Informed consent form

Official title of the study :

Assessing perceptual accuracy for task-specific motor performance in individuals with multiple sclerosis.

EU number: B1152024000009

Client of the study: *Hasselt University, Martelarenlaan 42, 3500, Hasselt*

Name of study center: *The study will be conducted at Hasselt University, Noorderhart Rehabilitation & MS and National MS Center Melsbroek.*

Main address study center:

Hasselt University: REVAL, Science Park 7B-3590 Diepenbeek

Noorderhart rehabilitation & MS: Boemerangstraat 2, 3900 Pelt

National MS Center Melsbroek: Vereeckenstraat 44, 1820 Melsbroek

Study at a glance:

For someone with multiple sclerosis, walking and standing up from a sitting position are daily activities. Even if your limitations are mild, you might notice that you walk more slowly and/or that it takes more energy. You might also notice changes in your walking style, both in how you move and the quality of your movements. During prolonged walking tests, such as the 6-Minute Walk Test, you might experience a discrepancy between how you feel and what you actually do. This could potentially be related to multiple sclerosis-related symptoms, such as fatigue.

When performing movements, our brain uses various signals to determine how well we perform. The accuracy of perceiving these signals can vary depending on several factors, such as the part of the body being used and the activity being performed. It's important to measure the accuracy of movement perception in a way that's appropriate for the specific task being performed, for example, by measuring how well someone can detect subtle changes in their movements.

This research focuses specifically on walking and standing from a sitting position, as these activities are crucial for daily functioning. Their perception accuracy will be measured while performing these tasks using motion-recording devices. This will help them better understand how multiple sclerosis affects motion perception.

Overview of changes to the document

Not applicable; this is a first submission.

Who can I contact if I have questions?

Name	Function	For	Contact details
Professor Dr. Feys Peter	Principal Investigator , PhD	Information, problems, concerns	Prof. dr. at the Faculty of Rehabilitation Sciences at UHasselt peter.feys@uhasselt.be +32 11 29 21 23
Gianluca Florio	Study staff	Information, problems, concerns	PhD student at the Faculty of Rehabilitation Sciences, UHasselt gianluca.florio@uhasselt.be +32 11 26 84 35
Noorderhart Rehabilitation & MS: Dr. Griet Gysemberg National MS center Melsbroek: Prof. Daphne Kos	Contact for urgent cases	Emergency during testing in the centers	Noorderhart Rehabilitation & MS: +32 (0) 11 80 92 23 National MS Center: +32 (0) 25 97 80 42
	Ombudsperson patient rights	Concerns about your rights as a study participant	Secretariat of the Committee for Medical Ethics UHasselt : cme@uhasselt.be Noorderhart Rehabilitation & MS: ethisch_comite@noorderhart.be National MS center Melsbroek: ombudsdienst@mscenter.be ; 02 597 88 09
Allianz Global Corporate & Specialty SE Branch Office Belgium	Client's insurance company	Dispute or complaint about a claim for damages	Allianz approved and added Allianz Global Corporate & Specialty SE Branch Office Belgium Expansion Street 86 - B-2600 Berchem 72770 Tel. +32 3 304 16 00

			Fax +32 3 304 16 99
	Data Protection Officer of the **Study Center**	Questions about the confidentiality of your data	UHasselt : privacy@uhasselt.be dpo NMS: dpo@mscenter.be or 02 597 80 03
	Belgian Data Protection Authority t	Complaints about the confidentiality of your data	E-mail: contact@apd-gba.be

Version number: 2

CHAPTER I - DESCRIPTION OF THE STUDY AND YOUR RIGHTS WHEN PARTICIPATING

The study consists of three parts and is carried out over three days: 1) Clinical examination; 2) Part A = Feeling of bodily sensations while performing motor tasks, at own pace and 3) Part B = Feeling of bodily sensations at imposed speeds and seat height.

1) Clinical examination : In this session, we will assess whether you meet the requirements to participate in this study (see p. 9 for inclusion criteria). If you are included in the study, you will first be asked for information such as gender, age, body mass index, employment status, year of diagnosis (if applicable), and use of a walking aid. You will also be asked to complete several questionnaires about physical activity, self-efficacy, sensitivity and attention to neutral and unpleasant bodily sensations, interoceptive perception, awareness of symptoms in daily life, falls, walking ability, fatigue, anxiety and depression, and sleep quality. You can complete the questionnaire at home and bring it to the next session (Part A). If you have any questions about how to complete the questionnaire or if you do not want to complete any of the questionnaires, you can leave them blank. Please inform the research staff about this during the next session.

Mental functions are assessed using the Symbol Digit Modalities Test and the Revised Brief Visuospatial Memory Test. Maximum walking speed is measured using the Timed 25-foot Walk Test (7.62 meters), balance, and sensory function are measured using force plates. Walking endurance is assessed using the 6-minute walk test. Lower extremity strength and coordination are measured using the 30-second Chair Stand Test. The Visual Analogue Scale for Fatigue is administered after completing both the 6-minute walk test and the 30-second Chair Stand Test.

