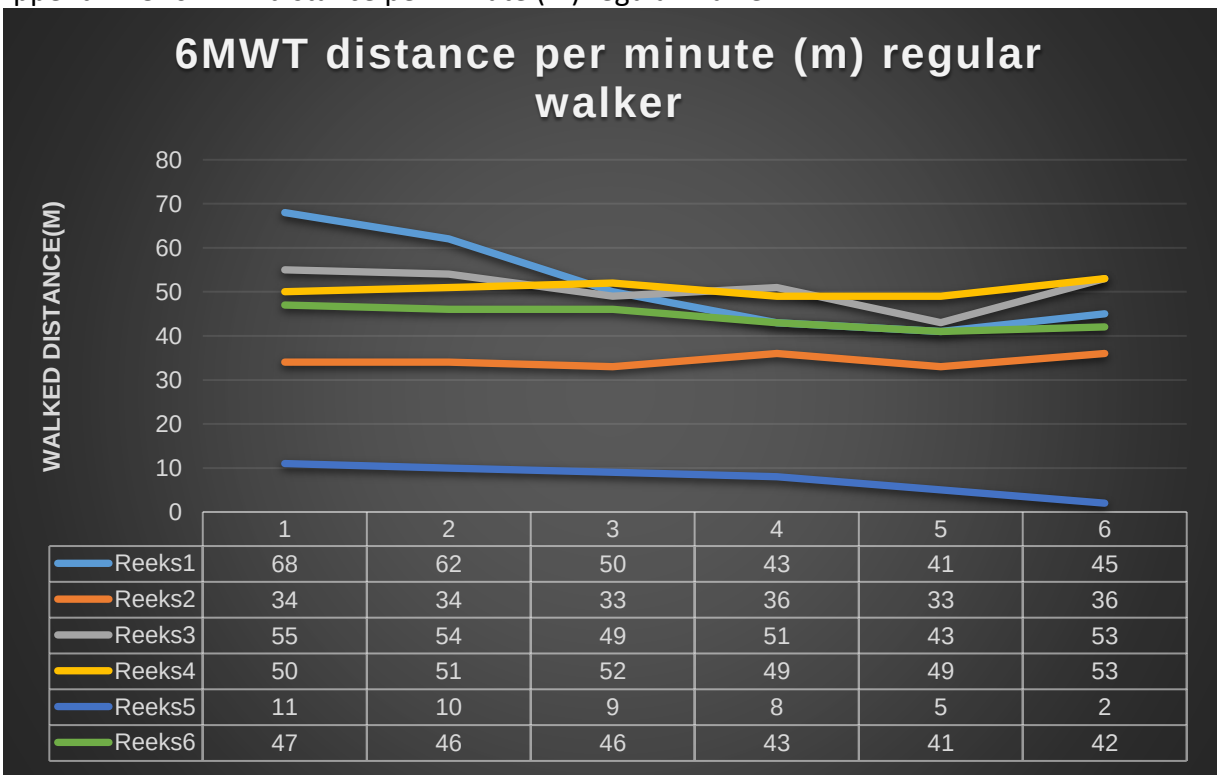
Appendix 14: 6MWT comparison Total distance (m)



	6MWT standard walker	6MWT prototype
Reeks1	309	341
Reeks2	206	223
Reeks3	305	237
Reeks4	304	245
Reeks5	45	54
Reeks6	265	270

6MWT comparison: total distance (m) p=1.00 median regular walker [284.5], median powered walker [241m], difference (-15.2%).
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

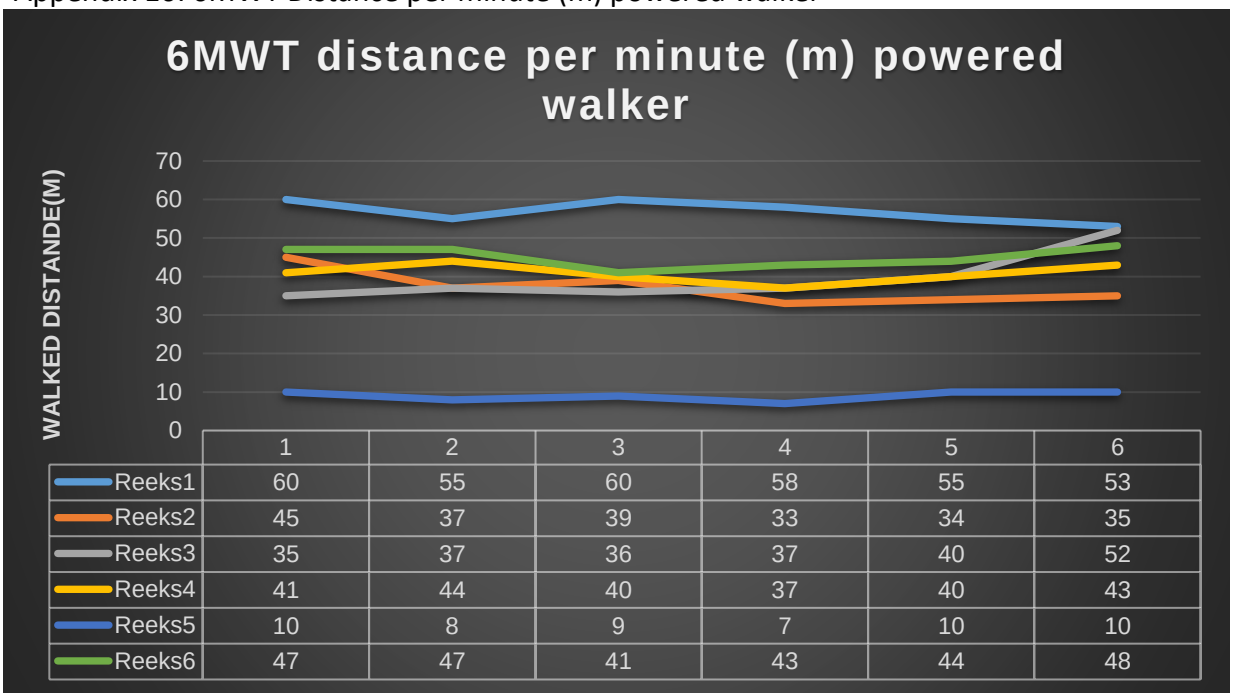
Appendix 15: 6MWT distance per minute (m) regular walker



	1	2	3	4	5	6
Reeks1	68	62	50	43	41	45
Reeks2	34	34	33	36	33	36
Reeks3	55	54	49	51	43	53
Reeks4	50	51	52	49	49	53
Reeks5	11	10	9	8	5	2
Reeks6	47	46	46	43	41	42

6MWT Distance walked (m) per minute regular walker: listed are six participants with their individual distance walked (m) displayed per minute.
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

