



UHASSELT

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Faculteit Geneeskunde en Levenswetenschappen

master in de revalidatiewetenschappen en de
kinesitherapie

Masterthesis

Predicting habitual walking in persons with Multiple Sclerosis: associations with cognitive-motor interference, mobility, cognition and quality of life

Tessa De Winter

Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie, afstudeerrichting revalidatiewetenschappen en kinesitherapie bij neurologische aandoeningen

PROMOTOR :

Prof. dr. Peter FEYS

COPROMOTOR :

dr. Ilse BAERT



UHASSELT

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www.uhasselt.be
Universiteit Hasselt
Campus Hasselt:
Martelarenlaan 42 | 3500 Hasselt
Campus Diepenbeek:
Agoralaan Gebouw D | 3590 Diepenbeek

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Acknowledgment

First, I would like to thank my promotor prof. dr. Peter Feys for the useful feedback at the end of the writing process. Dr. Ilse Baert I would like to thank for her advice on the study design and statistical analyses. Another person I would like to thank is Dra. Renee Veldkamp for answering my questions and organizing a practice presentation. To end, I want to thank my father for proofreading my writing.

Research context

Investigating the predictability of habitual walking in persons with MS gives physiotherapists a broader view on the elements that enhance habitual walking. When defining a therapy plan to improve habitual walking it is important to know the aspects a person with MS should train on. By identifying predicting factors, the effects on habitual walking can be improved. Explaining the elements that impact habitual walking to the patients will motivate them, resulting in a better outcome of the therapy.

This master thesis is the sequel to an earlier literature study where the effect of interventions on habitual walking was investigated. For this master thesis, all the data was acquired by a large multi-center study, "Cognitive-motor interference in persons with multiple sclerosis: dual-task assessment & training. A multi-center study. (MCS-IV-CMI&DTT)" That study is a cooperation between the UHasselt, REVAL and the Masku Neurological Rehabilitation center in Finland. It investigates the effectiveness of dual task training and the impact on the daily lives of persons with multiple sclerosis. Steps/day measured with a Yamax pedometer is one of the outcome measures used to assess the impact on the daily lives of persons with multiple sclerosis.

All data were required by the researchers of the cognitive motor-interference study (MCS-IV-CMI&DTT). I observed some dual task assessments, helped cleaning the APDM data and included them in the appropriate databases. A specific research method was written for this master thesis, which uses the same outcome measures as in the cognitive-motor interference study (MCS-IV-CMI&DTT). The statistical analysis was executed in consultation with Dr. Ilse Baert, who coordinates the study about cognitive-motor interference. The academic writing was fully executed by me with feedback of the promotor prof. dr. Peter Feys.

Manuscript

Abstract

BACKGROUND: Habitual walking is often affected in pwMS but there is little knowledge about the association of habitual walking with other factors like dual task capacity, mobility, quality of life or cognitive abilities.

OBJECTIVES: Investigate the predictability of habitual walking by steps/day in pwMS.

PARTICIPANTS: 45 pwMS with an EDSS score between two and five were recruited in different centers in Italy, Israel, and Belgium.

MEASUREMENTS: The outcome measures are divided into the categories mobility, cognition, cognitive-motor interference and quality of life. Habitual walking was the primary outcome measure. The outcome measures existed out of questionnaires, performance scales, and the Yamax pedometer.

RESULTS: The DGI is the most predicting factor for habitual walking. In general, mobility outcome measures are the most correlated with habitual walking. For the cognition, motor-cognitive interference and quality of life outcome measures none of the factors correlated to habitual walking.

CONCLUSION: In persons with mild MS, habitual walking can be predicted by the DGI with an RSquare score of 0,34. This model predicts only a small part, there could be several other factors that are not investigated in this study, but that have an influence on habitual walking. More research is necessary on bigger and more diverse samples, with older and more severely disabled patients, including more possible influencing factors.