After the screening, there will be an introduction to the research procedure. The research procedure is explained in more detail below.

2) Part A 'Sense of body sensation while performing motor tasks at own pace' : In this part two different movement tasks are performed: i) the 6-minute walk test and ii) sit-to-stand movements.

i) *Accuracy of perception of walking speed variations during the 6-minute walk test* : In this section, you will perform the 6-minute walk test. It will test whether you can perceive changes in speed at a self-selected walking pace. Before and after the 6-minute walk test, your fatigue will be assessed using the visual analog scale (Figure 1). After the test, you will be asked a short questionnaire: on a scale of 0-100, how confident are you that you have detected variations in your walking speed?

ii) *Accuracy of observation for variations in sit-to-stand duration during repeated sit-to-stand posture changes* : You perform the sit-to-stand exercise on a chair without

armrests. This section tests whether you can detect changes in duration at a self-selected speed. A 20-minute rest period is provided between the two tasks.

This is followed by a similar questionnaire as described for the 6-minute walk test.

3) Part B "Perception of bodily sensations at imposed speeds and chair heights" : In this part, two different tasks are performed: i) walking on a treadmill at different imposed speeds and ii) repeated posture changes from sitting to standing with variations in chair height.

i) *Accuracy of observations for imposed speed variations while walking on a treadmill* : You will start with a practice phase where your personalized speed range is determined. Then, the test phase begins: the speed will be slightly adjusted at random intervals. The treadmill test lasts a total of 6 minutes, similar to the 6-minute walk test. Every 10 seconds, you will be asked to rate your speed on a scale of 0 to 100.

Fatigue is assessed before and after the test using the visual analog fatigue scale (Figure 1). After the test, a short questionnaire is asked: on a scale of 0-100, how confident are you that you detected variations in walking speed?

ii) *Accuracy of observations for mandated chair height variations during repeated sitting-to-standing posture changes* : In this section, the sit-to-stand test is performed on a height-adjustable chair without armrests. This allows the researchers to examine your bodily sensations of the mandated height variations from sitting to standing. The chair height is set at 120% of your lower leg length. As you stand, the chair height is adjusted. This is followed by a similar questionnaire as described for the treadmill test.

1. Why are we doing this study?

Many people with MS experience difficulty walking and standing. Sensory and cognitive problems can also occur, making it difficult to perceive bodily sensations.

Our brains form a picture of what we perceive by combining new information with what we already know. In people with MS, this information can be less accurate, affecting their perception of the world around them. This can make it harder to adapt to new situations, which can lead to problems with daily activities and participating in physical activities.

When performing movements, our brains use information from both inside and outside our bodies, as well as signals from within the body, to determine how well we perform. All this sensory information is first combined into our internal image of the body, after which we assess how effectively we are performing a task.

The aim of this study is to investigate the accuracy of bodily sensation perception in individuals with MS compared to those without MS. The accuracy of bodily sensation perception will be assessed during walking and during sit-to-stand (standing from a chair), two important tasks frequently encountered in daily life.

The results of this study may reveal specific deficits in the MS population and will help define tailored exercise interventions.

2. Why am I being asked to participate?

You have MS . You are being asked to take part in this study because MS can cause you to have difficulty feeling bodily sensations when walking and standing up from a sitting position.

The other option is that you've been invited to participate in this study as a control, meaning you're someone without a diagnosis of MS, but with a similar age and gender. This is important for providing reference values for the tests for comparison.

The researcher or study staff will discuss with you the conditions for participating in this study.

3. Should I participate in a study?

Your participation in a study is voluntary and should never be done under pressure. This means you have the right not to participate. You may also withdraw at any time without giving a reason, even if you have previously agreed to participate. Your decision will not affect your relationship with the researcher or your treating physician, nor the quality of your future medical care.

4. What will happen during the study?

Your participation in the study means you will be asked to attend three sessions over three days. All sessions will take place at the MS center where you are being treated and/or at Hasselt University, REVAL. Approximately 40 people with MS and 40 healthy controls will participate in this study .

Figure 2 provides a summary of the study. After providing your consent, you will complete several questionnaires and perform some clinical tests. This will be followed by an introductory phase with the study procedure. Afterward, you will participate in Part A and Part B.

