FallSensing, a multifactorial screening tool for fall-risk in community dwelling adults aged 50 years or over: Study protocol

Abstract

**Background:** Falls are a major health problem among older adults. About a third of community-dwelling adults aged 65 years or over fall each year. The risk of falling can be increased by polypharmacy, vision impairment, high blood pressure, environmental home hazards, fear of falling and changes in function of musculoskeletal and sensory systems, associated with aging. Moreover, individuals who experienced previous falls are at higher risk. Nevertheless falls can be prevented by screening to detect risk factors.

**Objective:** To understand if FallSensing screening tool is able to determine the fall risk of community-dwelling adults aged 50 years or over.

**Methods:** FallSensing screening tool is a technological solution for fall risk screening, including a software, a pressure platform and two inertial sensors. The screening software includes questions about sociodemographic and health and lifestyle behaviors, a detailed explanation about procedures to accomplish six functional tests (Grip Strength, Timed Up and Go, 30 seconds Sit-to-Stand, Step test, 4 Stage Balance test “modified” and 10 meters Walking Speed) and three questionnaires concerning environmental risk, activities and participation profile related to mobility and self-efficacy for exercise. The questions registers information about demographic and anthropometric data (age, sex, height and weight), Fear of Falling, history of fall (previous 12 months), health conditions, medication, sedentary lifestyle, upper extremities assistance to stand from a chair, living settings, alcohol habits, self-perceived health and unintentional or involuntary weight lost. We will recruit community-dwelling adults aged 50 years or over, independent to be standing and walking with or without walking aids in different regions of continental Portugal. In order to be a representative sample of Portuguese population, a minimum of 385 participants is needed.

**Results:** The development of the FallSensing screening tool started in October 2015, and the screening of participants started in June 2016 and continues by the time of submission. A set of seniors’ university, parish councils, physical therapy clinics and other community facilities have consented to participate in the study.

**Conclusions:** In order to develop a multifactorial screening tool for fall risk in community-dwelling adults, it is essential to identify key risk factors for falls and select the best method to evaluate them. FallSensing screening tool, gathers a multifactorial assessment, designed and studied through the best evidence, which seek to identify factors that influence the fall risk. Understanding these factors, will allow that preventive strategies could be implemented and decrease falls rates.
**Keywords:** Falls prevention; Community-dwelling older adults; Pressure platform; Inertial Sensors

**Introduction**

Falls and fall related injuries are a major health problem among older adults [1]. About a third of community-dwelling persons aged 65 years or over fall each year [1,2]. Falls are complex and have a multifactorial etiology [3,4]. Different components can increase the risk of falling, namely psychotropic medications and polypharmacy, once its reduction as a single intervention has been found to reduce fall rate [5,6]. Vision impairment is also considered a fall risk factor inherent to changes in visual acuity, development of cataracts, macular degeneration, glaucoma, and other conditions related to the aging process [5]. High blood pressure and heart rate and rhythm abnormalities, such as carotid sinus hypersensitivity, vasovagal syndrome, bradyarrhythmias, and tachyarrhythmias are similarly associated with falls. Environmental hazards at home related to lighting, chair and bed height, floor surfaces and other, create opportunities for falls, and has been included as an essential component of fall prevention programs [5,7]. Additionally, changes in function of musculoskeletal and sensory systems, associated with aging, lead to deficits in maintaining postural stability [8]. In turn, fear of falling (FoF), can have a major impact on older adults, raising caution and restricting activities leading to physical fragility [9]. Finally, individuals who experienced previous falls and with multiple risk factors are at higher risk of falling [10,11].

Falls can lead to minor injuries such as bruises, lacerations or abrasions or, in 10% of the cases, can result in fractures [6,12], contributing to significant rates of morbidity and mortality [6,7]. Health care direct costs associated with this phenomenon are high [13], and reaches 25 billion euros/year in the European Union [2].

