Study Protocol

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1. Introduction

Falls are a serious healthcare problem worldwide[1,2] and the third biggest cause of chronic disability[1]. It is also estimated that falls are responsible for 20 to 30% of all injuries and for 10 to 15% of all emergency department episodes[3].

In the elderly population, falls are a particularly serious problem. Annually, it is estimated that 28 to 35% of individuals aged 65 or over suffer a fall[4,5], and this percentage goes up to 32 to 42% in individuals over 70.

Besides age, there are several other risk factors for falls, which have been reviewed elsewhere[6,7]. The most important are: a) living alone; b) previous history of falls; c) presence of other chronic conditions (heart disease, chronic obstructive lung disease, ostheoarthritis); d) previous stroke; e) cognitive deficits; f) low vision; g) low body mass index; h) osteoporosis; i) multi-medication (>4 concomitant drugs); j) psychotropic drugs (in particular benzodiazepines); k) diuretics and some antiarrithmic drugs; l) proprioceptive deficits.

The consequences of falls in the elderly population are more severe than in other age groups. This results in a greater percentage of fatal falls[8,9], but also in the percentage of hospital admissions related to falls, corresponding to 7% of all admissions and to 85% of all accident-related admisisons in this population [10]. Falls can also lead to insecurity [11], fear of falling [12] and loss of independence [13], worsening the problem even further.

With the aging world population, the number of falls is expected to increase[1]. Without preventive measures, this increase can reach 100% by 2030[14]. Falls prevention can help the older population in maintaining its independence and quality of life, while reducing healthcare costs at the same time.[15]

Physical exercise programs are one of the most effective tools in reducing the risk of falls in the elderly population, and their validity has been confirmed in several studies and meta-analysis[15–18]. To maximize their efficacy, these programs should be performed regularly, be progressive[19], have multiple components (postural exercises, balance exercises and strength/endurance exercises)[16,17] and be capable of promoting long-term engagement[20].

Despite good results demonstrated by these programs, the biggest challenge is to motivate older individuals to exercise and to maintain an active lifestyle [22]. To maximize patient motivation, several authors stress the need for a tailored program prescribed by a healthcare professional[23–25], additionally stating that the involvement of these professionals is one of the main motivating factors to this population [26] and that even general advice or brief telefone contacts can increase motivation [27].

Besides the importance of involving healthcare professionals, physical activity programs for this population need to be entertaining and stimulating [24]. This helps explain why digital systems have evolved so rapidly [28], with exergames attracting particular interest [29]. Indeed, several studies demonstrate that exergames are a viable and safe solution [30,31] and that they are more engaging than comon exercise prescriptions [32,33].

Additionally, there is evidence showing an increase on clinical benefits and a stronger engagement with physical activity programs when older people use biofeedback-associated tracking and activity control devices [28,34,35]. Moreover, given their potential benefits at such a low cost, biofeedback systems are becoming increasingly appealing [34].

Over the last few years, SWORD Health has developed a novel biofeedback system - SWORD Phoenix® - based on inertial motion trackers that digitize motion and use this information to provide real-time audiovisual feedback on performance. SWORD Phoenix® takes advantage of biofeedback principles to increase the efficiency of exercise programs. Plus, it maximizes engagement through clean and user-friendly interfaces and gamification strategies. Furthermore, SWORD Phoenix® allows users to perform their rehabilitation sessions independently at home, under remote monitoring from the clinical teams. This way, SWORD Phoenix® smart and efficiently responds to the needs previously identified.

Given the dimension of the problem of falls in the elderly population and the urgent need for a viable and cost-effective solution for falls prevention, SWORD Health has created an exercise program aimed at this problem, and integrated it within SWORD Phoenix®.

2. Study Design

This study is a single-center, prospective, non-blind, parallel-group, randomized controlled trial with an intervention and a control group.

3. Study Objective

The aim of this study is to evaluate the clinical impact of a home-based falls prevention program using a new biofeedback system - SWORD Phoenix® - on community-dwelling older adults with fall risk in comparison with standard of care.

