FallMI Protocol

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"Pilot study of fall prediction using motor imagery"

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LIST OF ABBREVIATIONS

BOW	Clinical Research Associate (monitor)
EYELASH	Data Protection Officer
CNIL	National Commission for Information Technology and Freedoms
CRF	Case Report Form (observation notebook)
eCRF	Electronic Case Report Form
IDE	State-Certified Nurse
INSERM	National Institute of Health and Medical Research
TEC	Clinical Research Technician
TUG	Timed Up and Go
rTUG	Timed Up and Go completed
iTUG	Timed Up and Go imagined
RNI	Non-Interventional Research

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INTRODUCTION

Falls in older adults are a major public health problem, particularly among those with bone fragility. Various tools are available to identify at-risk individuals. The Timed Up and Go (TUG) test is a clinical test used as a predictor of falls. However, its actual usefulness remains uncertain (Beauchet et al., 2011) . While a decline in TUG scores appears to be validated after a fall, its predictive value for subsequent falls is debated.
On the other hand, human movement can be separated into two phases: a programming (anticipation) phase and an execution phase (Jeannerod, 2001) . Movement programming can be reliably assessed using a simple test that evaluates the concordance between the duration of an imagined activity and an actual physical activity (Guillot, Hoyek, Louis, & Collet, 2012) . Adapted to the Timed Up and Go (TUG) test (realized – imagined TUG), a decline in this Isochrony Index clinically indicates a structural and functional impairment of cognitive abilities (Allali, Annweiler, Predovan, Bherer, & Beauchet, 2016; Beauchet, Launay, Sejdić, Allali, & Annweiler, 2014; Beauchet et al., 2010) . Furthermore, the decrease in isochrony is correlated with a decrease in walking speed during the dual task. This loss of isochrony could therefore indicate a risk of falls due to poor anticipation of actual motor skills.

At the Vendée Hospital Center (CHD Vendée), a primary and secondary osteoporosis screening program was implemented in 2014 in the medical (excluding oncology), gynecology, outpatient surgery, and orthopedics departments. Patients seen in the emergency department were not included due to its 24/7 operating hours. The objective of this program was to screen all patients at risk of osteoporosis; that is, not only patients with a recent or past history of fractures, but also patients with risk factors for osteoporosis but without a current history of fractures. This was done to provide referring physicians with a prevention strategy and thus reduce fracture risk. The administration of the Timed Up and Go assessment, which was both conceived and physically implemented, was added to the patient care process in July 2017 as part of this screening program.

During this screening, patients are asked to perform 2 realized Timed Up and Go (rTUG), followed by 2 imagined Timed Up and Go (iTUG).

The importance of preventing falls in osteoporotic patients leads us to offer this assessment as part of our osteoporosis screening program. We will invite patients undergoing osteoporosis screening through the existing program at the CHD (Centre Hospitalier Départemental) to participate in the FallMi study. If they agree, their primary care physician will be contacted to collect data on falls. Following a letter of invitation, each patient's primary care physician will be contacted six months and then one year after the thoracic pelvic tilts (TPUs). These contacts will ask physicians about any falls that have occurred since the TPUs and their severity. If the primary care physician cannot be reached, the patient will be contacted as a second option.

Our objective is to evaluate rTUG and iTUG as predictive factors of a fall with moderate to fatal consequences.
We hypothesize that a less good isochrony between rTUG and iTUG is predictive of a risk of falling.

1. JUSTIFICATION FOR THE STUDY

Falls among the elderly are a major public health problem. They affect 30% of people over 65 and 50% of those over 80 each year (INSERM, 2014) . Ten percent of elderly people who fall each year suffer serious injuries (sprains, fractures, or head trauma) (INSERM, 2014) .

Bone fragility, manifested by osteoporosis, appears in some studies as a risk factor for falls, but this seems to be characteristic of the health status of osteoporotic individuals (INSERM, 2014) . Dorsal kyphosis and fear of falling (Arnold, Busch, Schachter, Harrison, & Olszynski, 2005; Sinaki, Brey, Hughes, Larson, & Kaufman, 2005) and reduced muscle strength (da Silva et al., 2010) appear to be causes of loss of balance and mobility.