The evidence shows that falls can be prevented by screening to detect risk factors and by the prescription of tailored interventions [14]. The screening process should review a different number of items. The results will allow the professional to identify those with the need of a more detailed assessment [15].

The aims of the present study are to develop a multifactorial screening tool for fall risk according to the key risk factors for falls, within a context of community-dwelling adults aged 50 years or over and validate it to the Portuguese population.
Methods

Recruitment

Individuals were voluntarily recruited from community, in different regions of continental Portugal. Inclusion criteria consists of adults aged 50 years or over, independents to be standing and walking with or without walking aids, with interest to participate in the study. Individuals will be excluded if they have severe sensorial impairments (deafness or blindness) or cognitive impairments which precludes the ability to comprehend the questionnaires and functional tests included in the screening protocol.

Ethical considerations

Ethical approval was obtained from the Polytechnic Institute of Coimbra (Nº6/2017). All participants gave written informed consent before data collection began, according to the Declaration of Helsinki.

Details of the intervention

FallSensing screening tool is a technological solution for fall risk screening, composed by a screening tool that includes software, pressure platform and inertial sensors.

A questionnaire regarding information about demographic and anthropometric data (age, sex, height and weight), fear of falling, history of fall (previous 12 months), health conditions (heart attack, stroke, osteoarthritis, diabetes, Parkinson’s disease, osteoporosis, high blood pressure, high cholesterol, hearing and vision impairments, urinary incontinence), medication, sedentary lifestyle, upper extremities assistance to stand from a chair, living settings, alcohol habits, self-perceived health and unintentional or involuntary weight lost, will be assessed.

History of Fall

A fall can be defined as “an unexpected event in which the participant comes to rest on the ground, floor, or lower level” and “excludes coming to rest against furniture, wall, or other structure” [1,6,16].

The history of previous falls (HoF) is considered a risk factor for falls [17] and the strongest single predictor of future falls [18], since it is associated with reduced lower limbs strength and gait and balance impairments [10].

According to the literature, older adults who have experienced one or more falls have 3 times the risk of falling again within the following year compared to those with no history of falls [19].

The history of fall within the previous 12 months will be determined by self-report, answering the question “Did you fell in the past 12 months? Yes-No”. If the participant have fallen, it will be asked if the fall was outdoor or indoor, the reason of the fall (slip, stumble, loss of conciseness, dizziness, lower extremities weakness, no special reason and other), need of health services assistance, which health service (hospital, primary health care centre), hospitalization (how many days), activities
limitation and restrictions on participation (how many days), fractures occurrence
(wrist or hand, hip, skull or spine, others).
In order to collect more accurate data of previous falls, monthly phone calls will be
performed after screening over a year.

**Fear of Falling**
Fear of falling (FoF) is defined as “a lasting concern about falling that leads to an
individual avoiding activities that he/she remains capable of performing” [20].
Literature states that exposure to FoF contributes to a loss of independence or
disability through the restriction of activities [21,22] since it is associated with an
increased risk of functional decline [23], reduced physical activity, lower perceived
physical health status, lower quality of life and increased institutionalization [24].
Despites being more frequent among fallers, FoF and activity restriction are not
exclusive of these persons. In addition, FoF was significantly more frequent among
women and among people living alone [25].
Considering the negative influence of FoF, its existence will be assessed by self-
report through the question “Are you afraid of falling? Yes – No”.

**Health Conditions**
There are certain conditions that can have a significant effect on fall rates among
older adults, such as bladder incontinence, osteoarthritis, Parkinson’s disease,
cardiovascular accidents and conditions associated with cardiovascular disease, like
hypertension. Additionally, deficits in the somatosensory and vestibular systems can
also contribute to falls, since they are associated with an increase in postural sway, a
strong indicator of standing balance [26].
The question “Do you have trouble seeing well or it have been past more than 2
years since your eyes have been tested?” is also included in the protocol once vision
impairment is considered a fall risk factor. The changes in visual acuity, development
of cataracts, macular degeneration, glaucoma, and other conditions related to the
aging process contribute to risk of falling [5,26].