The hypothesis is that the home-based falls prevention program using the SWORD Phoenix® system will lead to a lower risk of falling than standard medical care.

4. Study Outcomes

4.1 Primary outcome

The primary outcome will be the change in fall risk between the baseline and the final assessment, measured through the "Five Times Sit to Stand Test".

4.2 Secondary outcomes

The secondary outcomes will be:

a) The change in fall risk between the baseline and the final assessment, measured by the "Berg Balance Test".
b) The change in fall risk between the baseline and the final assessment, measured by the "Timed Up and Go" test.
c) The change in fear of falling, through the change on "Falls Efficacy Scale" score between the baseline and the final assessment.
d) The percentage of participants with falls in the study population during the intervention period.

e) The percentage of participants with falls resulting in hospital admissions or emergency care visits, during the intervention period.

5. Sample Size Estimation

The sample size calculation was performed considering the variable chosen as the primary outcome - Five Times Sit to Stand Time (5XSST) - in a superiority scenario.

To characterize the behavior of the primary outcome, a falls risk screening was performed in a representative sample of the population consisting of 40 community-dwelling older individuals (>65 years old), followed at the Unidade de Saúde Familiar de Aldoar (USF Aldoar), who met the inclusion and exclusion criteria of this study. In this population, the mean score in the 5XSST was 19.67 seconds, with a standard deviation of 4.25.

Due to the lack of published data on the Minimal Clinically Important Difference (MCID) for the 5XSST, we considered the MDC95 (Minimal Detectable Change at the 95% confidence interval) reported by Goldberg *et al.* [36] in a population of community-dwelling elderly women.

Considering a statistical power of 80%, a significance level of 0.05 (two-tailed) and a dropout rate of 5%, 100 patients would be required to detect a difference of 2.5 points between the two groups (50 in each group).

An interim statistical analysis on the results of the study will be performed upon reaching the 70% inclusion mark. If the superiority of the intervention group is demonstrated at this point, patient inclusion may be terminated.

6. Inclusion Criteria

a) Patients aged over 65 years old
b) Ability to walk at least 20 meters, unaided or with unilateral support
c) Ability to understand motor complex commands
d) Mini-Mental State Examination (MMSE) score > 24 points
e) Functional independence for instrumental activities of daily living
f) Risk of recurrent falls, defined as 5xSST score > 15,00 seconds

7. Exclusion Criteria

a) Patients residing in nursing homes, daycare units or assisted-living facilities
b) Aphasia, dementia or psychiatric comorbidity, significantly interfering with communication or compliance with a home-based exercise program
c) Severe visual our hearing, interfering with communication or with compliance to a home-based exercise program
d) Cardiac, respiratory or other condition incompatible with at least 30 minutes of light to moderate physical activity
e) Osteoarticular conditions (e.g. severe osteoarthrosis), which prevent the patient from complying with a home-based exercise program
f) Patients with neurologic conditions (e.g. stroke, multiple sclerosis, Parkinson's disease)
g) Other medical complications, which prevent the patient from complying with a home-based exercise program
h) Illiteracy

8. Methods for identifying and recruiting patients

In each research center, the candidates for the study will be identified through routine screening of patient lists from primary care consultations.

Whenever a candidate is identified for the study, the participant will be approached by the investigator, who will explain the study in detail. The prospective candidate will be given the patient information document (**Annex 1 – Information to Participants**) and sufficient time to consider whether he wishes to participate in the study.

Subsequently, the prospective candidate will be given the opportunity to clarify any doubts, after which the informed consent form (**Annex 2- Informed Consent**) will be signed and dated in duplicate by the patient and the investigator. Only then will the randomization and baseline assessments be performed.

9. Patient allocation to study arms

Patients will be randomized in a 1:1 ratio between arms, with randomization blocks of 4 patients. Randomization will be performed centrally by the principal investigator – FDC – through an online randomizer (www.randomizer.org) and communicated by telephone to the investigator responsible for data acquisition only after patient enrollment.