Introduction

Multiple Sclerosis (MS) is an autoimmune neurodegenerative disease of the central nervous system (Hemmer, Nessler, Zhou, Kieseier, & Hartung, 2006). In Europe there are over 600 000 patients with MS (Bezzini & Battaglia, 2017). In MS there are typically two categories of symptoms, namely motor symptoms and cognitive symptoms. Motor symptoms include muscle weakness, spasticity, loss of balance, tremor, and fatigue. (Ghasemi, Razavi, & Nikzad, 2017) The most affected cognitive functions are short-term memory, concentration, information processing and executive functions.

In persons with Multiple sclerosis (pwMS) these symptoms usually become more manifest when the different motor and cognitive tasks are performed at the same moment (Leone, Patti, & Feys, 2015). The interaction between these tasks is called cognitive-motor interference (CMI) (Wajda & Sosnoff, 2015). To measure the CMI, the dual task cost (DTC) of every task can be calculated with the following formula:

$$DTC = \frac{\text{single task} - \text{dual task}}{\text{single task}} \times 100$$

(McIsaac, Lamberg, & Muratori, 2015).

The DTC can be calculated separately for the motor task or for the cognitive task. By calculating the DTC for both motor and cognitive performance it is possible to see which of both is influenced the most by dual tasking. Earlier research stated that the DTC of walking in people with MS varied between 6 a 27% (Wajda & Sosnoff, 2015). It is difficult to compare DTC between pwMS and healthy persons because healthy persons have in most cases already a high gait speed for the single task. Consequently, the dual task gait speed is higher in healthy persons compared to pwMS, but the DTC is similar (Learmonth, Pilutti, & Motl, 2015). In pwMS dual tasks influence different gait parameters like gait speed, cadence, and step length. In earlier stages of MS, cognitive problems are not yet much visible, they often become more present during dual tasks.

Habitual walking activity is also often lower in pwMS compared to healthy controls. Habitual walking is defined by Gijbels et al. (2010) as “the real number of steps that are performed in the customary living environment”. Since ambulation is one of the biggest impairments in pwMS, it impacts habitual walking substantially. PwMS have an average of 5903 steps/day

(Dlugonski et al., 2013), compared to 8038 steps/day in a healthy population. (Hansen, Kollé, Dyrstad, Holme, & Anderssen, 2012) Habitual walking can be measured by an accelerometer or pedometer that is worn throughout the day for several days in a row. The accelerometer or pedometer can be worn on the leg, on the hip attached to a belt or on the wrist like a watch. With daily habitual walking, often dual tasks are required, like for example, talking to someone or carrying a glass of water while walking.

This study investigates the predictability of the habitual walking based on the DTC and other influencing factors like mobility, cognition, quality of life and demographic measures. The biggest predictors for habitual walking can give an indication of which aspects of rehabilitation to focus on.

Methods

Participants

PwMS were recruited from an ongoing randomized controlled trial about the training of dual tasks which selected patients at different centres: Centre Hospitalier Universitaire de Liège, National Multiple Sclerosis Centre Melsbroek, Rehabilitation and Multiple Sclerosis centre Overpelt, AZ Klina campus De Mick Brasschaat, FISM Scientific Research AISM (Italy) and Sheba Medical Center Tel-Hashomer (Israel). The inclusion criteria to select the participants are: being diagnosed with MS based on the McDonald criteria (Polman et al., 2011), age between 18 and 65 years old, Expanded disability status scale (EDSS) (Kurtzke, 1983) between two and five, no relapse during the last 30 days, no adjustments in disease-modifying treatment and no corticoid-therapy during the last 50 days, mini-mental state examination (MMSE) of at least 26 and a dual task screening list score of one or more. The exclusion criteria are: other medical conditions interfering with mobility, other neurological diagnoses, MS like syndromes, not able to understand and execute simple instructions and problems with hearing or vision (even after adjustments). All participants gave written informed consent. Since most of these participants are professionally active, outpatients will be recruited by MS societies, newsletters, neurologists, social media ...

Study design and outcome measures

The applied study design is defined as an observational cross-sectional study design. There were five categories of outcome measures used: demographic measures, CMI measures, mobility measures, cognitive measures and quality of life measures.

