ChARM protocol

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"Evaluation of the impact of Slip Resistant Socks on Motor Recovery in the Elderly. *An* Open-Label, Single-Center, Randomized, Controlled *Pilot Study".*

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LIST OF ABBREVIATIONS

ANSM	Agence Nationale de Sécurité du Médicament et des Produits de Santé (French Agency for the Safety of Medicines and Health Products)
ARC	Clinical Research Associate (monitor)
BPC	Good Clinical Practice
PPC	Comité de Protection des Personnes
CNIL	Commission Nationale de l'Informatique et des Libertés (French Data Protection Authority)
CRF	Case Report Form (observation booklet)
eCRF	Electronic Case Report Form (cahier d'observation électronique)
MR	CNIL Reference Methodology
TEC	Clinical Study Technician

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INTRODUCTION

With advancing age, many patients lose their autonomy. This loss of autonomy can be increased during hospitalization, by the effect of the pathology itself, or by the effect of hospitalization. The aim of the rehabilitation team is to put in place tools to preserve patients' motor skills, through rehabilitation sessions and/or the use of appropriate equipment. In particular, they ensure that walking aids and footwear are adapted to the patient's clinical condition.

However, senior patients arriving on the medical ward do not always have adequate footwear. The teams in charge of these patients, including physiotherapists, are faced with the choice of either keeping the original footwear, or offering patients the option of walking barefoot. The choice of keeping the usual footwear is the most frequent.
For some time now, it has been possible to offer non-slip socks for walking around their wards. However, there is controversy in the scientific literature about the usefulness of these devices. In particular, it is impossible to transpose the results of studies to assess the benefits of these socks for senior citizens.

The aim of this study was to assess the effect of non-slip socks on motor recovery.

1. JUSTIFICATION FOR THE STUDY

1.1. Research positioning

1.1.1. Rational

In 2012, people aged 65 or over represented 17.1% of the population (16% in 2002), half of whom were aged 75 or over. This represents an increase of 45% in 20 years (INSEE, 2012). In 2015, 2.5 million seniors in France were losing their autonomy (INSEE, 2017). Among seniors aged 75 and over, 8.8% live in institutions (INSEE, 2017). The projection for 2050 is that 4 million seniors will lose their autonomy, i.e. 16.4% of all seniors (INSEE, 2017).

Frequently, the aging of sick or frail people undergoes physical deconditioning as a result of pathologies leading to hospitalization. Deconditioning is a psychophysiological process leading to physical inactivity. It is defined as "an amplifier of vulnerability, leading to situations of dependence and an altered quality of life**".** (Préfaut & Ninot, 2009) **.** Muscle mass, strength and power decline with age, and by the age of 80, older people have lost half their initial muscle mass (Professional Associations for Physical Activity, Sweden, 2010)

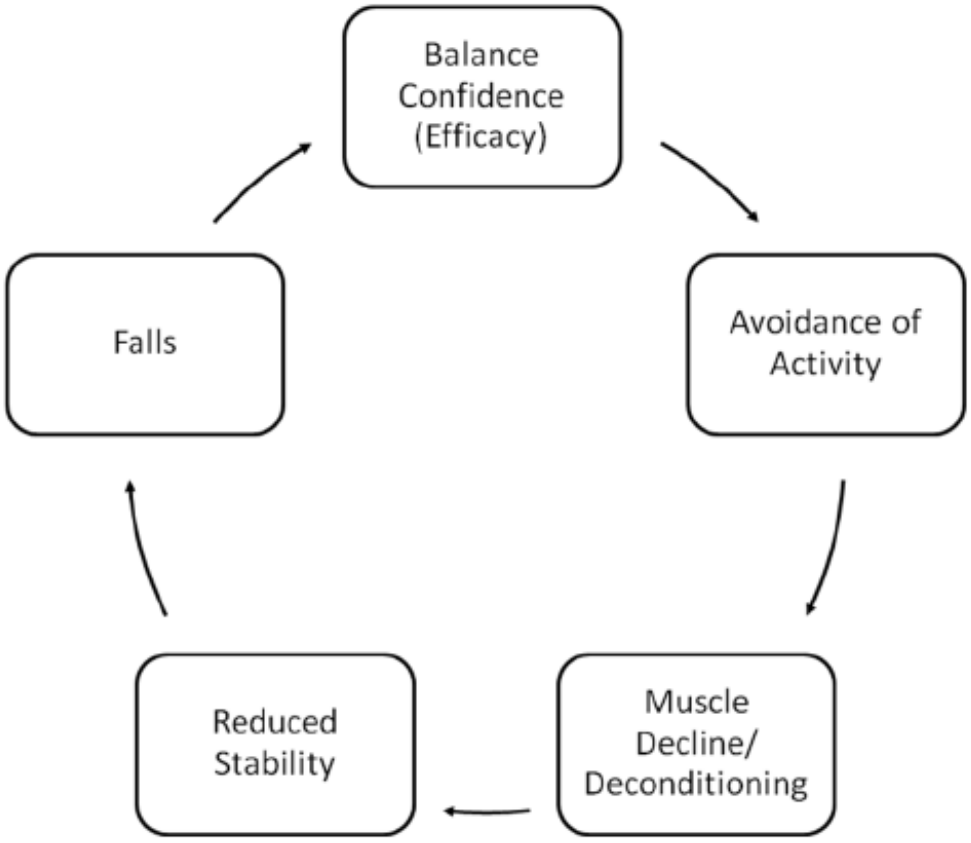


Figure 1: The vicious circle of deconditioning from Hadjistavropoulos et al (2011)