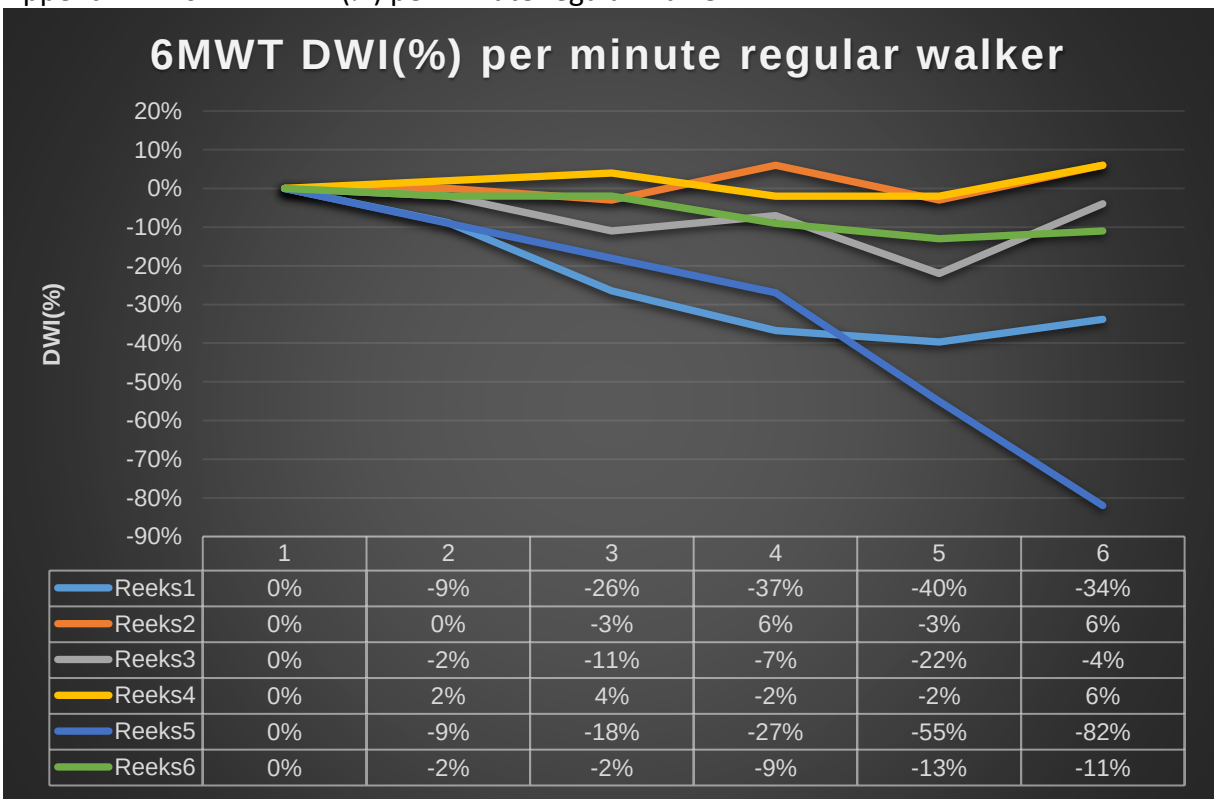
Appendix 16: 6MWT Distance per minute (m) powered walker



	1	2	3	4	5	6
Reeks1	60	55	60	58	55	53
Reeks2	45	37	39	33	34	35
Reeks3	35	37	36	37	40	52
Reeks4	41	44	40	37	40	43
Reeks5	10	8	9	7	10	10
Reeks6	47	47	41	43	44	48

6MWT Distance walked (m) per minute powered walker: listed are six participants with their individual distance walked (m) displayed per minute.
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

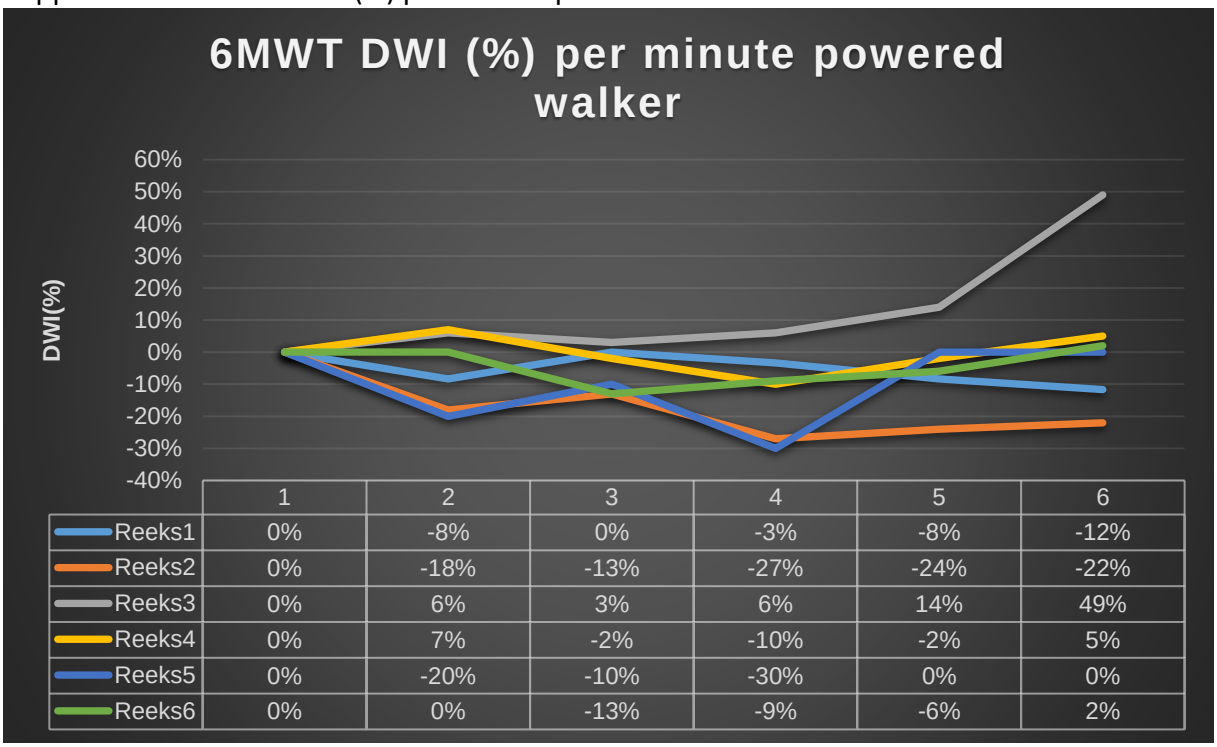
Appendix 17: 6MWT DWI (%) per minute regular walker