Demographic measures

The EDSS score and MS type was determined by a neurologist or trained clinician. All other demographic measurements like age, gender, disease duration since diagnosis, use of foot orthoses, history of falling, current disease-modifying and symptomatic drug use, employment status, educational level and years of highest education were administered with a questionnaire. Regarding the history of falling the following question was asked to the participants: how many times did you fall in the past six months and how many of them were injurious falls? For the employment status a division into four categories was used:

unemployed, partly employed, fully employed and retired. The registration of the educational level is based on the UNESCO International Standard Classification of Education ISCED (2011).

Cognitive-motor interference outcome measures

Participants perform single cognitive, single/dual motor and integrated cognitive-motor assessments. The order in which the blocks of single cognitive, single/dual motor and cognitive-motor trials and the sequence of each separate task within each block is randomized by a computer program. During the break halfway the dual task procedure, the participants filled in the short dual tasking questionnaire developed by Evans, Greenfield, Wilson, and Bateman (2009). The cognitive tasks exist out of a titrated digit span backward, auditory vigilance with alphabets and counting backward by seven. During the titrated digit span backward, the participants listen to a titrated string of digits at a rate of one/second and repeat them in reverse order. With the auditory vigilance with alphabets, the participants listen one minute to recorded letters at a rate one per two seconds and answer with 'yes', every time they hear the targeted letter. The motor tasks exist out of walking at a self-selected speed, walking at self-selected speed while stepping over low obstacles (10cm x 10cm) every tree meter on a straight line, walking at self-selected speed crisscross from cone to cone every two meter and walking at self-selected speed while carrying a cup of water. The gait parameters are recorded with wearable sensors (APDM) and the Mobility Lab software. The participants receive the instruction to perform the motor and cognitive task at the same time, and to perform both tasks at their best level, and not prioritize the motor or cognitive task. The combination of the 3 cognitive task and 4 motor tasks makes a total of 12 cognitive-motor dual-task trials.

Mobility outcome measures

The mobility measures used are self-reported questionnaires, mobility performance scales, and habitual walking. The questionnaires are the Multiple Sclerosis Walking Scale-12 (MSWS-12) (Hobart, Riazi, Lamping, Fitzpatrick, & Thompson, 2003) and the Falls Efficacy Scale – International (FES-I)(Yardley et al., 2005) about the concern to fall. The used mobility performance scales are the Timed 25 Foot-walk (T25FW)(Motl et al., 2017), time up & go (TUG)(Sebastiao, Sandroff, Learmonth, & Motl, 2016), dynamic gait index (DGI)(McConvey & Bennett, 2005), and two minutes walk test (2MWT)(Butland, Pang, Gross, Woodcock, & Geddes, 1982). To measure habitual walking a pedometer (Yamax SW-200 or Yamax digi-

walker SW-401) is used. The study of Le Masurier, Lee, and Tudor-Locke (2004) showed that the Yamax pedometer is the most accurate device in controlled and free-living, also with slow gait speed. With this pedometer steps/day are measured for five days in a row; one of these five days must be a weekend day. Participants wore the pedometers all day except for bathing or other activities involving water and sleeping. The participants receive oral instructions and an instruction manual for the placement and use of the pedometer.

Cognitive outcome measures

The participants completed the Brief Repeatable Battery of Neuropsychological Tests (BRBNT)(Boringa et al., 2001). The BRBNT will be assessed by a psychologist or trained assessor and includes tests of verbal memory acquisition and delayed recall (Selective Reminding Test, SRT), visual memory acquisition and delayed recall (Spatial Recall Test, SPART), attention, concentration and speed of information processing (Paced Auditory Serial Addition Test, PASAT; Symbol Digit Modalities Test, SDMT), verbal fluency on semantic stimulus (Word List Generation, COWAT). If possible the BRBNT can be derived from the medical record if it was assessed within 3 months before the start of the study and no relapse occurred since then.

Quality of life outcome measures

The participants completed two questionnaires: the Multiple Sclerosis Impact Scale-29 items (MSIS-29)(Learmonth, Hubbard, McAuley, & Motl, 2014) to measure the impact of MS and the Modified Fatigue Impact Scale measuring (MFIS) (Elbers et al., 2012)to measure the severity of the fatigue.