10. Blinding

The nature of the study does not allow blinding of the patients regarding study arms. However, participants will be blinded to the primary and

secondary outcomes being measured. In addition, patient assessment will be performed by one investigator blinded for data collection, for the intervention administration and for the study arm. Statistic analysis will be performed by a biostatistician blinded for the study arm.

11. Patient assessment

Patients will be assessed before the beginning of the intervention (**AO**), and then every four weeks - week 4 **(A4)**, 8 **(A8)** and 12 **(A12)**. A follow-up assessment will also be performed 12 weeks after the end of the intervention (**A24**).

The assessments will be performed in a window of five working days before or after the day on which the assessement should take place.

11.1 Baseline Assessment (AO)

In this assessment will be collected the following information:

a) Gender
b) Date of Birth
c) Educational Level (years)
d) Known fall risk factors
    a. History of falls in the last year
    b. Living alone
    c. Chronic disease
        i. DM
        ii. Cardiac disease
        iii. Respiratory disease (CPD/COPD)
        iv. Osteoarticular disease (osteoarthrosis and osteoporosis)

d. Concomitant Medication
    i. Number of medications
    ii. Use of benzodiazepines or other sedative medication
    iii. Use of antiarrhytmics
    iv. Use of diuretics
e. Body mass index
f. Visual acuity loss

A multi-dimentional characterization of the participants' functional status will also be performed, through specific performance tests (Five Times Sit to Stand Test and Timed up and Go Test), a balance test (Berg Balance Scale) and a self-reported fear of falling scale (Short Falls Efficacy Scale-International**) - see Annex 3: assessment scales and application instructions.**

The **5XSST** [37] is a performance test that measures the strength and the lower limb mobility, which has been validated by Buatois *et al.* as a reliable marker of falls risk in elderly community-dweller population [38]. The same investigators reported a cutoff value of 15 seconds to distinguish between individuals with and without risk of recurrent falls [39]. Although the Minimal Clinically Important Change has not been published for this test, *Goldberg et al* reported an MDC95 (Minimal Detectable Change at the 95% confidence interval) of 2.5 seconds in a elderly community-dweller women population [36]. This test was chosen as the primary outcome for its proven validity, simplicity of application, existence of a well-defined cutoff value and a well-defined MCD95.

The **TUG** is a performance test that assesses the mobility, balance and gait in elderly individuals and was developed in 1991 based on "Get up and Go Test" [40]. A shorter time indicates better performance, usually using the cutoff level of 13.5 seconds to identify individuals at risk of falling in the community [45]. However, the cutoff value reported in the literature varies between 10 and 33 seconds [46,47]. The TUG is a fall risk assessment tool recommended by several international guidelines [48]. However, a recent systematic review has shown that this test has limited utility in the prediction of falls in the elderly population inserted in the community, and should not be used alone for this purpose [41].

The **Berg Balance Scale (BBS)** [42] was developed to evaluate the static and dynamic balance in three domains: sitting, standing and changing posture. It is a scale composed of 14 items graded by an external observer on 5 levels (from 0 to 4). Scale scores range from 0 to 56, with higher scores representing a higher level of functionality. The validity of this scale in the prediction of fall risk was confirmed by several studies, including a recent meta-analysis [43]. However, there is no consensus regarding the cutoff level used in the published studies (from 29 to 52 points), and this meta-analysis suggested a cutoff level between 45 and 49 points to distinguish individuals at low risk from the rest [51]. In the absence of consensus on cutoff level, we chose not to use this scale as the primary outcome of the study.

The **Falls Efficacy Scale- International (FES-I)** [44] was developed in order to systematize on a scale the fear of falling. It is a questionnaire of 16 items filled by the user, evaluating from 1 to 4 the fear of falling during the

execution of a series of activities of daily living. It is a standardized and comparable measure over time, which provides an additional dimension in the characterization of participants. To maximize its practical applicability, a shortened version of the **Short Falls Efficacy Scale- International: Short FES-I** was developed and validated with 7 items (instead of 16) [53]. Delbaere *et al.* [45] subsequently validated the cutoff levels for Short FES-I: low fear (7-8); moderate fear (9-13) and high fear (14-28). A recent study also showed that this scale has a good correlation with objective fall risk measures such as TUG [55].