The frequency of falls, their impact on quality of life, mortality and morbidity, and healthcare costs necessitate the identification of high-risk elderly individuals. The use of simple, quick-to-implement, sensitive, specific, and reproducible fall prediction tools is therefore essential (INSERM, 2014) . Several tools are proposed that can be classified according to four themes: anamnesis (presence of history of falls), single-task screening tools (such as single-leg stance time, Functional Reach test, 180° turn, 5-time chair rise, walking speed), multi-task screening tools (such as Timed Up and Go, Performance-Oriented Mobility Assessment and Berg scale), and finally a multidimensional approach (such as questionnaires and dual-task physical and cognitive tests) (Bassett, Siu, & Honaker, 2017; Haute Autorité de Santé, 2005; INSERM, 2014) . In a recent literature review, Park (2017) advises the use of two tools from among those previously mentioned, while INSERM recommends searching for a history of falls and a simple test like the Timed Up and Go, which is easy to perform to identify fall risks.

In parallel, human movement can be separated into two phases: a planning (anticipation) phase and an execution phase (Jeannerod, 2001) . The concordance between the planning and execution of movement can be reliably assessed using a simple test that evaluates the temporal concordance between an imagined and a physical action (Guillot et al., 2012) . This concordance is reflected in an Isochrony Index. Adapted to the Timed Up and Go (TUG) test (=|actualized TUG – imagined TUG|), this index clinically indicates a structural and functional decline in cognitive abilities (Allali et al., 2016; Beauchet et al., 2014, 2010) . Interestingly, a decrease in isochrony is correlated with a decrease in walking speed during the dual task (Bridenbaugh et al., 2013) . This could indicate a risk of falling due to poor anticipation of actual motor skills.

To evaluate a tool for identifying and measuring fall risk, prospective longitudinal studies are the "gold standard" (INSERM, 2014) . The importance of preventing falls in osteoporotic patients leads us to propose this prospective evaluation within the framework of the "osteoporosis" screening program in place at the Vendée Departmental Hospital Center.

As part of the care of screened patients, patients will be asked to perform two Timed Up and Go real (rTUG), followed by two Timed Up and Go imagines (iTUG).

The patient sits in a chair with armrests, 3 meters from a wall. At the operator's "GO" signal, which starts the timer, the patient must stand up, walk 3 meters at their comfortable pace, and turn around without touching the wall. The patient must then sit back down and give the operator the final "GO" signal, at which point the timer will stop. For the iTUG, the patient sits in a chair with armrests, 3 meters from a wall. At the operator's "GO" signal, which starts the timer, the patient must imagine standing up, walking 3 meters at their comfortable pace, and turning around without touching the wall. The patient must then imagine sitting back down and giving the operator the final "GO" signal, at which point the timer will stop.

Our objective is to evaluate rTUG and iTUG as predictive factors of falls with moderate to fatal consequences.

We believe that an alteration of the isochrony between the duration of an imagined Timed Up and Go and an actually performed Timed Up and Go is correlated with a higher risk of falling.

The bibliographic references are included in the appendix to the document.

2. OBJECTIVES AND EVALUATION CRITERIA

2.1. OBJECTIVE AND MAIN EVALUATION CRITERION

2.1.1. Main objective

Evaluate the existence of an isochrony deficit between the imagined Timed Up and Go and the realized Timed Up and Go as predictive of a fall with moderate to severe consequences at 6 months.