According to Hadjistavropoulos et al. (2011)a vicious circle of deconditioning exists in senior citizens. A fall leads to a fear of falling, which leads to activity restriction, which leads to

functional decline, which leads to reduced stability, which leads to an increased risk of falling (**Error! Reference source not found.**).

On arrival on short-stay wards, patients may be tired and/or confused, depending on the reason for their hospitalization. This physical deconditioning may be compounded by a lack of stimulation, which will be an aggravating factor, particularly in the first few days of hospitalization. Physiotherapists will be called in to help.

Physiotherapists will ensure that senior citizens maintain good motor skills. Walking, transferring, moving around their living space and carrying out activities of daily living are essential to maintaining quality of life in the living environment of their choice. (Assessment of motor skills will be developed later). In addition to the intention to move, an important skill for elderly people is motor planning. Motor planning is the necessary step in building the basis of the motor program. The musculoskeletal system's redundancy means that the subject chooses a "typical movement" from among many possible alternatives. This motor planning seems to be impaired in some frail elderly patients (Kubicki & Mourey, 2015).. In this mission to recover motor skills, the physiotherapist must restore patients' ability to walk safely (self-assessment) and securely (physiotherapist's assessment) as soon as possible. To achieve this, and depending on the physiotherapist's assessment, various technical aids are available (Temfemo & Ahmaidi, 2018). These aids include the simple cane, the tripod cane, English canes, walkers with or without wheels etc. The physiotherapist will also need to pay attention to footwear.

In fact, poorly adapted footwear may be experienced as unsafe and/or insecure by the team or the patient. Luk et al. (2015) offered a narrative review of fall prevention in the elderly. They advocate fall prevention interventions such as exercise, environmental modifications, or medication review. These authors also suggest taking an interest in patient footwear. They report on proposals to avoid high heels and use non-slip shoes, based on other studies (McKiernan, 2005; Menant et al., 2008).
The footwear worn by elderly subjects on geriatric wards has also been studied by several teams. Vass et al. (2015) examined and described the type of footwear worn by elderly patients in hospital. They show that many patients wear footwear with insufficient structure to promote optimal stability or gait. Among the various types of footwear, they found non-slip socks for subjects living at home, in an institution or in hospital (Menant et al., 2008; Vass et al., 2015). A recent narrative review looked at the use of anti-slip socks to prevent falls in elderly patients (Hartung & Lalonde, 2017). In their conclusion, the authors do not recommend wearing socks for patients coming from home with limitations on the studies selected. One important limitation is the external validity of the studies, which are partly based on basic research. The other part, from clinical research, is not specifically concerned with our reference population. As a result, it is not possible for us to recommend whether or not non-slip socks should be worn by hospitalized senior patients. However, the question does arise under specific conditions, which we will describe in detail below.

In clinical practice, in the short-stay wards of many hospitals, including CHD-Vendée, patients arrive from the emergency department with either no adapted footwear or no footwear at all. The emergency situation has brought them to hospital without giving them time to pack. In the case of direct hospitalization, a re-evaluation of footwear is also often necessary, in order to adapt footwear to the patient's situation. Other patients, particularly those with major cognitive impairment, who appear to be most at risk, regularly forget their shoes both during the day and at night. All in all, autonomy seems to be impaired by the absence of adapted footwear. When providing care (toileting, dressing, etc.), care assistants will move the patient into his or her chair, rather than having him or her walk to the toilet. In rehabilitation, the practitioner may choose not to take charge of a patient, or to offer partial care to avoid the risks associated with unsuitable footwear. The patient may be asked to walk on his or her own outside the rehabilitation program.

1.1.2. The aim of the study

All in all, we can see that anti-slip socks may be of clinical interest. The scientific literature presents studies with methodological limitations, but above all a different population from the one we are interested in. It is therefore not currently possible to assess the specific benefit of anti-slip socks in an elderly hospitalized population.

Evaluating the benefits of these socks could enable us to recommend them on the basis of solid data. Preventing this iatrogenic loss of autonomy would have a positive impact on patients' motor skills, a quicker and easier return home, and lower healthcare costs.

We'd therefore like to know the benefits of wearing anti-slip socks in the management of these patients, and more specifically on the main objective of rehabilitation in geriatric physiotherapy: motor function.

We believe that wearing non-slip socks improves patients' motor recovery.