11.2 Interim assessments (A4 and A8), final assessment (A12) and follow-up assessment (A24)

These assessments will be performed by an investigator blinded to the randomization arm and will consist of:

a) TUG
b) 5XSST
c) BBS
d) FES

12. Intervention

Participants in the control group will benefit from standard medical care currently in place at the participating primary care facility.

Participants within the experimental group will perform a 12-week falls prevention program through SWORD Phoenix®, under remote monitoring from a physical therapist. Participants will be asked to perform sessions at

least 3 days per week. In case of non-compliance with this periodicity, patients will not be excluded from the study, but will not be considered in "per protocol" analysis. Notwithstanding, daily sessions will be recommended (although not mandatory).

The program will consist of the following exercises:

Exercise	Sets	Repetitions	Notes
Strengthening exercises			
Sitting exercises			
Sitting knee extension	1	20	Increase difficulty using ankle weights
Sit to Stand	1	12	
Standing exercises			
Standing hip abduction	1	20 reps	
Standing knee flexion	1	20 reps	
Squats	1	12 reps	
Forward lunge with hold	1	10 reps	
Balance exercises			
Single-leg stance	1	10 reps	Patient will earn 1 star for each 5 seconds, up to 25 seconds
Single-leg stance with hip abduction	1	10 reps	
Walking exercises			
March on the same spot	1	40 steps	
Multi-directional steps	1	20 steps	
Square walking	1	5 reps	

The exact composition of each program will be tailored according to the particpant's specific needs, as defined by the physical therapist, i.e., it is not mandatory that every participant performs all exercises listed above.

The difficulty of each exercise (number of repetitions, series, weight addition or withdrawal of support) will be adjusted by the physical therapist, according the participant's stage and evolution.

Face-to-face visits

Each study participant allocated to the experimental group will receive an initial visit from the physiotherapist, which will be responsible for his monitorization during the program. In this visit, an initial assessment of the user's needs will be perfromed to define a tailored program. Training on the system's usage will be given, and the first session will be carried out in the presence of the therapist, to ensure that the user can interact autonomously with the system (or leastwise caregiver-aided).

From this visit onwards, the participant will be monitored remotely by the physical therapist, without subsequent face-to-face sessions. In the 4th and 8th weeks, each participant will receive a visit from the physical therapist for reassessment and adjustment of the program. There will be no face-to-face sessions during these two visits.

A follow-up telephone call will take place every two weeks (weeks 2, 6, 10).

Finally, extra visits or telephone calls can also me made, if necessary, and these will be registered on patient's file (date, reason, duration).
Table 2 summarizes the interventional steps of the program:

Table 2. Schedule of face-to-face visits and telephone calls

Week	Face-to-face visits	Telephone calls
0	X	
2		X
4	X	
6		X
8	X	
10		X
12	X	

13. Safety and adverse events

Patient safety will be ensured during all the process. For patients in the experimental group, safety will be evaluated through pain and fatigue scores (graduated from 0 to 10), collected at the end of each session. These will be presented to the patient using the mobile App and will be available for remote monitoring by the physical therapist. In case of excessive pain or fatigue, patients will be contacted to ascertain the cause and readapt prescription. Patients will also be instructed to report any other adverse events to their physical therapist by phone.

In the control group, in addition to the interim assessments, patients will be instructed to report any adverse events to a study investigator and, for this purpose, a direct phone contact will be provided.

All adverse events will be recorded on the participant's file (start date, resolution date - if applicable), resolution status and severity).

14. Statistic analysis

To assess differences in clinical and demographic variables of the patients allocated to the two study groups, independent samples test or Mann–Whitney U test will be used for quantitative variables. For qualitative variables, Chi-squared test Fisher's exact test will be used.

Outcome analysis will be performed using a "per-protocol" analysis. Patients with adherence less than 43% (corresponding to at least 3 weekly sessions) will not be considered on the "per protocol" analysis.

The impact of the interventions in the primary and secondary outcomes will be evaluated considering the change between baseline and week 12. Differences between the two study groups will be assessed using independent samples test or Mann-Whitney U test.