	1	2	3	4	5	6
Reeks1	0%	-9%	-26%	-37%	-40%	-34%
Reeks2	0%	0%	-3%	6%	-3%	6%
Reeks3	0%	-2%	-11%	-7%	-22%	-4%
Reeks4	0%	2%	4%	-2%	-2%	6%
Reeks5	0%	-9%	-18%	-27%	-55%	-82%
Reeks6	0%	-2%	-2%	-9%	-13%	-11%

6MWT DWI (%) per minute regular walker: listed are six participants with their individual DWI (%) displayed per minute.
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

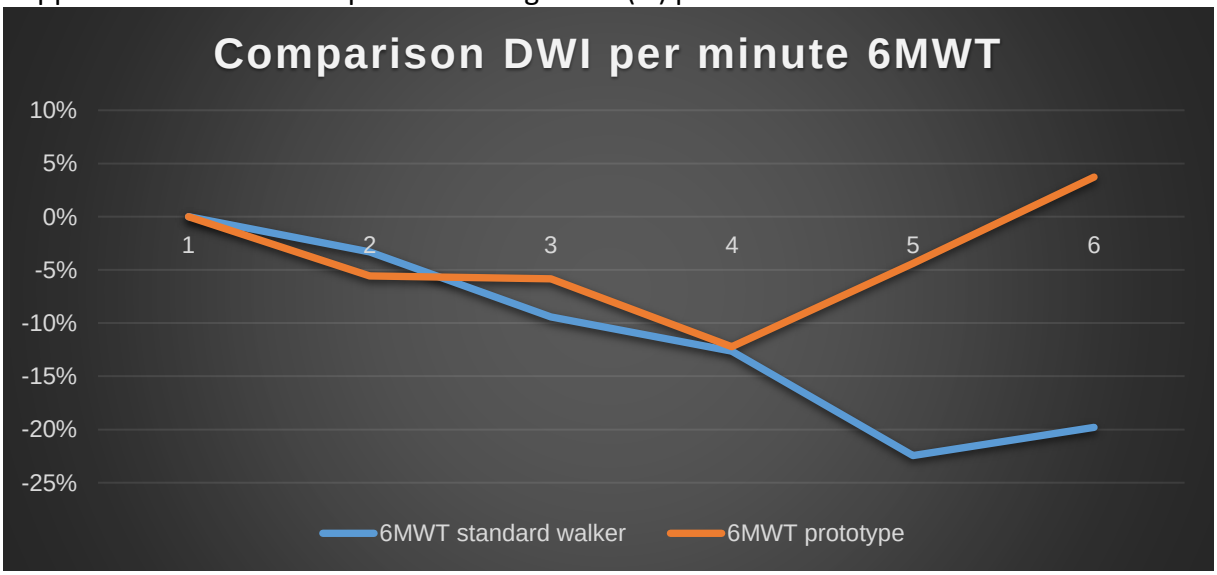
Appendix 18: 6MWT DWI (%) per minute powered walker



	1	2	3	4	5	6
Reeks1	0%	-8%	0%	-3%	-8%	-12%
Reeks2	0%	-18%	-13%	-27%	-24%	-22%
Reeks3	0%	6%	3%	6%	14%	49%
Reeks4	0%	7%	-2%	-10%	-2%	5%
Reeks5	0%	-20%	-10%	-30%	0%	0%
Reeks6	0%	0%	-13%	-9%	-6%	2%

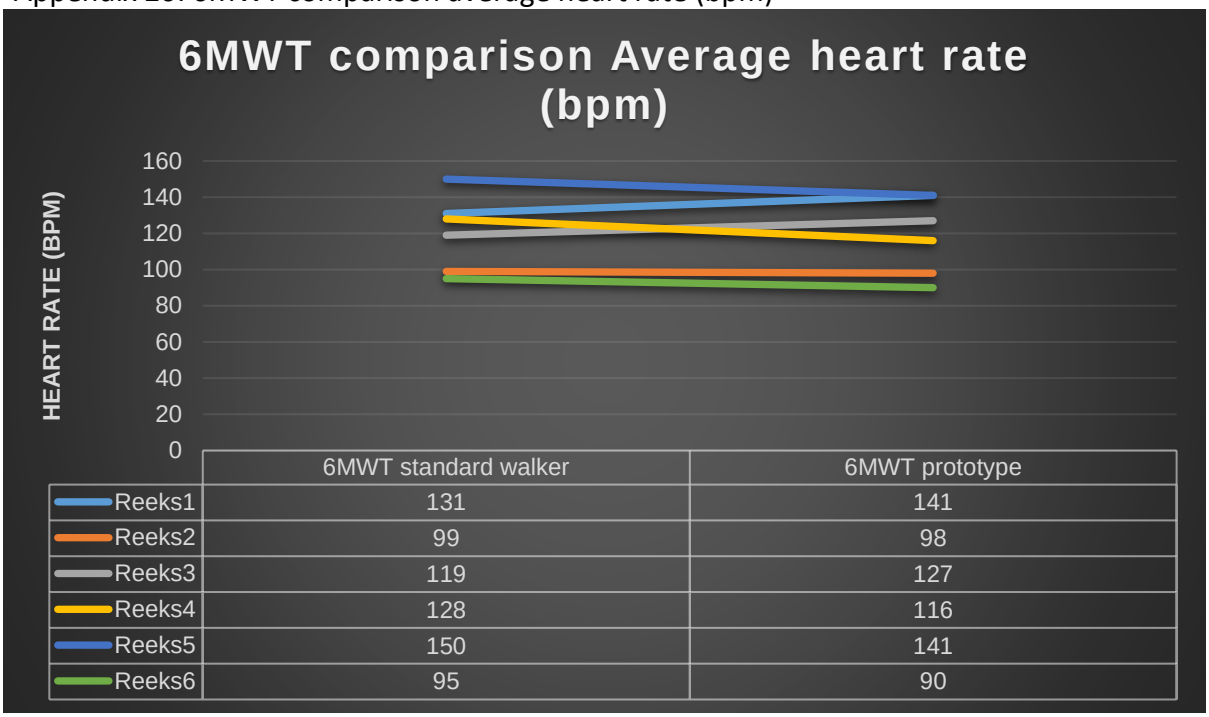
6MWT DWI (%) per minute powered walker: listed are six participants with their individual DWI (%) displayed per minute.
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 19: 6MWT comparison average DWI (%) per minute



6MWT comparison DWI per minute (%) p=0.28 average regular walker [-13.4%], average powered walker [-4.8%], difference (-64.2%).
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