1.2. Benefits and risks for research subjects

1.2.1. Benefits

1.2.1.1. Individual profit

Improved motor control
Improved practices with the use of non-slip socks

1.2.1.2. Group profit

Improved motor care for senior citizens, at a lower cost to society thanks to a shorter length of stay,
Improved motor management for faster discharge

1.2.2. Foreseeable risks and constraints

Constraints :
For both groups, the only constraint added by the research is the specific tests to be taken and the questionnaire to be filled in. Patients will also be asked to use a wheelchair if they leave the hospital ward.
For the experimental group, the additional constraint is the wearing of non-slip socks.

Foreseeable risks :
There is no increased risk associated with wearing anti-slip socks in senior patients.

1.2.3. Benefit/risk balance

This study qualifies as interventional research with minimal risks and constraints, as defined in article L1121-1 of the French Public Health Code. On the basis of all the above-mentioned information, the benefit-risk balance of this study is favorably assessed.

2. OBJECTIVES AND JUDGING CRITERIA

2.1. Objective and primary endpoint

2.1.1. Main objective

Assessing **the impact of anti-slip socks on motor recovery** in the elderly during hospitalization

2.1.2. Primary endpoint

Evolution of **walking speed at the patient's preferred speed over 10m** between D1 (start of physiotherapy treatment) and D8. Two tests will be performed at each assessment, and the average of the two tests will be used.

2.2. Objectives and secondary endpoints

2.2.1. Secondary objective(s)

1. Assessing the impact of anti-slip socks on short-term motor skills
2. Evaluate the impact of anti-slip socks on motor planning in the short term and during hospitalization
3. Evaluate the impact of wearing socks on dual-task abilities in the short term and during hospitalization
4. Evaluate the evolution of fear of falling with the use of socks in the short term and during hospitalization.
5. Evaluate the impact of socks on the presence of fall(s)
6. Length of stay in geriatric care or post-emergency medicine

2.2.2. Secondary endpoints

1. Change in 10m walking speed between D1 (start of physiotherapy treatment) and D1' ("after a 3-minute walk with the shoe assigned following randomization"),
2. Evolution of isochrony between the speed of walking actually performed and the speed of walking imagined over 10m at D1, D1' and D8. The mean of two tests of each modality will be used.
3. Evolution of isochrony between walking speed and double-task walking speed over 10m at D1,D1' and D8 (Beauchet et al., 2010; Menant et al., 2014). The mean of two tests of each modality will be used.
4. Total score > 10 on the Short-Falls Efficacy Scale International questionnaire at D1, D1' and D8
5. Presence of fall(s) and their consequences during hospitalization
6. Length of stay calculated from start of hospitalization to end of hospitalization

3. STUDY POPULATION

3.1. Description of the population

This study is aimed at patients admitted to the CHD Vendée in Post-Emergency Medicine and Geriatric Short Stay who require physiotherapy treatment.

3.2. Inclusion criteria

- Patient in Geriatric Short Stay or Post-Emergency Medicine,
- Patient aged 75 and over,
- Patient requiring physiotherapy,
- Patient with at least 7 days of physiotherapy treatment
- Patient arrives with unsuitable footwear (assessment at clinician's discretion: no back support, unsuitable size, etc.) or no footwear at all,
- Patient able to walk at least 10 m with or without technical aids,
- Patient with oral consent
- Patient with social security coverage.

3.3. Non-inclusion criteria

- Inability to understand or perform clinical tests specific to the study
- Known cognitive impairment, disease or condition that compromises comprehension of information or informed consent by the patient
- Blind patient
- Patients under guardianship or trusteeship
- Patient participating in an interventional clinical research protocol likely to modify the assessments of the present protocol.
- Patient previously included in the Charm study
- Patient with identified risk of being unable to wear socks or go barefoot within the next 7 days (need for compression stockings or socks, wound, excessive edema, orthostatic hypotension, other).

The investigator/qualified person, or a person designated by the investigator/qualified person, must keep an up-to-date list of patients not included throughout the study. This list should include all patients from the population who do not meet the eligibility criteria. The list should also indicate, for each patient, the reason for non-inclusion in the study.

4. DESIGN AND STUDY PROCESS

4.1. Study schedule

4.1.1. Inclusion and baseline tests (J1)

Patients arrive on the ward and are assessed by the doctor, who prescribes physiotherapy if necessary.
The physiotherapist takes note of the prescription on the first working day thereafter. The physiotherapist carries out a routine analysis of the patient's footwear. If the footwear is unsuitable, or if the patient is barefoot, the physiotherapist checks the patient's eligibility criteria. If the patient meets these criteria, he or she is informed of the study. If the patient gives oral consent, the physiotherapist will perform the Baseline tests (D1).

Baseline: J1 tests

The physiotherapist assesses the patient during the first diagnostic session, and performs the *Confusion Assesment Method* if it has not been done in routine practice.

A Visual Analogue Fatigue Assessment will be carried out prior to clinical testing.

For research purposes, the **J1** tests will be performed barefoot:

1. Patient's walking speed over 10 m (2 times)
2. Walking speed in dual-task situation over 10 m (2 times)

Two other less common but validated assessments in this population will be carried out.