**Medication**
It is reported that about 20,3% of persons aged 55 years or over takes four or more
medicines [27]. Older adults taking more than three or four medicines were found to
be at increased risk of recurrent falls [28]. Additionally, a significant association
between falls and the use of sedatives and hypnotics, antidepressants and
benzodiazepines were found [27].
The number of medicines taken by each person was assessed by self-report through
the question “Do you take 4 or more different medicines per day? Yes-No”. The name
of the medicines was also registered and they were identified according to their
pharmaceutical group (benzodiazepines, antidepressants, antipsychotics, anti-
inflammatory drugs, antihypertensive drugs and others drugs).
**Sedentary Lifestyle**
Regular physical activity in daily life results in significant decrease of falling in older people, consequently, sedentary behaviour is associated with an increased incidence of falls [29,30]. In order to understand if community-dwelling older adults have a sedentary behaviour, participants will be asked “Do you spend at least 4 hours seated, 5 days a week?”.

**Upper Extremities Assistance to Stand from a Chair**
The upper extremities assistance to stand from a chair was assessed through the question “Do you need assistance from the upper extremities to stand up from a chair? Yes-No”.

**Living settings**
Since FoF is more frequent among older adults living alone [25], this protocol intends to assess the living settings through the question “Do you live alone? Yes-No”.

**Alcohol habits**
Regular alcohol consumption among older adults has been linked to impaired balance and postural hypotension, which has been associated with frequent falls [31]. Furthermore, the intake of certain medications, such as benzodiazepines, even with small amounts of alcohol, can increase the risk of falling, because of the interactions that can occur[32].
The participants will be asked about their daily alcohol habits, “Do you drink alcohol every day? Yes-No”.

**Self-Perceived Health**
The self-perceived health (SPH) is considered a valid and reliable indicator of overall health status, a predictor of mortality and health services use. Several studies found an association with sociodemographic characteristics (such as sex, age or education), chronic diseases and functional status. This one in particular, is recognised as a powerful determinant of SPH in older adults [33]. Older adults with FoF also demonstrated poor SPH [34].
SPH will be assessed by self-report through the question “In general, do you perceived your health as excellent, very good, good, sufficient or poor?”

**Unintentional or involuntary weight loss**
The involuntary weight loss is one of the features that, simultaneously present with others, can help to define a frailty phenotype [35].
The literature reveals an association between the frailty phenotype and the number of previous falls in older people [36]. The participants will be asked if they had experienced a weight loss higher than ≥4,5kg or ≥5% of body weight during the previous 12 months.
**Functional Tests**

**Grip Strength**
The hand grip strength is significantly correlated with lower limb muscular strength [37], being a powerful predictor of disability, morbidity and mortality [38]. This test will be performed with the person seated on a standard chair without armrests [39], shoulder adducted and neutrally rotated, elbow flexed at 90 degrees, forearm neutral, wrist held between 0-15 degrees of ulnar deviation and with the arm not supported [40]. A Jamar™ Hydraulic Hand Dynamometer will be settled at the second handle position, held with the dominant hand, and during the performance of the test will be presented vertically in line with the forearm. The test is performed only one time and the person is encouraged to exert her/his maximal grip strength for 5 seconds [40,41]. The final score is measured in kilograms force (kgf). Normative data for this test are commonly analysed by gender, with males showing higher grip strength at all ages [42]. A score below 15 kgf, for women, and 21 kgf, for men, identify those with higher risk of falling [43].