2.1.2. Main evaluation criterion

- Isochrony index =| rTUG-iTUG |
- (Absolute value of the difference between the execution time of rTUG and iTUG)
- iTUG Time
- Time at rTUG
- Presence of a fall with moderate to severe consequences within six months of the test

2.2. SECONDARY OBJECTIVES AND EVALUATION CRITERIA

2.2.1. Secondary objective(s)

- Evaluate the predictive factors of a fall
- Evaluate the predictive factors of a first fall
- To assess whether factors are predictive of the severity of a fall

2.2.2. Secondary evaluation criterion(a)

- iTUG Time
- Time at rTUG
- The occurrence of one or more falls in the year following the test
- ATCD of falls in the medical history
- Consequences of the fall (fatal, severe, moderate, no)

3. STUDY POPULATION

3.1. POPULATION DESCRIPTION

Patients are recruited through the routine osteoporosis screening program at the Vendée Hospital Center (CHD Vendée) by nurses in the rheumatology department. The study population consists of women aged 50 to 80 years hospitalized in the medical (diabetes-endocrinology, hepatology-gastroenterology, nephrology, neurology, oncology-hematology, pulmonology, rheumatology), orthopedics, surgery, and gynecology departments. Patients contacted to participate in the FAllMI study (by the rheumatology department nurses) are those who have undergone routine osteoporosis screening at CHD Vendée and have had at least one positive result. When a risk of osteoporosis is detected, iTUG and rTUG tests are performed.

3.2. INCLUSION CRITERIA

1. Patients who underwent osteoporosis screening at CHD Vendée (aged 50 to 85 years)
2. Proven presence of an osteoporotic risk (positive response to screening tests),
3. No fractures of the lower limbs making walking impossible,
4. Implementation of iTUG and rTUG.
5. No objection to the collection and analysis of personal data collected,
6. Patient who can be followed for the duration of the study (12 months),
7. Patient followed by a treating physician and having given her consent for the latter to be contacted as part of the study.

3.3. EXCLUSION CRITERIA

1. demented patient
2. Deaf patient
3. Completely blind patient
4. Patient unable to express themselves
5. End-of-life patient
6. Patients already treated for osteoporosis or with a recent DXA less than 3 years old at the time of screening
7. Patient who did not receive osteoporosis screening at the Vendée Hospital Center

8. Presence of equipment (e.g., IV drip) making walking impossible or rendering the reliability of the TUG unreliable.

4. DESIGN AND STUDY PROCESS

4.1. GENERAL RESEARCH METHODOLOGY

The research has the following characteristics:

- **single-center** , non-interventional study

The expected number of patients is 150, with follow-up at 6 and then 12 months.
Inclusion period: 72 months
Duration of patient participation: 12 months
Study duration: 84 months

4.2. RESEARCH AND ANALYSIS TECHNIQUES

4.2.1. Detailed description of evaluation parameters

The Get Up and Go test is a qualitative clinical test in which patients are asked to stand up from a chair with armrests, walk to a wall, turn around, and return to a seat (Mathias, Nayak, & Isaacs, 1986) . From this assessment, the Timed Up and Go test was developed, a multitask fall detection tool that replicates the Get Up and Go test in a timed version (Podsiadlo & Richardson, 1991) . Several retrospective and prospective studies have been conducted to try to determine fall prediction thresholds. To our knowledge, four systematic reviews of the literature analyze the results and suggest cutoff times between 12 and 20 seconds as predictive of a fall.
The imagined Timed Up and Go (iTUG) is the imagined version of the realized Timed Up and Go (rTUG) described above. Its use was described by Beauchet's team in the Structural and functional decline in cognitive abilities (Allali et al., 2016; Beauchet et al., 2014, 2010) is also correlated with a fear of falling (Sakurai et al., 2017) . It is possible to calculate the absolute value of the difference between the imagined and actual execution time of the dual task. This difference is called the isochrony index. Alterations in this isochrony index are correlated with a decrease in walking speed during the dual task (Bridenbaugh et al., 2013) . This test is performed during osteoporosis screening consultations.

For patients agreeing to participate in the FallMI study, the name and contact details of the treating physician will be collected during this same consultation.

After an initial phone call, a standardized call will be made to the patient's primary care physicians to gather information about falls and their consequences. If the primary care physician cannot be reached, the

patient will be contacted as a second option. Falls will be classified as **fatal** (death), **severe** (requiring hospitalization for more than 24 hours; for example, a serious fracture or rhabdomyolysis), **moderate** (requiring hospitalization for less than 24 hours or outpatient care; for example, a minor fracture or abrasion with dressing), and **without** consequence. Due to the inability to obtain reliable and comprehensive information on falls without consequence, and the lack of severity associated with these falls, we will not include them in our analysis.