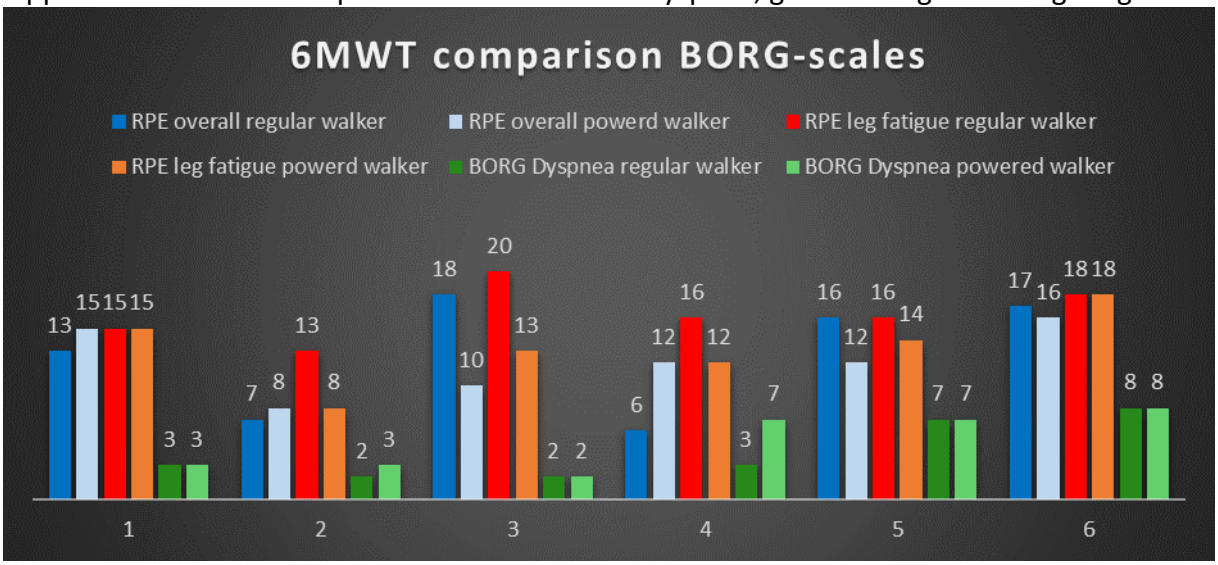
Appendix 20: 6MWT comparison average heart rate (bpm)



	6MWT standard walker	6MWT prototype
Reeks1	131	141
Reeks2	99	98
Reeks3	119	127
Reeks4	128	116
Reeks5	150	141
Reeks6	95	90

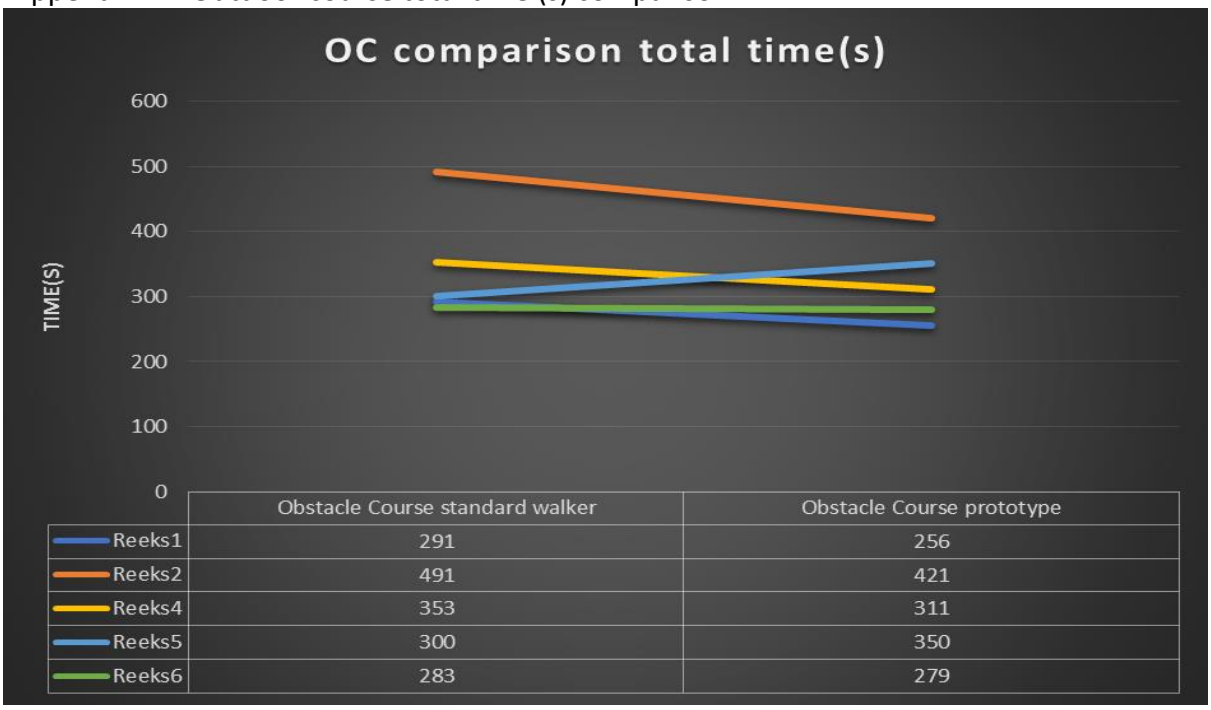
6MWT comparison average heart rate (bpm) p=0.68 average regular walker [120bpm], average powered walker [118bpm], difference (-0.9%).
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 21: 6MWT comparison BORG-scales of dyspnea, general fatigue and leg fatigue



6MWT comparison BORG-scales:
BORG-dyspnea p=0.50 median regular walker [3], median powered walker [5] difference (66.6%)
RPE overall fatigue p=0.56 median regular walker [14.5], median powered walker [12], difference (-17.2%)
RPE leg fatigue p=0.12 median regular walker [16], median powered walker [13.5], difference (-15.6%).
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