3. Imagined walking speed over 10 m (2 times)

The average of each of the two tests will be used for items 1 to 4.
Together, these tests take the patient around 10 minutes.

4. Short-Falls Efficacy Scale International Questionnaire

4.1.2. Randomization

Once the tests have been carried out, randomization will be carried out by the physiotherapist.

Randomization arm :

- **Control arm: usual care with bare feet.**
- **Experimental arm: specific management with non-slip socks.**

Depending on the randomization arm, the physiotherapist will put non-slip socks on patients in the experimental arm and leave patients in the control arm barefoot. He will then encourage the patient to walk for 3 minutes.

4.1.3. J1' follow-up

After these 3 minutes of walking with or without the socks, depending on the randomization arm, and in order to assess the immediate effect of wearing anti-slip socks on motor skills, the patient will perform the same tests as on D1, in the same order.

A Visual Analogue Fatigue Assessment will be performed prior to the following clinical tests:

1. Patient's walking speed over 10 m (2 times)
2. Walking speed in dual-task situation over 10 m (2 times)
3. Imagined walking speed over 10 m (2 times)

The tests will be carried out by the patient with bare feet (control arm) or with non-slip socks (experimental arm).

4.1.4. Patient care procedures during the stay

Following this second evaluation and for the duration of hospitalization, socks will be left on patients in the experimental arm, and patients in the control arm will remain barefoot. A notice will be posted in the patients' rooms to inform the nursing teams so that the randomization arm is respected.

Between D1' and D8, the patient will undergo rehabilitation according to a pre-established plan based on the conclusions of the BDMK. The patient will benefit from 3 sessions, the first of which includes the assessment on D1.

4.1.5. Follow-up J8

At D8, in order to assess the effect of socks on motor preservation/recovery, the patient will be reassessed under the same conditions as at D1, i.e. barefoot, using the same tests as at D1 and in the same order.

A Visual Analogue Fatigue Assessment will be performed prior to the following clinical tests:

1. Patient's walking speed over 10 m (2 times)
2. Walking speed in dual-task situation over 10 m (2 times)
3. Imagined walking speed over 10 m (2 times)
4. Short-Falls Efficacy Scale International Questionnaire

Study schedule

Actions	J1	J1' (after 3 minutes of free walking)	J8	Hospital discharge
Patient information	X			
Informed Consent	X			
Checking inclusion and non-inclusion criteria	X			
Randomization	X			
Confusion Assessment Method	X			
EVA fatigue	X	X	X	
History (falls, MMSE, etc.)	X			
Type of technical aid	X	X	X	
Clinical examination	X		X	
Tests : • Walking speed at patient's preferred speed over 10m (x2), • Double-task walking speed over 10m (x2), • Imagined walking speed over 10m (x2),	X	X	X	
Short-FESI questionnaire	X		X	
Length of stay in geriatric care or post-emergency medicine				X

4.2. General research methodology

The research has the following characteristics:

- Open study,
- Monocentric (CHD Vendée)
- Controlled,
- Superiority,
- Randomized