4.2.2. Description of techniques and analyses

A procedure sheet and training were provided to nurses performing osteoporosis screening at the Vendée Hospital Center. The nurses inform the patient and obtain her consent, as well as the name and contact information of her primary care physician.

During osteoporosis screening:

The presence of a history of falls:

Do you recall one or more falls in the last 6 months? (enter the number)

(Mechanical fall, while walking or moving in one's usual environment)

The Timed Up and Go:

The operator begins by explaining how two physically performed tests were carried out, followed by two imagined tests without movement.

He specifies that the tests will begin at the operator's starting "top" and will end at the patient's final "top" when he sits back down.

The execution speed is the subject's "normal" speed. The eyes must be kept open during the imagined test.

The Timed Up and Go (rTUG) assessment was completed:

The patient is seated on a chair with standard-height armrests, placed 3 meters from a wall. The instruction is: "to stand up, walk to the wall without touching it, turn around, return to the chair, turn around and sit down."

The operator gives the "go" signal to start the timer with a countdown: "Are you ready? 3, 2, 1 go",

The patient must give the final "go" by sitting down.

The operator notes the test completion time between the two "beats". Repeat twice.

The execution of the imagined Timed Up and Go (iTUG):

The patient is seated on a chair with standard-height armrests, placed 3.2 meters from a wall. The instruction is: "Without moving, imagine yourself standing up, walking to the wall without touching it, turning around, returning to the chair, turning around and sitting down."
The operator gives the "go" signal to start the timer with a countdown: "Are you ready? 3, 2, 1 go",
The patient must give the final "go" when he imagines sitting down.
The operator notes the test completion time between the two "beats". Repeat twice.

In the event of a fall or pathological result from the TUG procedure, the attending physician will be informed via the patient's hospitalization report according to standard practice.

Letter to the attending physician:

A standardized letter will be sent to the attending physician to inform him that the patient has agreed to participate in the FallMi study and that she has given her consent for the collection of her medical data within the framework of this study.

6 months and 12 months after screening, telephone call to the attending physician:

The attending physician's office will be contacted, and then a standardized call will be made to the patient's attending physician or their office to gather the following information. If the attending physician cannot be reached, the patient will be contacted as a second option.

- Has the patient fallen during the 6 months (or 12 months) since screening? If a fall is found, details will be requested regarding the number and severity of falls (Haute Autorité de Santé, 2009) .
- The fall and its consequences are investigated and classified as fatal (death), severe (requiring hospitalization for more than 24 hours), moderate (requiring hospitalization for less than 24 hours or outpatient care), and without consequence. The absence of a fall and falls without consequence are treated in the same way.
- The person calling and collecting fall data from the attending physician will be blind to the results of the TUG planned and carried out.

4.3. STUDY SCHEDULE

STUDY TIMETABLE

Actions	Inclusion D0 Osteoporosis screening	Call/email to the attending physician (M6 ±15 days post-screening)	Call/email to the attending physician (M12 ±15 days post-screening)
Patient information: collection of oral non-opposition	X		
Data collection on falls		X	X
Collection of data on the death (if applicable)		X	X

The other medical data that will be analyzed will come from the patient's medical file as part of the osteoporosis screening program implemented at the CHD Vendee.

5. DATA MANAGEMENT AND STATISTICS

5.1. DATA COLLECTION AND PROCESSING FOR THE STUDY

5.1.1. Data collection and circulation methods

5.1.1.1. Data coding

By agreeing to participate in this protocol, the principal investigator and all co-investigators undertake to keep confidential the identities of the patients who participated in the study.

The transmission of a person's data for research purposes will therefore only be possible subject to the application of a coding system; the presentation of the research results must exclude any direct or indirect identification.

No personally identifiable information will be collected as part of this research.
The data will be coded with a unique patient number and the first letter of the patient's first and last name.
A lookup table will be created, under the investigator's responsibility, to link the patient code to the patient's personal data. This table will be kept by the investigator, who will have sole access to this document.