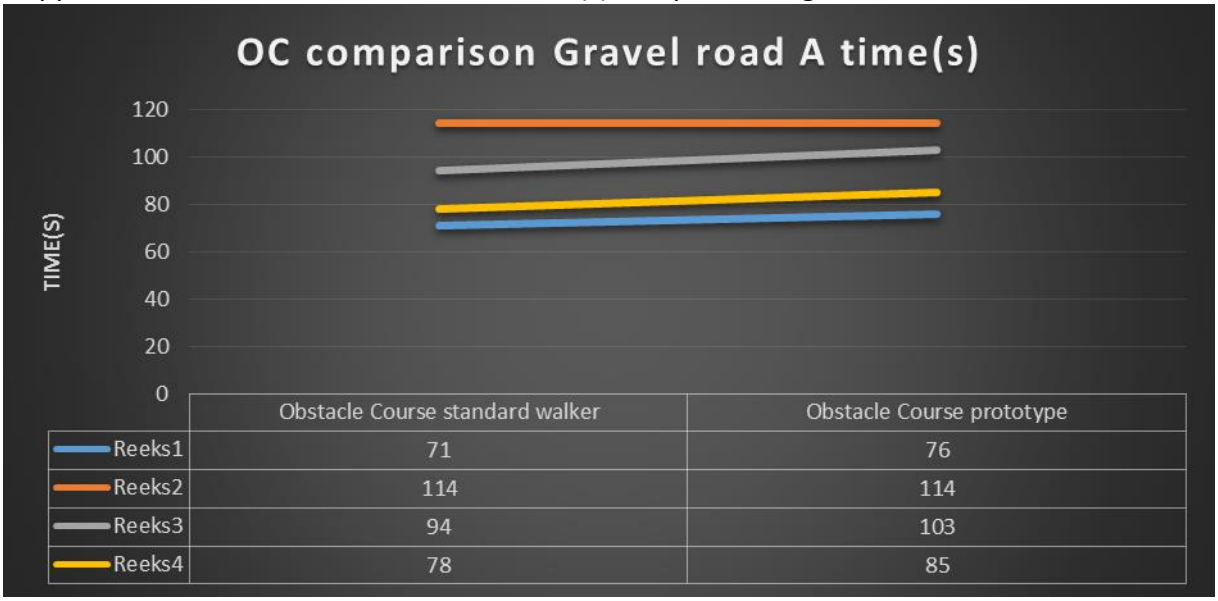
Appendix 22: Outdoor course total time (s) comparison



	Obstacle Course standard walker	Obstacle Course prototype
Reeks1	291	256
Reeks2	491	421
Reeks4	353	311
Reeks5	300	350
Reeks6	283	279

Outdoor course comparison total time (s) p=0.43 median regular walker [300s], median powered walker [311s], difference (3.6%).
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

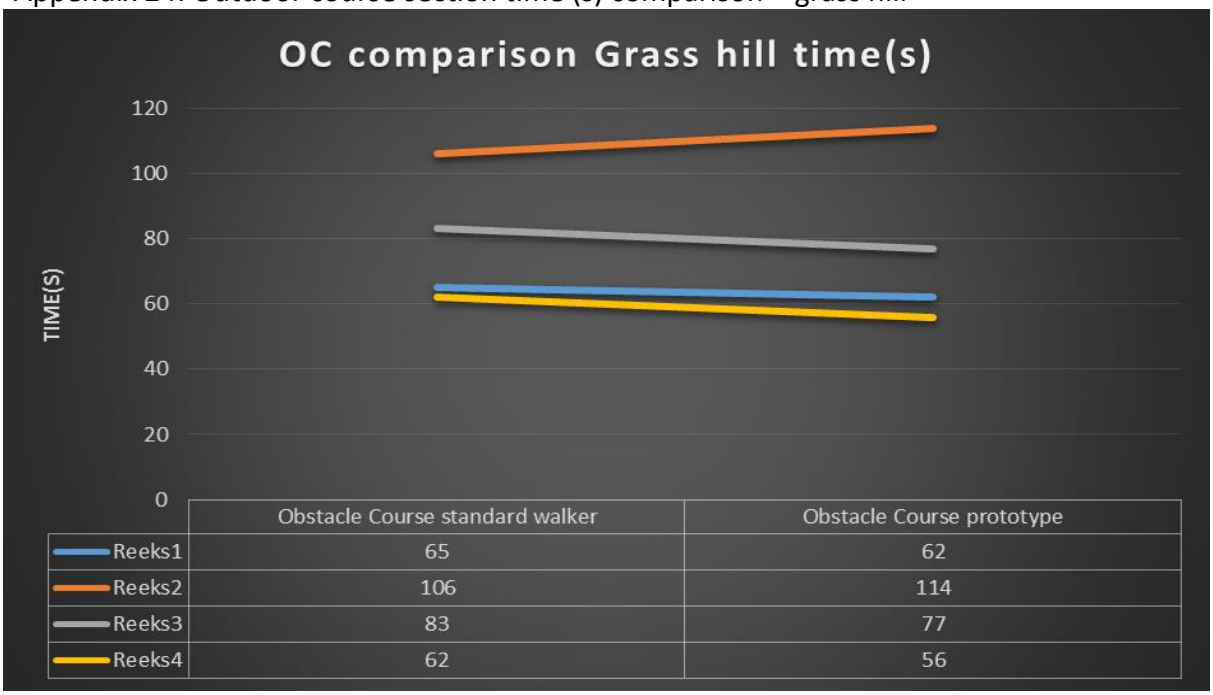
Appendix 23: Outdoor course section time (s) comparison – gravel road A



	Obstacle Course standard walker	Obstacle Course prototype
Reeks1	71	76
Reeks2	114	114
Reeks3	94	103
Reeks4	78	85

Outdoor course comparison gravel road A time (s) p=0.25 median regular walker [86s], median powered walker [94s], difference (9.3%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

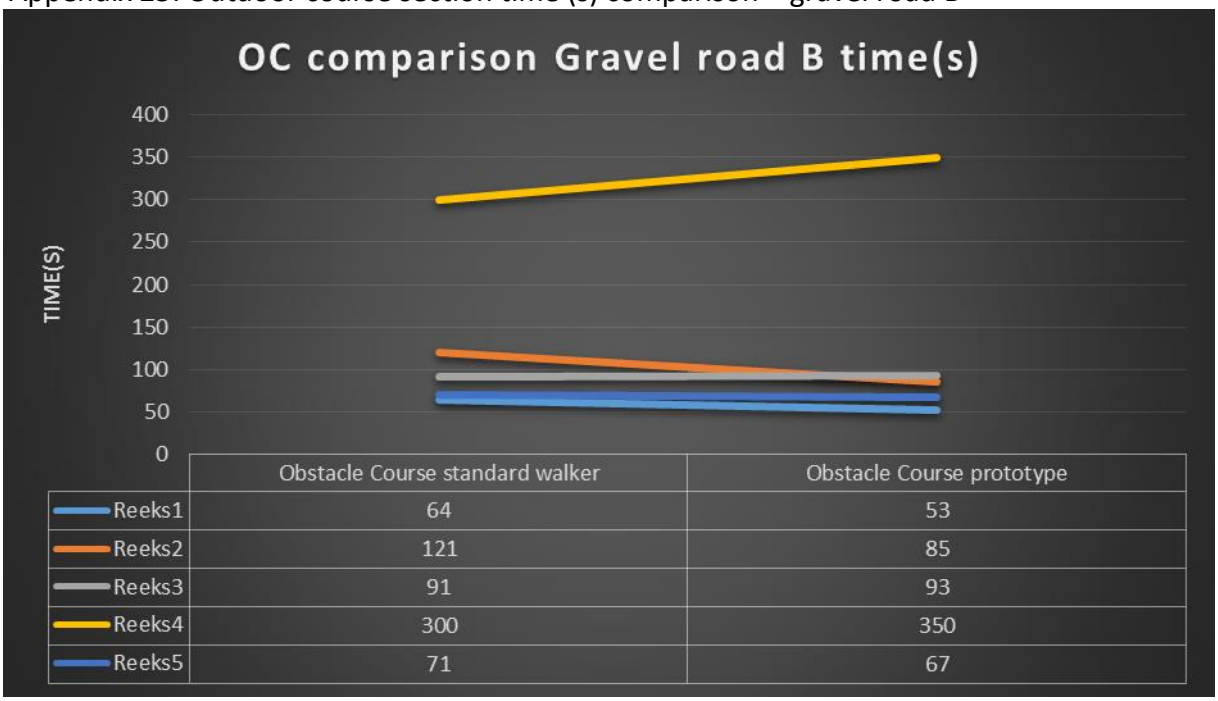
Appendix 24: Outdoor course section time (s) comparison – grass hill