Statistical analysis

To perform a stepwise multiple regression, it is necessary to limit the independent variables to a maximum of 4 or 5 variables. Stepwise multivariate regressions are first executed for each category of outcome measures (demographic, CMI, mobility, cognitive and quality of life measures). The significant measures from these multivariate regressions were used for the final multiple stepwise regression. Prior to the stepwise multiple regressions for each category, a univariate linear regression was performed on each independent variable with habitual walking as the dependent variable. Only variables with a p-value of 0.10 or less were added to the stepwise multiple regression for each category. If necessary, the Pearson and Spearman Rho correlation coefficients were used to make decision to further reduce the number of variables. The significant variables of these separate stepwise multiple regressions are used for the final stepwise multiple regression. The results are always checked for multicollinearity with the variance inflation factor (VIF). The distribution of the residuals was checked by visual inspection. The VIF must be lower than ten. The analysis was done with SAS JMP PRO 12.

Table 1

Descriptive statistics of demographic measures

Variable	pwMS (n=45)
Gender (male/female)	19/26
Age (years)	51 (8,15)
Weight (kg)	73,9 (15,28)
Height (cm)	170,36 (9,27)
BMI	25,35 (4,42)
Employment status (unemployed/partly employed/fully employed/retired/other)	10/13/13/6/3
Living arrangement (alone/ with partner/with family/other)	4/13/25/3
Education level (1-6)	6 (1) *
Education (years)	16,33 (1,97)
Disease duration (years)	10,93 (10,47)
Type of MS (PP/RR/SP)	4/34/5
Use of a walking aid	10
Use of an orthosis	9
Number of falls in the last 6 months	1,21 (2,01)
EDSS	3,5 (1,5) *

BMI=body mass index, PP= primary progressive, RR= relapse remitting, secondary progressive and EDSS=expanded disability status scale

Values are mean (standard deviation) or number of participants

** Median (IQR),*

Results

Table 1 shows the mean and standard deviation for all descriptive measures. The mean EDSS score of 3.5 indicates that the majority of the sample has no or minimal problems with walking. The EDSS also indicates that most of the participants are in a mild stage of the disease. This corresponds with the fact that more than half of the sample is still fully or partly employed (26/45).

Table 2 provides the mean and standard deviation for all other categories of variables. With 7080 steps/day, the habitual walking in this sample is lower compared to a healthy population (8038 steps/day)(Hansen et al., 2012). For the mobility outcome measures, the mean scores are relatively high for pwMS. This can be explained by the EDSS score of 3.5. For the DGI the mean score is 20.69(3.22) and 15 participants got the maximum score of 24 points. The mean DTC of 11.13% corresponds with earlier findings in pwMS(Wajda & Sosnoff, 2015).

For demographic and mobility outcome measures, some variables show a relationship with habitual walking and others not. The categories of CMI, cognitive and quality of life outcome variables do not have a significant correlation with habitual walking. Table 3 displays the highest correlated variables that are used for the stepwise multiple regressions per category. Age and EDSS score correlate best with habitual walking for the category of demographic outcome measures. For the mobility outcome measures, there were seven variables with a p-value smaller than 0.10 in the univariate regressions. To further reduce the number of variables for the multiple regression on these measures, Pearson and Spearman Rho correlations are calculated. Affected side, T25WT at usual speed($r_s=-0.38$), TUG ($r=-0.40$), DGI ($r_s=0.53$), and 2MWT($r=0.31$) are selected for the multiple regression of the mobility outcomes.

When performing stepwise multiple regressions for the categories of demographic and mobility outcomes, the variables age, EDSS and DGI contributed the most to the prediction of habitual walking. These three variables were used for the final stepwise multiple regression. This resulted in an RSquare of 0.34 and an RSquare adjusted of 0.30.