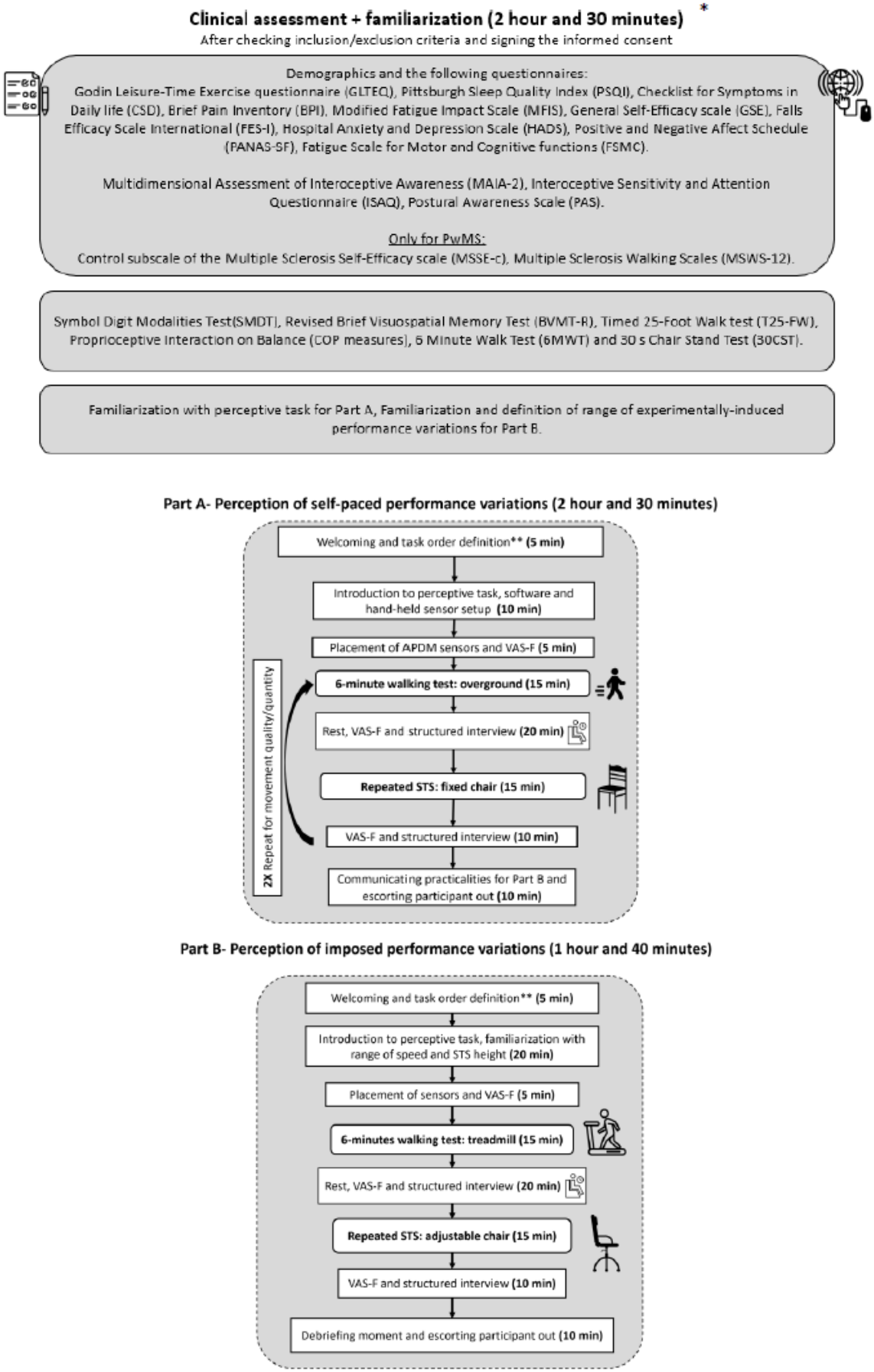

Figure 2: Experimental design of the study. STS = Sit-to-stand, COP = Center of pressure

Do you meet the conditions?

Inclusion criteria for persons with MS:

- Age between 18 and 70 years old
- A diagnosis of MS (2017 revised version of McDonald's criteria)*
- The ability to walk for 6 minutes without rest and without a walking aid
- The ability to perform the sit-to-stand and stand-to-sit positions on a standard chair (height is 43 cm), without hand support

Exclusion criteria:

- Cognitive impairment, which results in a failure to understand the study instructions
- Pregnancy. If you're unsure whether or not you're pregnant, we offer a free pregnancy test.
- Acute and subacute (<1 month) lower limb musculoskeletal disorders (not related to MS)
- Cardiovascular red flags for physical activity (assessed with the Physical Activity Readiness Questionnaire)
- Other diagnosis of neurological or metabolic disorders that limits the full performance of the tests
- A relapse less than 1 month before the start of the study*

All criteria except those marked with * also apply to the healthy controls

Research procedure:

If you meet all the eligibility requirements and decide to participate in the study, you will complete the following tests. After you have signed your consent, your age and gender will be recorded. In addition, for participants with MS, MS-related information such as EDSS, type of MS, and the number of years since diagnosis will be provided by the MS centers or requested from you (if applicable).