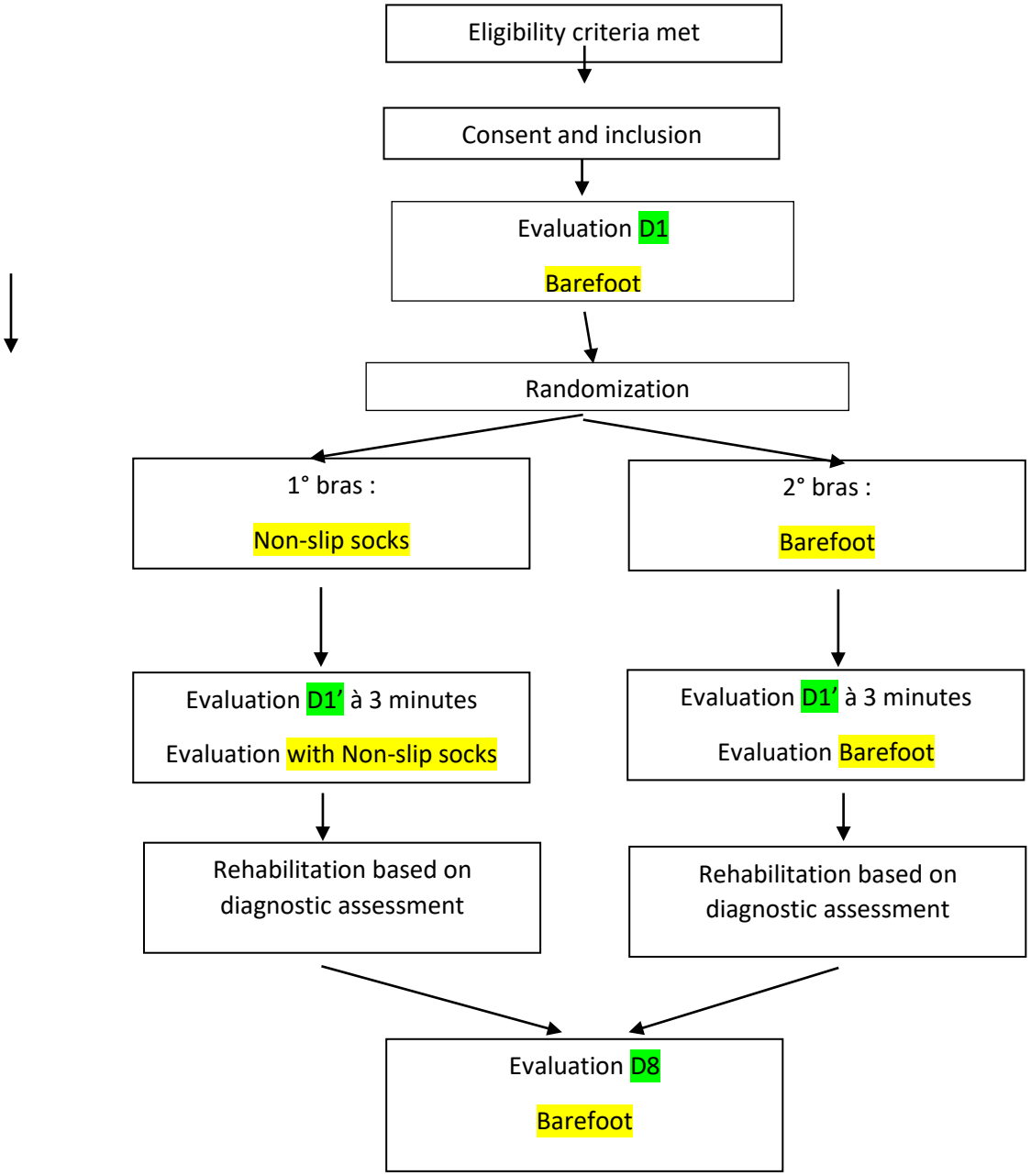
Inclusion period: 18 months

Participation period: 7 days

Research duration: 19 months maximum

Number of patients to be randomized: 50

4.3. Study diagram



4.4. Description and justification of the therapeutic regimen/method studied

The aim of the study is to evaluate the effect of wearing non-slip socks on motor recovery. We have therefore chosen a design where we will be able to evaluate the evolution of motor skills between a control group and the experimental group wearing the socks.

The non-slip socks used in this study (Appendix 3) will be those used in normal practice in our care department.
These socks from *CA Diffusion* feature picot strips on the outer 2 sides for continuous grip, even when the sock is turned. They have a resistant interior to keep out the cold. They are latex-free to prevent allergies.
Socks are changed every day to ensure good foot hygiene. They will be changed by the medical staff at the patient's bed.

4.5. Description of evaluation and data collected

4.5.1. Walking speed

Walking speed is a common physiotherapy test used to assess motor function. It is easy to use, even for patients with cognitive and confusional disorders. Gait speed in patients over 80 years of age is 0.943m/seconds ± 0.091 (Bohannon & Williams Andrews, 2011; Menant et al., 2014)
The best initial estimates of small significant changes are close to 0.05 m/s for walking speed. (Perera et al., 2006)
Substantial changes are of the order of 0.10 m/s (Perera et al., 2006).
There are several ways of performing the test, at usual walking speed or at fast walking speed. For the purposes of this protocol, we have chosen the patient's preferred walking speed modality (Bohannon & Williams Andrews, 2011).
Ground markings or studs provide visual cues for the patient. The patient stands facing the 10m course, with visual cues to remind him or her of the course.
The walking speed test will be performed twice. The instructions are :
"At my starting marker, you'll have to walk at your usual speed to pass the marker".
"Are you ready?"

4.5.1. Double-task walking speed

Double-task walking speed gives an indication of available cognitive reserve (Lundin-Olsson et al., 1997). Stopping walking or reducing walking speed by more than 30% is predictive of a fall (Beauchet & Berrut, 2006).

Ground markings or studs provide visual cues. The patient stands facing the 10m course, with visual cues to remind him or her of the course.
The walking speed test will be performed twice. The instructions are :
"At my starting signal, you'll have to walk at your usual speed to pass the marker/plot on the ground. During this walk, you must name as many animals as possible.
"Are you ready?"

4.5.2. Imagined walking speed

Human movement can be separated into 2 phases, a programming phase (anticipation) and an execution phase (Jeannerod, 2001). The concordance between movement planning and execution can be reliably assessed using a simple test evaluating the temporal concordance between an imagined practice and a physical practice (Guillot et al., 2012). This concordance is expressed by an Isochrony Index. Adapted to imagined walking speed, this is a simple test designed to assess motor prediction abilities (Rulleau et al., 2015). Interestingly, the decrease in isochrony correlates with the decrease in gait speed during the dual task (Bridenbaugh et al., 2013)). It could thus mark a risk of falling due to poor anticipation of actual motor abilities.