Since outcomes will be measured in several different times during the program, a repeated measures analysis will also be performed, using a 3x2/4x2 ANOVA, with group as an independent factor and time as a within-subjects factor.

15. Potential risks and benefits to participants

There are no invasive procedures involved in this protocol and no relevant risks are foreseen in both groups.

Participants in the control group will continue to benefit from the standard

medical care currently in place at the participating center, and thus no increased associatred risk is expected in this study. Conversely, direct clinical benefit from the study is not expected as well. However, participants will be contributing to the development and testing of an innovative tool that could have a significant positive impact on the older population's quality of life.

Participants in the experimental group will perform a falls prevention program through SWORD Phoenix®, under remote monitoring of a physical therapist. The therapist will have access to patient performance data, as well as pain and fatigue scores, as rated by the patient at the end of each session. This allows the therapist to detect adverse events and to act promptly. In addition, no adverse events resulting from the use of SWORD Phoenix® have been reported so far. Thus, participants in the intervention group are not at increased risk and may directly benefit from the intervention, by improving their muscular strength and balance and, consequently, by reducing falls risk.

16. Data protection

Data collection for this study was authorized by the National Commission on Data Protection, with the authorization number 5457/2018. Personal data will only be accessible to authorized individuals in this study. Personal data will not be entered into the database as part of this research. The clinical data collected will only be linked to the patient by a unique study number and will contain no personal identifiers. Informed consent will be obtained from participants to collect and retain this data. The data that will be used for analysis and dissemination for research purposes will be completely anonymized.

17. Ethical issues

All participants will be provided with information about the purpose and procedures of the study and must give written informed consent before inclusion.

The study was approved by the relevant Ethics Committee - Comissão de Ética da ARS Norte (Chair: Prof Doutor Pedro Hespanhol) and will be conducted in accordance with the relevant guidelines and regulations.

18. Dissemination of results

The results of the study will be published in peer-reviewed scientific journals and presented at relevant national and international meetings.

19. System Technical Specifications

SWORD Phoenix® is a CE- and FDA- certified class I medical device composed of the following components:

Inertial motion trackers

These are small high-precision motion trackers that capture and digitize the user´s motion, which is then transmitted via Bluetooth to the Phoenix App. The motion trackers are fixed to Velcro straps placed in specific body positions. To assist in the correct placement of the motion trackers, both the trackers and the matching straps are color-coded. In this study, the following setup will be used:

- **Red tracker:** over the sternal manubrium

- **Green trackers:** on the lateral surface of the leg, approximately midway between the trochanter and the lateral epicondyle
- **Blue trackers:** on the upper third of the antero-medial surface of the tibia

Phoenix App

The App guides the patient in each exercise session. Before each exercise, the patient is presented with a real-life video and audio explanation of that exercise. The execution interface is subsequently shown, featuring a simple and intuitive interface indicating the movement to be performed, a repetition counter and a star counter. Patients earn stars for every correct repetition, which is defined as a movement starting at the baseline and reaching or surpassing a movement threshold, without violating movement or posture constraints. In case the patient violates a movement constraint, a message is prompted, showing which movement error was performed, so that the patient can correct the movement in the following attempts. At the end of each session, the patient is presented with a summary of the number of completed repetitions and stars, as well as with rewarding badges for his main achievments.

Phoenix Portal

The portal is a web-based platform that allows the clinical team to create new patient profiles and create exercise sessions for each patient. To prescribe a session the clinician needs to select the exercises, number of sets and number of repetitions. When a patient performs a session, the results are uploaded to the platform and available for review. Based on this information,

the clinical team can edit the parameters of each exercise according to patient performance and progress.

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ANNEX 1

INFORMATION TO PARTICIPANTS

Version 1.3
Date: 11/14/2018

CLINICAL IMPACT OF A DIGITAL HOME-BASED FALLS PREVENTION PROGRAM ON ELDERLY PEOPLE – A RANDOMIZED CONTROLLED TRIAL

PARTICIPANT INFORMATION

Version 1.3
Date: 11/14/2018

This leaflet is intended to inform you of a clinical trial that USF Aldoar and SWORD Health are currently undertaking.