	Obstacle Course standard walker	Obstacle Course prototype
Reeks1	65	62
Reeks2	106	114
Reeks3	83	77
Reeks4	62	56

Outdoor course comparison grass hill time (s) p=0.87 median regular walker [74s], median powered walker [69.5s], difference (-6.1%).
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

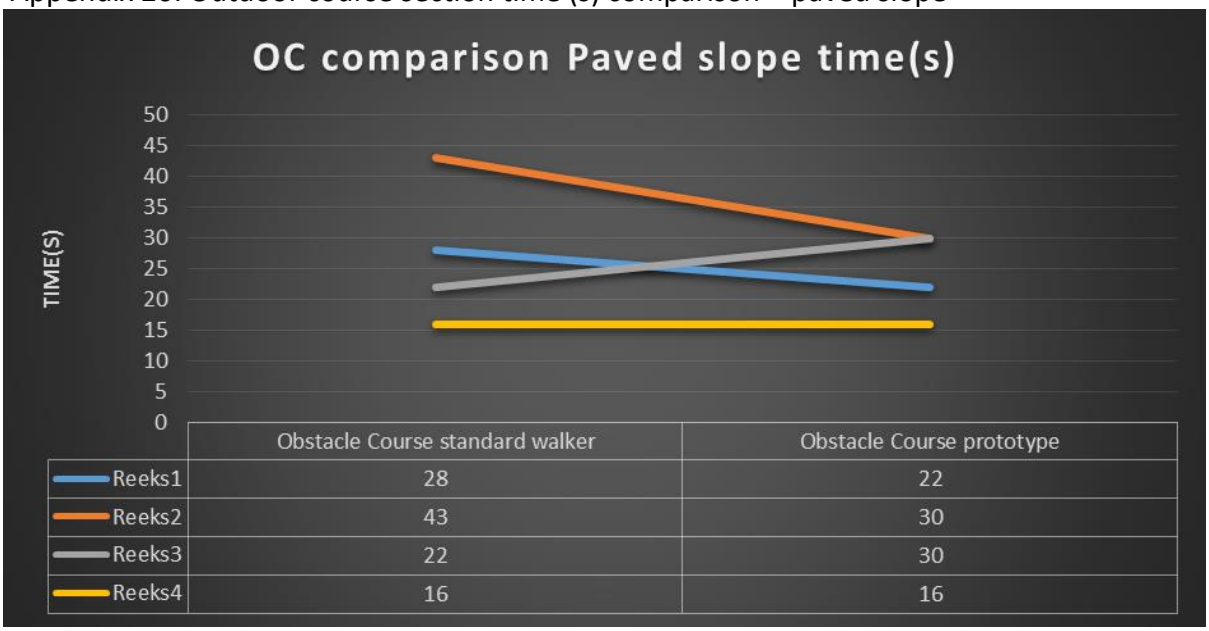
Appendix 25: Outdoor course section time (s) comparison – gravel road B



	Obstacle Course standard walker	Obstacle Course prototype
Reeks1	64	53
Reeks2	121	85
Reeks3	91	93
Reeks4	300	350
Reeks5	71	67

Outdoor course comparison gravel road B time (s) p=0.81 median regular walker [91s], median powered walker [85s], difference (-6.6%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 26: Outdoor course section time (s) comparison – paved slope



	Obstacle Course standard walker	Obstacle Course prototype
Reeks1	28	22
Reeks2	43	30
Reeks3	22	30
Reeks4	16	16

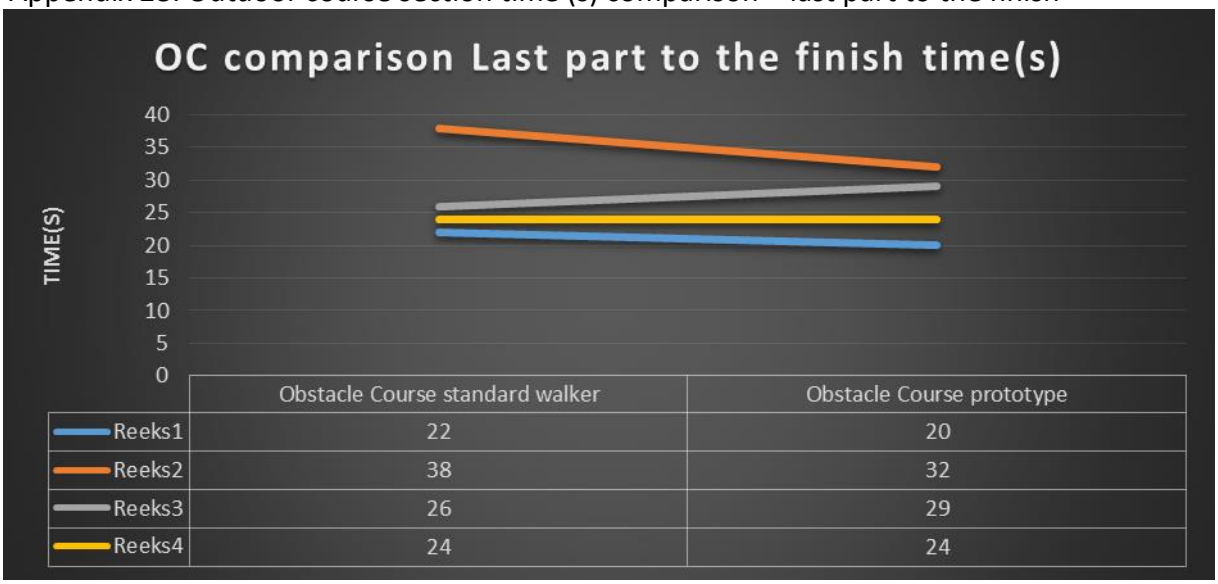
Outdoor course comparison paved slope time (s) p=0.75 median regular walker [25s], median powered walker [26s], difference (4%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 27: Outdoor course section time (s) comparison – curb & gutter