Ground markings or studs provide visual cues. The patient stands facing the 10m course, with visual cues to remind him or her of the course.
The imagined walking speed test is performed twice. The instructions are
"At my starting signal, you'll have to imagine yourself walking at your usual speed to pass the marker/plot on the ground. When you imagine passing it, you'll say "stop".
"Are you ready?"

4.5.3. Fear of falling (Appendix 2)

The Short-Falls Efficacy Scale International (Short-FES-I) is a patient-completed self-questionnaire comprising 7 items with 4 possible answers. It has excellent internal consistency (Cronbach's alpha = 0.96 and 0.92) and test-retest reliability (ICC = 0.96 and 0.83). The convergent construct validity of the Short-FES-I was confirmed for: previous falls; depressive symptoms; general disability; low quality of life; and physi-caloric impairment (Dewan & MacDermid, 2014).
A threshold for fear of falling has been defined as > 10 on the Short-FES-I scale scale (Dewan & MacDermid, 2014).

4.5.4. The presence of a fall

The occurrence of a fall during hospitalization, the time of the fall and its consequences, and the total number of falls during the hospital stay will be recorded.
Falls and dates of falls prior to hospitalization of less than 6 months will also be collected.

4.5.5. Confusion Assesment Method (appendix 3)

This tool is designed to be used by healthcare personnel, who search for 4 groups of clinical signs (Haute Autorité de Santé, 2009; Kharat & Simonet, 2013) :

1. Sudden onset and fluctuating symptoms;
2. Inattention;
3. Disorganized thinking ;
4. Impaired alertness.

Diagnosis requires the presence of 3 of the 4 criteria. Criteria 1 and 2 are always required, along with 3 or 4 (Laplante & al, 2005,. Appendix 3).

4.5.6. Visual Analog Fatigue Scale

The visual analog scale is commonly used in pain assessment (Hawker et al., 2011). In addition, other authors propose its use in fatigue assessment, using the same modality (Hewlett et al., 2011)..
The slide is presented to the patient as follows:
"I'm going to ask you to move the slider to your current level of fatigue. I'm going to ask you to move the cursor to your current level of fatigue".
The operator rates fatigue from 0 to 100.

4.5.7. Length of stay

The length of stay in days and hours in geriatric short-stay or post-emergency medicine, calculated between the start of hospitalization and the end of hospitalization, will be recorded.

4.6. Identification of all source data not contained in the medical record

1.	Confusion Assesment Method scale	at D1
2.	Visual Analogue Fatigue Scale	at D1, D1' and D8
3.	Type of technical aid(s)	at J1, J1', J8
4.	Duration of 10 m walk (2 times) performed	at D1, D1' and D8
5.	Duration of double-task 10 m walk (2 times) performed	at D1, D1' and D8
6.	Duration of imagined 10 m walk (2 times) performed	at D1, D1' and D8
7.	Short-Falls Efficacy Scale International questionnaire	at D1, D1' and D8

4.7. Rules for terminating a person's participation

4.7.1. Criteria for premature termination of a person's participation in research

A person's participation may be terminated prematurely for the following reasons:
- Withdrawal of consent by the patient
Patients will be able to withdraw their consent and ask to leave the study at any time, for any reason.
- Death.

4.7.2. Monitoring and data collection schedule

Patients withdrawn from the study will not continue in the study schedule.

In the event of withdrawal of consent by the patient, and without prejudice to the patient's rights, the data already collected will be analyzed in accordance with regulatory texts.

However, no other tests specifically provided for in the protocol will be carried out, and no data will be collected.

Discharging a patient from the study program will in no way change his or her usual management of his or her pathology.

4.7.3. Criteria for discontinuing all or part of a research project (excluding biostatistical considerations)

Part or all of the study may be stopped permanently or temporarily by decision of the ANSM, the CPP and/or the study Sponsor.

In all cases :
- A written confirmation will be sent to the investigator coordinating the study (specifying the reasons for premature termination)
- All patients in the study will be informed.

4.7.4. Patient management at the end of the research study

Patients will be cared for according to the department's usual practices.

4.8. COMPENSATION

No compensation is provided for participation in this study.

5. SAFETY ASSESSMENT

As the study corresponds to a category 2 RIPH (Research Involving the Human Person), the applicable vigilance measures are those put in place for the practice of care and the use of products associated with the study, in accordance with article L1123-10 of the French Public Health Code. The investigator will therefore be responsible for reporting the occurrence of any undesirable event, in accordance with the procedures applicable to the CHD Vendée.

6. DATA MANAGEMENT AND STATISTICS

6.1. Study data collection and processing

6.1.1. Data collection

An observation notebook (eCRF) will be created for each patient. All information required by the protocol must be provided in the eCRF. It must include the data needed to confirm compliance with the protocol and all the data required for statistical analysis; it must also enable major deviations from the protocol to be identified.

The person(s) responsible for filling in the eCRFs (investigator, CRA, etc.) must be defined and is/are identified in the task delegation form (kept in the investigator's folder).

At the end of the study, the investigator will sign the eCRFs to certify the conformity of the data collected.