Table 2*Mean and standard variation of the outcome measures*

Variable	pwMS (n=45)
<i>Mobility outcome measures</i>	
habitual walking (steps/day)	7080,97 (3075,60)
Most affected side (l/r/both)	19/17/3
Timed 25 Feet Walking test at usual speed (seconds)	6,88 (1,58)
Timed 25 Feet Walking test at fast speed (seconds)	5,19 (1,35)
Timed Up & Go (seconds)	7,21 (1,60)
Multiple Sclerosis Walking Scale - 12 (percentage)	41,85 (22,85)
Dynamic Gait Index	20,69 (3,22)
Falls Efficacy Scale - International	28,80 (9,59)
2 Minute Walking Test (meters)	165,39 (39,37)
<i>Cognitive outcome measures</i>	
Selective Reminding Test - Long term	46,07 (14,08)
Spatial Recall Test	20,98 (6,21)
Symbol Digit Modalities Test	44,98 (13,70)
Paced Auditory Serial Addition Test 3sec	47,26 (8,98)
Paced Auditory Serial Addition Test 2sec	35,14 (9,59)
Selective Reminding Test - delay	9,70 (2,00)
Word List Generation	28,48 (7,36)
Brief Repeatable Battery of Neuropsychological Tests	-0,10 (0,59)
<i>Cognitive-motor interference outcome measures</i>	
Dual Task Questionnaire	14,16 (8,70)
Motor Dual Task Cost	
Dual Task Cost crisscross (%)	9,80 (8,65)
Dual Task Cost walk (%)	13,94 (9,07)
Dual Task Cost obstacles (%)	10,08 (8,42)
Dual Task Cost cup (%)	11,69 (11,86)
Cognitive Dual Task Cost	
Dual Task Cost digit span (%)	13,74 (9,73)
Dual Task Cost subtraction (%)	14,34 (8,68)
Dual Task Cost vigilance (%)	6,21 (7,49)
Dual Task Cost all tasks (%)	11,13 (6,45)
<i>Quality of life outcome measures</i>	
Multiple Sclerosis Impact Scale-29 total	63,67 (21,97)
Multiple Sclerosis Impact Scale-29 physical	43,02 (15,68)
Multiple Sclerosis Impact Scale-29 psychological	20,64 (7,64)
Modified Fatigue impact Scale total	34,93 (17,55)
Modified Fatigue impact Scale physical	15,61 (9,39)
Modified Fatigue impact Scale psychological	2,77 (2,24)
Modified Fatigue impact Scale cognitive	15,61 (9,39)

*Values are mean (standard deviation)***significance level < 0.10 and will be incorporated into the specific multiple regression models*

This means the prediction model explains for 34% the results of our sample. Age and DGI are included in the model and have respectively an estimate of 123.35 and 486.55(habitual

walking=123.35*age+486.55*DGI-9360.40). So, for every year, a pwMS becomes older his/hers habitual walking increases with 123.35 steps/day and for every point, he/she scores better on the DGI his/her habitual walking increases with 483.55 steps/day. Both VIF's were 1.00 indicating there are no signs of multicollinearity. The residuals of the predicted model are evenly distributed.

Table 3
The most predictive variables for habitual walking per category on univariate regression

Category variable	R ²	R ² adj	β	SE	t-value	p-value
Demographic outcome measures						
Age	0.08	0.06	121.03	68.59	1.76	0.09
EDSS	0.11	0.08	-973.37	487.36	-2.00	0.05
Mobility outcome measures						
Most affected side	0.19	0.13			3.47	0.04
Timed 25 Feet Walk at usual speed	0.16	0.14	-800.96	325.80	-2.46	0.02
Timed Up & Go	0.16	0.14	-765.27	293.03	-2.61	0.01
Dynamic Gait Index	0.28	0.26	494.05	129.90	3.80	0.01
2 Minute Walk test	0.10	0.07	24.25	12.10	2.00	0.05

Discussion

With 7081 steps/day, the mean habitual walking in this study is higher than in the study of Dlugonski et al. (2013), where a step count of 5903 steps/day was found in pwMS. This can be explained by a lower EDSS score in the study of Dlugonski et al. (2013). The median of the EDSS scores in this sample is 3.5, meaning the participants have complaints on different levels but are able to walk at least 500 meters without rest or assistive device. This explains why their number of steps/day comes closer to the mean of 8038 steps/day in a healthy population (Hansen et al., 2012).