**Timed Up and Go**
Timed Up and Go test (TUG) is used to assess dynamic balance during gait and transfers tasks, mobility and lower body strength [44,45]. To perform this test, the person, wearing his/her regular footwear, is instructed to sit on a standard chair (chair height between 44 and 47 cm [46]) with his/her back against the chair back[40], to stand up and walk straight for 3 meters as fast as possible, turn around, walk back and sit down [45,47]. The person must stand up without help (cannot use the upper extremities for support), however if a walking aid is needed it should be placed next to the chair and can be used to perform the gait component of the test [45]. The test is performed only one time, the timing begins at the instruction “go” and stops when the patient seats on the chair [40]. A score higher than 10 seconds will indicate which community-dwelling older adults are more likely to be fallers [44].

**30 seconds Sit-to-Stand**
Lower body strength is a significant element to maintaining functional capacity in older adults, therefore its evaluation is critical [48–50]. 30 seconds Sit-to-Stand (STS), being a simple and effective instrument for assessing lower body strength and identifying muscle weakness in community-dwelling older adults, is one of the most important functional evaluation clinical tests [48,51]. The person is instructed to perform cycles of sits and stands up from a chair, as many times as possible over 30 seconds [48,52].
The person starts the test seated in the middle of the chair (chair height between 40 and 43.3cm), feet approximately shoulder-width apart and placed on the floor, and arms crossed by the wrists placed against the chest. The vocal instruction “go” sets the test’s beginning and if the participant completes more than halfway up at the end of 30 seconds it is counted as a full stand. Final score involves recording the
number of stands a person can complete in 30 seconds [48,51]. The normative levels for number of stands depends on age and gender [53].

**Step Test**
The step test, was designed to assess the dynamic standing balance and reproduces lower-extremity motor control and coordination [54,55]. In order to perform the test, the person is asked to step on and off a block (7.5 cm height, 55 cm width, 35 cm depth), placed against a wall, as many times as possible during 15 seconds. The whole foot is required to step onto the block and then return it fully to the ground. The total number of completed steps in 15 seconds is recorded. The patient is unsupported and should look straight forward, although investigator must stand close by for safety. In the case of patient overbalanced or need stabilization during the test, counting of steps stops and it is recorded the complete number of steps prior to overbalancing [55–57]. This test is performed only for the dominant side, indicated by the person. A performance lower than 10 steps indicates higher risk of falling [58].

**4 Stage Balance Test “Modified”**
Deficits in balance can lead to falls and fall related injuries, representing one of the most important intrinsic fall risk factors among older adults [59–61], being commonly assessed in this population.
The 4 Stage Balance Test “modified” is one of the tests available to evaluate balance. In order to complete this test, the person needs to progressively accomplish four different feet positions: side by side stance, semi-tandem stance (preferred foot forward with the instep of one foot touching the big toe of the other foot), tandem stance (one foot in front of the other, heel touching toe) and one legged stance (preferred leg for support) [62].
The person is instructed to stand quietly on the pressure platform, arms along the body, neither with shoes or assistive devices. The positions must be held by 10 seconds each, without moving the feet, needing support, losing balance or touching the leg of support with the other leg [59,62], and must be performed with eyes open and then closed (excluding one legged stance position). The sequence will be side by side stance eyes open, side by side stance eyes closed, semi-tandem stance eyes open, semi-tandem stance eyes closed, tandem stance eyes open, tandem stance eyes closed and one leg stand eyes open. If the person failed to accomplish one of the test positions, the test finishes. The final score will be the number of positions successfully completed. The inability to complete 10 seconds in the tandem stance position, with eyes open, has been associated with higher risk of falling and mobility dysfunction [63,64].

**10 meters Walking Speed**
Walking speed is the result of a complex interaction of multiple body structures and functions, such as lower extremity strength, proactive and reactive postural control, motor control or musculoskeletal condition [65,66]. Accessing the gait speed (GS) as a screening tool can be useful to identify those at risk or in need of
intervention [66], since the gait speed results are related to various health outcomes, like functional decline or fear of falling, besides GS can be a predictor of falls [65]. The performance of this test requires a 20 meters straight path, with 5 meters for acceleration, 10 meters for steady-state walking and 5 meters for deceleration. Markers are placed at the 0, 5, 15 and 20 meters positions of the path and the time to walk along the 5 and 15 meters is registered [67]. The person is instructed to walk at his/her faster walking speed, without running, along the 20 meters path; an assistive device can be used if needed and the person should wear his/her regular footwear.