What is the purpose of the study?

This study aims to assess the clinical impact of a home-based falls prevention program using a new technology named **SWORD Phoenix**® in people over 65 years in risk of falling, compared to standard medical care.

What is SWORD Phoenix?

SWORD Phoenix® is a system composed of motion trackers placed on the trunk and on lower limbs through Velcro straps. These trackers digitize your movements and send this information to a mobile App (on a tablet). This App guides you through the exercise sessions and tells you whether you are performing them properly or not, helping you to correct any errors.

The information is then uploaded to an internet platform, where the clinical team can remotely analyze the sessions, introducing changes as needed. Thus, you will have a clinical team monitoring you remotely.

Is this study for me?

This study is intended for people over the age of 65, living in the community,

and who are at risk of falling. This leaflet was delivered to you because you are a potential candidate to participate in the study.

What happens next?

If you agree to participate, and you meet the study criteria after an initial assessment, you will be assigned to one of two groups: an experimental group or a control group.

Participants in the experimental group will perform a falls prevention program through the SWORD Phoenix® system, under the remote supervision of a physical therapist. This program will last 12 weeks, during which you must perform at least 3 exercise sessions per week. Throughout the program, the sessions will be adapted by the physiotherapist according to the performance.

Participants in the control group will continue to benefit from health care routinely provided at the USF Aldoar, which includes fall risk assessment, optimization of medication and information on how to prevent falls. Participants in this group will not do any specific fall prevention program.

What are the risks associated with participating in the study?

There are no risks associated with participation in any of the groups, as no risks arising from the use of the SWORD Phoenix® system are known.

Am I required to participate? And what are the costs?

No. Participation in this study is entirely voluntary and does not entail any financial burden.

What happens if I do not want to participate?

If you do not want to participate, this will not have any negative consequences to you. In this case, you will continue having your usual follow-up with your Primary Care Physician.

Who will have access to my data?

Identification data will only be known to the trial investigators and will not be made public under any circumstances.

All data collected will solely and exclusively be used for the production of scientific articles that will always be anonymous, guaranteeing privacy and the protection of participants's personal data.

If you have further questions about the study, please contact your Physician or the Study Investigators through the following contacts:

Dr Mariana Sant'Ana:

Dr Fernando Correia: 966557789

ANNEX 2

INFORMED CONSENT

CLINICAL IMPACT OF A DIGITAL HOME-BASED FALLS PREVENTION PROGRAM ON ELDERLY PEOPLE – A RANDOMIZED CONTROLLED TRIAL

INFORMED CONSENT

Version 1.3
Date: 11/14/2018

Clinical impact of a digital home-based falls prevention program on elderly people – a randomized controlled trial

Informed Consent

I declare that I have received verbal and written information about the study in which I was invited to participate.

I read and understood all the information that was transmitted to me and had the opportunity to put the doubts that I thought necessary, which have been clarified to me.

I also understand my right to withdraw this study at any time, without having to give any explanation and without suffering any reprisals.

I understand that the results of the study can be published in Scientific Journals and used in other investigations, without any breach of confidentiality. I hereby authorize the use of the data for these purposes.

For these reasons, I agree to participate voluntarily in this study.

Name of participant: _____
Signature of participant: _____

Date: __ /__ /____

Name of investigator: _____
Signature of investigator: _____

Date: __ /__ /____

ANNEX 3

ASSESSMENT SCALES AND APPLICATION INSTRUCTIONS

Version 1.3
Date: 11/14/2018

MMSE (Mini-Mental State Examination)

The MMSE measures cognitive ability and begins with the assessment of spatial and temporal orientation, with a maximum of 10 points. Then, two aspects of memory are tested.

The first consists of the immediate memory of three orally presented objects, followed by a serie of seven intercalated tasks that evaluate attention, concentration and calculation, preventing the user from memorizing the three previously learned objects. In this section a maximum of 11 points can be obtained.