The DGI has the best correlation with habitual walking. This could be expected as the DGI tests actions, like looking around and taking obstacles during walking, actions that are very common in everyday situations. Of all mobility tests, the DGI takes the longest time making it more sensitive to fatigue, a common symptom in MS.

Age is another predicting factor for habitual walking in this study. The older a pwMS, the more steps/day are taken. This finding is counterintuitive and could be due to coincidence. The p-value in the multiple regression was only slightly significant for age (0.04) and in the univariate regression age was not significant (0.08), nevertheless it was included in the multiple regression. All variables with a univariate p-value of 0.10 or less were included for completeness. In the univariate regression age only has an RSquare of 0.08 where DGI has an RSquare of 0.28. DGI explains almost the entire model and the contribution of age is rather small.

One possible explanation of the correlation could be that the participants get more conscious of the importance of physical activity when they get older and start to increase their habitual walking.

The low EDSS score can be a reason for the low RSquare (0.34). This study mainly focused on the factors that are symptoms or consequences of MS, but since these participants do not yet have many complaints, other factors could be more relevant for habitual walking; for example, weather circumstance, living in a city or a more rural environment, ...

This study found a correlation between habitual walking, age, and DGI. Age and DGI are both positively correlated to habitual walking. While selecting the variables for the multiple regression it became clear that only outcome measures related to mobility had a small

correlation with habitual walking. Other outcome measures like cognition, quality of life or cognitive-motor interference did not show any correlation to habitual walking. To improve habitual walking the focus in rehabilitation must be on higher level mobility.

In the study of Dlugonski et al. (2013) a correlation of habitual walking with employment, education, disability and disease type was found. This study existed of a sample of 645 participants compared with 45 in this research. Consequently, the study of Dlugonski et al. (2013) has more statistical power. In the study of Dlugonski et al. (2013) another statistic method was used to calculate the correlations. All the variables were simplified to dichotomous variables. In this case: employed/unemployed, high school or less/some college, PDDS scale score $<2/>3$ and disease duration $<10\text{ year}/>$ year. Both the statistical power and the dichotomous variables could explain the incongruency between the findings of the study of Dlugonski et al. (2013) and this study.

Motl, Pilutti, Learmonth, Goldman, and Brown (2013) also found a correlation with MSWS-12 and concluded that a 10-point increase at the MSWS-12 scale is similar to a reduction of 642 steps/day. The fact that they did find a significant correlation where none was found in this study can be explained by the large sample in the study of Motl et al. (2013). This could be a sign that the power of this study was too low.

Study limitations

This study has a few limitations. First of all, because of an RSquare of 0.34 only 34% of the results of the sample can be explained by this model. This means there are other variables which have an influence on habitual walking that were not included in this study. Possible other variables are season and weather conditions, geographical location like urban or more rural environment, but also cultural factors like religion or beliefs.

Also, it is possible that increased their habitual walking because they were aware of being monitored with the pedometers and did extra their best. This is called the Hawthorne effect (Portney and Watkins, 2009) and is classified as an experimental bias. This bias is hard to avoid because the pedometer is necessary to measure the habitual walking. However, the effect could be minimized by increasing the number of days that the pedometer is worn so the participants get used to it.

The participants were instructed to wear the pedometer for five consecutive days and one of these days must be a weekend day. The systematic review of Block et al. (2016) describes a 7-day period as the most reliable in pwMS. This may explain the correlations with TUG and MSWS-12 found in the studies of Weikert, Motl, Suh, McAuley, and Wynn (2010); Weikert et al. (2012). There the steps/day were measured for a 7-day period. While in this study only a small correlation with TUG was found and no correlation with MSWS-12. Note that the samples in the studies of Weikert have moderate MS and the sample of this study has only mild MS.