The range of normal walking speed is between 1,2 and 1,4 m/s, since it varies by age, gender and anthropometrics A value lower than 0,4m/s indicates a probability of needing an assistive device at home; 0,4 to 0,8 m/s is correlated with limited mobility; 0,8 to 1,25 m/s ambulation in the community with some risks; < 1m/s subjects should start a program to reduce the risk of falling; ≥ 1,42 m/s is the safe streets crossing speed [65].

Software
The software that is comprised in this screening tool includes a questionnaire about demographics, a detailed explanation about procedures to accomplish every functional test and the three questionnaires concerning environmental risk, activities and participation profile related to mobility (PAPM) and self-efficacy for exercise.

The chronometer used to measure time scores or state test time for TUG test, 30seconds STS test, Step test, 4 Stage Balance test “modified” and 10 meters walking speed test is integrated into this application. In de 30s STS, the number of stands will be registered manually by the physiotherapist. The same procedure will be used register the number of steps.

FallSensing Screening Tool software records demographic data, functional tests scores and inertial sensors and pressure platform raw data, questionnaires scores, information about the limb that was used to accomplish the test, notes about difficulties or dissimilarities during tests performance (e. g. use of an assistive device) and reasons to not complete the tests, in a cloud server designed for the screening tool.

Pressure platform (USB cable)
PhysioSensing platform® (Sensing Future Technologies, Lda) measures the pressure distribution data, running at frequency of 50Hz. It comprises 1600 pressure sensors (10mm by 10mm) with maximum value of 100N/sensor. Voltage data is converted with an 8-bit A/D converter and is transmitted via USB (Universal Serial Bus). Therefore, it is possible to receive raw data of each pressure sensor as well as the raw center of pressure coordinates (CoP), in cm. In order to obtain more precision in CoP displacements, an algorithm was employed to obtain CoP positions in millimeters, using the matrix of pressure sensors [68].
The pressure platform collects valuable balance information during the STS, Step test and 4 Stage Balance test “modified”. To collect useful information, participants should be barefoot.

**Inertial sensors (Bluetooth connection)**
The wearable inertial sensors were developed and assembled at Fraunhofer AICOS Portugal. Inertial data is collected from the built-in 3-axial accelerometer and 3-axis gyroscope, both sampled at 50 Hz. Raw data from the accelerometer is acquired for all the tests in m/s² and raw data from the gyroscope is acquired in degrees/s². For the TUG test, 30 seconds Sit-to-Stand test, Step test, 4 Stage Balance test “modified” and 10 meters Walking Speed test, one inertial sensor is placed at the lower back and one at the ankle. In the case of Step test and 4 Stage Balance test “modified”, the ankle inertial sensor is placed at the support leg. Instrumentation with inertial sensors during the execution of standard tests gives additional quantitative information, such as duration of the standing phase on TUG, contributing to better assess and characterize a person’s mobility and balance conditions. Another advantage of using inertial sensors is that they eliminate the bias introduced by observation of movements and subjective assessment and the output extracted are potentially more reliable and reproducible [69].

**Questionnaires**

**Self-efficacy for exercise**
The self-efficacy reflects the confidence that a person has to perform a certain behaviour [70].
The self-efficacy for exercise is a 5-items scale intended to analyse the confidence that a person has to perform exercise according to five different emotional states, like feeling worried/having problems, feeling depressed, feeling tired, feeling tense and being busy.
Ratings are done using a 5-points Likert scale from 1 “not at all true” to 4 “completely true”; in between, 2 “slightly true” and 3 “moderately true” [71].