The last section assesses aphasia, testing naming, repetition, perceiving a three-step command, reading, writing, and copying a drawing. A maximum of 9 points can be obtained for a maximum total of 30 points.

I. ORIENTATION

1) Ask for: the year, season, date, day, month. Then ask specifically for parts omitted e.g. "Can you also tell me what season it is?". One point for each correct.

2) Ask in turn, "Can you tell me the name of this department? (state, country, town, hospital, floor.)

II. REGISTRATION

Ask the patient if you may test his memory. Then say the names of 3 unrelated objects, clearly and slowly, about one second for each. After you have said all 3, ask him to repeat them. This first repetition determines his score (0-3) but keep saying them until he can repeat all 3, up to 6 trials. If he does not eventually learn all 3, **recall** cannot be meaningfully tested.

III. ATTENTION AND CALCULATION

Ask the patient to begin with 100 and count backward by 7. Stop after 5 subtractions (93, 86, 79, 72, 65). Score the total number of correct answers. If the patient cannot or will not perform his task, ask him to spell the word "world" backward. The score is the number of letters in correct order, e.g., dlrow=5, dlorw=3.

IV. RECALL

Ask the patient if he can recall the 3 words you previously asked him to remember in the registration section. Score 0-3.

V. LANGUAGE

NAMING: Show the patient a wrist watch and ask him what it is. Repeat for pencil. Score 0-2.

REPETITION: Ask the patient to repeat the sentence "No ifs, ands, or buts" after you. Allow only one trial. Score 0-1.

3 STAGE COMMAND: Give the patient a piece of plain blank paper and ask him to follow your instructions: "Take the paper in your right hand, fold it in half and put it on the floor." Score 1 point for each part correctly performed.

READING: On a blank piece of paper, print the sentence, "Close your eyes," in letters large enough for the patient to see clearly. Ask him to read it and do what it says. Score 1 point only if he actually closes his eyes.

WRITING: Give the patient a blank piece of paper and ask him to write a sentence for you. Do not dictate a sentence. It is to be written spontaneously. It must contain a subject and a verb and be sensible. Correct grammar and punctuation are not necessary.

COPYING: On a clean piece of paper, draw two intersecting pentagons, each side about 1 inch, and ask him to copy it exactly as it is. All 10 angles must be present and 2 must intersect to score 1 point. Tremor and rotation are ignored.

Timed up and Go Test

The Timed Up and Go is a test that assesses mobility, balance, walking ability in older adults.

To perform the test, follow the instructions:

1) Select a chair with armrests and a seating height of 44-47 cm
2) Measure 3 meters in a straight line from the chai rand place a mark on the floor
3) Ask the patient to sit in a chair with his/her back against the chair back
4) Instruct the patient to rise from the chair on the command "go", walk 3 meters at a comfortable and safe pace, turn, walk back to the chai rand sit down
5) Begin timing at "go" and stop when the patient is seated
6) Register the time with two decimal digits in the patient file

Five Times Sit to Stand Test

The Five Times Sit to Stand Test is a functional measure of lower limb muscle strength that quantifies the functional change of transitional movements.

To perform the test, follow the instructions:

1) Select a chair with armrests and ask the patient to sit in the middle of the seat with arms crossed behind the neck or arms crossed with hands touching the shoulders. Advise the patient to keep their feet on the ground and correct posture
2) Instruct the patient to rise from the chair and sit five times as fast as possible on the command "start"
3) Ask the patient to stand up completely between the test repetitions and not touch the back of the chair during each repetition
4) The counting begins on the command "start" and ends when the hips are in contact with the chair after the fifth repetition.
5) Register the time with two decimal digits in the patient file (maximum 2 minutes)
6) Failure to complete the five repetitions without assistance or support from the upper limb indicates non-compliance with the test.

Berg Balance Scale

Description:
14-item scale designed to measure balance of the older adult in a clinical setting.