A more detailed description of all tests:

Clinical research method

You will receive the following questionnaires to complete at home and bring back to the next session:

- Physical activity : Goddess Leisure- Time Exercise questionnaire (GLTEQ)
- Sleep Quality: Pittsburgh Sleep Quality Index (PSQI)
- Self-Perception of Self-Efficacy: General Self-Efficacy scale (GSE)
- Self-perception of the different dimensions of interoception : Multidimensional Assessment of Interoceptive Awareness (MAIA-2)
- Interoceptive signals : Interoceptive Sensitivity and Attention Questionnaire (ISAQ)
- Symptoms in Daily Life: Checklist for Symptoms in Daily life (CSD)
- Awareness of body position: Postural Awerenes Scale (PAS)
- Pain symptom recording: Brief Pain Inventory (BPI)
- Falling : Falls Efficacy Scale International (FES-I)
- Anxiety and depression : Hospital Anxiety and Depression Scale (HADS)

- Positive and negative effects : Positive and Negative Affect Schedule (PANAS-SF)
- Fatigue : Fatigue Scale for Motor and Cognitive functions (FSMC) and Modified Fatigue Impact Scale (MFIS)

Only for people with MS:

- Self-efficacy for persons with MS: control subscale of Multiple Sclerosis Self-Efficacy scale (MSSE-c)
- Self-Reported Impact of MS on walking: Multiple Sclerosis Walking Scale (MSWS-12)

Cognitive functions are assessed using the Symbol Digit Modalities Test and the Revised Brief Visuospatial Memory Test. If you are contacted through the rehabilitation center, the center will provide us with the results of these tests, with your consent. Maximum walking speed is measured using the Timed 25-foot Walk Test (7.62 meters), balance and proprioception are measured using force plates, and walking endurance is measured using the 6-minute walk test. Lower limb strength and coordination are measured using the 30-second Chair Stand Test. After completing both the 6-minute walk test and the 30-second Chair Stand Test, the Visual Analogue Scale for Fatigue is administered (Figure 1).

Figure 1: 10-point visual analog fatigue scale

Method Part A: Feeling of bodily sensations while performing motor tasks at your own pace

First, the perception task (6-minute walk test and sit-to-stand) will be introduced. After this, the software and sensors will be explained. After the introduction, the 6 sensors (OPAL V.2, APDM, USA, https://www.apdm.com/wearable-sensors/) and a chest strap with a POLAR (https://www.polar.com/be-nl/products/heart-rate-sensors) heart rate sensor attached to measure your walking speed and heart rate.

Two sensors are placed on your feet and lower legs, and one around your torso and sternum (see figures 3 and 4). The sensors pose no risk or pain. After placing the sensors, you perform the 6-minute walk test. If you notice a change in your walking speed, you press the button you carry in your hands. Pressing this button registers your physical sensations related to your walking speed. The 6-minute walk test course is 30 meters long, with a turn at each end.

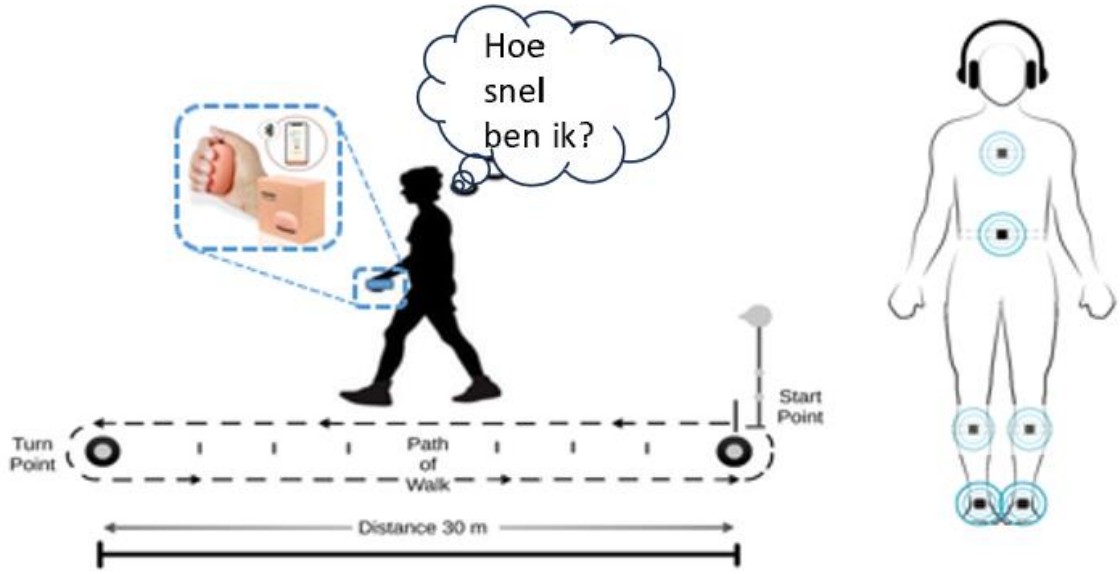

Figure 3: Perception accuracy of gait speed variations during overground 6MWT: Illustration of task 1, wearable placement, and graphical illustration of perception versus performance

After completing the 6-minute walk test, a 20-minute rest period is provided. This is followed by the sit-to-stand task, in which participants stand up repeatedly for 6 minutes and then sit back down after ten seconds. If they notice any changes in speed while standing, the participant presses the button.