Information regarding the patients' treating physicians will not be entered or included in the study database.
This data will be retained only for the duration of the patient's participation in the study, for the purposes of conducting calls and collecting data.

5.1.1.2. Description of the use (exclusive or not) of data extracted from existing information systems or databases of previously conducted studies

N / A

5.1.1.3. Origin and nature of the personal data collected and justification for its use

No personally identifiable information will be collected as part of this research.
The code will be limited to the patient's number and initials (first letter of first name and first letter of last name).
This code will be the only information that will appear on the observation book and that will allow the CRF to be linked to the patient retrospectively.

The investigator is also required to code patient data on all documents in their possession (imaging reports, biology reports, etc.) that would be attached to the CRF.

A cross-reference table will be established, under the responsibility of the coordinating investigator, which will link the patient code to the patient's data. This table will be kept within the department by the investigator, who will be the only one with access to this document .

5.1.1.4. Data recipients

The people who will have access to the collected encrypted data are:

- The staff of the Rheumatology department (doctors, nurses, etc.)
- The statistician of the study
- The data manager of the study
- The coordinator
- The Clinical Research Unit team at CHD Vendée

5.1.2. Data processing

The collection of clinical data will be based on the establishment of a database in accordance with the protocol and regulations currently in force.
The database structure will be approved by the research manager.

5.1.3. Data retention period and transfer

The data will be kept for a period of 15 years after the end of the research.
No data will be transferred to a third party or outside the EU.

5.2. STATISTICS

Head of Statistical Analysis: Ms. Lucie Planche

5.2.1. Description of the planned statistical methods, including the schedule of planned interim analyses

Patients will be classified into 2 groups: Patients who have fallen at 6 months versus patients who have not fallen in 6 months.

All variables will be described both globally and by groups. The description will include the frequencies and percentages of categories for qualitative variables and the minimum, maximum, mean, standard deviation, and median for quantitative variables.

For each patient, the mean time will be calculated for rTUG and iTUG. The absolute difference between the two mean times will then be calculated (= isochrony index).

Within each group, the average isochrony index will be calculated. The comparison between the two groups will be made using a student’s t-test.

Depending on the data, a cutoff value for the isochrony index can be sought. A logistic regression with the isochrony index as the explanatory variable will be applied to estimate the associated ROC curve and

determine the optimal cutoff value for the isochrony index. The sensitivity, specificity, positive predictive values, and negative predictive values associated with this cutoff value will be estimated with a 95% confidence interval.

Risk factors for a fall and the severity of a fall will be investigated using multivariate logistic regressions.

5.2.2. Statistical justification for the number of inclusions

This is a pilot study to evaluate the contribution of rTUG and iTUG in predicting falls in the elderly.
Over a one-year period, it is estimated that 150 patients could participate in the study. From the age of 75, the risk of falling is estimated at 25% each year. This sample size will allow us to gather initial data on the predictive value of the isochrony index for falls occurring within the first 6 months following the administration of rTUG and iTUG.

5.2.3. Expected degree of statistical significance

The alpha risk is set at 5%

5.2.4. Statistical criteria for stopping the search

N / A

5.2.5. Method for handling missing, unused, or invalid data

All missing data and their reasons will be described in each of the groups.

The analysis will include all evaluable patients, that is, all patients for whom the isochrony index can be calculated and for whom the presence or absence of at least one fall has been recorded within 6 months. Deaths will be included in the "Fall within the first 6 months" group.

6. SAFETY / ADVERSE EFFECT

In the context of this non-interventional study, the protocol does not involve any modification to the usual care of patients, therefore any events or adverse effects that may be observed will be unrelated to the study.

The occurrence of an Adverse Effect related to the care of the patient during this protocol will give rise to a declaration in the appropriate vigilance system (pharmacovigilance, biovigilance, hemovigilance, materiovigilance, etc…).

Data on any hospitalizations and falls will be collected as study data and not as safety data since it is not related to the research itself.