The last limitation is a sampling bias due to recruiting outpatients. The sample exists of patients with a low EDSS score. This results in an overestimation of habitual walking in the general population of pwMS. The DGI also show a lot of maximum scores. Which might be caused by the high EDSS score. Another cause could be the level of the assessments. For further research on populations with mild disability more challenging tests like a High-Level Mobility Assessment Tool (HiMAT)(Williams, Robertson, Greenwood, Goldie, & Morris, 2005), Community Balance and Mobility Scale (CB&M scale)(Inness et al., 2011; Knorr, Brouwer, & Garland, 2010; Wright, Ryan, & Brewer, 2010) or a six-minute walk test (6MWT) (Enright, 2003) instead of a two-minute walk test, could be more correlated. Gijbels et al. (2010) found in their study that in pwMS who have a mild form of the disease the 6MWT is the most predicting for habitual walking, but in the sample with pwMS who have a moderate form of the disease the 6MWT and the 2MWT are both predictive for habitual walking. The 6MWT is in this study, for the population with lower EDSS scores, the 6MWT is more predictive than the 2MWT.

The findings of this study give an idea of which factors to focus on when improving habitual health is a therapy goal. Improving habitual walking is important because it has several advantages for the health of pwMS, like lower fall risk (Sebastiao, Learmonth, & Motl, 2017) and a lower risk for cardiometabolic diseases (Tudor-Locke et al., 2017).

Conclusion

In persons with mild MS, habitual walking can be predicted by the DGI with an RSquare score of 0,34. This model predicts only a small part, there could be several other factors that are not investigated in this study, but that have an influence on habitual walking. More research is necessary on bigger and more diverse samples, with older and more severely disabled patients, including more possible influencing factors.

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Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège (707)



Sart Tilman, le 5 octobre 2016

Monsieur le **Prof. P. MAQUET**
Monsieur **X. GIFFROY**
Service de **NEUROLOGIE**
CHU B35

Concerne : Votre demande d'avis au Comité d'Ethique
Nr belge : B707201628796 ; Notre réf : 2016/141

Cher Collègue,

J'ai le plaisir de vous informer que le Comité d'Ethique a donné une réponse favorable à votre demande d'avis intitulée :

"La pratique simultanée de tâches motrices et cognitives chez des personnes souffrant de sclérose en plaque : évaluation de la double tâche (MCS-IV-CMI&DTT)"
Protocole : **MCS-IV-CMI&DTT**

Vous trouverez, sous ce pli, le formulaire de réponse reprenant, les différents éléments examinés et approuvés et la composition du Comité d'Ethique.

Je vous prie d'agréer, Cher Collègue, l'expression de mes sentiments les meilleurs,

Prof. V. SEUTIN
Président du Comité d'Ethique

Copie au Promoteur : **UNIVERSITEIT HASSELT**
Copie à la **Direction de l'AFMPS**

COMITE D'ETHIQUE HOSPITALO-FACULTAIRE UNIVERSITAIRE DE LIEGE
(707)

Approbation d'une demande d'étude clinique
Approval form for a clinical trial

Documents examinés et approuvés

0. Année et nr Dossier : 2016-141
1. Service de : NEUROLOGIE
2. Chef de Service : Prof. P. MAQUET
3. Investigateur principal : X. GIFFROY
4. Promoteur : UNIVERSITEIT HASSELT
5. Représentant légal du promoteur dans l'Union européenne (lorsque le promoteur n'est pas établi dans l'UE) _____
6. N° belge : B707201628796
7. Titre du projet : (en version originale) La pratique simultanée de tâches motrices et cognitives chez des personnes souffrant de sclérose en plaque : évaluation de la double tâche (MCS-IV-CMI&DTT)

8. Numéro du protocole et date : MCS-IV-CMI&DTT 14/04/2016

9. Nature de l'expérim. :

Ph I	Ph II	Ph III	Ph IV	Non interv.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Protocole complet 14/04/2016