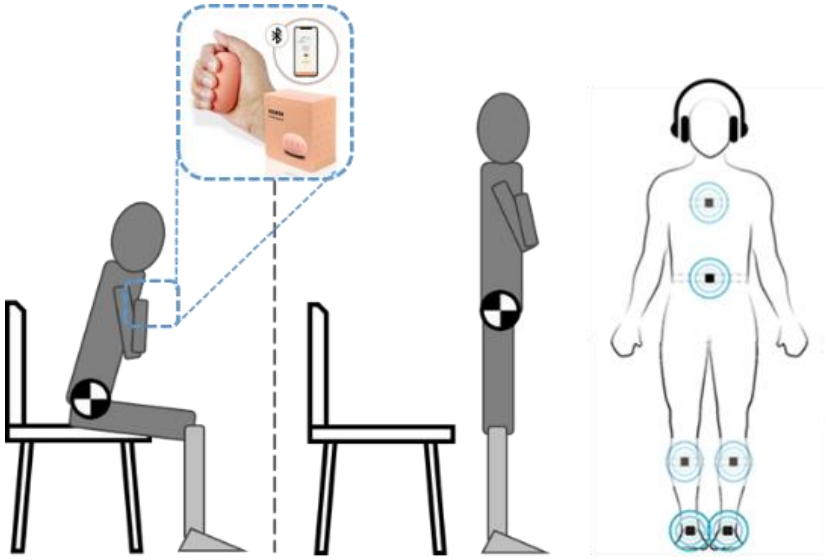

Figure 4: Perception accuracy for STS duration variations during repeated STS postural transitions: Illustration of task 2, wearable placement.

Fatigue is assessed before and after the 6-minute walk test and the sit-to-stand task using the visual analog fatigue scale (Figure 1). After each test, a short questionnaire

is given: on a scale of 0-100, how confident are you that you detected variations in walking speed?

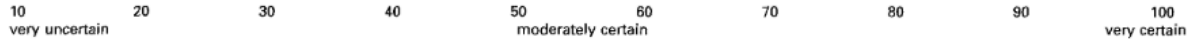

Figure 5: Visual scale for confidence rating: subjective beliefs about their observational accuracy

Method Part B: Feeling of bodily sensations at imposed speeds and seat heights

You'll begin with an introduction to the perception tasks: the 6-minute walk test on the treadmill and the sit-to-stand test. You'll then be introduced to the treadmill's speed range. After this introduction, six sensors will be placed on your body, following the same principle as the 6-minute walk test in Part A.

Next, you'll start the 6-minute treadmill walk test. During this test, the speed will be adjusted randomly. You'll need to rate the changes in speed on a scale from 0% to 100% (Figure 6), with 0% representing your comfortable treadmill walking speed and 100% representing your maximum speed. After the test, you'll have 20 minutes of rest, followed by the sit-to-stand section.

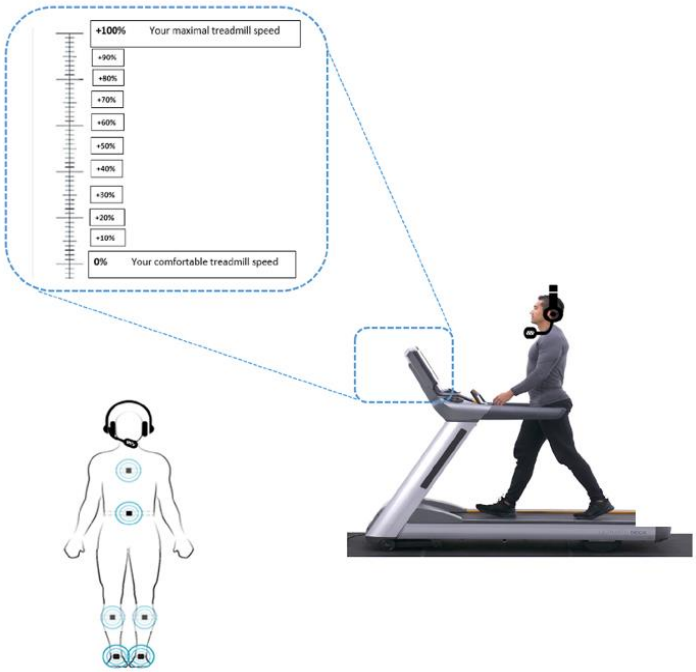

Figure 6: Perception accuracy for imposed speed variations during treadmill walking: Illustration of task 1, wearable placement, zooming in on an example imposed speed pattern.

This part of the sit-to-stand test begins with an introduction. This is followed by a familiarization with the height of the chair for the sit-to-stand test, similar to the familiarization phase for the treadmill. The chair height is adjusted based on the length of your lower leg.