	Obstacle Course standard walker	Obstacle Course prototype
Reeks1	21	23
Reeks2	67	44
Reeks3	44	36
Reeks4	29	28

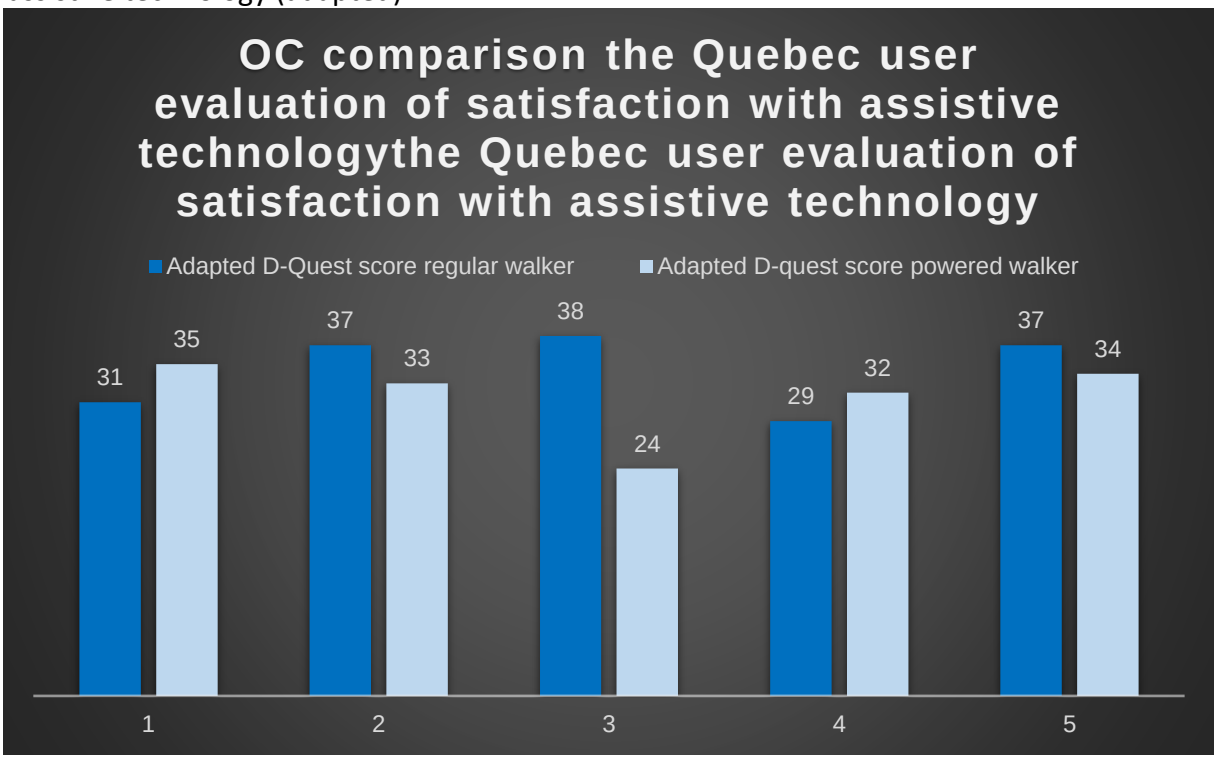
Outdoor course comparison curb & gutter time (s) p=0.37 median regular walker [36.5s], median powered walker [32s], difference (-12.3%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 28: Outdoor course section time (s) comparison – last part to the finish



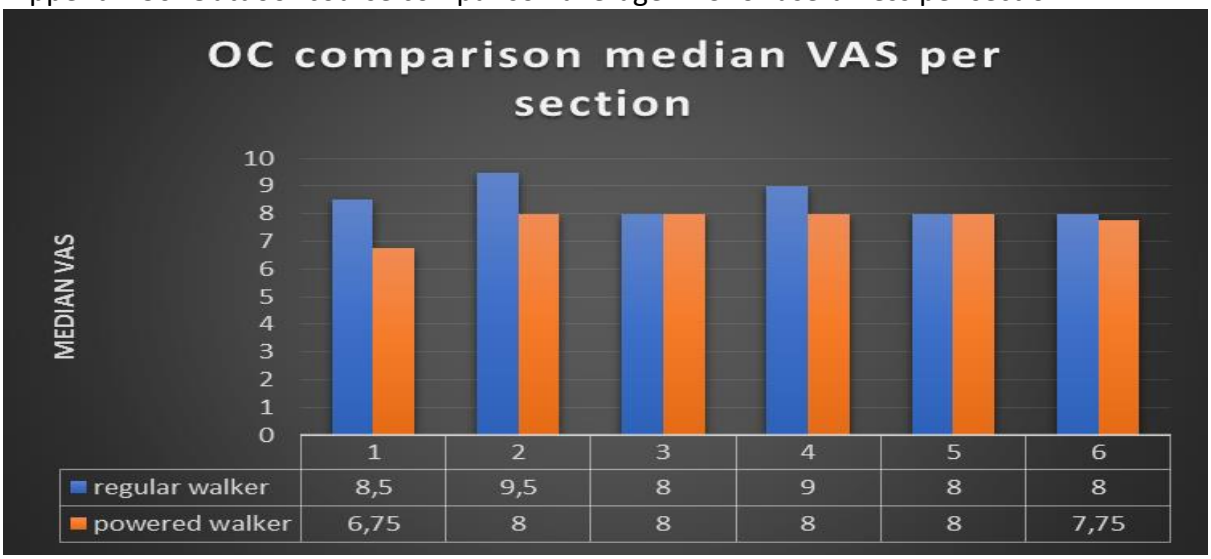
Outdoor course comparison last part to the finish time (s) p=0.75 median regular walker [25s], median powered walker [26s], difference (6%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 29: Outdoor course comparison of the Quebec user evaluation of satisfaction with assistive technology (adapted)