11. Résumé du protocole 14/04/2016

12. Brochure pour investigateur
(uniquement pour les substances nouvelles)

13. Form. Info. et Cons. patient (fr) 04/10/2016

14. Form. Info. et Cons. patient (nl) 04/10/2016

15. Un § « Assurance » précise que les dommages sont couverts par une assurance conforme à la loi

17. Les modalités du contrat financier entre le Promoteur et le Site sont fournies

18. Attestation de la société d'assurance conforme à la loi 26/04/2016

Notre Dossier nr : *Our File nr* : 2016 / 141

Approbation d'une demande d'étude clinique (suite)
Approval form for a clinical trial (following page)

Protocole

La pratique simultanée de tâches motrices et cognitives chez des personnes souffrant de sclérose en plaque : évaluation de la double tâche (MCS-IV-CMI&DTT)

Service de : NEUROLOGIE
Clinical unit

Chef de Service : Prof. P. MAQUET
Director of the clinical unit

Expérimentateur principal : X. GIFFROY
Principal investigator

Par décision collégiale, le Comité d'Ethique (voir liste des membres en annexe) :
By collegial decision, the Ethics Committee (see enclosed list of the members) :

Oui/Yes Non/No

■ estime que l'étude peut être réalisée
has accepted the performance of the study

Signature
Signature



Nom : Prof. V. SEUTIN Président
Printed name :

Date, *Date* :

5 octobre 2016

The Ethics Committee states that it is organized and operates according to the ICH/GCP guidelines, the applicable laws and regulations, and their own written operating procedures

Cette approbation ne signifie pas que le comité prend la responsabilité de l'étude.
This approval does not mean that the Ethics Committee takes the responsibility of the study

MEMBRES DU COMITE D'ETHIQUE MEDICALE
HOSPITALO-FACULTAIRE UNIVERSITAIRE DE LIEGE

Monsieur le Professeur **Vincent SEUTIN**
Pharmacologue, membre extérieur au CHU

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Monsieur le Professeur **Jean DEMONTY**
Interniste, CHU (B35)

Vice Président

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Pharmacien hospitalier, CHU

5 octobre 2016

Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège (707)



Sart Tilman, le 5 octobre 2016

Au Président du Comité d'Ethique
Maria Ziekenhuis Noord Limburg
Maesensveld, 1
3900 OVERPELT

Concerne :

N° belge : **B707201628796** ; Notre dossier : **2016-141**

Cher Collègue,

Après avoir examiné le dossier, les remarques des comités périphériques, les réponses du promoteur aux questions complémentaires éventuelles et les **ICF 4.0 fr et nl du 04/10/2016**, une réponse favorable est fournie à la demande d'avis intitulée :

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Protocole : ***MCS-IV-CMI&DTT***

En conséquence, j'ai le plaisir de vous informer que votre Centre peut participer à cet essai clinique.

Prof. V. SEUTIN
Président du Comité d'Ethique

Cet accord n'est valide que dans la mesure où le comité responsable de l'avis unique est en possession du contrat financier signé par le promoteur, l'investigateur et l'autorité responsable de l'institution.

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Copie à la **Direction de l'AFMPS**

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Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège (707)



Sart Tilman, le 5 octobre 2016

Au Président du Comité d'Ethique
Nationaal Multiple Sclerose center
Vanheylenstraat, 16
1820 MELS BROEK

Concerne :

N° belge : **B707201628796** ; Notre dossier : **2016-141**

Cher Collègue,

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Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège (707)



Sart Tilman, le 5 octobre 2016

Au Président du Comité d’Ethique
Algemeen Ziekenhuis Klina
Augustijnslei, 100
2930 BRASSCHAAT

Concerne :

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Sart Tilman, le 5 octobre 2016

Au Président du Comité d'Ethique
Universiteit Hasselt
Campus Diepenbeek, Agoralaan gebouw D
3500 HASSELT

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Pharmacien hospitalier, CHU

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Ik/wij verlenen het wereldwijde auteursrecht voor de ingediende eindverhandeling:
Predicting habitual walking in persons with Multiple Sclerosis: associations with cognitive-motor interference, mobility, cognition and quality of life

Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij neurologische aandoeningen**

Jaar: **2018**

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Voor akkoord,

De Winter, Tessa