Equipment needed: Ruler, 2 standard chairs (one with arm rests, one without) Footstool or step, Stopwatch or wristwatch, 15 ft walkway

Completion:

Time: 15-20 minutes

Scoring: A five-point ordinal scale, ranging from 0-4. "0" indicates the lowest level of function and "4" the highest level of function. Total Score = 56

Interpretation:
41-56 = low fall risk
21-40 = medium fall risk
0 –20 = high fall risk

Criterion Validity:
"Authors support a cut off score of 45/56 for independent safe ambulation".

Riddle and Stratford, 1999, examined 45/56 cutoff validity and concluded:

- Sensitivity = 64% (Correctly predicts fallers)
- Specificity = 90% (Correctly predicts non-fallers)
- Riddle and Stratford encouraged a lower cut off score of 40/56 to assess fall risk

Comments: Potential ceiling effect with higher level patients. Scale does not include gait items

Norms:
Lusardi, M.M. (2004). Functional Performance in **Community Living Older Adults**. *Journal of Geriatric Physical Therapy*, 26(3), 14-22.

Table 4. Berg Balance Scale Scores: Means, Standard Deviations, and Confidence Intervals by Age, Gender, and Use of Assistive Device

Age (y)	Group	N	Mean	SD	CI
60-69	Male	1	51.0	—	35.3 – 66.7
	Female	5	54.6	0.5	47.6 – 61.6
	Overall	6	54.0	1.5	52.4 – 55.6
70-79	Male	9	53.9	1.5	48.7 – 59.1
	Female	10	51.6	2.6	46.6 – 56.6
	Overall	19	52.7	2.4	51.5 – 53.8
80-89	Male	10	41.8	12.2	36.8 – 46.8
	Female	24	42.1	8.0	38.9 – 45.3
	No Device	24	46.3	4.2	44.1 – 48.5
	Device	10	31.7	10.0	28.3 – 35.1
	Overall	34	42.0	9.2	38.8 – 45.3
90-101	Male	2	40.0	1.4	28.9 – 51.1
	Female	15	36.9	9.7	32.8 – 40.9
	No Device	7	45	4.2	40.9 – 49.1
	Device	10	31.8	7.6	28.4 – 35.2
	Overall	17	37.2	9.1	32.5 – 41.9

Name: _____ Date: _____

Location: _____ Rater: _____

ITEM DESCRIPTION	SCORE (0-4)
Sitting to standing	_____
Standing unsupported	_____
Sitting unsupported	_____
Standing to sitting	_____
Transfers	_____
Standing with eyes closed	_____
Standing with feet together	_____
Reaching forward with outstretched arm	_____
Retrieving object from floor	_____
Turning to look behind	_____
Turning 360 degrees	_____
Placing alternate foot on stool	_____
Standing with one foot in front	_____
Standing on one foot	_____

Total _____

GENERAL INSTRUCTIONS

Please document each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if:

- the time or distance requirements are not met
- the subject's performance warrants supervision
- the subject touches an external support or receives assistance from the examiner

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5, and 10 inches. Chairs used during testing should be a reasonable height. Either a step or a stool of average step height may be used for item # 12.

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is place in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touch the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on.
( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

Short Falls Efficacy Scale - International

Short FES-I

Now we would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don't do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please tick the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

		Not at all concerned 1	*Somewhat concerned 2*	*Fairly concerned 3*	*Very concerned 4*
1	Getting dressed or undressed	*1* ☐	*2* ☐	*3* ☐	*4* ☐
2	Taking a bath or shower	*1* ☐	*2* ☐	*3* ☐	*4* ☐
3	Getting in or out of a chair	*1* ☐	*2* ☐	*3* ☐	*4* ☐
4	Going up or down stairs	*1* ☐	*2* ☐	*3* ☐	*4* ☐
5	Reaching for something above your head or on the ground	*1* ☐	*2* ☐	*3* ☐	*4* ☐
6	Walking up or down a slope	*1* ☐	*2* ☐	*3* ☐	*4* ☐
7	Going out to a social event (e.g. religious service, family gathering or club meeting)	*1* ☐	*2* ☐	*3* ☐	*4* ☐

Kempen GIJM, Yardley L., Haastregt JCM van, Zijlstra GAR, Beyer N, Hauer K, Todd C.