After the introduction, the actual test follows. The chair is set at the base level (120% of your lower leg length). You are expected to indicate the chair height on the scale.

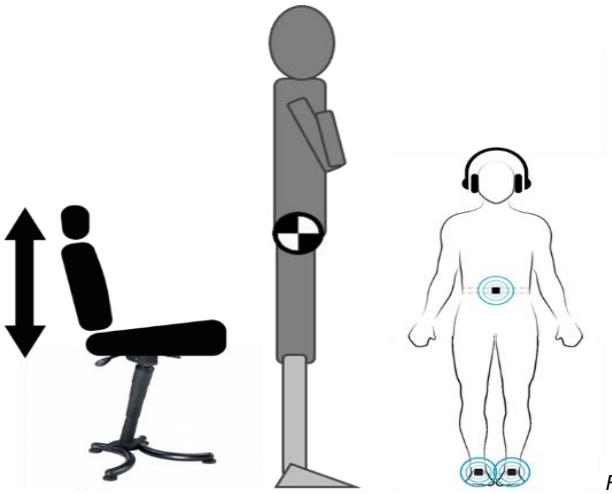

Figure 7: Perceptive accuracy for imposed seat height variations during STS postural transitions: Task 2 illustration, wearables placement, and Perception vs. Performance plot graphic illustration. The same question as in Part A is asked after both the 6-minute treadmill walk test and the sit-to-stand test.

5. Will I benefit from the study?

The information obtained during the study may contribute to a better understanding of perception during walking and standing up from a chair in persons with MS.

6. What are the possible risks and discomforts of participating in the study?

6.1. What are the possible risks or discomforts of the examinations during the study?

The tests during the study may cause minor discomfort and risks: it may be uncomfortable to walk with the sensors because you can feel the Velcro . There is a risk of falling during the 6-minute walk test. This will be minimized by researchers with medical backgrounds walking alongside the participant if a fall risk is identified.

There is a risk of falling while walking on the treadmill. Appropriate safety measures are implemented to address this. For example, the safety key is attached to the participant's clothing. This will cause the treadmill to shut down if there is a problem. The examiner is positioned behind the participant and is always present so the patient can speak with the examiner.

Prolonged walking during the tests may cause fatigue and a decrease in your running performance, but this is only temporary.

6.2. other) medicines during the study ?

Yes, you can take your usual medication. For further clarification, see 6.1.

6.3. Will my participation in the study affect my daily activities ?

No.

7. What if something goes wrong during my studies?

Even in the absence of fault, the sponsor is liable for any damage you suffer that is directly or indirectly related to your participation in the study. The sponsor has taken out insurance to cover this liability (with " NO-FAULT " LIABILITY) [1]. A copy of the insurance certificate can be obtained from the investigator or study staff. The study is insured by Allianz Global Corporate & Specialty SE - Belgium Branch .

If you (or your heirs, if you die) wish to receive compensation for any damage you suffer as a direct or indirect result of your participation in the study, you must inform the researcher or study staff as soon as possible.

If the researcher believes there is a possible link between new or worsening health complaint(s) and the study, they will report this to the study sponsor. The sponsor will then immediately file a claim with their insurance company. If the company deems it necessary, they will appoint an expert to assess whether there is a link between your reported health complaint(s) and the study. Insurance does not cover the natural progression of your illness/condition or the known side effects of the treatment you would have received without participating in the study (this is your standard treatment).

If you deem it necessary, or in case of disagreement with the investigator or the insurance company's expert, you or your heirs can contact the insurer or, if necessary, summon them. You can find the contact information on the cover page of this form.

8. What if other rehabilitation strategies for walking and sit-to-stand activities, or new information about the rehabilitation strategy, become available during the study?

During the course of the study, new, important information may become available . For example, alternative treatments for your condition or important new information about rehabilitation may become available. It is the researcher's responsibility to discuss this new information with you and give you the opportunity to reconsider your participation in the study.

If you decide to end your participation in the study or if you can no longer participate, your researcher will ensure that you continue to receive the best possible treatment.

9. Can my participation in the study end early?

As discussed further in this section, you may end your participation in the study early if:

- you decide to withdraw your consent,
- the researcher decides to stop your participation in the study, or

[1]This is in accordance with Article 29 of the Belgian law of 7 May 2004 on experiments on humans and the applicable royal decrees.

- other authorities interrupt or terminate the study.

The client may continue to store and use data collected before your participation ends. This is to prevent misinterpretation of the study results (as described in section I.§ 11.4, page 15) .

If you experience a new side effect after completing your participation in the study, you may contact the researcher and request follow-up.

9.1. You decide to withdraw your consent

You have the right to withdraw your consent without giving a reason. However, for your own safety, you must inform the researcher of your decision. Although it's not mandatory, it can be helpful for both the researcher and the sponsor to know the reason for your decision (e.g., side effects, excessive travel, etc.).