7. ADMINISTRATIVE AND REGULATORY ASPECTS

7.1. JUSTIFICATION FOR THE POSITIONING IN NON-INTERVENTIONAL RESEARCH

This is a research study based on patient data.
The study does not involve any additional visits, sampling, or procedures compared to standard care.
The study includes two telephone calls made to the treating physician to gather information on the presence of falls that may have occurred since their osteoporosis screening.

These two calls do not compromise the safety of the person and the data will not lead to any change in the usual care of the participant and therefore do not fall under the category of so-called interventional research, nor interventional research with minimal risks and constraints (RIRCM) according to the decree of 03/05/2017 establishing the list of research mentioned in point 2° of article L.1121-1 of the public health code.

7.2. RIGHT OF ACCESS TO SOURCE DATA AND DOCUMENTS

Each patient's medical data will only be transmitted to the sponsor or any person duly authorized by the sponsor under conditions guaranteeing their confidentiality.
If necessary, the sponsor may request direct access to the medical file for verification of procedures and/or research data, without violating confidentiality and within the limits authorized by laws and regulations.

7.3. COMPUTERIZED DATA AND SUBMISSION TO THE CNIL

The data collected during the study will be stored in a computer file in compliance with the "Data Protection Act" of 6 January 1978 as amended in 2004.

The protocol will be subject to a normal declaration to CNIL as part of this single-center study.

7.4. INSPECTION / AUDIT

As part of this study, an inspection or audit may take place. The sponsor and/or participating centers must be able to grant access to the data to the inspectors or auditors.

7.5. AMENDMENTS TO THE PROTOCOL

The modified protocol will need to be updated with a date.
Any amendment will be subject to prior submission to the CPP.

7.6. RULES RELATING TO PUBLICATION

The study may not be the subject of any written or oral commentary without the agreement of the promoter; all information communicated or obtained during the course of the study belongs by right to CHD Vendée, which may freely dispose of it.

All information resulting from this study is considered confidential, at least until proper analysis and review by the study sponsor, coordinator, and statistician are completed.
The publications and scientific reports corresponding to this study will be produced under the responsibility of the study coordinator.

The coordinator will be the main signatory of the publication and the draft of the documents. He may delegate this task to another person.

The coordinating investigator establishes the list of authors. The study statistician will be cited as the third author.

As this study is promoted by the CHD Vendee, the sum of all the ranking scores of the authors from the CHD Vendee must be greater than the sum of all the ranking scores of the authors from the other establishments and represent at least 25% of the points awarded by the publication.

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

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

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

7.7. ARCHIVING OF SOURCE DATA

The investigator must retain all study-related information for at least 15 years after the end of the study.

8. ETHICAL CONSIDERATIONS

8.1. PATIENT INFORMATION

Each patient must be informed of the performance of any research, even non-interventional, carried out using their medical data and/or biological samples and must give, according to their choice, their consent or not to the performance of the research.

The nurses involved in the study, who recruit the patients, must provide clear oral information and answer the patients' questions.

The investigator undertakes to inform the patient clearly and fairly about the protocol
He will specify to her the possibility for the patient to refuse to participate in the research, her right to object and the possibility for the patient to withdraw at any time.

The patient's non-opposition will be collected during the osteoporosis screening consultation if the patient meets the inclusion criteria of the FallMI study.

The investigator will keep a written record of obtaining the patient's oral consent to participate and for this data to be collected and analyzed in a dedicated anonymous and coded database.

The patient will receive a written summary of the study and her rights regarding the personal data collected.

8.2. COMMITTEE FOR THE PROTECTION OF PERSONS

The research director undertakes to submit the study project for prior authorization from an Ethics Committee (CPP). The information provided relates, on the one hand, to the methods and nature of the research and, on the other hand, to the safeguards provided for patients participating in this trial.

The research manager undertakes to submit a request to the CPP before any substantial modification to be applied to the protocol.

LIST OF ANNEXES

- *APPENDIX 1: Bibliographical References*

APPENDIX 1: BIBLIOGRAPHICAL REFERENCES

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