**Activities and Participation Profile related to Mobility (PAPM)**
The PAPM is an 18-items scale intended to improve understanding of the difficulties an individual experiences in performing certain daily activities in their natural environment. These activities can be conditioned by mobility and are related to the interactions and social relations, education, employment, money management, social and community life, influencing the active participation of any person as a full member of the society [72].
Ratings are done using a 5-points Likert scale from 0 “no limitation/restriction” to 4 “complete limitation/restriction”. In between, 1 “mild limitation/restriction”, 2 “moderate limitation/restriction” and 3 “severe limitation/restriction”. Since some activities may not apply, not all activities may be rated. As a result, an individual’s participation profile will be produced [72].
Home safety checklist
The Home safety checklist is a 38-items scale intended to identify home hazards in each room of a person’s home, namely hall and hallways, stairs, living/dining room, kitchen, bathroom, bedroom and outdoors [73,74]. Ratings are done using a 3 points scale from 0 “no risk”, 1 “risk” to 99 “do not apply”. A risk score is produced both to each room and for the home in general.

Statistical Analysis
Statistical analysis will be performed using IBM SPSS (v.24) software, considering a representative sample of Portuguese population (sample calculation for finite population for a 95% confidence interval and 5% margin of error). The statistical approach will be different according to the level of measurement for the variables. The analysis could include the t-student test of independent samples, Chi-squared test and Fisher’s exact test.

Results
Primary and secondary outcome measures and assessment points
Primary outcome measures of this study are the characterization of Portuguese population in terms of HoF, FoF, functional status (measured by Grip Strength, TUG, STS, Step test, 4 Stage Balance test “modified” and 10 meters Walking Speed), environmental hazards, activities and participation profile related to mobility and self-efficacy for exercise.
Secondary outcomes are also related to Portuguese population characterization in terms of health conditions, medication intake, sedentary lifestyle, living settings, alcohol habits, self-perceived health and unintentional or involuntary weight loss. Development of a multifactorial fall risk scale based on functional tests metrics and questionnaires answers that could be used to screen elderlies into the fall risk level.

Discussion
In order to develop a multifactorial screening tool for fall risk in community-dwelling persons, key risk factors for falls were identified. It is acknowledged that the occurrence of previous falls, visual impairment, urinary incontinence and use of benzodiazepines are strong predictors for occurrence of falls [75]. In this protocol, different questions were included regarding the strongest predictors of falls. However, this screening protocol intended to collect more specific data which allows the characterization of each person. Different functional tests and questionnaires were included in the FallSensing screening protocol to accomplish a detailed evaluation of each case. In this way, a multidisciplinary perception of each individual can be achieved, allowing a tailored intervention by different health care professionals.
Therefore, FallSensing screening tool, gathers an amount of instruments, designed and studied through the best evidence, which seek to identify every element that influence the fall risk. By understanding these major factors that increase fall risk,
preventive strategies tailored for community-dwelling older adults can lead to a decrease of falls rates and fall related injuries. A lengthy screening will probably represent a limitation of this protocol. However, one of the goals of this project is to identify, in conjunction with the data collected by the pressure platform and inertial sensors, the most valuable functional tests, in order to shorten the protocol. This investigation also intends to understand if FallSensing screening protocol is feasible and acceptable in the Portuguese population context, and its application will allow to perceive its strengths and limitations and lead to the adaptations required.

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**Authors’ Contributions**
ACM and IS developed study conception and design. JM, CS and DB were the primarily responsible for literature review. CR and TP will perform analysis of data. JM and CS were responsible for the drafting and writing of the manuscript. JS and CT performed a critical revision. All authors read and approved the final version of the manuscript.

**Conflicts of Interest**
None declared.

**Abbreviations**
CoP: Center of Pressure Coordinates
FoF: Fear of Falling
GS: Gait speed
HoF: History of Fall
PAPM: Activities and participation profile related to mobility
SPH: Self-perceived health
STS: 30 seconds Sit-to-Stand
TUG: Timed Up and Go test
USB: Universal Serial Bus

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