If you withdraw your consent, this means that you decide to stop all consultations and examinations associated with the study.

Please discuss the practicalities of stopping your participation with the researcher (depending on your situation), including your further follow-up.

Under no circumstances will any new data be provided to the client.

9.2. The researcher decides to stop your participation in the study

The researcher may terminate your participation in the study because

- it is better for your health,
- he/she experiences that you are not following the instructions given to the participants, or
- there is another reason which will be explained to you.

9.3. Other authorities may interrupt or terminate the study

The sponsor and the competent Belgian health authorities may interrupt or terminate the study for a reason to be explained by the authority concerned.

10. Will my participation in the study incur additional costs for me?

10.1. Research and treatments paid for by the client

Participation in this study will not incur any additional costs for you. Therefore, you will not be charged for the research specifically for this study.

11. What information will be collected about me during the study and what will happen to it?

11.1. What data is collected and processed during the study?

The personal data collected and processed relates to your health and medical condition, including your medical history, some of your background information (e.g. your age, gender and ethnic origin) and the results of the study examinations.

11.2. How will the researcher handle my personal data?

The researcher is bound by professional secrecy when collecting and processing your data.

This means that he/she will never reveal your identity, not even in a scientific publication or a lecture, and that he/she will code your data (i.e. replace your identity in the study with an identification code) before sending them to the client.

Therefore, the researcher and the study staff under the researcher's responsibility will be the only ones who will be able to link your identity to the data provided during the study, with the exceptions mentioned in § 11.6.

The data that the client receives will therefore not enable him to identify you.

11.3. What will happen to the information about me collected during the study?

Your participation in the study means that your personal data

- are collected by the researcher, and
- used in coded form by the client of the research.

The researcher and the client may only use the coded personal data for research purposes in connection with scientific publications within the framework of the study in which you participate.

If wider use of the coded data is planned, this will be stated below.

Furthermore, the sponsor may grant external researchers (who are not involved in this study) access to the coded data. If an external researcher wishes to use the data in research not yet described in this document, the research must be approved by an Ethics Committee. If your coded data is sold, you will not receive compensation.

11.4. How will my data be processed?

Your study data will be processed in accordance with the General Data Protection Regulation (GDPR) (Ref. [2]) and the Belgian Data Protection Act of 30 July 2018 (Ref. [3]). The client is responsible for this.

The reason why we are allowed to process your personal data is that we conduct scientific research and

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[2]General Data Protection Regulation No 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

[3]Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

- that you **have given permission** .

11.5. Do I have access to my data collected and processed during the study and can I correct it?

You have the right to ask the researcher what data is collected about you and what it is used for in this study.

You have the right to

- to access and review this data,
- to have all your data deleted,
- to receive the collected personal data,
- to ask for correction if they are not correct,
- to limit the processing of your data,
- to object to the processing of your personal data,
- to withdraw your consent to the processing of personal data.
- Your personal data collected before your withdrawal will be retained to avoid misinterpretation of the study results.

11.6. Who other than the researcher and his staff has access to my personal data?

To monitor the quality of the study, your unencrypted personal data or information relevant to this study from your medical file may be inspected by people other than study staff. This inspection will be supervised by the researcher, and these individuals are bound by professional secrecy or a confidentiality agreement.

If necessary for the study, the coded study data may be sent to other countries within and outside the European Union (EU) and reviewed by:

- the Belgian Evaluating Ethics Committee(s),
- external researchers, and/or
- the client for the study, staff designated by the client, and people or organizations that provide services to or collaborate with the client.

You can always contact your researcher for more information about such transfer.

11.7. What will happen with the results of the study?

After the study is completed, a description and the results of the study will be published in specialized medical journals. A copy of the scientific publication is available from the investigator or study staff.

A description of the study will also be available online at the clinical trials archive. You can access this study using the study number found on the cover of this document. A

summary of the results will be available on the websites within one year of the study's completion (Ref. [4]).

These websites or publications will not contain any information that could identify you.

11.8. Will my data be used for purposes other than the study I am participating in?

The results of the study will only be used to answer the scientific questions in this study.

Any additional or future research outside the study must always be approved by a recognized Belgian Ethics Committee.

You agree or disagree to the use of your study data for other purposes by checking the appropriate box in Chapter II, page 20.

11.9. How long will my data be retained?

After the study ends, your coded data will be retained for at least 25 years (Ref. [5]) to ensure the validity of the research. This will also be the case if you stop participating prematurely.

12. Who reviewed and approved the study documents?

The study documents were reviewed by:

- The central ethics committee of Hasselt University and the local ethics committees of the Multiple Sclerosis Centers: Noorderhart Rehabilitation, National MS Center Melsbroek.

The competent health authorities and ethics committees are responsible for protecting the individuals participating in a study. The competent health authorities will ensure that the study is conducted in accordance with applicable legislation.

You should not construe their approval as an incentive to participate in the study.