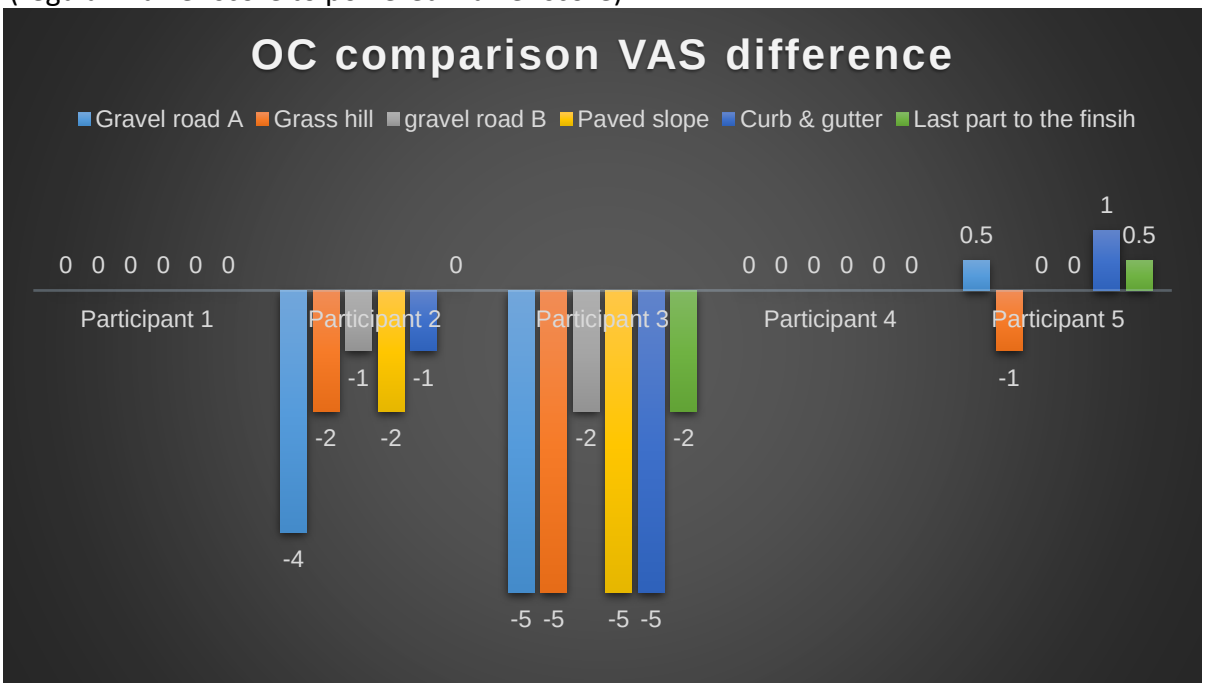
Outdoor course comparison adapted Quebec user evaluation of satisfaction with assistive technology p=0.43 median regular walker [37], median powered walker [33], difference (-10.8%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 30: Outdoor course comparison average VAS for usefulness per section



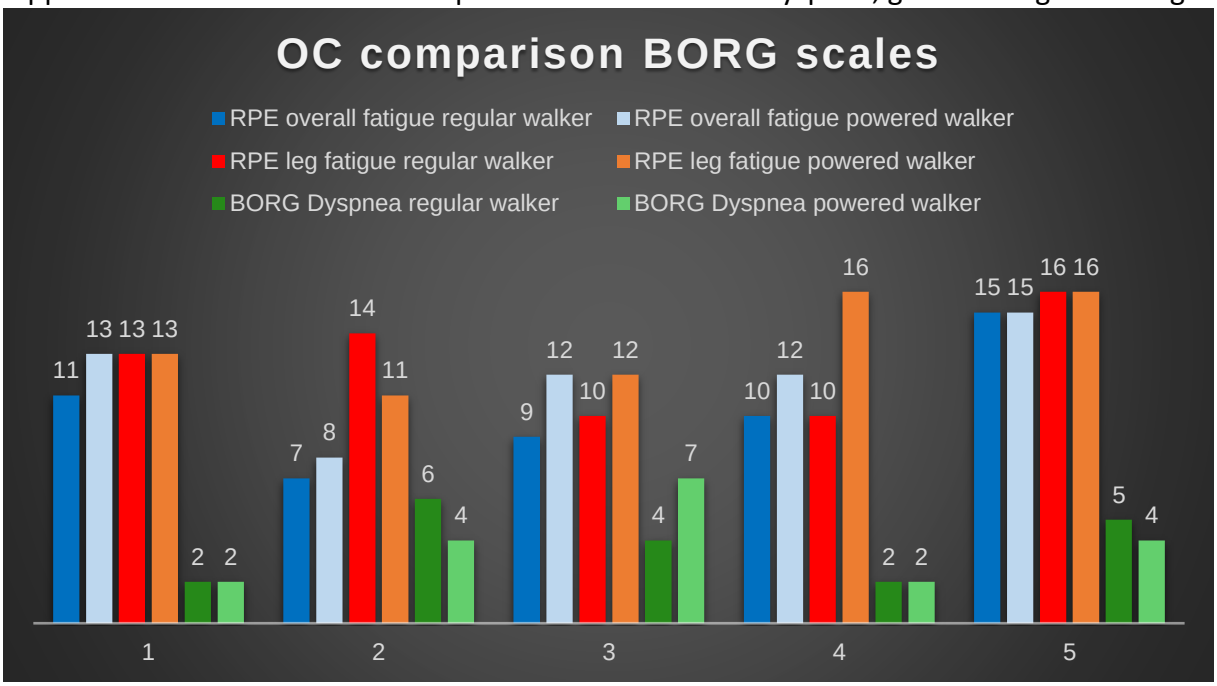
Outdoor course comparison average VAS per section:
1. Gravel road A p=0.50 median regular walker [8.5], median powered walker [6.75], difference (-21.2%)
2. Grass hill p=0.25 median regular walker [9.5], median powered walker [8], difference (-15.8%)
3. Gravel road B p=0.50 median regular walker [8], median powered walker [8], difference (0%)
4. Paved slope p=0.50 median regular walker [9], median powered walker [8], difference (-11.1%)
5. Curb & gutter p=0.75 median regular walker [8], median powered walker [8], difference (0%)
6. Last part to the finish p=1.00 median regular walker [8], median powered walker [7.75], difference (-3.7%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 31: Outdoor course comparison VAS-score difference per section per participant (regular walker score to powered walker score)



Outdoor course comparison VAS difference per participant per section: lister are sections 1-6 from left to right for every participant. A score of 0 means no difference between VAS regular walker and VAS powered walker. A negative score means a smaller VAS for the powered walker, a positive score means the opposite.
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

Appendix 32: Outdoor course comparison BORG-scales of dyspnea, general fatigue and leg



Outdoor course comparison BORG-scales:
BORG dyspnea p=1.00 median regular walker [4], median powered walker [4], difference (0%)
RPE overall fatigue p=0.12 median regular walker [10], median powered walker [12], difference (20%)
RPE leg fatigue p=0.75 median regular walker [13], median powered walker [13], difference (0%)
The effect of a powered walker on motor fatigability during a six-minute walk test and on an outdoor course in persons with Multiple Sclerosis 2017

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Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij inwendige aandoeningen**
Jaar: **2017**

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