6.1.2. Data coding

By signing this protocol, the principal investigator/qualified person and all the members of his or her team undertake to keep confidential the identities of the patients who have participated in the study.

The transmission of a person's data for research purposes will therefore only be possible if a coding system is used, and the presentation of research results will exclude any direct or indirect identification.

Patients will be identified in order of inclusion by a number automatically assigned by the Ennov Clinical software (eCRF), then completed by the patient's initials (1st letter of first name + 1st letter of last name).

This code will be the only information on the eCRF that can be used to link the eCRF to the patient.
The investigator/qualified person is also required to code patient data on any documents he/she may have in his/her possession which are attached to the eCRF.

A correspondence table will be set up at the participating center. This table will be kept in a secure place by the principal investigator/qualified person at the center, and will contain the patient code and nominative data, so that it can be traced back to the patient file in the event of missing or erroneous data. No clinical data will be collected in these correspondence tables.

6.1.3. Data processing

The collection of clinical data will be based on the creation of a database and data entry masks similar to the observation book, in compliance with the protocol and regulations currently in force.

6.2. Statistics

Software
Analyses will be performed using R software version 3.5.1

6.2.1. Description of planned statistical methods, including schedule of planned interim analyses

All variables will be described globally and by group. The description will include the number and percentage of modalities for qualitative variables, and the minimum, maximum, mean, standard deviation and median for quantitative variables.

All gait speed criteria, isochrony between imagined and executed gait speed, isochrony between normal gait speed and double-task gait will be compared using linear models taking into account the baseline J1 value.

As the evaluation conditions between D1' and D8 are different, the models evaluating evolution at D1' and D8 will be independent.
Fear of falling will be assessed using the Falls Efficacy Scale International questionnaire. Fear of falling is defined with a cut-off score equal to 10 on this questionnaire.
The number and percentage of patients with a fear of falling will be presented and compared at D1' and D8 using a Chi2 test.

Length of stay will be compared using a Student's t test.

The presence of falls and their consequences will be described during the hospital stay.

6.2.2. Statistical justification of the number of inclusions

Walking speed is a common physiotherapy test used to assess motor function. It is easy to use, even for patients with cognitive and confusional disorders. Gait speed in patients over 80 years of age is 0.943m/seconds ± 0.091 (Bohannon & Williams Andrews, 2011; Menant et al., 2014)

According to Perera et al. an improvement in walking speed of 0.10m/s is considered clinically relevant (Perera et al., 2006).
For the purposes of this study, we therefore assume a difference of 0.10m/s between the 2 groups, and a standard deviation of 0.10 for the difference.

Based on these assumptions, and for an alpha risk of 5% and power of 90%, a total of 46 patients are required. To guarantee the power of the study, 50 patients will be randomized.

6.2.3. Expected statistical significance

The alpha risk is set at 5%.

6.2.4. Statistical criteria for discontinuing research

NA

6.2.5. Method for taking into account missing, unused or invalid data

All missing data and their reasons are described for each group.

For the primary endpoint, if data are missing at D8, they will be imputed by the patient's baseline value (D1).
If, for this criterion, more than 10% missing data are observed, a sensitivity analysis of the imputation method will be carried out: a multiple imputation method will be applied.

6.2.6. Managing changes to the initial strategy analysis plan

NA

6.2.7. Choosing the people to include in analyses

The main analysis will be carried out on the Intent-to-Treat (ITT) population, i.e. on all randomized patients.

A complementary analysis will be carried out on the Per Protocol (PP) population, including randomized patients for whom no major protocol deviations have been identified.
A data review meeting will be organized to review and define the major criterion or not for each deviation.

6.2.8. Randomization

Randomization will not be stratified
It will be carried out in a 1:1 ratio and in blocks.

Randomization will be carried out in Ennov Clinical by connecting to the website: https://nantes-lrsy.hugo-online.fr/EnnovClinical/. The connection will be made using a login, a password and a study number, issued by the data manager of the Research Unit of the CHD La Roche sur Yon. The following information must be entered:

-First initial of the name,
-First initial of the first name,
-Month and year of birth,
Compliance with inclusion and non-inclusion criteria (yes/no),

Randomization will be carried out by the physiotherapist or other authorized person after confirming the patient's inclusion in the study and obtaining oral consent. Randomization will be carried out prior to the D1 assessments. The inclusion number will be assigned automatically during randomization. An e-mail confirmation will be sent to the person who carried out the randomization, and to all those concerned.

The randomization list will be drawn up by the biometrics team at the CHD La Roche sur Yon Research Unit. An explanatory guide to randomization will be available online at Ennov Clinical.

7. ADMINISTRATIVE AND REGULATORY ASPECTS

7.1. Right of access to source data and documents

The investigators will make available to those responsible for monitoring, quality control or auditing the research, the documents and individual data strictly necessary for this control, in accordance with the legislative and regulatory provisions in force (articles L.1121-3 and R.5121-13 of the Public Health Code).