13. What happens in the case of accidental discoveries?

A result that happens to occur during the study and in addition to the study objectives is called an incidental finding. If this result could be important for your health or that of your relatives, the sponsor will inform the researcher. With your consent, the researcher will inform you and your treating physician of your results and any potential consequences.

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[4] In accordance with Chapter 4.3. of the Commission Directive: Guidelines for the posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 - 2012/302/03.

[5] In accordance with Article 58 of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

If necessary, the researcher and/or treating physician will advise you on what to do. You can indicate whether or not you agree to be informed by checking the appropriate box in Chapter II on page 20.

CHAPTER II - INFORMED CONSENT

PARTICIPANT

REQUIREMENTS FOR YOUR PARTICIPATION IN THE STUDY

- I declare that I have been informed about the purpose of the study, its duration and consequences, potential risks and discomforts, the precautions I must take, and what is expected of me, and that I have understood all of this. My rights as a study participant have been explained to me and I understand them.
- I have had sufficient time to think about it and discuss it with a trusted person (e.g. friends, family, treating physician, etc.).
- I was given the opportunity to ask all the questions that came to my mind and I received satisfactory answers.
- I understand that I will participate in this study voluntarily and without being forced to do so, and that I may discontinue my participation in the study at any time.
- I understand that data about me will be collected and that it will be treated confidentially.
- I agree that my personal data will be processed as described in Chapter I, § 11 pages 14 - 17.
- I understand that the client has taken out insurance in case I suffer any loss in connection with my participation in this study.
- I understand that I will not incur any costs for participating in this study, unless these are for the standard treatment of my illness.
- I agree that my treating physician(s) will be informed of my participation in this study.
- I agree that I will not participate in another study simultaneously without informing the investigator or study staff, and that they may refuse this participation for justified reasons.
- I understand that I must cooperate and follow the instructions of the researcher and study staff regarding the study.
- I understand that my participation in the study may be terminated without my consent if I require alternative treatment, do not follow the study schedule, have a study-related injury, or for any other legitimate reason.
- I confirm that all information I have provided regarding my medical history is correct. I understand that failure to inform or point out potential exclusion criteria to the researcher may cause me harm.

OPTIONAL CONSENTS THAT ARE NOT ABSOLUTE CONDITIONS OF YOUR PARTICIPATION IN THIS STUDY

1. As mentioned in Chapter I, § 1 1.8 , page 17, the client would like to receive your study data intend to use it for other research and development activities (and related scientific publications). These research objectives must be approved by a recognized Belgian Ethics Committee.

   Do you agree that your data obtained in this study will be used for further research within this domain?

   (Check the appropriate box; if you leave this question blank, we'll assume the answer is "I disagree.")

☐ **I agree**	☐ **I do not agree**

2. Do you agree to be informed about other studies concerning rehabilitation research by the principal investigator or research associate ?

   (Check the appropriate box; if you leave this question blank, we will assume the answer is "I disagree.")

☐ **I agree**	☐ **I do not agree**

3. Would you like to receive the results after completing your study?

   (Check the appropriate box; if you leave this question blank, we'll assume the answer is "Yes, I want to be notified.")

☐ **No, I do not want to be notified**	☐ **Yes, I want to be notified**

I agree to participate in the study, with the above restrictions, and I have received a signed and dated copy of all pages of this document.

Participant's first and last name:

Date (DD/MMM/YYYY):

Time:

Signature of the participant:

RESEARCHER

I, the undersigned researcher, confirm

- that the participant has been given the necessary information about the study orally, that the content has been explained to him/her and that he/she has been given an original signed version of this document.
- that I have checked whether the participant has understood the study.
- that I have given the participant sufficient time to think about his/her participation and to ask questions.
- that no pressure was exerted on the participant to agree to take part in the study.
- that I work in accordance with the ethical principles as stated in the most recent version of the "Declaration of Helsinki", the "Good Clinical Practices" and the Belgian law (Ref. [6]).

Name and surname of the researcher's representative:

Role of the researcher's representative:

Date (DD/MM/YYYY):

Time:

Signature of the researcher's representative:

Name and surname of the researcher :

Date (DD/MMM/YYYY):

Time:

Signature of researcher:

[6]Belgian law of 7 May 2004 on experiments on humans and the applicable royal decrees.

GLOSSARY

FAGG: Federal Agency for Medicines and Health Products

GBA: The Belgian Data Protection Authority ensures that personal data is used and secured with care, and that your privacy continues to be guaranteed in the future.

INSURANCE WITH "NO FAULT" LIABILITY :

The client is liable for any injury or damage to the participant directly or indirectly related to the study. You do not need to demonstrate fault in this regard.

MONITOR and AUDITOR:

Both the monitor and the auditor work for the client.
The monitor ensures continuous quality control throughout the study. The auditor conducts an investigation after the study is completed. They verify that the study is/was conducted according to the protocol, that the reported data are reliable, and that the study complies with applicable laws.

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