7.2. Data confidentiality

Persons having direct access will take all necessary precautions to ensure the confidentiality of information relating to the persons concerned, in particular as regards their identity and the results obtained.
These people, like the investigators themselves, are bound by professional secrecy (under the conditions defined by articles 226-13 and 226-14 of the French penal code).
During or at the end of the research, the data collected on the subjects and transmitted by the participants will be pseudonymized.
Under no circumstances may the names or addresses of the persons concerned appear in plain text.
Only the first letter of the patient's surname, the first letter of the patient's first name and the year of birth are recorded, along with a coded number specific to the study, indicating the order of patient inclusion.

7.3. Monitoring the study

Monitoring will be carried out by the Promotion Department of the Research Division. A Clinical Research Associate (CRA) will regularly visit each site to check the quality of the data reported in the observation books.

The monitoring plan is defined and adapted to the level of risk estimated for the patient undergoing research. It will be monitored as follows:

Risk A: low or negligible foreseeable risk

On-site monitoring visits will be organized by appointment with the investigator/qualified person. CRAs must have access to :
- data collection notebooks for included patients,
- patient medical and nursing records,
- the investigator binder.

7.4. Inspection / Audit

In the context of this study, an inspection or audit may take place. The sponsor and/or the participating center must be able to give access to the data to the inspectors or auditors.

7.5. Delegation of tasks

The principal investigator at the research site draws up and keeps up to date a task delegation form specifying the respective tasks he delegates to members of his team for the study, according to their competence.
Each of the investigator's collaborators draws up an up-to-date, dated and signed curriculum vitae (CV).
The investigator ensures that the collaborators to whom he delegates tasks within the framework of the study have the appropriate competence for these tasks. The investigator remains responsible for the conduct of research at the site.

7.6. Declaration to the competent authorities

The sponsor undertakes to submit the study project for prior authorization by a Comité de Protection des Personnes (CPP). The information provided covers the nature of the research and the safeguards provided for patients taking part in the study. The sponsor submits the curriculum vitae of the principal investigator at the research site to the CPP for its opinion.
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The ANSM will also be informed of this protocol.

7.7. Protocol amendments

Requests for substantial modifications will be sent by the promoter to the relevant CPP for its opinion, in accordance with the law in force and its implementing decrees.

An updated version of the modified protocol must be dated and signed.
Information letters and the patient's oral consent form should be modified if necessary.

7.8. Computerized data and submission to the CNIL

The data collected as part of this study is for scientific research purposes, in the public interest.

This study falls within the scope of the "Reference Methodology" MR-001 registered, for the CHD Vendée, under n°2060482 v 0 for the following reasons:
- Health data collection for research purposes
- Obtaining the opinion of a CPP to begin research
- Use of pseudonymized data
- Individual information for data subjects
- Access to data only by professionals (healthcare and sponsor) involved in the study.

The fact that this study falls within the scope of MR001 and the reasons why will be notified in the sponsor's treatment register.

7.9. Patient information

7.9.1. Informed consent oral

The investigator/qualified person undertakes to obtain the person's free, informed and express consent, obtained orally, after having provided information on the protocol. He/she will give the patient a copy of the information note. The person can only be included in the study after having read the information note and given oral consent, after having had time to reflect, if necessary.
The patient's information and agreement to participate in the research must be recorded in his or her medical file.

A record of the patient's express oral consent will be kept in the study documents.

If the patient's next of kin is not present at the time of inclusion in the study, an explanatory triptych will be given to the patient's family (appendix 4).

7.10. Financing and insurance

The sponsor finances the study and takes out an insurance policy to cover the financial consequences of its civil liability, in accordance with regulations.

7.11. Publication rules

The study will be registered on the Clinical trial open access website prior to the inclusion of the 1er patient in the study.

The study may not be the subject of any written or oral comment without the agreement of the sponsor; all information communicated or obtained during the course of the study is the property of the CHD Vendée, which may freely dispose of it.

All information resulting from this study is considered confidential, at least until appropriate analysis and control by the study sponsor, coordinator and statistician have been completed.

Scientific papers and reports relating to this study will be produced under the responsibility of the study coordinator.

The study coordinator will be the principal signatory of the communication and the editor of the documents, and will necessarily be one of the first or last authors. He/she may delegate this task to another person.

The coordinating investigator draws up the list of authors. Investigators will be listed in proportion to the number of patients recruited. The study statistician will also be cited.

Similarly, publications of ancillary results will include the name of the person who carried out the ancillary work, as well as the names of all other people involved in the ancillary work.

All publications, abstracts or presentations including study results must be submitted to the sponsor (CHD Vendée) for approval.

Publication rules will follow international recommendations (N Engl J Med, 1997; 336 :309-315). .

7.12. Archiving source data

The investigator/qualified person must keep all information relating to the study for at least 15 years after the end of the study.

At the end of the study, the investigator/qualified person will receive a copy of each patient's data from the sponsor.
No removal or destruction may be carried out without the agreement of the Promoter. At the end of the 15-year period, the Promoter will be consulted for destruction. All data, documents and reports are subject to audit or inspection.

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